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Paper No. 7
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEVRO CORP.,
Petitioner,

v.

BOSTON SCIENTIFIC NEUROMODULATION CORPORATION,
Patent Owner.

IPR2019-01341
Patent 8,682,447 B2

Before MICHAEL W. KIM, ROBERT A. POLLOCK, and JASON W. MELVIN, *Administrative Patent Judges*.

MELVIN, *Administrative Patent Judge*.

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314, 37 C.F.R. § 42.4

I. INTRODUCTION

Petitioner, Nevro Corp., filed a Petition (Paper 2, "Pet.") requesting *inter partes* review of claims 1, 3, 5–7, and 9 ("the challenged claims") of U.S. Patent No. 8,682,447 B2 (Ex. 1001, "the '447 patent"). Patent Owner, Boston Scientific Neuromodulation Corp.,[1] timely filed a Preliminary Response. Paper 6 ("Prelim. Resp."). Pursuant to 35 U.S.C. § 314 and 37 C.F.R. § 42.4(a), we have authority to determine whether to institute review.

An *inter partes* review may not be instituted unless "the information presented in the petition . . . and any 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). For the reasons set forth below, we conclude that Petitioner has shown a reasonable likelihood it will prevail in establishing the unpatentability of at least one challenged claim. We, therefore, institute *inter partes* review.

A. RELATED MATTERS

As required by our rules, each party identifies related judicial or administrative proceedings that this proceeding may affect. Pet. 58; Paper 4. The parties have identified: U.S. Patent No. 6,993,384 ("the '384 patent"), of which the '447 patent claims benefit; U.S. Patent No. 7,853,330 ("the '330 patent"), which claims benefit of the '447 patent; pending U.S. Patent Application No. 16/018,568, filed June 26, 2018, which claims benefit of the

[1] Patent Owner is a wholly owned subsidiary of Boston Scientific Corp., which Patent Owner identifies as a real party in interest. Paper 4.

’447 patent; and the district court case *Boston Scientific Corp. et al. v. Nevro Corp.*, No. 1:18-cv-00644 (D. Del.). Pet. 58, Paper 4.

B. THE ’447 PATENT

The ’447 patent relates to neurostimulation systems such as for spinal cord stimulation. Ex. 1001, 1:15–16. It addresses the need for verifying the position of electrode leads. *Id.* at 1:20–52. The ’447 patent describes two techniques for determining relative orientation of an electrode on one lead to electrodes on another lead—measuring interelectrode impedance and measuring field potentials. *Id.* at 1:44–52, 3:9–14. Figure 1 of the ’447 patent is reproduced below:

