Trials@uspto.gov
Tel: 571-272-7822

Paper 11
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AXONICS MODULATION TECHNOLOGIES, INC.,
Petitioner,

v.

MEDTRONIC, INC.,
Patent Owner.

IPR2020-00714
Patent 9,463,324 B2

Before WILLIAM V. SAINDON, JAMES A. TARTAL, and ALYSSA A. FINAMORE, *Administrative Patent Judges*.

SAINDON, *Administrative Patent Judge.*

DECISION
Denying Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

Axonics Modulation Technologies, Inc. ("Petitioner") filed a petition requesting *inter partes* review of claims 1–24 of U.S. Patent No. 9,463,324 B2 (Ex. 1001, "the '324 patent"). Paper 1 ("Pet."). Medtronic, Inc. ("Patent Owner") filed a Preliminary Response. Paper 7 ("Prelim. Resp.").

We have authority under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted unless the information presented in the Petition and the Preliminary Response shows that "there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a); *see also* 37 C.F.R. § 42.4(a) ("The Board institutes the trial on behalf of the Director."). Taking into account the information presented in the Petition and Preliminary Response, we conclude that Petitioner has not established a reasonable likelihood that it would prevail with respect to at least one challenged claim. Accordingly, we do not institute an *inter partes* review.

A. Related Matters

Petitioner also challenges U.S. Patent No. 9,821,112 B2, which is a child application of the '324 patent, in IPR2020-00713. Paper 5, 2 (Patent Owner's Mandatory Notices).

According to the parties, the '324 patent is involved in *Medtronic, Inc. v. Axonics Modulation Technologies, Inc.*, Case No. 8:19-cv-02115-DOC-JDE (C.D. Cal.). Pet. 75; Paper 5, 2.

B. Real Parties In Interest

Petitioner asserts that it is the sole real party in interest. Pet. 75. Patent Owner asserts that it is the real party in interest, that "Medtronic plc is

the ultimate parent of Medtronic, Inc.," and that "Medtronic, Inc. has granted certain rights with respect to the patent-at-issue to Medtronic Puerto Rico Operations Co., which in-turn has granted certain rights to Medtronic Logistics, LLC, which in-turn has granted certain rights to Medtronic USA, Inc." Paper 5, 1 n.1.

C. The '324 Patent

The '324 patent is directed to charging an implantable medical device having a battery, such as a cardiac pacemaker. Ex. 1001, Abstract, 1:34–42. Rather than remove and re-implant the devices whenever the battery is about to run out, these devices provide for transcutaneous ("through-skin") energy transfer using inductive coupling to charge a rechargeable battery. *Id.* at 1:58–2:11. To recharge the battery, and external power source is temporarily positioned on the surface of the skin. *Id.* at 4:65–5:11. An induction coil in the external power source transfers energy to an induction coil in the implant. *Id*. The efficiency of the energy transfer is dictated by how well the two coils are aligned with one another. *Id.* at 5:11–45. The '324 patent indicates that it improves such existing systems by providing a sensor that measures and controls the temperature of the external device's housing during charging. *Id.* at 7:13–29.

D. Challenged Claims

Claims 1–24, which represent each claim in the '324 patent, are challenged. Claims 1, 12, and 20 are independent. Claim 1 is reproduced below:

> 1. A system, comprising:
> an implantable medical device comprising a secondary coil; and
> an external device comprising:

a primary coil adapted to be transcutaneously coupled to the secondary coil to transfer energy to the implantable medical device;

a housing having a side adapted to be positioned in proximity to the secondary coil when the primary coil is transcutaneously coupled to the secondary coil;

a temperature sensor adapted to provide an output indicative of a temperature of the side of the housing; and

control circuitry adapted to control the transfer of energy to the implantable medical device based on the output of the temperature sensor to limit a temperature to which a patient is exposed during the transfer of energy to the implantable medical device.

