UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Boston Scientific Corporation, and Boston Scientific Neuromodulation Corporation,

Petitioners

v.

Nevro Corporation,

Patent Owner

Patent No. 10,076,665
Filing Date: Mar. 22, 2017
Issue Date: Sep. 18, 2018

Title: Devices for Controlling Spinal Cord Modulation for Inhibiting Pain, and Associated Systems and Methods, Including Controllers for Automated Parameter Selection

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IPR2020-01563

PETITION FOR *INTER PARTES* REVIEW

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1003	Richard T. Mihran CV
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1023	Falowski, S. *et al*, Spinal Cord Stimulation: An Update in *Neurotherapeutics: The Journal of the American Society for Experimental NeuroTherapeutics* Vol. 5, 86-99 (January 2008)
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1025	U.S. Patent No. 9,358,390 ("Polefko")
1026	U.S. Publication No. 2011/0307032 ("Goetz")
1027	U.S. Publication No. 2011/0093051 ("Davis")
1028	Shealy et al., Electrical Inhibition of Pain: Experimental Evaluation in *Anesthesiology and Analgesia* 46(3):299-305 (May-June 1967)
1029	September 1, 2020 Email between T. Broughan (Nevro's counsel) and M. Petegorsky (BSC counsel)
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I. INTRODUCTION

Petitioners Boston Scientific Corp. and Boston Scientific Neuromodulation Corp. (collectively, "BSC" or "Petitioners") request *inter partes* review ("IPR") of claims 1-21 (the "Challenged Claims") of Nevro Corp.'s ("Nevro" or "Patent Owner") U.S. Patent No. 10,076,665 (the "'665 Patent") (Ex. 1001).

The '665 Patent relates generally to spinal cord stimulation ("SCS"). The Challenged Claims are directed to providing SCS therapy by identifying where implanted leads are within a patient's body and transmitting electrical pulses through contacts (electrodes) on the leads to stimulate target tissue. These foundational principles of SCS had been known for years prior to Nevro's work.

The Challenged Claims issued only after Nevro amended pending claims to require the use of "impedance values" to align computer-based images of leads. Nevro argued that the claimed use of impedance values for alignment distinguished the pending claims over the prior art. A year later, Nevro filed an IPR petition challenging claims in BSC's earlier U.S. Patent No. 8,682,447 (the "'447 Patent") (Ex. 1007), which also claims the use of impedance to determine lead position and to display an image of the aligned leads. *See, e.g.*, Ex. 1007 at 10:66-11:5 (claim 3), 11:11-15 (claim 5). In contrast to what Nevro told the Examiner to support the issuance if its own claims, Nevro argued that the impedance-based alignment method disclosed in BSC's '447 Patent, "describes a simple technique of

determining the relative orientation between a pair of multi-electrode leads [that] relies on well-known relationship [sic] between impedance and distance in implanted electrodes." Ex. 1008 at 8.[1] This "simple" and "well-known" technology is precisely what Nevro added to its pending claims to secure their issuance.

Nevro cannot have it both ways. It cannot be that the conventional use of impedance measurements was obvious when incorporated into BSC claims filed in 2001, but, 11 years later, sufficiently inventive to support the issuance of Nevro's claims filed in 2012.

The Challenged Claims recite a known combination of teachings from ***BSC's*** earlier patents and publications. The primary reference relied on here—Bradley857—is a BSC publication that describes and incorporates by reference the disclosures of foundational BSC patents relied on in Grounds 1 and 2. With those disclosures, Bradley857 anticipates the Challenged Claims. Moreover, even without such incorporation, the references themselves provide an express motivation to combine—they explain that using impedance to test electrode operability or to align electrodes was, by the time of Nevro's work, well-known in SCS.

[1] The '447 Patent is a continuation of, and shares a specification with, U.S. Patent No. 6,993,384 ("Bradley384"), one of the references relied on herein.

This petition is part of a stream of disputes that spans three district court proceedings and sixteen IPR petitions filed by Nevro, including the pending IPR challenging the '447 Patent, mentioned above. The parties are close competitors and make (and will continue to make) competing products.

The Challenged Claims are anticipated or obvious over BSC's earlier patents and publications. The Board should institute review and cancel the Challenged Claims.