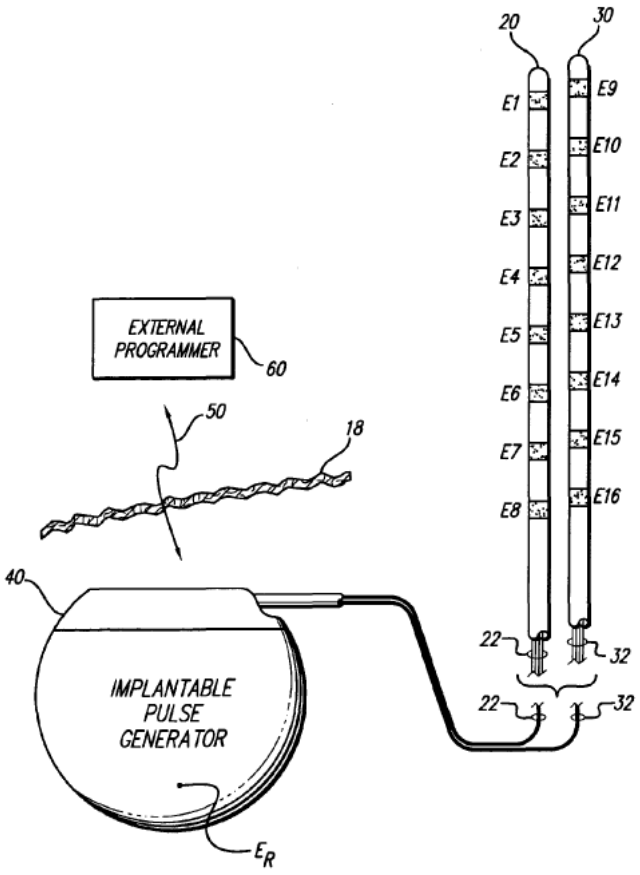


FIG. 1

Figure 1 depicts a neurostimulation system as used in the ’447 patent, containing implantable pulse generator (IPG) 40 connected to first implantable lead 20 with a series of in-line electrodes, E1 through E8, and second implantable lead 30 with a series of in-line electrodes, E9 through E16. *Id.* at 3:15–37. Each electrode may be individually selected to receive an electrical stimulus from the IPG. *Id.* at 3:38–58. The IPG may source or sink current having a desired amplitude through a given electrode, and also may measure an electrode’s voltage, regardless of whether current is flowing through the electrode. *Id.* at 4:50–65.

To measure electrode relative locations, the described system can measure impedance vectors—the impedance values between pairs of electrodes in the body. *Id.* at 6:23–39. The ’447 patent also describes an alternative technique for determining relative electrode positions, using electric field measurements of the electrodes. *Id.* at 7:51–9:8. Once determined, relative electrode locations “may be used to track lead migration, to setup stimulation configurations and parameters for nominal stimulation and/or navigation, and to automatically adjust stimulation energy to a previously-defined optimal potential field in the case of lead migration or postural changes.” *Id.* at 9:8–13.

C. CHALLENGED CLAIMS

Challenged claim 1 is independent and is reproduced below:

1. A method, comprising:

determining, using circuitry, a relative two-dimensional orientation of first and second multiple-electrode leads implanted within a user;

conveying electrical stimulation energy from a pulse generator implanted within the user into tissue of the

user via the first and second multiple-electrode leads; and

displaying the relative two-dimensional orientation of the first and second multiple-electrode leads.

Id. at 10:51–59. Claims 3, 5–7, and 9 each directly depend from claim 1. *Id.* at 10:66–11:38.

D. Prior Art and Asserted Grounds

Petitioner asserts the following grounds of unpatentability:

Claims Challenged	35 U.S.C. §	References
1, 3, 5, 9	103	Barreras,[2] Swanson[3]
6, 7	103	Barreras, Swanson, Meadows[4]

Pet. 4. Petitioner also relies on the Declaration of Dr. Mark Kroll (Ex. 1003). *See generally* Pet. 2–57.

II. ANALYSIS

A. Level of Ordinary Skill in the Art

Petitioner submits that a person of ordinary skill in the art at the time of invention would have had "(1) at least a bachelor's degree in electrical engineering, biomedical engineering, or equivalent coursework, and (2) at least one year of experience researching or developing implantable medical devices." Pet. 15 (citing Ex. 1003 ¶¶ 15–18). Petitioner further submits that such a person "would have had general knowledge of implantable medical devices and various related technologies as of December 4, 2001." *Id.* (citing

[2] US 5,895,416, issued Apr. 20, 1999 (Ex. 1005).
[3] US 5,876,336, issued Mar. 2, 1999 (Ex. 1006).
[4] WO 02/09808 A1, published Feb. 7, 2002, filed July 26, 2000 (Ex. 1007).

same). At this stage, Patent Owner adopts Petitioner's definition of a skilled artisan. Prelim. Resp. 6. We agree that Petitioner's definition of the level of ordinary skill in the art reflects the disclosures of the '447 patent and the prior art at issue, and therefore adopt it.

B. Claim Construction

For an *inter partes* review petition filed after November 13, 2018, we construe claim terms "using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. 282(b)." 37 C.F.R. § 42.100(b) (2019).

Petitioner asserts that the terms in the challenged claims should receive their plain meaning and that none requires an express construction. Pet. 15–16. Patent Owner agrees that, at this stage, no term requires express construction. PO Prelim. Resp. 6. We agree that no express constructions are required to resolve the question of institution. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017); *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999).

