UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEVRO CORP.
Petitioner

v.

BOSTON SCIENTIFIC NEUROMODULATION CORPORATION
Patent Owner

Case IPR2019-01341
Patent 8,682,447

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 8,682,447

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Boston Scientific Neuromodulation Corporation ("BSNC") is the assignee of U.S. Patent No. 8,682,447 (EX1001). Petitioner Nevro Corporation seeks *inter partes* review of claims 1, 3, 5-7, and 9 of the '447 patent.

I. Introduction

The '447 patent is directed to a "method for determining the relative position and orientation of electrodes on a neurostimulation lead or leads used with such a system." EX1001, 1:15-19. Independent claim 1 is an extremely broad method claim. It claims the mere *concept* of "determining, using circuitry" the relative two-dimensional orientation of a pair of multi-electrode leads implanted within a user, and then displaying that orientation. The specific "circuitry" employed by the method is left undefined and unclaimed. The patentee obtained allowance only after multiple amendments to the claims that ultimately added an implantable pulse generator for conveying stimulation energy to the leads, and then arguing that the applied art, which was in the cardiac ablation space, did not include an implanted pulse generator. But implanted pulse generators were well-known in the art, including in art the patentee itself cited in its IDS. The examiner did not evaluate that art, on the record, and should not have allowed the challenged claims to issue based on that amendment.

Implantable medical devices ("IMDs") of the type described in the '447 patent—namely, implantable leads and pulse generators for electrical stimulation—were well known in the art by December 4, 2001, the earliest possible priority date of the ’447 patent. They were known in both the spinal cord and cardiac stimulation spaces. Since the leads are designed to stimulate very particular areas and tissues within the body, knowing their location is important. And in systems with multiple leads, knowing the relative position of the plurality of leads with respect to each other is also important because the leads work together to define a particular stimulation pattern. This is also true because the leads can unintentionally move after implantation. For these reasons, physicians, clinicians and others responsible for programming the stimulation parameters naturally wanted to be able to ascertain whether and how much the implanted leads have moved from an initial position. EX1003, ¶¶23-28.

While the ’447 patent’s independent claim 1 does not so specify, one recognized way to determine whether the leads have moved relative to each other is by monitoring or measuring the impedance between selected electrodes on the plurality of implanted leads. This is because it was well known that the impedance between implanted electrodes will change as the distance between the electrodes change—typically, the further the distance, the higher the impedance.[1] The prior-

[1] Electrical impedance is the apparent opposition in an electrical system to the flow of an alternating current that is analogous to the actual electrical resistance

art Barreras (EX1005) reference, which is in the spinal cord stimulation space, explains some of these common principles. Barreras also unambiguously has an implantable pulse generator—the last feature added during prosecution that finally distinguished the applied prior art.

In the cardiac stimulation space, it is also important to be able to locate a stimulation electrode, or electrodes used for other purposes like ablation surgery. EX1003, ¶30; *see also* EX1003, ¶¶1-29. Prior-art like Swanson (EX1006), as the examiner recognized during prosecution, shows that it was well-known that one can determine the relative location of a lead in a multiple lead system by monitoring and measuring the impedance between electrodes on opposite leads. More specifically, Swanson infers the position of one or more cardiac ablation electrodes by measuring impedance between an electrode on the ablation lead relative to electrodes on one of a plurality of leads that make up a "basket" of electrodes also implanted within the heart. EX1003, ¶30.

Swanson and Barreras, together, thus render obvious at least claims 1, 3, 5, 6, and 9 of the '447 patent. EX1003, ¶31. The examiner during prosecution never substantively considered the combination of Swanson and Barreras.

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to a direct current. EX1003, ¶29. How it behaves in the human body was well known at the time of the alleged invention. EX1003, ¶29.

II. Identification of Challenge

Nevro requests *inter partes* review of claims 1, 3, 5-7, and 9 of the ’447 patent and a determination that those claims are unpatentable based on the following grounds:

Ground	References	Basis	Claims Challenged
1	Barreras and Swanson	35 U.S.C. § 103	1, 3, 5, and 9.
2	Barreras, Swanson, and Meadows	35 U.S.C. § 103	6 and 7.

The prior art references cited for each ground above qualifies as prior art to the ’447 patent for the following reasons:

- U.S. Pat. No. 5,895,416 to Barreras (EX1005) qualifies as a prior art patent under 35 U.S.C. § 102(b) because it was published on April 20, 1999, which precedes the earliest priority date (December 4, 2001) of the ’447 patent by over a year.
- U.S. Patent No. 5,876,336 to Swanson (EX1006) qualifies as a prior art patent under 35 U.S.C. § 102(b) because it was published on March 2, 1999, which precedes the earliest priority date (December 4, 2001) of the ’447 patent by over a year.

Other prior art considered to demonstrate the state-of-the art at the time of filing includes:

- International Publication WO 02/09808 A1 to Meadows (EX1007). Meadows qualifies as prior art under at least 35 U.S.C. § 102(e).

III. The ’447 Patent

A. Overview

The ’447 patent is directed to an apparatus and method for determining the relative position and orientation of neurostimulation leads. EX1001, Title. The ’447 patent explains that neurostimulation systems (such as spinal cord stimulation, or “SCS”) depend at least in part on the relative position and orientation of electrodes on a neurostimulation lead (or leads) used with such a system. EX1001, 1:15-19; EX1003, ¶32. During surgery, a provider (e.g., surgeon) places the leads to locate electrodes proximal to neural elements that are the target of the stimulation, and verifies appropriate placement by applying stimulation energy to ensure that the patient experiences the desired effect. *See* EX1001, 1:20-26; EX1003, ¶33.

During normal use, however, the leads may shift position. And if that happens, the targeted neural elements may no longer be appropriately stimulated. EX1001, 1:27-28. This may require reprogramming or surgical revision. *See, e.g.*, EX1001, 1:29-40. The ’447 patent purports to improve on prior methods of determining whether and how a lead has shifted by utilizing, for example, interelectrode impedance. *See* EX1001, 1:44-57; EX1003, ¶33.

Specifically, the ’447 patent discloses that the value of an “impedance vector” is due primarily due to (1) the electrode-electrode interface; and (2) the bulk impedance between electrodes. EX1001, 6:39-43. The patentee expressly defined the term “impedance vector” as “an impedance value measured between two electrodes in the body.” EX1001, 6:38-39. The specification then describes an “impedance tomography technique” that relies on the latter of those properties—the bulk impedance between electrodes. EX1003, ¶¶33-34.

According to the specification, the relative lead orientation “may be inferred by making the following measurements: 1. Monopolar impedances for all electrodes; and 2. Bipolar impedances between each electrode on opposing leads.” EX1001, 7:1-6. The “monopolar impedances are used to ‘correct’ the bipolar impedances for the first factor of bulk impedance, the strongly-weighted impedance near the electrode.” EX1001, 7:7-9. The specification then discloses that “after the bipolar impedances are corrected …, the relative orientation of the leads may be inferred by the relative minima of the impedance values.” EX1001, 7:22-24. Specifically, “[w]here the corrected bipolar impedance between two electrodes is a minimum relative to other electrodes on an opposing array, those electrodes are relatively adjacent.” EX1001, 7:24-27. Any POSA would have easily recognized the fact that the impedance between two electrodes decreases with decreasing distance. EX1003, ¶¶35-36. Indeed, the ’447 patent itself describes this as a “simple interelectrode impedance technique.” EX1001, 7:44-45; EX1003, ¶36.

With respect to the claimed step of "displaying the relative two dimensional orientation," the '447 patent specification discloses that the information obtained from the impedance measurements and calculations "may be loaded into a programmer, which can then provide a graphic display of the assumed relative lead positions." EX1001, 7:27-29. That data can then "be compared with previously measured or entered and stored graphics, indicating earlier orientations" and that comparison "can help the physician/clinician to track the lead orientation to determine appropriate programming, reprogramming, or need for surgical revision." EX1001, 7:29-34; EX1003, ¶¶37-38.

With respect to the comparing step, the '447 patent specification is broad. It discloses that "[t]he previously-saved electric field data may have been obtained during initial implantation of the leads, or during the last visit (several weeks or months ago) to the doctor. Or, the previously saved electric field data may have been obtained just a [f]ew hours or minutes ago at a time when the patient's body had assumed a different posture position." EX1006, 9:33-38. Irrespective of when the prior measurement was made, the '447 patent is clear that "the purpose of the comparison … is to determine if the relative position of the leads has changed, which change in position would also have caused a relative change in the position of the electrodes carried on the leads." EX1006, 9:38-47; EX1003, ¶38.

*   *   *

In sum, the ’447 patent describes a simple technique of determining the relative orientation between a pair of multiple-electrode leads. It determines the bulk bipolar impedance between two electrodes, corrects for the monopolar impedance around single electrodes, and infers that two electrodes on opposite leads will be nearest each other when the bulk impedance is at a relative minimum. This admittedly simple technique relies on well-known relationship between impedance and distance in implanted electrodes. EX1003, ¶39.

B. Prosecution History Summary

Originally filed independent claim 1 was sought to preclude all methods of determining and displaying the relative position of pair of multiple-electrode leads. It recited:

> 1. A method, comprising:
>
> determining the relative position of first and second multiple-electrode leads; and
>
> displaying the relative position of the first and second multiple-electrode leads.

EX1002, 210.

The examiner rejected that claim, and the rest of the claims over U.S. Patent 6,662,053 to Borkan. EX1002, 156. The patentee overcame the rejection by arguing that Borkan “does not disclose that the positions of the electrode are determined relative to each other, but rather determined relative to the tissue (see col. 5, lines 21). In fact, since the relative positions of the electrodes on a lead are already known (based on the fact that the electrodes on any lead will have a known spacing therebetween), there would be no reason to determine the positions of the electrodes on the Borkan lead relative to each other." EX1002, 149.