E. Prior Art and Asserted Grounds

Petitioner asserts the following grounds:

Claims Challenged	35 U.S.C. §	References
1, 2, 4, 9, 11, 12, 14, 15, 18–20	103	Torgerson,[1] UL 544[2]
3, 6–8, 13, 16, 17, 21–24	103	Torgerson, UL 544, Wang[3]
5, 10	103	Torgerson, UL 544, Mann[4]
1, 2, 4, 9, 11, 12, 14, 15, 18–20	103	Barreras,[5] Taylor[6]
3, 6–8, 13, 16, 17, 21–24	103	Barreras, Taylor, Wang
5, 10	103	Barreras, Taylor, Mann

[1] PCT Pub. No. WO 01/83029 A1, pub. Nov. 8, 2001 (Ex. 1005).

[2] UL 544, Standard for Medical and Dental Equipment (4th ed. 1998) (Ex. 1006).

[3] U.S. Patent No. 5,702,431, iss. Dec. 30, 1997 (Ex. 1007).

[4] U.S. Patent No. 4,082,097, iss. Apr. 4, 1978 (Ex. 1008).

[5] U.S. Patent No. 5,733,313, iss. Mar. 31, 1998 (Ex. 1009).

[6] U.S. Patent No. 6,685,638 B1, filed Dec. 23, 2002, iss. Feb. 3, 2004 (Ex. 1010).

Petitioner relies on testimony from Michael Colvin, Ph.D, who has a doctorate in Physical Chemistry and 30 years of experience in the implantable medical device industry. Ex. 1003 ¶ 4.

II. PATENTABILITY ANALYSIS

A. Claim Construction

"[W]e need only construe terms 'that are in controversy, and only to the extent necessary to resolve the controversy.'" *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)). No terms require explicit construction in this Decision.

B. Level of Ordinary Skill in the Art

Petitioner asserts that a person of ordinary skill in the art would have had "a bachelor's degree in engineering as well as at least three years of experience in the industry working with active implantable medical devices; or with a bachelor's of science degree, a POSITA would have six years of experience designing, manufacturing, or overseeing active implantable medical systems." Pet. 5 (citing Ex. 1003 ¶ 52).

Patent Owner "does not acquiesce to Petitioner's definition," but does not propose its own definition. Prelim. Resp. 10. Instead, it states that it "reserves the right to propose an alternative definition of a POSITA should the Board grant institution." *Id.* at 11.

For purposes of this Decision, we apply Petitioner's proposed definition of the level of ordinary skill.

C. Analysis of the Torgerson—UL 544 Obviousness Grounds

Petitioner asserts that independent claims 1, 12, and 20 would have been obvious in view of Torgerson and UL 544. Pet. 13–17, 18–26, 28–31, 33–36. In general, independent claim 1 recites an external device for transferring energy to an implanted device. The external device has a housing, a temperature sensor, and control circuitry. The temperature sensor indicates the temperature of the housing, and the control circuitry controls the transfer of energy to limit the temperature to which a patient is exposed. Independent claims 12 and 20 have similar scope.[7]

Petitioner chiefly relies on Torgerson, which is directed to "a battery recharge management system for implantable medical devices." Ex. 1005, 1:5–6; *see also* Pet. 13–15. Like the '324 patent, Torgerson addresses the problem of heat generation during recharging of an implantable device. Ex. 1005, 3:8 ("it is undesirable to overheat and damage the battery if it is discharged too rapidly"), 9:21–23 (describing circuitry to ensure that "any temperature rise during recharge does not create an unsafe condition for the patient"). To that end, Torgerson includes a temperature sensor and control circuitry adapted to control energy transfer to the implantable device based on the output of the temperature sensor, in order to ensure that the temperature rise does not create an unsafe condition for the patient. *See, e.g.*, *id.* at 4:22–25 ("The recharge management system regulates the recharge energy that is provided to the battery during recharge by limiting

[7] Claim 12 is directed to a "method for transferring energy from an external device" using components similar to those in claim 1. Claim 20 is directed to a "system for transferring energy to an implantable medical device" and recites components similar to those in claim 1.

the current into the battery, ensuring against overcharging of the battery, . . . and ensuring against overheating of the implantable medical device."). However, the temperature sensor in Torgerson is concerned with the temperature in the *implant*, not the external device. *Id.* at 9:17–26 (describing how the recharge module, "serves to maintain INS [(Implantable Neural Stimulator)] temperature"); Pet. 15 ("Torgerson does not . . . disclose a temperature sensor located on the external charging device and measuring a temperature of the external housing of the external charging device."). Thus, Petitioner turns to UL 544.