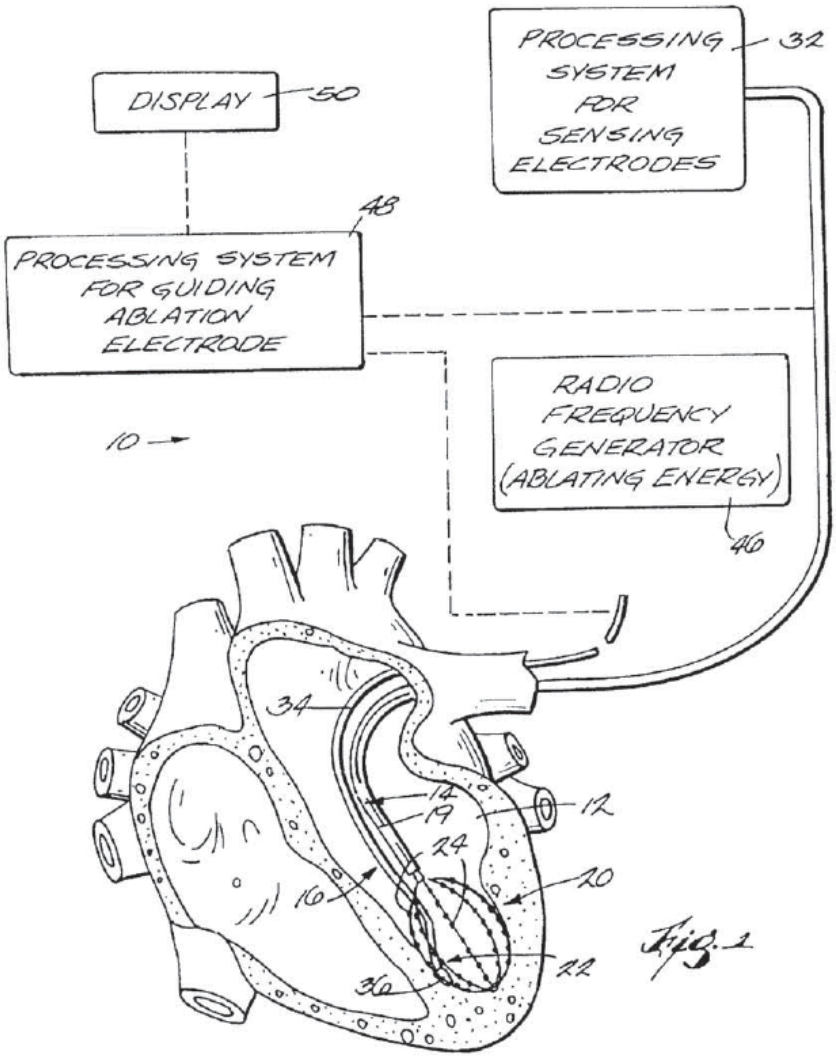
C. Unpatentability over Barreras and Swanson

Barreras describes a method and apparatus for electrically stimulating nerve tissue using implanted electrodes. Ex. 1005, 1:8–27. Barreras includes embodiments with multiple leads, each with multiple electrodes. *Id.* at 5:6–30, Figs. 5, 6. An implanted stimulator can assign individual electrodes as positive (an anode) or negative (a cathode) to create the desired stimulation field. *Id.* at 5:6–30. Barreras refers to that approach as field steering. *Id.* at code (57), 1:7–27. Further, Barreras discloses a technique of measuring

electrode impedance and using it to determine the applied voltage, thus maintaining a desired stimulation pattern. *Id.* at 2:60–65, 8:22–34.

Barreras additionally describes a mechanical steering system, used by a physician to achieve the desired positioning when implanting the electrodes. Ex. 1005, 2:18–31, 3:15–24. The system allows the physician to guide a lead's distal end to navigate away from obstacles and achieve the desired final implantation position. *Id.*

Swanson describes "systems and methods for guiding or locating diagnostic or therapeutic electrode elements in the interior regions of the body." Ex. 1006, 1:13–15. To guide an electrode such as an ablation probe relative to another electrode such as one that is part of a mapping probe having electrodes 24, Swanson uses "processing element 48 electrically coupled to the mapping probe 14 and the ablation probe 16." *Id.* at 6:61–63. Swanson's processing element "collects and processes information regarding the location of the ablation probe 16 within the space 22 defined by the basket structure 20, in term of its position relative to the position of the electrodes 24." *Id.* at 6:63–67. Swanson's Figure 1 is reproduced below:



Swanson's Figure 1 depicts system 10 with processing element 48 electrically coupled to ablation probe 16 and mapping probe 14, which has electrodes 24 making up basket structure 20. Ex. 1006, 6:61–67, Fig. 1.