In the next Office action, the examiner dropped Borkan and rejected the claims over U.S. Patent 5,722,402 to Swanson (EX1008). EX1002, 125-126. The '402 patent is related to the Swanson reference used in Ground 1 of this IPR, and shares substantially the same disclosure. The patentee attempted to argue around Swanson, alleging that "Swanson does not disclose displaying the relative position of the ablation probe 16 and splines 30 of the mapping probe, and there is no suggestion to do so." EX1002, 119. But Swanson does, in fact, display the relative position of the ablation probe with respect to the mapping probes. *See e.g.*, EX1008, '402 patent, 4:64-67 (describing Figure 14 as "representative iso-delay display generated by the element shown in FIG. 12 and showing the location of the ablation electrode within the multiple-electrode structure.").

The examiner thus correctly maintained the rejection over Swanson in the next Office action. The examiner further included a rejection under 35 U.S.C. § 101. EX1002, 111-112.

The patentee then chose to amend claim 1, again, as follows:

1. (Currently Amended) A method, comprising:

> determining ~~the relative position~~ a relative two-dimensional orientation of first and second multiple-electrode leads using circuitry; and
>
> displaying the relative ~~position~~ two-dimensional orientation of the first and second multiple-electrode leads.

EX1002, 092.

The patentee again attempted to distinguish Swanson, arguing that "Swanson does not disclose that the relative orientation between the ablation catheter 16 and the mapping catheter 14 is determined and displayed, and certainly does not disclose that a relative two-dimensional orientation between the catheter 16 and mapping catheter is determined and displayed." EX1002, 098. The examiner again correctly maintained the rejection over Swanson, and further included a rejection under 35 U.S.C. § 112.

The patentee amended claim 1 again, as follows:

> 1. (Currently Amended) 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 the first and second multiple-electrode leads into tissue of the user; and
>
> displaying the relative two-dimensional orientation of the first and second multiple-electrode leads.

EX1002, 061.

The amendment limits the claim to multiple electrode leads that are *implanted within a user*. The patentee argued that Swanson did not disclose that particular feature. *See* EX1002, 070. The examiner again rejected the patentee's argument, alleging that when properly construed, Swanson discloses implanted leads. *See* EX1002, 052.

The patentee again amended claim 1, as follows:

> 1. (Currently Amended) 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 <u>a pulse generator implanted within the user</u> ~~the first and second multiple electrode leads into~~ tissue of the user<u> via the first and second multiple-electrode leads</u>; and
>
> displaying the relative two-dimensional orientation of the first and second multiple electrode leads.

EX1002, 039.

The patentee next argued that Swanson did not disclose an implanted pulse generator, EX1002, 044, and the examiner subsequently allowed the claims, without further comment, EX1002, 017-023. Having worn down the examiner through multiple amendments and argument, this final amendment adding an implanted pulse generator finally secured allowance. That Swanson's surgical ablation system does not include an implantable pulse generator makes sense—Swanson's device is implemented in a surgical setting that does not require such an implantation.

Barreras (EX1005) was cited by the patentee during prosecution of the '447 patent in an Information Disclosure Statement, EX1002, 165, 190, but was not applied in any rejection. There is thus no indication in the prosecution history—the only record available—that the examiner ever revisited any art already made of record, let alone art that included implantable pulse generators. Had the examiner considered Barreras, he would have seen the express disclosure of implanted leads, an implantable pulse generator, and further recognition of relative position shifting leads post-implantation as a problem to be solved, at least in part, through impedance monitoring and measurements.

* * *

The examiner's failure to consider, on the record, Barreras or any other related art having implantable leads and implantable pulse generators is particularly important since Barreras teaches both (1) the exact claim limitations alleged in the final amendment to be missing from Swanson, and (2) an express motivation for looking to references such as Swanson to supply additional improvements using impedance measurements to not only allow for correction of the stimulation pattern, but to further ascertain the relative position of electrodes within a patient.

C. The Office has not previously considered the combination of Barreras and Swanson.

To gain allowance, the patentee amended the claims to be limited to devices having an implanted pulse generator. The examiner did not further investigate, on the record, whether there was relevant prior art having implanted pulse generators. There was, and the patentee had actually cited that art to the examiner. *See* EX1002, 165, 190. However, there is no record showing that the examiner revisited the art cited in the IDS following the patentee's last amendment. *See, e.g.*, EX1002, 017-038. Had the examiner revisited the art in the IDS, the examiner would have recognized the applicability of Barreras, which is specifically directed to implanted devices having an implanted pulse generator. Indeed, Barreras discloses exactly the features that the Applicant added by amendment to secure allowance of the '447 patent.

D. The Claimed Invention

Claim 1 is the only independent claim challenged in this IPR. It 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.

This independent claim recites only the most *basic concept* of determining the relative orientation of two implanted leads and displaying the result. The middle step of conveying electrical stimulation energy from an implanted pulse generator was added during prosecution to avoid prior art in the cardiac space (i.e., Swanson), even though the claims are not limited to any particular type of electrical stimulation.

The challenged dependent claims provide more detail. For example, dependent claim 3 recites that determining the relative two-dimensional orientation of the first and second multiple-electrode leads "comprises measuring impedance vectors between respective electrode pairs that each include one of the electrodes on the first multiple-electrode lead and one of the electrodes on the second multiple-electrode lead." Dependent claim 5 locates the display on a "programmer." Dependent claim 6 describes the obvious step of comparing a prior display of measured orientation, with a currently displayed orientation. But none of the dependent claims recite features that a POSA would not have found obvious at the time of their purported invention.

IV. Level of Ordinary Skill in the Art

A POSA in the context of the ’447 patent at the time of its earliest priority date of December 4, 2001, would have been a person who 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. EX1003, Kroll, ¶¶15-18. A POSA during the relevant timeframe of the ’447 patent would have had general knowledge of implantable medical devices and various related technologies as of December 4, 2001. *Id*.

V. Claim Construction

The claim construction standard set forth in *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005), applies to this proceeding. 83 Fed. Reg. 51,341 (Oct. 11, 2018); 37 C.F.R. § 42.100. Under this standard, words in a claim are given their plain meaning, which is the meaning understood by a person of ordinary skill in the art at the time of the alleged invention after reading the entire patent. *Phillips*, 415 F.3d at 1312-13.

Here, no claim terms appear to be used outside their ordinary and customary meaning, as understood by a POSA and in view of the specification. Accordingly, Petitioner believes the claim terms should receive their plain meaning, in the context of the ’447 patent specification from the perspective of a POSA. At this juncture of the proceeding, no claim terms need be construed to demonstrate that the claims are unpatentable. *Vivid Techs., Inc. v. Amer. Science & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 2000) ("only those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy").

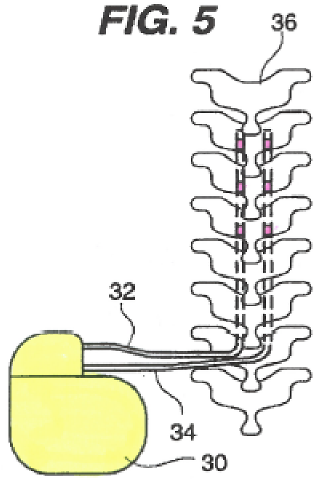
VI. Overview of the Applied References

A. Barreras (EX1005)

Similar to the '447 patent, Barreras relates to selective electrical stimulation of nerve tissue for treating specific diseases or physical disorders. EX1005, 1:7-10 and 1:31-35; EX1003, ¶¶40-41. Specifically, Barreras is directed to a method and apparatus for controlling and steering an electric field in a multi-lead spinal cord stimulation (SCS) device. EX1005, 1:7-10, Title; EX1003, ¶41. Barreras discloses that it had been "well established for a number of years" to use surgically implantable electrical neurological stimulators for control of nerve or brain response to treat intractable pain, epileptic seizures, and tremors from Parkinson's disease. EX1005, 1:30-40; EX1003, ¶41.

Barreras discloses an implantable pulse generator or (implantable stimulator 30) and two implanted multi-electrode leads 32, 34 placed within the epidural space at either side of the midline. EX1005, 5:6-18; EX1003, ¶42. Barreras's FIG. 5 is reproduced below for convenience.

FIG. 5

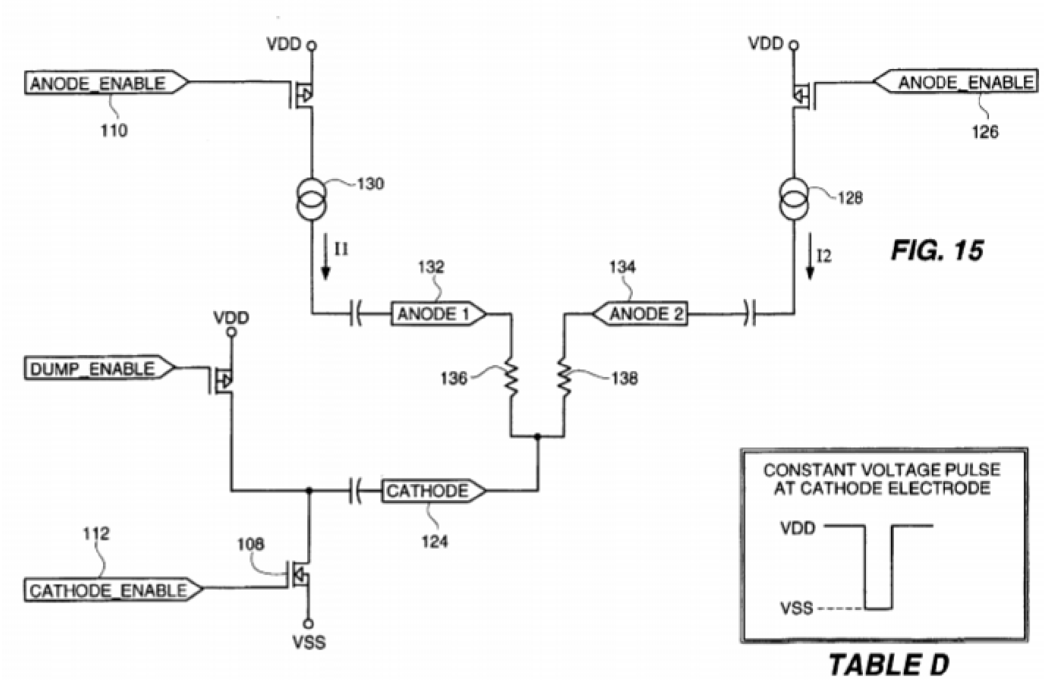


EX1005, FIG. 5 (annotated).