UL 544 describes a standard for safety in medical equipment, and in particular, sets forth the maximum allowable external surface temperature of components that touch a patient. Ex. 1006 ¶ 36. The standard sets out a testing procedure that requires a thermocouple to be attached to the surface of the device to be tested. *Id.* ¶ 45.1.9; *see also id.* ¶¶ 45.1.1–45.1.3 (setting out the temperature test procedure). According to the standard, "[d]uring the temperature test, the temperature on the part that is necessary to be applied to the patient so as to perform its intended function, but not intended to supply heat to patient, shall not exceed 41°C (106°F)." *Id.* ¶ 36.2.

Taking into account these disclosures, Petitioner proposes to modify the device in Torgerson using knowledge gleaned from UL 544. Pet. 16–17. Petitioner states that Torgerson's device is applied to the skin of the patient, and therefore is subject to the standard in UL 544 relating to maximum temperatures. *Id.* at 16. Petitioner asserts that the charging device would not have been approved for marketing to patients unless it met the standard. *Id.* Thus, according to Petitioner, "it would have been obvious, if not compulsory, for one of skill in the art in the medical device industry to

include a thermocouple . . . connected to the [external device housing] and to include control circuitry to ensure the external charging device does not exceed" the temperature set forth in the UL 544 standard. *Id.* at 17.

Patent Owner argues that UL 544 teaches a laboratory testing procedure that is not a part of the medical device during its normal operation, and thus does not lead one to a device as claimed. Prelim. Resp. 14–17. We are persuaded by Patent Owner that Petitioner fails to provide a sufficient rationale in support of the asserted combination.

UL 544 describes requirements a product must satisfy in order for it to be covered by Underwriters Laboratories Inc. *See generally* Ex. 1006, 8–9. One requirement is to pass a temperature test. *Id.* ¶¶ 36, 45. However, requiring a device to pass a one-off temperature test in a laboratory is not the same *controlling* the transfer of energy *to limit* temperature exposure. Petitioner has not shown that the prior art presented here teaches monitoring the temperature of an external housing or controlling energy transfer based on the temperature of the external housing. Petitioner's contentions do not bridge the gap between a one-off test and a device that not only monitors temperature, but controls it. In sum, Petitioner has not demonstrated sufficiently a rationale to modify Torgerson's device to include an external housing sensor, nor a teaching in the art to control the energy transfer based on the sensor reading. Petitioner's Torgerson grounds fail for these reasons.

D. Analysis of the Barreras—Taylor Obviousness Grounds

Petitioner asserts that independent claims 1, 12, and 20 would have been obvious in view of Barreras and Taylor. Pet. 51–65, 67–69, 70–72. At a high level, Petitioner proposes to take the rechargeable implant system of Barreras and modify it to include a temperature sensor on the exterior

device's housing, as allegedly taught in Taylor. *Id.* at 56 ("While Barreras teaches control circuitry that utilizes the output of a temperature sensor to restrict temperature rise during recharging . . . it does not disclose . . . a temperature sensor directly coupled to such housing. Taylor, in contrast, focuses on the housing of an external transmitter and . . . monitors the external surface temperature.").