II. MANDATORY NOTICES, STANDING, AND FEES

A. Real Party-In-Interest

Petitioners Boston Scientific Corp. and Boston Scientific Neuromodulation Corp. are real parties-in-interest.

B. Related Matters

Petitioners also filed a petition for IPR of Nevro's related U.S. Patent No. 9,002,460 (the "'460 Patent"). Nevro asserted both the '460 and '665 Patents in counterclaims against Petitioners in currently-pending patent infringement litigation captioned *Boston Scientific Corp. et al v. Nevro Corp.*, Nos. 16-cv-1163, 18-cv-00644 (consolidated) (D. Del. 2018) (the "Litigation"). *See* §III.

C. Lead and Backup Counsel

Petitioners provide the following designations of counsel:

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D. Service Information

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E. Certification of Grounds for Standing

Petitioners certify that the '665 Patent is eligible for IPR and that Petitioners are not barred or estopped from challenging the claims of the '665 Patent.

F. Fees

Under 37 C.F.R. § 42.103(a), Petitioners authorize the Office to charge the fee set forth in 37 C.F.R. § 42.15(a) to Deposit Account No. 50-2310, as well as any additional fees that might be due in connection with this petition.

III. THE LITIGATION

The parties are involved in extensive litigation relevant to this IPR. On November 28, 2016, Nevro sued BSC for patent infringement in the Northern District of California (the "California Case") (Ex. 1012). On December 9, 2016, BSC sued Nevro for patent infringement in the District of Delaware (the "DE1 Case") (Ex. 1013). In 2017, Nevro filed ten IPR petitions challenging claims of the asserted patents.[2] The Board instituted three of those IPRs (covering two patents), and, upon Nevro's motion, the district court stayed the case. Ex. 1009.[3]

On April 27, 2018, BSC initiated the Litigation alleging trade secret misappropriation and infringement of four patents. BSC amended its complaint on July 18, 2018, to assert additional patents, including the '447 Patent (Ex. 1007) and Bradley384 (Ex. 1005). Ex. 1018. Nevro moved to dismiss that complaint. While Nevro's motion was pending, the Board issued decisions in the IPRs challenging

[2] IPR2017-01811, IPR2017-01920, IPR2017-01831, IPR2018-00147, IPR2018-00141, IPR2018-00143, IPR2018-00148, IPR2018-00175, IPR2017-01899, and IPR2017-01812.

[3] Fact discovery was substantially complete, expert discovery was underway, the court had issued a partial claim construction order, and trial was scheduled for October 22, 2018, approximately four months later. Ex. 1017.

DE1 patents in February, 2019, and BSC appealed. In July 2019, Nevro filed seven IPR petitions challenging a subset of the patents asserted in the Litigation in 2018, including the '447 Patent.[4]

The court denied-in-part Nevro's motion to dismiss BSC's second amended complaint and Nevro filed an answer and counterclaims on December 9, 2019, asserting infringement of five Nevro patents, including the '665 Patent challenged here. Ex. 1019.

In January 2020, the Board instituted Nevro's IPR petitions challenging BSC's patents and Nevro moved to stay. BSC requested that the court lift the stay of the six patents from the DE1 Case for which IPRs were not instituted and consolidate them with its trade secret claims in the Litigation, while staying the other patent claims and counterclaims in the Litigation pending IPR. Ex. 1021. Nevro opposed, but stated that it "would not object to a stay of its counterclaims to maximize judicial and party efficiencies." Ex. 1022.

The court held a hearing on June 22, 2020 and consolidated BSC's remaining patent claims from the DE1 Case with BSC's trade secret claims from the Litigation.

[4] IPR2019-01284, IPR2019-01313, IPR2019-01318, IPR2019-01341 ('447 Patent), IPR2019-01340, IPR2019-01216, and IPR2019-01315.

The court stayed litigation over BSC's patent claims involved in pending IPRs, but did not stay Nevro's infringement counterclaims. Ex. 1010.