Each of Barreras's electrodes (pink) can serve as an anode or cathode and the size and location of the field can be modulated (via dual channel stimulator 30, shown in yellow) to recruit target nerve tissue—excluding non-target tissue. *See* EX1005, 5:6-18; EX1003, ¶43.

To address the problem of shifting electrode leads after implantation,, Barreras discloses the use of circuitry for automatically changing voltage amplitude at each anode (electrode) to maintain a constant current to preserve the original electric field found to be effective during the course of treatment. EX1005, 1:18-23; EX1003, ¶¶44-45. Maintenance of a constant current is based on measuring the impedance between pairs of electrodes on opposite, multi-electrode leads.

Barreras's FIG. 15 is exemplary and is reproduced below:



EX1005, FIG. 15.

Specifically, Barreras describes a technique for "maintaining the electric field focused at the target nerve area even when changes in electrode impedances 136 and 138 occur, by automatically changing the positive voltage at anodes 132 and 134 as required in order to maintain currents I1 and I2 constant…." EX1005, 8:26-31. According to Barreras, this will "preserv[e] for the duration of the therapy, the original electric field found to be effective at implant time." EX1005, 8:31-32; EX1003, ¶¶44-46.

So Barreras thus constantly monitors and measures the impedances between at least two electrodes on opposite stimulation leads—e.g., electrodes 136 and 138 in FIG. 15—to maintain the stimulation pattern found to be effective at the time of implant. EX1003, ¶47. Barreras allows each electrode of its multi-electrode leads to be so programmed, EX1005, FIG. 13, 7:8-8:13, and thus extends the concept of monitoring impedances to multiple electrodes across the opposing leads, thereby providing a sophisticated means for steering the electric field. EX1003, ¶47.

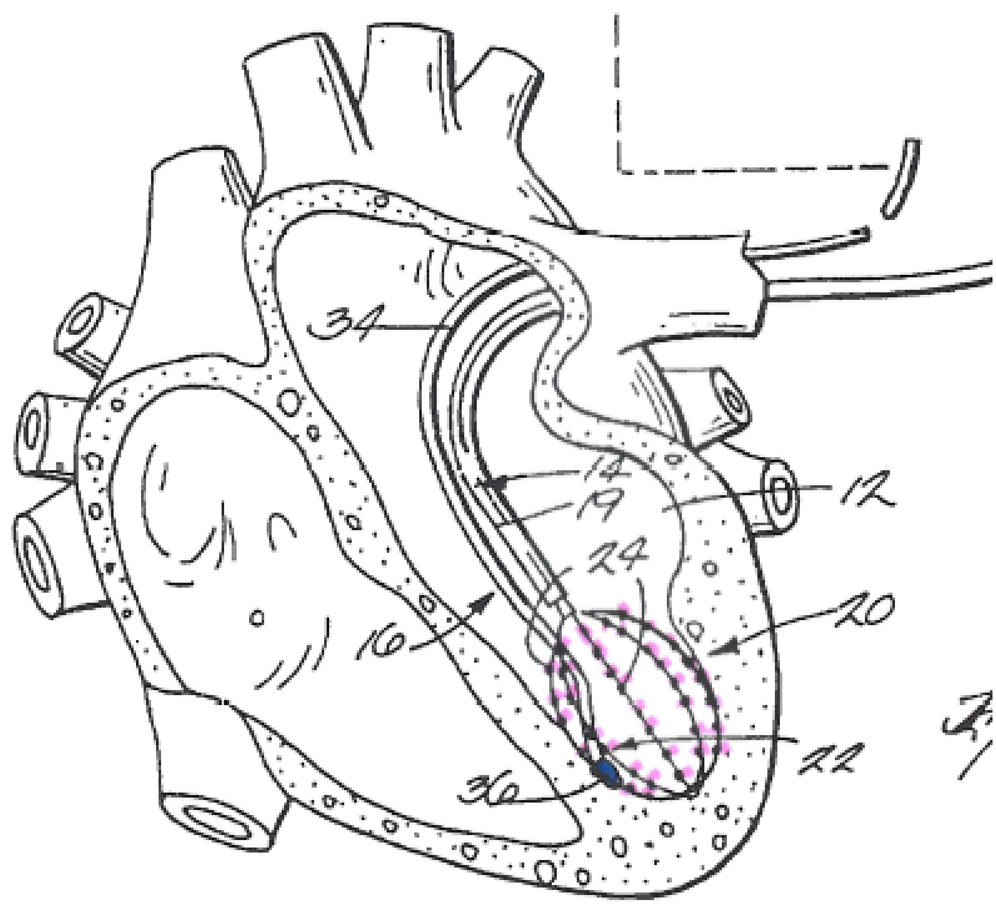
Barreras could be improved if its technique for measuring the impedances across electrodes on opposing leads were leveraged to also provide a relative two-dimensional orientation of the two leads, as recognized and taught by Swanson. EX1003, ¶48. That information would further inform a physician or clinician using Barreras to assist in maintaining the therapy found to be effective at implantation, or to evaluate the need for surgical intervention. EX1003, ¶48. It would also assist a physician in mechanically steering one of the leads relative to another of the leads, which Barreras itself discloses as desirable. EX1005, 3:15-24.

B. Swanson (EX1006)

Swanson relates to "systems and methods for guiding or mechanically steering movable electrode elements within multiple-electrode structures." EX1006, Title; EX1003, ¶49. Swanson emphasizes desirability of being able to determine precise location of electrode elements within a heart, for example, during a surgical ablation procedure. EX1006, 7:4-8, 12-18; EX1003, ¶49.

Specifically, Swanson discloses an ablation probe 16 having "one or more ablation electrodes 36." EX1006, 6:17-19; EX1003, ¶50. A processing element 48 is coupled to a mapping probe 14. EX1006, 6:61-63. The ablation probe 16 collects information, via circuitry, regarding the location of the ablation probe relative to the mapping probe electrodes 24. EX1006, 7:4-12. The locations may be displayed on a display device to allow a physician to remotely guide the ablation electrode. EX1006, 6:61-67, 7:4-9; EX1003, ¶50.

Swanson's FIG. 1 (an enlarged annotated portion of which is reproduced below) shows a general overview of the system, with a set of mapping lead or probe electrodes in a basket configuration, highlighted pink, and a lead carrying one or more ablation electrodes highlighted in blue :

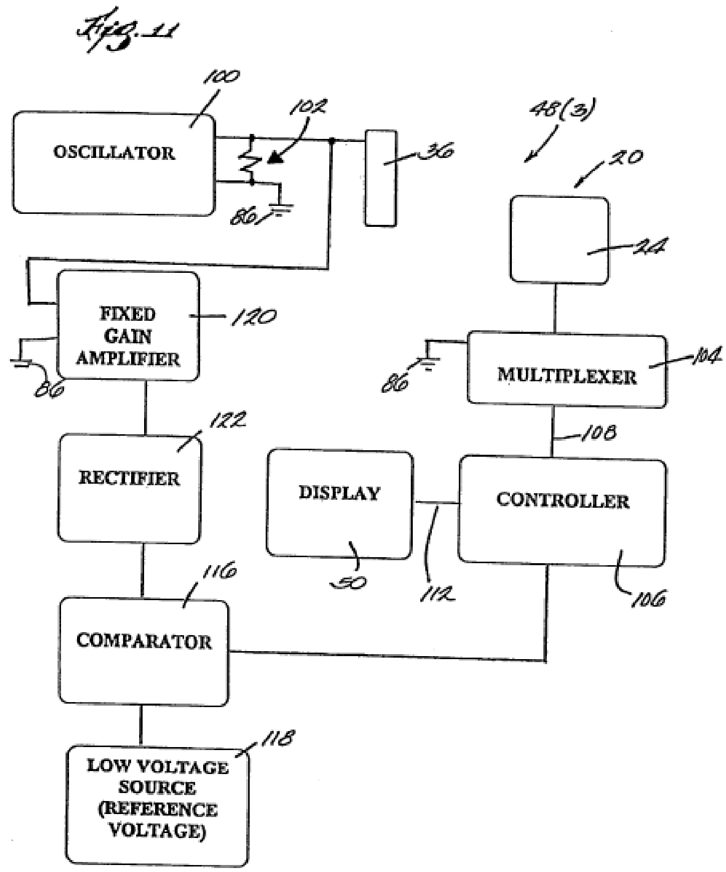


EX1006, FIG. 1.

Swanson describes a number of ways to measure the location of the ablation electrode, including by "analyzing spatial variations in the electrical potentials within the array." EX1006, 2:57-61; EX1003, ¶51. Swanson teaches that "[t]he variations can comprise variations in phase, variations in amplitude, or both." EX1006, 2:59-61. Alternatively, Swanson teaches that "the processing element generates the output by analyzing spatial variations in impedances between the emitting and sensing electrodes." *See, e.g.*, EX1006, 2:61-3:4; EX1003, ¶¶51-53. As two electrodes on opposite leads approach each other, the system senses the "reduced impedance of the blood pool path" when it creates a voltage sensed by a comparator.

Swanson goes on to describe, in detail, how it uses measured impedance to locate the ablation probe, and provide distances between the ablation probe electrode and the array of electrodes. EX1006, 15:27-16:61; EX1003, ¶53. Specifically, Swanson's circuitry embodiments 48(1) and 48(2) "can each additionally employ impedance sensing to indicate when the ablation electrode is in very close proximity to (for example, within 1 to 2 mm) or actually touching the electrode 24 closest to the ablation site." EX1006, 15:37-42. Swanson goes on to disclose that "[i]mpedance sensing can be used with [other techniques to augment] general realtime guidance with great accuracy to finally locate the ablation electrode 36 in the precise location identified for ablation." EX1006, 15:42-46.