Barreras discloses an implantable medical device with the battery recharged by an external device. *See* Ex. 1009, Abstract, Fig. 1. The internal and external devices in Barreras each have a microcontroller, which communicate via RF signals. *Id.* at 7:36–38, 7:44–47. The microcontroller in the external device adjusts the level of RF energy generated based on data transmitted from the microcontroller in the internal device. *Id.* at 8:43–49. The data transmitted represents the voltage level of the RF energy received by the internal device. *Id.* at 8:46–49. The internal microcontroller also monitors the temperature of the internal battery and the voltage level, and will transmit a "'stop' recharging" command to the external device when the battery is charged or if the battery gets too hot. *Id.* at 8:56–9:18.[8]

Petitioner asserts that Barreras teaches all limitations of the independent claims, except "a temperature sensor located on the external

[8] Barreras states that "the micro controller regulates, as a function of temperature, the current level used to recharge the [battery]," but in this instance fails to identify which controller to which it refers. Ex. 1009, 8:56–58. However, later in this passage, Barreras describes the internal microcontroller and circuitry on the internal device regulating the current to the battery "[to] form[] a temperature-controlled, current-regulated [re]charging system." *Id.* at 8:58–9:5. This passage suggests the unspecified microcontroller is the internal one.

charging device to measure a temperature of the external housing." Pet. 54. For that limitation, Petitioner turns to Taylor.

Taylor is directed to an acoustic monitoring system that verifies the adjustment of a valve implanted in the body. Ex. 1010, Abstract. The valve could take the form of a shunt that directs body fluid from one region to another. *Id.* at 1:23–24. For example, a shunt could be implanted into the brain to alleviate buildup of cerebrospinal fluid. *Id.* at 1:25–45. The threshold pressure to permit fluid flow often must be adjusted, and to that end, adjustable valve systems not requiring invasive procedures had been developed. *Id.* at 1:64–2:16. The valves are adjusted using electromagnetic fields. *Id.* at 2:23–33. According to Taylor, x-rays were used to verify the valve positioning after each adjustment, but it was not desirable to expose patients to radiation energy repeatedly. *Id.* at 2:38–54. Thus, Taylor provided an acoustic monitoring system that can be used to verify valve positioning. *Id.* at 2:58–62.

In one embodiment, Taylor describes a device that contains coil pairs used magnetically to adjust the valve, as well as an acoustic sensor that listens for the movement of the valve in response to the magnetic fields. *See, e.g.*, *id.* at 6:51–54 (describing the coil pairs), 7:22–31 (describing the acoustic sensor). The acoustic sensor is in a moveable coupling member to maintain contact with the patient's skin. *Id.* at 7:42–60. Surrounding the coupling member are feet that extend from the coil pairs and serve to rest and balance the housing against the patient and to focus the magnetic fields of the coils. *See, e.g.*, *id.* at 7:64–8:5, 9:3–21; *see also id.* at Fig. 3B (noting that each foot 158 extends from a coil 156). Taylor states that these feet may include a thermistor to assure that the temperature of the feet do not

exceed a particular temperature during patient contact. *Id.* at 9:17–21, 14:31–33, 16:23–26.

With the disclosure of Taylor, Petitioner asserts that it would have been obvious to incorporate the housing and temperature sensor of Taylor into the external device of Barreras, in order to ensure patient safety and regulatory approval for commercial marketing of the medical device. Pet. 56. Petitioner further asserts that it would have been obvious to modify the control circuitry in Barreras to regulate the energy transfer from the external device based on the output of the temperature sensor of Taylor. *Id.* at 56–67. According to Petitioner, such modifications would have been obvious to ensure "safety standards were not exceeded during operation[, which] would have prevented pre-market approval and/or exposed marketers of the device to civil liability." *Id.*

Patent Owner argues that Petitioner has not explained why a person of ordinary skill in the art would seek to incorporate Taylor's feet. Prelim. Resp. 30–31. According to Patent Owner, adding feet would increase the distance between the external and internal devices in Barreras, which would reduce energy transfer efficiency. *Id.* Patent Owner further argues that the proposed combination merely identifies a control circuit and a temperature sensor, but not controlling the energy transfer based on the temperature. *Id.* at 34–36.