Discovery regarding Nevro's '665 Patent is starting. Nevro served its initial infringement contentions on March 19, 2020, and BSC served initial invalidity contentions on June 1, 2020. The parties have served some written discovery, but there have been no depositions. Claim construction briefing has not started. A *Markman* hearing is scheduled for January 6, 2021. Ex. 1020. Fact discovery is currently scheduled to close on February 18, 2021, with expert discovery currently scheduled to close on May 27, 2021. *Id.* Trial is set to begin on October 18, 2021. *Id.*

IV. THE *FINTIV* FACTORS SUPPORT INSTITUTION

As detailed in § III, above, there is a co-pending litigation involving the '665 Patent. The Board recently issued its precedential decision in *Fintiv*. *See Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper No. 11 (P.T.A.B. Mar. 20, 2020) (precedential) (explaining discretionary factors). In a recent informative decision, the Board recognized that there are circumstances where, as here, the Board should institute review despite a trial scheduled for prior to the final written decision's due date. *See Sand Revolution II, LLC v. Continental Intermodal Grp.—Trucking LLC*, IPR2019-01393, Paper No. 24 (P.T.A.B. June 16, 2020).

A. At Nevro's Request, the Court Granted Two Stays Based on Instituted IPRs in Related Proceedings; There is Evidence the Court Will Do the Same Here

Approximately four months before trial, the district court stayed the DE1 case at Nevro's request because the Board instituted review of a small subset of the patents in that litigation. Ex. 1009. Similarly, at Nevro's request, the district court stayed all patents asserted by BSC in 2018 because the Board instituted review of some, but not all, of those patents. There, Nevro waited until the day prior to the 1-year bar date to file its petitions.

Here, a stay based on institution of BSC's IPR petitions would occur more than seven months prior to trial, before expert discovery and before dispositive motion practice. And unlike Nevro, BSC filed this petition months prior to the 1-year bar date. Moreover, because BSC's 2018 affirmative patent claims are currently stayed—including asserted patents that are not the subject of any pending IPR—there will be another as-of-yet unscheduled trial over at least some of BSC's stayed patent claims. Thus, the court has a readily-available option to stay Nevro's counterclaims upon institution here, and resolve them at the same time it resolves BSC's claims. There is ample evidence that the court will stay Nevro's counterclaims if the Board institutes review here. This factor weighs in favor of institution.

B. There is no Trial Date Scheduled Yet for BSC's Infringement Claims; the Current Trial Date for Nevro's Counterclaims is October 18, 2021

As described above, the district court has not yet scheduled the trial date for BSC's 2018 affirmative patent infringement claims.

If the schedule for Nevro's counterclaims holds, trial will occur approximately four and a half months before the Board's final written decision would be due. As recently as September 1, however, Nevro suggested that due to COVID complications, deadlines ought to be extended. Ex. 1029 at 1, 5-6 (despite fact discovery not closing until February 18, 2021, Nevro's counsel suggested that "Nevro may request a two month extension of fact discovery and related deadlines."). Under such circumstances, it would be inequitable for Nevro to argue against institution based upon the current trial date and then to turn around to the district court after discretionary denial and argue for delay.

C. Neither the Court Nor the Parties Have Invested Significant Resources Relating to Nevro's Counterclaims

Although BSC filed the complaint that led to the Litigation in April 2018, Nevro did not assert the '665 Patent until it served counterclaims on December 9, 2019. BSC has not yet answered the operative counterclaims in the Litigation due to its pending motion to dismiss. As described above, fact discovery is in its early stages and claim construction briefing has not started. Like in *Sand Revolution*, this factor weighs in favor of institution. *See also Apple, Inc. v. Seven Networks, LLC*,

IPR2020-00266, Paper No. 12, at 13 (P.T.A.B. Aug. 14, 2020) (petition filed over three months before deadline mitigated investment in litigation).

D. The Petition Raises Issues that the District Court Will Not Resolve

The Petition challenges all 21 claims of the '665 Patent. On July 16, Nevro identified only 12 claims—1-4, 6, 8, 10-12, 18-19, 21 (the "Asserted Claims")—as those it intended to pursue in the Litigation. Accordingly, the IPR will resolve the validity of 9 claims that the district court will not address. Moreover, BSC has stipulated that, if the Board institutes review here, BSC will not pursue district court invalidity challenges on the same grounds raised herein. *See* Ex. 1011. Such a stipulation lessens concerns of duplicative efforts and conflicting decisions. *Sand Revolution*, IPR2019-01393, Paper No. 24 at 11-12; *Apple v. Seven Networks*, IPR2020-00266, Paper No. 12, at 15.