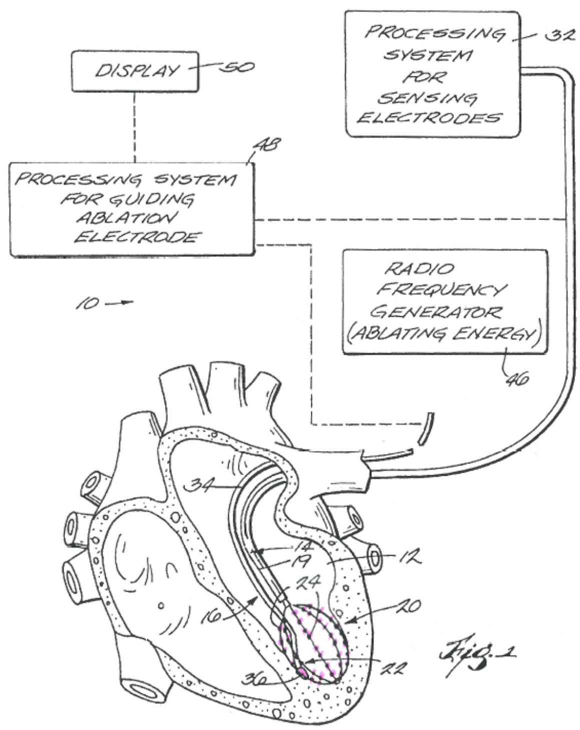
Circuit element 48(3) illustrates the circuitry used to enable the impedance sensing embodiment:



EX1006, FIG. 11.

According to Swanson, "FIG. 11 is a schematic view of an element for determining the location of an ablation electrode within a multiple electrode structure using impedance sensing." EX1006, 4:15-17; EX1003, ¶¶54-55.

Swanson also displays the results on an external programmer. A "programmer" is the part of the system that a physician or clinician, for example, communicates with, and controls, the implanted device through a suitable communications link. *See e.g.*, EX1001, 3:59-63; EX1003, ¶¶55-57. Swanson discloses an "ablation probe guiding system." EX1006, 7:1-22. Swanson's FIG. 1 is illustrative:



EX1006, FIG. 1, FIG. 11, 15:38-16:61 (describing impedance sensing embodiment).

The heart of the ablation probe guiding system is processing system 48. Processing element 48 is electrically coupled to the mapping probe 14 and the ablation probe 16. EX1006, 6:61-65. It also collects and processes information regarding the location of the ablation probe 16 within space 22 defined by the basket structure 20, in terms of its position relative to the position of the electrodes 24." *Id*., 6:62-67. In the impedance sensing embodiment, proximity of two electrodes on opposing leads is indicated by the reduced impedance of the blood pool path between the two electrodes. EX1003, ¶57.

Swanson's ablation probe guiding system also has a display 50 coupled to the processing element 48. EX1006, FIG. 11, FIG. 1, 7:4-10. According to Swanson, the display may be a CRT, LED display, or a printer that that "preferably presents the position identifying output in real-time format most useful to the physician for remotely guiding the ablation electrode 36 within the basket structure 20." EX1006, 7:13-18; EX1003, ¶58. For the impedance sensing embodiment, when the system senses a minimum impedance between two electrodes on opposing leads, "[t]he controller 106 identifies this array electrode on the output display 50 (with, for example, a flashing indicator and an audible prompt), thereby showing the physician the location of the ablation electrode 36 and the identified electrode 24 to be essentially the same." EX1006, 16:42-49.

*   *   *

Swanson thus discloses, in the cardiac ablation space, an apparatus and method for determining the relative position and orientation of implanted multi-electrode leads so that a cardiac ablation electrode can be mechanically steered to the correct location for surgery. EX1003, ¶¶59-60. It does so by measuring the impedance values between electrodes on opposite leads—i.e., an electrode on the ablation probe and an electrode on a mapping probe—and then inferring the relative orientation of the leads by the reduced impedance sensed as the two electrodes approach each other. EX1003, ¶¶59-60. Swanson's method would have thus complemented Barreras desire to also improve mechanical steering of implanted leads. EX1003, ¶¶59-60.

C. Applicant Admitted Prior Art and Other Art

The '447 patent confirms that the general concepts associated with electrical impedance tomography were well known. *See* EX1001, 1:38-40 (citing U.S. Pat. Nos. 4,486,835; 4,539,640; and 5,184,624, which are incorporated by reference in the '447 patent). Additionally, further proof of the state of the art with respect to programmers in the spinal cord stimulation space can be found in the Meadows reference (EX1007). Meadows is directed to a spinal cord implantation system. EX1007, 1, Abstract. It includes both a hand held programmer 202 and a clinician programmer 204. EX1007, 1, Abstract Meadows discloses that its clinician programmer has a "measurement window." EX1007, 31:1-3. Additional details of Meadows disclosure is discussed below. EX1003, ¶¶62-63.

VII. Ground 1: Claims 1, 3, 5, and 9 are rendered obvious in view of Barreras and Swanson.

A POSA would have found claims 1, 3, 5, and 9 of the '447 patent to have been obvious in light of the disclosures of Barreras (EX1005) and Swanson (EX1006).

A. Obviousness principles

In assessing whether a claim is obvious, one must consider (1) the scope and content of the prior art; (2) the level of ordinary skill in the field of the invention; (3) the differences between the claimed invention and the prior art; and (4) any objective evidence of non-obviousness. *See* M.P.E.P. § 2141. An invention is obvious if a person of ordinary skill in the art would have arrived at a claimed invention when it was allegedly invented by the patentee by (a) combining prior art elements according to known methods to yield predictable results; (b) applying a solution from a finite number of identified, predictable solutions, with a reasonable expectation of success; (c) substituting a known element for another to obtain predictable results; and/or (d) using a known technique to improve similar devices (methods, or products) in the same way, the claimed invention would likely have been obvious to a POSA. *See* M.P.E.P. §§ 2141, 2143.

B. Motivation to Combine Barreras and Swanson

Barreras recognizes the same problem articulated in the '447 patent—namely, recognition that electrodes can shift after implantation, thereby shifting the applied electric field, to the detriment of the patent. EX1005, 1:61-67. Barreras also recognizes a similar solution to the problem that monitors and measures the impedance between electrodes on opposite leads. EX1005, 2:60-65, 8:22-34. Barreras solves the problem by automatically adjusting the voltage applied to the electrodes to maintain a constant stimulation pattern. EX1005, 2:60-65, 8:22-34. Barreras thus recognizes that "[a] precise rate of ion flow is required for pain relief" and that "the magnitude of this electron current (and rate of ion flow) is controlled by the impedance between electrodes." EX1005, 2:13-17. Barreras then explains that "[w]hen this impedance changes, the size and or location of the electric field also changes." EX1005, 2:13-17; EX1003, ¶¶64-65.

Beyond electrically steering and impacting the electric field, Barreras also recognizes that physicians need assistance in placing the leads properly within the body. *See* EX1005, 2:18-31. In fact, Barreras explains that one aspect of the invention is to also provide "a mechanical steering system for each of the leads." EX1005, 3:15-24. Benefits of precise mechanical steering include, as Barreras explains, positioning the leads to obtain "paresthesia with the lowest possible electrical energy, thereby recruiting only the target nerve tissue an excluding unwanted nerve tissue." EX1005, 3:20-24. 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. EX1003, ¶¶66-67. Likewise, 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. The device can change the voltages applied to each electrode to maintain constant current based on changes in impedance, and it would be beneficial for a physician adjusting the programming to know this information. EX1003, ¶¶67-68.

Since a POSA would have also recognized the general relationship between distance and impedance between a pair of electrodes implanted in a body, a POSA would have thus been motivated to further leverage Barreras's impedance measurements to improve Barreras. EX1003, ¶69. A POSA would have turned to the cardiac ablation art for additional methods on how to steer a multi-electrode lead within the human body. EX1003, ¶69.

Swanson (EX1006) is a similar field of art as the '447 patent—namely, providing precise electrical stimulation (or ablation energy in Swanson's case) to selected tissue in a human body via an implanted, multi-electrode lead. Indeed, the examiner during original prosecution of the '447 patent applied a related Swanson patent against the application claims. *See* Section III.B. *supra*.

Swanson describes a system and method for mechanically steering an ablation electrode to a precise position within a basket structure of a plurality of mapping probes. *See* Section VI.B. *supra*. Specifically, Swanson describes a variety of ways to determine and display the relative two-dimensional location of a pair of multi-electrode leads, including by measuring impedance between a pair of electrodes on opposite leads. EX1006, 15:26-16:61; EX1003, ¶¶70-72. A POSA would have recognized the applicability of Swanson's teachings to Barreras, and vice versa, because both express a desire for precise mechanical steering of multi-electrode leads implanted within a body, and both recognize and employ electrical impedance tomography in evaluating the location and performance of those leads. EX1003, ¶¶70-72.

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. And use of Swanson's method would have been little more than using a known technique to improve a similar devices or methods, in the same way. EX1003, ¶¶72-73. As such, use of Swanson's technique with Barreras would have been obvious.

C. Independent claim 1

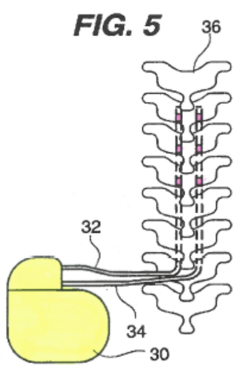
Nevro now specifically maps the claims to the cited art. This mapping supplements the arguments and proof outlined above.

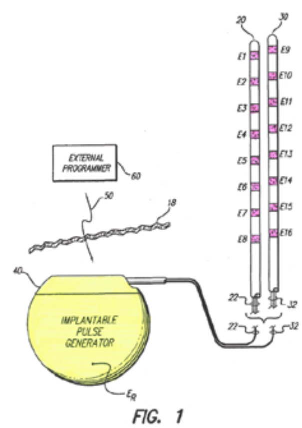
1. A method, comprising:

To the extent this preamble is limiting, Barreras is directed to a method and apparatus for controlling and steering an electric field in a multi-lead spinal cord stimulation (SCS) device. EX1005, 1:7-10, Title; EX1003, ¶¶74-75. Similarly, Swanson relates to "systems and methods for guiding movable electrode elements." EX1006 at Abstract; EX1003, ¶75.