Swanson discloses multiple modes of operation to determine the relative position of the ablation and mapping probes. Petitioner relies on Swanson's impedance-sensing mode, in which the processor measures the impedance between the ablation electrode and the electrodes on the mapping probe. *Id.* at 15:27–16:41.

Petitioner recognizes that Barreras implements a system capable of directing stimulation energy to a desired site by controlling the electric field across a number of electrodes. Pet. 26–27. Petitioner further points out that Barreras includes a mechanical steering system to help position the electrode leads during implantation. *Id.* at 27 (citing Ex. 1005, 2:18–31, 3:14–24). Thus, reasons Petitioner, "[a] physician engaged in attempting to mechanically steer the leads upon initial insertion would thus clearly benefit from knowing the relative orientation of the second lead to be implanted relative to first implanted lead." *Id.* at 27–28 (citing Ex. 1003 ¶¶ 66–67).[5] In light of the similarities between Barreras's need for guiding an electrode lead and Swanson's ability to help guide such leads, Petitioner asserts that skilled artisans would have improved Barreras's with Swanson's method. *Id.* at 28–29 ("The use of Swanson's method for determining and displaying the relative two-dimensional orientation of an implanted, multi-electrode cardiac ablation lead relative to a plurality of implanted, multi-electrode, mapping leads would have been applicable in improving Barreras's mechanical steering embodiment."). Patent Owner disputes that assertion.

Patent Owner argues that because Barreras describes a system agnostic to lead orientation, there would have been no reason to modify it to determine lead orientation. Prelim. Resp. 15–22. In that argument, Patent Owner relies on Barreras's ability to adjust its applied voltages to maintain a constant stimulation pattern. *Id.* at 17–18 (citing Ex. 1005, 2:46–48, 8:13–

[5] Petitioner argues further that "a physician adjusting the programming would benefit from knowing whether and how the leads had shifted over time, allowing more precise programming of the device." *Id.* at 28 (citing Ex. 1003 ¶¶ 67–68).

34, code (57)). According to Patent Owner, because Barreras "purported to have already solved the problem of lead migration, it teaches away from adding another redundant solution" Prelim. Resp. 19.

We do not find Patent Owner's argument persuasive. Petitioner relies on the idea that skilled artisans had reason to enhance Barreras's system to benefit the implantation process, when a physician uses Barreras's mechanical steering system to guide the leads for implantation. Pet. 27–28. Thus, the combined system offers a benefit that does not "disregard and contradict Barreras's inventive concept" as Patent Owner asserts. *See* Prelim. Resp. 19. Rather, it would allow an improved ability to determine lead orientation during implantation, a situation unaddressed by Barreras's field steering.

Patent Owner recognizes Petitioner's focus on improving Barreras's mechanical steering; however, Patent Owner argues that the claims cannot encompass measuring electrode position during implantation because the challenged claims require "conveying electrical stimulation energy from a pulse generator implanted within the user." Prelim. Resp. 21 (quoting Ex. 1001, claim 1). Thus, according to Patent Owner, the claims are directed to the post-implantation period, when the electrodes have been placed and connected to an implanted stimulator. *Id.* at 21 n.1. But Patent Owner's argument seems to assume that because conveying stimulation energy from the implanted pulse generator may occur only after electrode placement, the other claimed method steps must follow that same sequence. Such a sequence does not appear to be required by the claim language, and we decline to impose such a requirement without the parties developing the argument further.

Patent Owner argues additionally that fundamental differences between the applications for Barreras's and Swanson's devices mean skilled artisans would not have looked to Swanson for an enhancement to Barreras. Prelim. Resp. 22–30. Patent Owner points out that because Barreras's device operates in the epidural space, which is heterogeneous, it requires corrective calculations to account for the tissue variation. *Id.* at 25–26 (citing Ex. 1005, 2:6–9, 2:19–32). In contrast, urges Patent Owner, Swanson's device operates in the heart's blood pool, which is homogeneous. *Id.* at 26–27 (citing Ex. 1006, 9:31–32, 16:20–24). According to Patent Owner, Swanson's lack of compensation renders it inapplicable to Barreras or the invention claimed in the '447 patent. *Id.* We do not find this argument persuasive on the present record because the challenged claims do not recite any requirement to compensate for variation in a heterogeneous tissue field.