We are persuaded that Petitioner has not demonstrated a reasonable likelihood of success. Petitioner looks to a different type of medical device (i.e., not an implant recharging device) operating under different principles (acoustics, physical magnetic coupling) and proposes to incorporate structures (feet) seemingly at odds with the operating principle in Barreras

(i.e., the feet would decrease energy transfer). Petitioner has not addressed sufficiently any of these shortcomings in the asserted combination.

For example, Petitioner asserts that its proposed combination would "ensure patient safety" by providing temperature control of the external component. Pet. 56. But Petitioner offers no persuasive evidence that heat build-up in the external component in Barreras is of concern. Although Taylor discloses heat build-up in an external component, Taylor is not a charging device like Barreras. Instead, Petitioner seems to rely solely on the testimony of its expert for its "patient safety" premise. *Id.* (citing Ex. 1003 ¶ 173). Petitioner's expert testifies, "*if* the external recharger were of a design that was prone to overheating, then inclusion of legs as taught in Taylor would be considered." Ex. 1003 ¶ 173 (emphasis added). Thus, Petitioner's expert does not provide evidence that Barreras's external device would overheat, and instead merely assumes it without evidence or technical analysis to support the assumption. Accordingly, Petitioner's statement that adding the temperature sensors from Taylor would "ensure patient safety" is not sufficiently based on evidence before us.

Similarly, Petitioner asserts that it would have been obvious to regulate the energy transfer "in order to ensure that the temperature limits set by relevant safety standards were not exceeded . . . because [they] would have prevented pre-market approval and/or exposed marketers of the device to civil liability." Pet. 56–57. But Petitioner offers no persuasive evidence in support of that contention. Specifically, Petitioner fails to identify evidence that there was a requirement to continuously monitor the temperature of devices (as opposed to merely passing a laboratory test, such as in UL 544 discussed above). There is no evidence that Barreras, or

devices like it, generates excess heat in the external component. Petitioner's assertions regarding pre-market approval or exposure to liability are speculative (Pet. 56–57), and not sufficiently supported by the evidence before us.

Even if a person of ordinary skill would have had a reason to remedy heat buildup in Barreras's external device, Petitioner has not shown that a person of ordinary skill would rely on the teaching of Taylor's feet, especially given that RF energy transmission is so sensitive to distance. *See* Ex. 1003 ¶ 173 (Petitioner's expert testifying that "the feet/legs of Taylor *per se* may not be desirable . . . as they would increase the distance between the coils and thus reduce charging efficiency"); *see also* Prelim. Resp. 31 (arguing that "addition of the feet would . . . only make the problem [of excess heat] worse").

In sum, there is insufficient evidence that the external component in Barreras would have been subject to overheating on the surface, or that modification with Taylor's legs would have been desirable. Together, therefore, we conclude that Petitioner has not shown a reasonable likelihood of success for the Barreras combination because it has not provided a persuasive rationale for the asserted combination.

E. Discretionary Denial Under 35 U.S.C. § 325(d)

Patent Owner suggests that we deny the Petition under 35 U.S.C. § 325(d). Prelim. Resp. 40–44; *see also* Paper 9 (Petitioner's Reply); Paper 10 (Patent Owner's Sur-Reply). Because we have determined that the Petition has not shown a reasonable likelihood of success, we do not address discretionary denial.

III. ORDER

We determine that Petitioner has not demonstrated a reasonable likelihood of success that one or more challenged claims of the '324 patent would have been unpatentable under the grounds asserted in its Petition.

In view of the foregoing, it is hereby

ORDERED that the Petition is *denied* and that we do not institute an *inter partes* review of the '324 patent.

For PETITIONER:

A. James Isbester
Babak S. Sani
KILPATRICK TOWNSEND & STOCKTON LLP
jisbester@kilpatricktownsend.com
bssani@kilpatricktownsend.com

For PATENT OWNER:

Naveen Modi
Chetan R. Bansal
PAUL HASTINGS LLP
PH-Axonics-MedtronicIPR@paulhastings.com