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

Barreras explicitly discloses first and second multiple-electrode leads, along with a pulse generator, that are implanted within a user. EX1005, 3:41-43, FIG. 5. Barreras's IPG and lead structure is shown below at left, and the '447 patent's IPG and lead structure is shown below at right, for comparison.

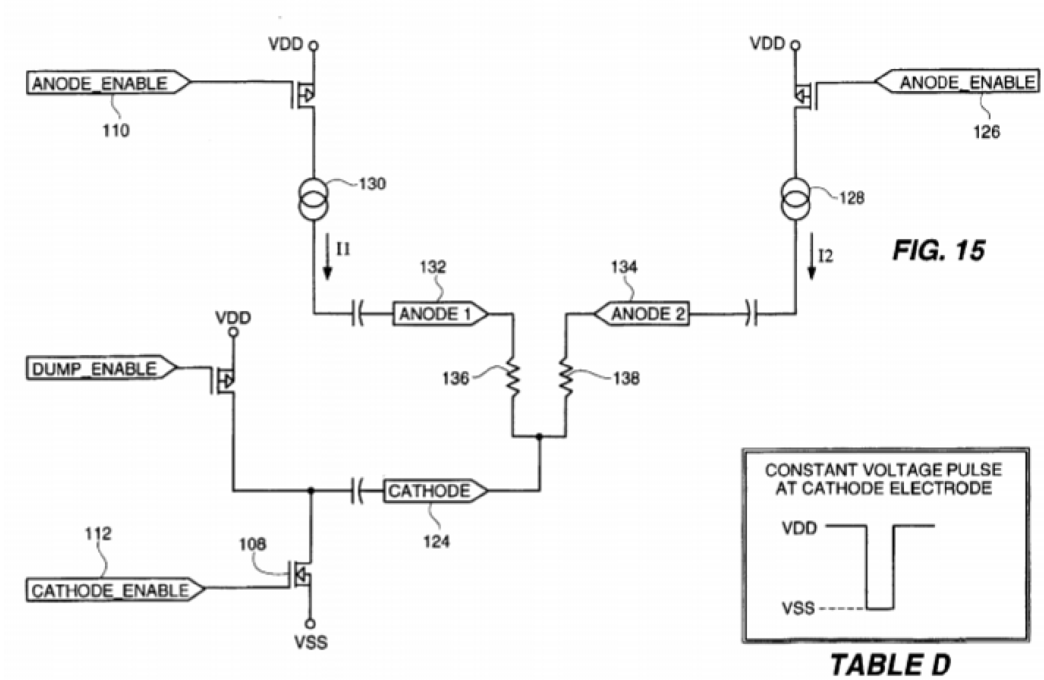




EX1005, FIG. 5, annotated; EX1001, FIG. 1, annotated.

Barreras expressly recognizes the same problem expressed in the '447 patent—namely, that spinal cord movement and changes in body position may result in movement of the electrodes from their optimal position, resulting in undesired variations in the size or location of the electric field generated by the electrodes. EX1005, 1:61-67; EX1003, ¶¶76-77. Specifically, Barreras discloses the need to compensate for changes in electrode impedance due to "1) growth of connective tissue around the electrodes, 2) histological changes, and 3) *changes in lead position* which alters the distance between the electrodes and the dura." EX1005, 2:6-11 (emphasis added); EX1003, ¶77. Shifting leads result in undesirable variations in the size and location of the applied electric field, with possibly negative implications for the patient. For example, the shifting size and location of the applied electric field clearly may decrease the effective treatment zone. Additionally, depending on a patient's sensitivity or anatomy, a shift may induce stimulation in an area to be avoided (e.g., where stimulation may produce discomfort, etc.). And as a POSA would have understood, the physical shifting of the leads themselves may introduce discomfort in the patient. EX1003, 76-78. Barreras thus identifies the movement of electrodes from the optimal position as a "major problem when the patient becomes active." EX1005, 1:61-67; EX1003, ¶78.

Barreras's proposed solution—via circuitry—is to steer the electric field in response to relative lead movement to automatically attempt to maintain the electric field focused at the target nerve that was found to be effective at the time of implant. *See* Section VI.A. *supra*; EX1003, ¶79. The circuitry to achieve the automatic correction is illustrated in Barreras's figure 15, illustrated below:

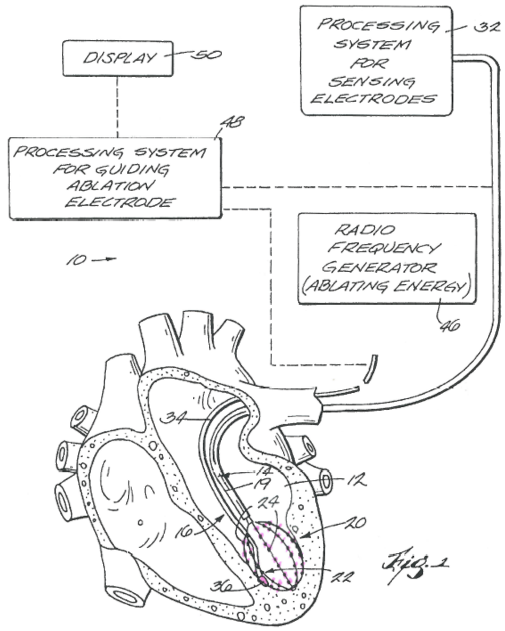


EX1005, FIG. 15.

To accomplish the automatic field steering, Barreras recognizes that relative movement between a pair of implanted leads will impact the measured impedance between two electrodes on opposite leads, such as between electrodes 136 and 138 above. EX1003, ¶80. However, Barreras is primarily concerned with compensating for the changing impedance to maintain constant current and does not necessarily explicitly disclose determining the relative location of the leads or electrodes—although it appears to require that in order to keep the electric field focused at the target nerve if the leads have shifted. EX1003, ¶80.

But a POSA would have recognized the utility in knowing the relative position of Barreras's leads to better understand the shifting of the leads within the body and provide appropriate countermeasures. Even more, Barreras explains that one aspect of the invention is to also provide a "mechanical steering system for each of the leads." EX1005, 3:15-16. Swanson provides a method for mechanically steering an implanted, multi-electrode lead by ascertaining the relative two-dimensional orientation of a pair of leads using impedance values measured between electrodes on opposite leads. *See* Section VI.B. *supra*. Indeed, the examiner below recognized this too with arguments that the patentee never successfully rebutted. *See* Section III.B. *supra*. A POSA would have recognized the utility of Swanson's method to improve Barreras. *See* Section VII.B. *supra*; EX1003, ¶81.

Swanson discloses a system and method for determining and displaying the relative two-dimensional orientation of a first and second multiple-electrode leads in the context of steering a lead carrying an ablation electrode to be used in cardiac surgery within a basket of multiple-electrode mapping probes (i.e., leads). *See e.g.* EX1006, 7:1-22; 15:17-16:49. Swanson's figure 1 shows an overview of the system:



As described in detail above in Section VI.B., Swanson discloses a processing element 48 that is coupled to a mapping probe 14 and the ablation probe 16. EX1006, 6:25-28; EX1003, ¶¶81-83. Swanson's ablation probe 16 "includes a flexible catheter body 34 that carries one or more ablation electrodes 36." EX1006, 6:18-22. Although Swanson's method is described using an ablation probe with one electrode at the distal tip of the catheter, Swanson expressly states that "[o]f course, other configurations employing multiple ablation electrodes are possible…." EX1006, 6:22-30 (referring to U.S. patent application no. 08/287,310).

The processing element 48 collects information regarding the location of the ablation probe relative to the mapping probe electrodes 24. EX1006, 6:61-7:15. Specifically, Swanson discloses that "[t]he element 48 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." EX1006, 6:63-67. Swanson describes a number of ways to measure the location of the ablation electrode including by "analyzing spatial variations in the electric potentials within the array." EX1006, 2:57-59. Swanson also teaches that "[t]he variations can comprise variations in phase, variations in amplitude, or both." EX1006, 2:59-61; EX1003, ¶¶83-84.

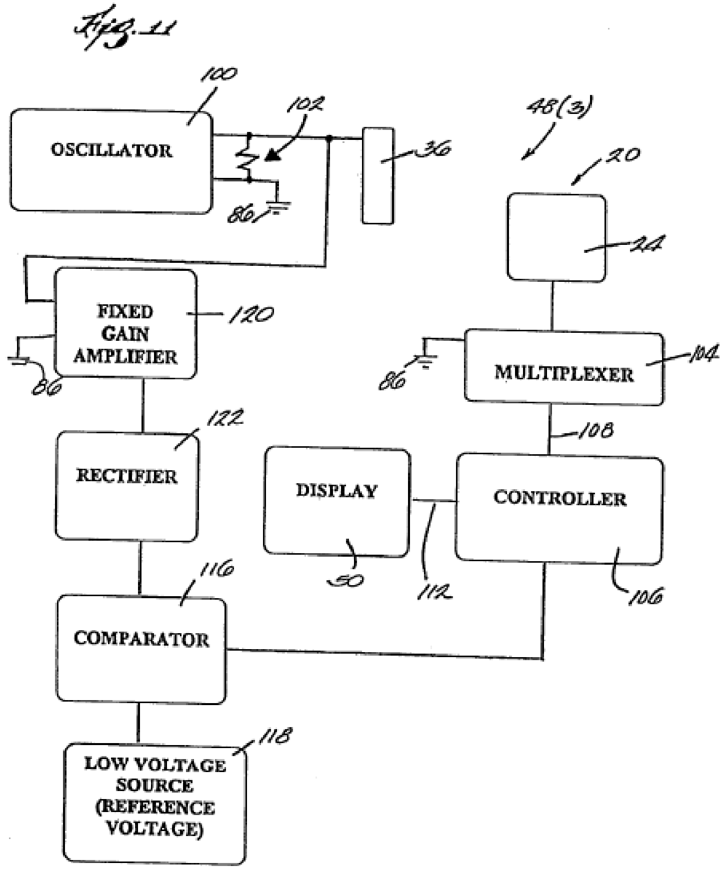
The specific circuitry for achieving the relative two-dimensional orientation of the ablation electrode 36 with respect to the mapping electrodes 24 is described in Swanson's figure 4, describing element 48(1), which sets forth "a schematic view of an element for determining the location of an ablation electrode within a multiple electrode structure using phase/amplitude sensing). EX1006, 3:47-49; EX1003, ¶¶84-86. The specific circuitry for another embodiment is set forth in and figure 10, describing element 48(2), which sets forth "a schematic view of an element for determining the location of an ablation electrode within a multiple electrode structure using ultrasonic time-delay sensing." EX1006, 4:11-13. Because Swanson "determines the location" of the ablation electrode "within a multiple electrode structure," Swanson's circuitry thus determines, at least, a "two-dimensional orientation" of the ablation electrode 36 relative to at least one of the mapping electrodes 24, as set forth in the claims. EX1003, ¶¶84-86

Independent claim 1 does not specify *how* the determining step is performed, except "*using circuitry*." EX1001, 10:52-54. So each of these embodiments in Swanson reads directly on the '447 patent's broad independent claim 1. EX1003, ¶¶87-88.