Patent Owner relies additionally on the effect that encapsulation, the body's response to an implanted electrode, has on impedance measurements. Prelim. Resp. 27–30. Patent Owner points out that chronic epidural implantation, such as in Barreras, results in electrode encapsulation. *Id.* at 27–28. Because Swanson's system does not account for encapsulation, Patent Owner argues its methods are not applicable to Barreras. *Id.* at 29–30. That argument, however, does not consider that Petitioner asserts the use of Swanson's measurement techniques while using Barreras's mechanical steering system—i.e., during the initial implantation procedure—when encapsulation would not have been a factor. Thus, we do not agree with Patent Owner's argument that the Petition is deficient for failing to explain why a skilled artisan would use Swanson's system even though it did not account for electrode encapsulation. *See* Prelim. Resp. 30.

Considering Petitioner's submissions against Patent Owner's arguments in light of the record at this stage of the proceeding, we are persuaded that Petitioner has provided an adequate reason that skilled artisans would have used Swanson's teachings for determining electrode orientation in combination with Barreras's system of stimulation electrodes.

Patent Owner does not challenge any other aspect of Petitioner's contentions against claim 1 at this stage. We have considered Petitioner's contentions and determine that they are sufficient for institution. Petitioner has shown a reasonable likelihood it will prevail with respect to unpatentability of claim 1 over Barreras and Swanson.

Petitioner provides additional contentions regarding the disclosures of Barreras and Swanson relevant to claims 3, 5, 9. Pet. 41–50. Patent Owner does not challenge those contentions at this stage. We have considered Petitioner's contentions and determine they are sufficient for institution.

D. UNPATENTABILITY OVER BARRERAS, SWANSON, AND MEADOWS

Claims 6 and 7 each depend from claim 1 and further recite a step of "comparing the displayed relative two-dimensional orientation of the first and second multiple-electrode leads" with a display of "a previously measured" (claim 6) or "a previously entered" (claim 7) relative orientation of the two leads. Petitioner asserts that a physician using claim 1's method must perform the comparison, "otherwise the currently measured information is useless." Pet. 51 (arguing also that "the physician would not be able to ascertain relative motion between two leads" without comparing the displayed orientation to a previous orientation (citing Ex. 1003 ¶¶ 122–123)). Petitioner asserts further that "Meadows confirms the state-of-the-art" as including the claimed comparisons. *Id.* (citing Ex. 1003 ¶ 124). Thus,

according to Petitioner, "it would have been obvious for the device to also perform a comparison with a previously measured and saved value" or "a previously entered orientation, e.g., an initial, as implanted, orientation." Pet. 53–54 (citing Ex. 1007, 8:21–25, 30:14–32, 46:31–33; Ex. 1003 ¶¶ 128–130), 55–57 (citing Ex. 1007, 8:21–25, 31:1–12; Ex. 1003 ¶¶ 131–136).

Patent Owner argues that Petitioner's reliance on Meadows is improper because Meadows is not prior art. PO Prelim. Resp. 31–32. According to Patent Owner, because Meadows was filed before November 29, 2000, it may be applied only as of its publication date under §§ 102(a) or (b), not as of its application date under § 102(e). *Id.* (citing MPEP § 2136.03 II.B).

We do not address Patent Owner's argument at this time, as an institution decision treats all claims collectively. In light of our conclusion above that Petitioner has met the institution threshold for claim 1, we leave Meadows's availability as prior art, and the effect of that issue, if any, on Petitioner's challenge to claims 6 and 7, for resolution through trial.

III. CONCLUSION

For the reasons discussed above, we conclude Petitioner has shown a reasonable likelihood of prevailing with respect to at least one claim.

IV. ORDER

Accordingly, it is

ORDERED that, pursuant to 35 U.S.C. § 314(a) *inter partes* review of the '447 patent is instituted on all claims and grounds set forth in the Petition;

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial commencing on the entry date of this decision.

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