The '447 patent specification and some of its dependent claims, however, specify that the determining step ascertain the relative orientation of the pair of multiple-electrode leads is by measuring the impedance between two electrodes on opposite leads. But Swanson covers that embodiment as well. EX1003, ¶88.

Specifically, Swanson discloses that "the processing element generates the output by analyzing spatial variations in impedances between the emitting and sensing electrodes." EX1006, 2:61-63; EX1003, ¶88. Swanson goes on to describe, in detail, how it uses measured impedance to locate the ablation probe and identify distances between the ablation probe and basket structure electrodes. *See* Section VI.B. *supra*; EX1006, 15:10-16:41; EX1003, ¶88.

Swanson's figure 11 illustrates the circuitry used in its impedance sensing embodiment:



EX1006, FIG. 11, 4:15-17.

For the above reasons, a POSA seeking to improve Barreras's mechanical steering system would have turned to prior art like Swanson, to leverage Barreras's detection of electrode impedance, EX1005, 2:60-65, and to determine the relative two-dimensional orientation of first and second multiple-electrode leads implanted within a user. EX1003, ¶¶89-91. The determining step of claim 1 would thus have been obvious to a POSA as of the earliest filing date of the '447 patent. EX1003, ¶¶89-91.

3. 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

Barreras explicitly discloses this feature. Barreras discloses that before the filing of the ’447 patent it was “well established for a number of years” to use surgically implantable electrical neurological stimulators for control of nerve or brain response to treat intractable pain, epileptic seizures, and tremors from Parkinson’s disease. EX1005, 1:36-40; EX1003, ¶92. Indeed, Barreras’s device uses an implantable pulse generator or (implantable stimulator 30), and two implanted multi-electrode leads 32, 34, placed within the epidural space at either side of the midline. EX1005, 5:6-18; EX1003, ¶92. Each of Barreras’s electrodes can serve as an anode or cathode and the size and location of the field can be modulated to recruit target nerve tissue—excluding non-target tissue. *See* EX1005, 5:6-18; EX1003, ¶¶92-93.

Barreras thus unambiguously discloses the claim 1 step of “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,” as claimed.

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

While Barreras identifies the need to measure changes in electrode impedance that may occur from movement of the lead positions, Barreras is primarily concerned with compensating for the changing impedance to maintain constant current and does not explicitly disclose determining the relative location of the leads or electrodes. *See* EX1003, ¶94. But to improve Barreras's embodiment directed to "mechanical steering system," a POSA would have recognized the utility in providing a display. EX1003, ¶94. As such, a POSA would have been lead to Swanson's real-time display so a physician responsible for implanting the multiple-electrode leads or monitoring the patient's treatment after implantation can determine and see their orientation relative to one another. *See* EX1003, ¶94.

Swanson describes a display embodiment for each of its embodiments. For its "Voltage Phase/Amplitude Mode," Swanson discloses that "[t]he host processor 60 preferably outputs the derived i, j, and k indices to the real time display device 50 for viewing by the physician." EX1006, 13:65-67. Swanson describes the display characteristics in detail. EX1006, 14:10-36. For its "Ultrasound Time-Delay" mode, Swanson discloses that "the display 88 shows the location of the electrodes 24, other structure of the basket 20 (for example, splines), and the targeted ablation area." EX1006, 15:14-17. Thus, states Swanson, "the display 88 graphically shows processed ultra-sonic information in real time [which] allows the physician to progressively maneuver the ablation electrode 36 within the basket structure 20 while viewing the location of the electrode 36 relative to the targeted ablation area." EX1006, 15:21-25. Swanson thus unambiguously discloses and renders obvious the claim 1 step of "displaying the relative two-dimensional orientation of the first and second multiple-electrode leads," as claimed. EX1003, ¶95.

Swanson also discloses the "displaying" step in the context of its impedance measuring embodiment. Swanson uses a comparator such that when its ablation electrode is "not sufficiently close" to any of the electrodes in the basket volume, the comparator generates no output (denoting a high impedance state). EX1006, 16:20-31; EX1003, ¶96. When the ablation probe comes into close proximity with one of the electrodes, the reduced impedance creates a voltage input for the comparator, which then generates an output. EX1006, 16:32-41; EX1003, ¶96. The controller then identifies which electrode the ablation probe has approached and shows the physician, via a display. Specifically, Swanson's "controller 106 registers and identifies [the particular] array electrode on the output display 50 (with, for example, a flashing indicator and an audible prompt), thereby showing the physician the location of the ablation electrode 36 and the identified electrode 24 to be essentially the same." EX1006, 16:42-49; EX1003, ¶96.

Thus, with its impedance measuring embodiment, Swanson also discloses and renders obvious the step of "displaying the relative two-dimensional orientation of the first and second multiple-electrode leads," as claimed. EX1003, ¶97.

D. Claim 3

1. A method as claimed in claim 1,

See Section VII.C *supra*.

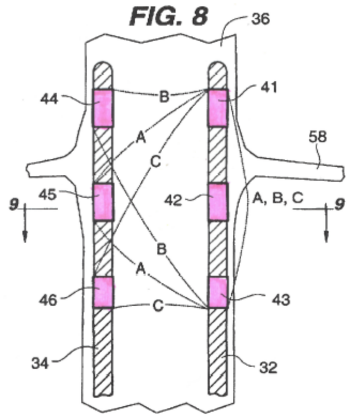
2. wherein determining the relative two-dimensional orientation of the first and second multiple-electrode leads comprises measuring impedance vectors between respective electrode pairs that each include one of the electrodes on the first multiple-electrode lead and one of the electrodes on the second multiple-electrode lead.

Dependent claim 3 imposes two further limitations on the "determining" of claim 1. Specifically, it simply requires (1) "measuring impedance vectors" between "electrode pairs," (2) where the pair of electrodes includes one electrode from the first lead and one electrode on the second lead. With respect to the requirement to measure "impedance vectors," the '447 patent expressly defined "impedance vector" as "an impedance value measured between two electrodes in the body." EX1001, 6:38-39. Both Barreras and Swanson measure impedance between two electrodes.

With respect to Barreras, it discloses the use of circuitry for automatically changing voltage amplitude at each anode (electrode) to maintain a constant current to preserve the original electric field found to be effective during the course of treatment. EX1005, 1:18-23; EX1003, ¶¶98-100. Barreras does so by "maintaining the electric field focused at the target nerve even when changes in electrode impedances 136 and 138 occur, but automatically changing the positive voltage at anodes 132 and 134 as required in order to maintain currents I1 and I2." EX1005, 8:21-34; EX1003, ¶100. As Barreras's figure 15 illustrates, Barreras thus measures the impedance 136 between anode (electrode) 132 and cathode (electrode) 124. Barreras also measures impedance 138, between anode (electrode) 134 and cathode (electrode) 124.

Barreras's FIG. 8 gives a practical example, though it does not use the same numbering scheme as FIG. 15 for the two anodes and the cathode. Figure 8 shows three electric fields marked A, B, and C:

FIG. 8



EX1005, FIG. 8 (annotated).

If a POSA were to implement Swanson's method for determining the relative two-dimensional orientation of a pair of leads, a POSA would have found it obvious to measure the impedance value between one electrode on the first lead (e.g., electrode 44) and one electrode on the second lead (e.g., electrode 41). EX1003, ¶¶101-102. It would make no logical sense to measure the impedance value between two electrode values on the same lead, because the distance between a pair of electrodes on the same lead would presumably never change, and such a measurement would not provide useful information about the relative position of the opposite lead. EX1003, ¶102.

In any event, Swanson also measures impedance vectors in its impedance sensing embodiment. *See* Section VII.C.2. Specifically, Swanson measures impedance vector measurements between respective electrode pairs that each include one of the electrodes on the first multiple-electrode lead (e.g., the ablation probe) and one of the electrodes on the second multiple-electrode lead (e.g., the spline leads of the measuring probes that make up the basket). EX1006, 16:32-49; EX1003, ¶103. Swanson uses a comparator such that when the ablation probe comes into close proximity with one of the electrodes, the reduced impedance creates a voltage input for the comparator, which then generates an output. EX1006, 16:32-41. Swanson thus discloses "measuring impedance vectors" between "electrode pairs," where the pair of electrodes includes one electrode from the first lead (i.e., an ablation electrode) and one electrode on the second lead (a mapping electrode).

Barreras and Swanson, together, thus render obvious dependent claim 3's further limitations on claim's determining step—namely, "measuring impedance vectors between respective electrode pairs that each include one of the electrodes on the first multiple-electrode lead and one of the electrodes on the second multiple-electrode lead." *See* EX1003, ¶104.

E. Claim 5

1. A method as claimed in claim 1,

See Section VII.C *supra*.

2. wherein displaying the relative two-dimensional orientation of the first and second multiple-electrode leads comprises displaying the relative two-dimensional orientation of the first and second multiple-electrode leads on a programmer display.

Dependent claim 5 further limits claim 1's displaying step so that the display occurs on "a programmer display." Swanson and Barreras render this feature obvious. A "programmer" is simply a device designed to communicate with an implanted device so a physician can monitor or change the implanted device's settings. Various programmers were well-known and common in the implantable medical device space. EX1003, ¶¶105-106. Indeed, since devices like Barreras are designed to be implanted in a human body, external programmers are essential. EX1003, ¶106.

Swanson has an external programmer designed to communicate with implanted (or inserted) portions of the device. Swanson's programmer is embodied, for example, in its processing system 48 and display 50 for guiding the ablation electrode. EX1006, FIG. 1. Processing system 48 has a display 50 coupled to a controller 106. EX1006, FIG. 11 (describing the processing system used in

Swanson's impedance sensing embodiment), 15:64-16:4. The controller 106 communicates and controls both the ablation electrode 36 and the mapping electrodes 24. EX1006, FIG. 11, 15:67-16:4. Swanson's "controller 106 identifies [the particular] array electrode on the output display 50 (with, for example, a flashing indicator and an audible prompt), thereby showing the physician the location of the ablation electrode 36 and the identified electrode 24 to be essentially the same." EX1006, 16:42-49; EX1003, ¶107.

A POSA looking to improve Barreras's mechanical steering system, as outlined above, would recognize the utility of Swanson's programmer and its corresponding display. Swanson's display, as described above in Section VI.B and VII.C.4, would enable a physician to evaluate a real-time display of at least the relative two-dimensional orientation of the second electrode to be implanted as relative to the first implanted electrode. EX1003, ¶108.

Further proof of the state of the art with respect to programmers in the spinal cord stimulation space can be found in the Meadows reference (EX1007). EX1003, ¶109. Meadows is directed to a spinal cord implantation system. EX1007, Abstract. It includes both a hand held programmer 202 and a clinician programmer 204. EX1007, Abstract. Meadows discloses that its clinician programmer has a "measurement window." EX1007, 31::1-3. A representative measurement window is shown in Meadows's FIG. 6:

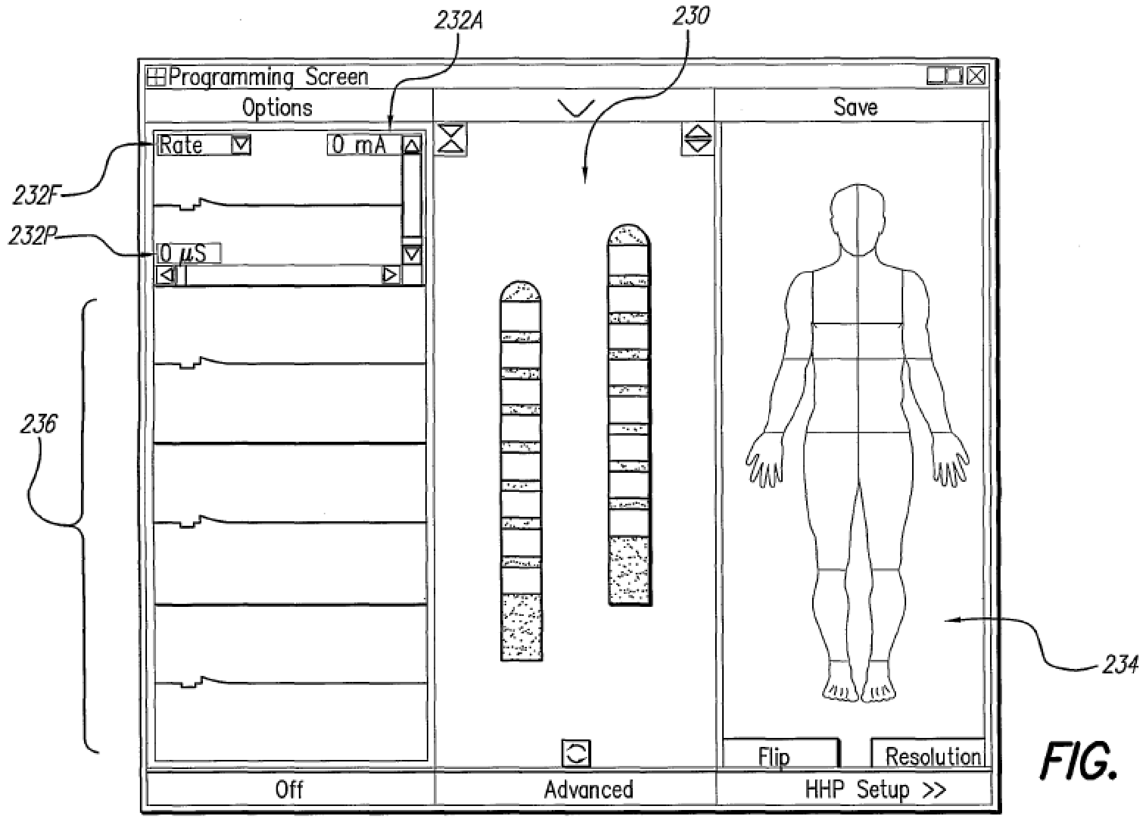


FIG. 6

EX1007, FIG. 6.

Meadows discloses that its measurement window includes "a representation 230 of the type and orientation of the electrode array(s) that has been selected." EX1007, 31:5-6. In fact, Meadows discloses that "[t]he number of implanted and available electrodes is typically automatically determined by impedance measurements during hardware interrogation" and that "electrode box 230 provides an electrode array selection, based on the number of electrodes, with present visual forms. EX1007, 31:34-37. Meadows thus confirms the state of the art with respect to programmers in the spinal cord stimulation space, the exact same space as Barerras. EX1003, ¶¶110-111. And it confirms that a POSA would have found "a programmer" to be the obvious place to display "the relative two-dimensional orientation of the first and second multiple-electrode leads," as claimed, since a programmer is what a physician would be using to monitor, evaluate, and communicate with the implanted device. EX1003, ¶¶111-112.

A POSA would have recognized the combined disclosures of Barreras and Swanson to render obvious displaying the relative two-dimensional orientation of the first and second multiple-electrode leads *on a programmer display*, as claimed. Such displays, along with their utility, were well known and common in the art. EX1003, ¶¶111-112.

F. Claim 9

1. A method as claimed in claim 1,

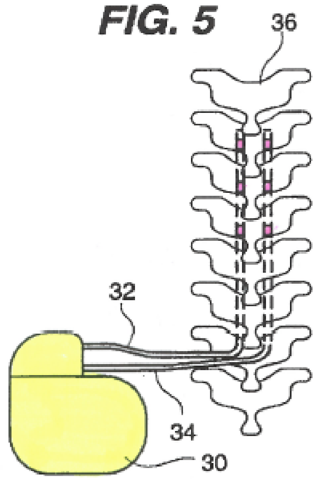
See supra Section VII.C.

2. wherein determining the relative two-dimensional orientation comprises determining the distances between two or more electrodes carried by the first lead and two or more electrodes carried by the second lead.

Dependent claim 9 simply adds the requirement that process for determining the relative two-dimensional orientation be iterative—instead of just performing the measurements between a single pair of electrodes, it would be done for two or more pairs of electrodes. A POSA would have found this iterative proves to be obvious. EX1003, ¶¶113-114.

Barreras suggests an example of this feature in at least Figure 5 as shown above:

FIG. 5



EX1005, FIG. 5 (annotated).

In FIG. 5, Barreras details the use of a dual channel stimulator 30 having anodic current control connected to two percutaneous epidural leads 32 and 34. EX1005, 5:6–8. As discussed in the background section, each lead 32, 34 is placed within the epidural space at either side of the midline proximal to the target vertebrate bodies 36, and each electrode 41-43 (or 44-46 in FIG. 8, for example) in each lead 32 or 34 can be programmed positive (anode) or negative (cathode), and the anodic current at each positive electrode (41, 43 or 44, 46) can be programmed to a value different from the other anodes. EX1005, 5:9–13.; EX1003, ¶¶115-121.

A POSA would have further understood that in view of Barreras, "maintaining the electric field focused at the target nerve even when changes in electrode impedances 136 and 138 occur, by automatically changing the positive voltage at anodes 132 and 134 as required in order to maintain currents I1 and I2" (Ex1005, 8:21-34; EX1003, ¶¶117-118) effectively renders obvious determining the distances between two or more electrodes carried by the first lead and two or more electrodes carried by the second lead, e.g., to maintain the desired currents. EX1003, ¶121. As one example, Barreras specifically identifies in FIG. 8 that such measurements are advantageous. There, each of electric fields A, B, or C may include plural anodes and plural cathodes, and the variation in the electric fields is appreciated by Barreras in order to target the specific nerve tissue. Barreras's disclosure that "[e]ach electrode 71-79 in the leads 61-63 can be programmed positive (anode) or negative (cathode), and the anodic current at each positive electrode can be programmed to a value different from the other electrode, which electrode(s) serve as the cathode….[and] [t]he size and location of the stimulating field can be modulated for the purpose of recruiting only the target nerve tissue and exclude unwanted nerve tissue," confirms this. EX1005, 6:18-25; EX1003, ¶¶117-119.

To be sure, Swanson also discloses such voltage measurements. When Swanson's ablation probe comes into close proximity with one of the electrodes, the reduced impedance creates a voltage input for the comparator, which then generates an output based on distance. EX1006, 16:20-41. The controller then identifies which electrode the ablation probe has approached and shows the physician. Specifically, Swanson's "controller 106 identifies [the particular] array electrode on the output display 50 (with, for example, a flashing indicator and an audible prompt), thereby showing the physician the location of the ablation electrode 36 and the identified electrode 24 to be essentially the same." EX1006, 16:42-49. A POSA would have understood that such a voltage measurement from the stimulation electrode (e.g., the ablation probe) would be applied and measured at the non-stimulation electrodes (e.g., the array electrode). EX1003, ¶¶120-121.

As such, a POSA would thus have been motivated to seek Swanson out and apply its display principles along with the actual determination of relative orientation of the implanted multiple-electrode leads of Barreras. And a POSA would have recognized the combined disclosures of Barreras and Swanson to render obvious determining the distances between two or more electrodes carried by the first lead and two or more electrodes carried by the second lead. EX1003, ¶121.

VIII. Ground 2: Claims 6 and 7 are rendered obvious in view of Barreras, Swanson, and Meadows.

Dependent claims 6 and 7 are each directed to a comparing step. Dependent claim 6 adds comparing the displayed relative two-dimensional orientation of the first and second multiple-electrode leads with a display of a previously *measured* orientation, whereas dependent claim 7 compares the orientation to a previously *entered* orientation. Both comparing steps would have been obvious.

Generally, in the relevant prior art, a physician *must* complete some comparison of a prior orientation to a new orientation, otherwise the currently measured information is useless. Indeed, if the physician were not comparing the displayed orientation to a previously obtained orientation (whether measured or entered), the physician would not be able to ascertain relative motion between two leads. For Swanson, a physician would not be able to determine the relative movement of Swanson's ablation probe, and for Barreras, the physician would not be able ascertain the relative motion of the second implanted lead, relative to the first implanted lead. EX1003, ¶¶122-123.

Swanson and Barreras do not expressly disclose a comparison, either with previously measured or previously entered orientations. But to show that it would have been obvious, Meadows confirms the state-of-the-art, as discussed below. EX1003, ¶124.

A. Claim 6

1. A method as claimed in claim 1,

See supra Section VII.C.

2. comparing the displayed relative two-dimensional orientation of the first and second multiple-electrode leads with a display of a previously measured relative two-dimensional orientation of the first and second multiple-electrode leads.

If interpreted broadly, dependent claim 6 does not explicitly require that the comparison of the displayed relative two-dimensional orientation be performed by any device or circuitry. EX1003, ¶¶125-126. This step could thus be performed by a physician. For example, a physician using Swanson's device and its real time display would be constantly comparing a currently displayed relative orientation of the ablation electrode with a previously measured and displayed position. EX1003, ¶126. If this were not the case, the physician would be unable to ascertain relative motion.

Indeed, Swanson teaches that "the processing element generates the output by analyzing spatial variations in impedances between the emitting and sensing electrodes." *See*, *e.g.*, EX1006, 2:61-3:4; EX1003, ¶127. As two electrodes on opposite leads approach each other, the system senses the "reduced impedance of the blood pool path" when it creates a voltage sensed by a comparator. And as described above, Swanson's circuitry embodiments 48(1) and 48(2) "can each additionally employ impedance sensing to indicate when the ablation electrode is in very close proximity to (for example, within 1 to 2 mm) or actually touching the electrode 24 closest to the ablation site." EX1006, 15:37-42. Swanson goes on to disclose that "[i]mpedance sensing can be used with [other techniques to augment] general realtime guidance with great accuracy to finally locate the ablation electrode 36 in the precise location identified for ablation." EX1006, 15:42-46. And as described above, the benefits of precise mechanical steering include, as Barreras explains, positioning the leads to obtain "paresthesia with the lowest possible electrical energy, thereby recruiting only the target nerve tissue an excluding unwanted nerve tissue." EX1005, 3:20-24; EX1003, ¶127.

The state of the art at the time of invention shown in Meadows confirms that it would have been obvious for the device to also perform a comparison with a previously measured and saved value. EX1003, ¶128. For example, Meadows discloses that it is well known to save the case history files as permanent archived files to be able to show a series of graphs and measurement histories, etc. See EX1007, 30:14–32; EX1003, ¶128. Specifically, a previously measured impedance may be stored or otherwise processed so that any significant changes in impedance can be immediately noted and communicated. *See* EX1007, 46:31–33; EX1003, ¶128. In fact, Meadows identifies—as does Barreras—the problem of migration of leads disadvantageously changing the location and nature of the field and required stimulation level leading to reprogramming being required or surgical correction. *See* EX1007, 8:21-25; EX1003, ¶128.

A physician engaged in attempting to mechanically steer the leads upon initial insertion would clearly benefit from knowing the relative orientation of the second lead to be implanted relative to first implanted lead. EX1003, ¶¶129-130. Likewise, a physician adjusting the programming would benefit from knowing whether and how the leads have shifted over time according to previously measured orientations, allowing more precise programming of the device. *Id.*

Thus, a POSA would have found it obvious in view of Barreras and Swanson, and in further view of Meadows, to compare the displayed relative two-dimensional orientation of the first and second multiple-electrode leads with a display of a previously measured relative two-dimensional orientation of the first and second multiple-electrode leads. The motivation would have been, at least, to ascertain the relative motion of Swanson's ablation probe, for example, or to ascertain the relative motion of Barreras's second implanted lead, relative to the first implanted lead. *See id.*

B. Claim 7

1. A method as claimed in claim 1,

See supra Section VII.C.

2. comparing the displayed relative two-dimensional orientation of the first and second multiple-electrode leads with a display of a previously entered relative two-dimensional orientation of the first and second multiple-electrode leads.

Dependent claim 7 recites the same comparison step as claim 6, except that the comparison relies on a previously *entered* orientation, instead of a previously *measured* orientation. The Board should preserve the difference between an "entered" orientation and a "measured" orientation. *See, e.g.*, *Ethicon Endo-Surgery, Inc. v. U.S. Surgical Corp.*, 93 F.3d 1572, 1579 (Fed. Cir. 1996)(presuming different meanings attach to different words when construing claim language and reversing lower court's ruling that a "pusher assembly" and a "pusher bar" have the same meaning). As with dependent claim 6, the state-of-the-art at the time of invention confirms that it would have been obvious for the device to also perform a comparison with a previously entered orientation, e.g., an initial, as implanted, orientation. EX1003, ¶¶131-132.

As one example, Meadows discloses that it was well-known to provide a display within a measurement window showing a representation 230 of the initial "type and orientation of the electrode array(s) that has been selected," e.g., entered by a physician or clinician, from a group of possible electrode choices so that pain and paresthesia mapping may be completed. *See* EX1007, 31:1-12. And as described above, Meadows identifies—as does Barreras—the problem of migration of leads disadvantageously changing the location and nature of the field and required stimulation level leading to reprogramming being required or surgical correction. *See* EX1007, 8:21-25; EX1003, ¶133.

In either case, a physician engaged in attempting to mechanically steer the leads after initial insertion would thus clearly benefit from knowing the relative orientation of the second lead to be implanted relative to first implanted lead, i.e., how it has shifted based on the originally selected type and orientation. EX1003, ¶134. Likewise, a physician adjusting the programming would benefit from knowing whether and how the leads had shifted over time according to *input* orientations, allowing more precise programming of the device. *Id.*

Thus, a POSA would have found it obvious in view of Barreras and Swanson, and in further view of Meadows, to expressly compare the displayed relative two-dimensional orientation of the first and second multiple-electrode leads with a display of a previously entered relative two-dimensional orientation of the first and second multiple-electrode leads. The motivation would have been to, at least, ascertain the relative motion of Swanson's ablation probe, for example, or to ascertain the relative motion of Barreras's second implanted lead, relative to the first implanted lead from an initial position selected or entered after implantation. EX1003, ¶135.

Finally, to the extent "entered" is interpreted more broadly to also encompass a previously measured orientation, then claim 7 would have been obvious for the same reasons as claim 6, above. EX1003, ¶136.

IX. Secondary considerations of non-obviousness

At this time, Petitioner is unaware of any secondary indicia of non-obviousness that would impact the above grounds of unpatentability. EX1003, ¶¶137-138.

X. Conclusion

For the reasons provided above, Nevro requests *inter partes* review of claims 1, 3, 5-7, and 9 of the '447 patent, and a determination that those claims are unpatentable as obvious under 35 U.S.C. § 103 according to the proposed grounds. *See* EX1003, ¶¶139-140.

XI. Mandatory Notices (37 C.F.R. § 42.8(a)(1))

REAL PARTY IN INTEREST: The real party-in-interest is Petitioner Nevro Corp.

RELATED MATTERS: The ’447 patent is involved in the following pending litigation proceeding: *Boston Scientific Corp. et al. v. Nevro Corp.*, No. 1:18-cv-00644 (D. Del.). The ’447 patent claims the benefit of U.S. Patent No. 6,993,384 (“the ’384 patent”). U.S. Patent No. 7,853,330 (“the ’330 patent”) claims the benefit of the ’447 patent. Both the ’384 patent and the ’330 patent are at issue in the above-captioned litigation. Pending U.S. Patent Application No. 16/018,568, filed June 26, 2018, claims the benefit of the ’447 patent.

LEAD AND BACKUP COUNSEL: Under 37 C.F.R. §§ 42.8(b)(3) and 42.10(a), Petitioner appoints **Jon E. Wright** (Reg. No. 50,720) as lead counsel and **Ian Soule** (Reg. No. 74,290) as back-up counsel, both at the address: STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C., 1100 New York Avenue, N.W., Washington, D.C., 20005, phone (202) 371-2600, and facsimile (202) 371-2540. Additional back-up counsel include **Ching-Lee Fukuda** (Reg. No. 44,334, clfukuda@sidley.com, 212-839-7364) at the address: Sidley Austin LLP, 787 Seventh Avenue, New York, New York 10019, and **Thomas A. Broughan**, III

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

The undersigned and Petitioner certify that the '447 patent is available for *inter partes* review. Petitioner is not barred or estopped from requesting this *inter partes* review on the grounds herein.

[2] Nevro will file a motion for Sharon Lee to appear *pro hac vice* according to the Board's orders and rules.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

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CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATION, TYPEFACE REQUIREMENTS, AND TYPE STYLE REQUIREMENTS

1. This Petition complies with the type-volume limitation of 14,000 words, comprising 10,772 words, excluding the parts exempted by 37 C.F.R. § 42.24(a).

2. This Petition complies with the general format requirements of 37 C.F.R. § 42.6(a) and has been prepared using Microsoft® Word 2010 in 14 point Times New Roman.

Respectfully submitted,

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CERTIFICATION OF SERVICE (37 C.F.R. §§ 42.6(e), 42.105(a))

The undersigned hereby certifies that on July 18, 2019, true and correct copies of the foregoing **PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 8,682,447**, Petitioner's Power of Attorney, and all associated exhibits were served in their entireties on the following parties via U.S.P.S. Express Mail® or FedEx Express®:

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