Finally, as described above, the Litigation is not the full extent of the parties' disputes. The parties are competitors involved in extensive litigation related to a number of similar products. Ex. 1012; Ex. 1013. Due to the one-year time bar of § 315(b), BSC's opportunity to challenge the '665 Patent via an IPR is now, regardless of whether claims of this patent become relevant to any future BSC products. This is particularly important where, as here, the patent claims have a relatively recent priority date and significant remaining term. This factor weighs strongly in favor of institution.

E. The Petitioner and Defendant are the Same Entity

BSC is the Counterclaim-Defendant in the Litigation and the Petitioner here.

F. Other Circumstances Impact the Board's Exercise of Discretion, Including the Merits

The circumstances of this particular case weigh heavily in favor of institution. First and foremost, the merits of BSC's challenge are strong. The Challenged Claims are unpatentable under both 35 U.S.C. §§102 and 103 based on BSC's prior work set forth in its patents and publications.

Second, Nevro should be held to account for the arguments in its IPR petitions challenging BSC's claims with substantively similar limitations to a limitation Nevro added and relied on during prosecution. Ex. 1008; Ex. 1015 at 195, 204-205. The Board should institute review to ensure consistency before the agency.

Third, as noted in § IV.D, above, there are efficiency reasons that suggest the Board should resolve validity of all of the '665 Patent's claims at one time.

Fourth, the Board should take into account that it is already reviewing a number of other patents in the Litigation. *See Apple v. Seven Networks*, IPR2020-00266, Paper No. 12, at 19. Earlier this year the Board granted Nevro's petitions and instituted review of five BSC Patents asserted in the Litigation.[5] The subject

[5] IPR2019-01284, IPR2019-01313, IPR2019-01318, IPR2019-01340, IPR2019-01341. Litigation over those patents is currently stayed. *See* §§III, IV.A.

matter of some of those patents is similar to the subject matter at issue here. For example, in IPR2019-01341 the Board is reviewing claims of the '447 Patent, which shares a specification with Bradley384 (Ex. 1005), relied on here.

Finally, BSC filed this Petition approximately three months before the one-year deadline. BSC prefers to challenge the '665 Patent claims before the agency—as Nevro has done repeatedly with the patents BSC has asserted—and its ability to do so should not be foreclosed by events in the Litigation.[6] These considerations weigh strongly in favor or institution.

* * *

Here, most of the *Fintiv* factors favor institution. An earlier trial date is ***always*** going to be present if the Board is considering the *Fintiv* factors and the parties will often be the same in an IPR and co-pending litigation. *Sand Revolution*, IPR2019-01393, Paper No. 24 at 12-13. All four of the other factors weigh in favor of instituting review. As a whole, here, the *Fintiv* factors strongly counsel in favor of instituting review. *See Apple v. Seven Networks*, IPR2020-00266, Paper No. 12, at 9-21.

[6] Because of Nevro's motion to dismiss, Nevro did not file its counterclaims until fifteen months after BSC's first amended complaint.

V. OVERVIEW OF THE '665 PATENT

A. Disclosure

The '665 Patent relates to systems for controlling spinal cord stimulation for inhibiting pain (Ex. 1001 at 1:24-27, 4:38-44) by applying electrical signals to specific areas of the spinal cord (*id.* at 1:31-60, 35:12-44). This had long been accomplished by traditional spinal cord stimulation (SCS) systems, including where the electrical signals would create a feeling of "paresthesia," for example a "tingling" sensation that many patients report as less uncomfortable than the underlying pain. *Id.* at 1:45-56; Ex. 1002 ¶¶50-52. The '665 Patent further discusses, but does not claim, the use of "high frequency" stimulation signals to treat pain without producing paresthesia. *See, e.g.* Ex. 1001 at 3:4-47, 7:10-11:41, 29:58-30:7.

The disclosed systems (*see* Ex. 1002 ¶¶48-58) use the same hardware components as standard prior art SCS systems, as depicted in Figure 1A:

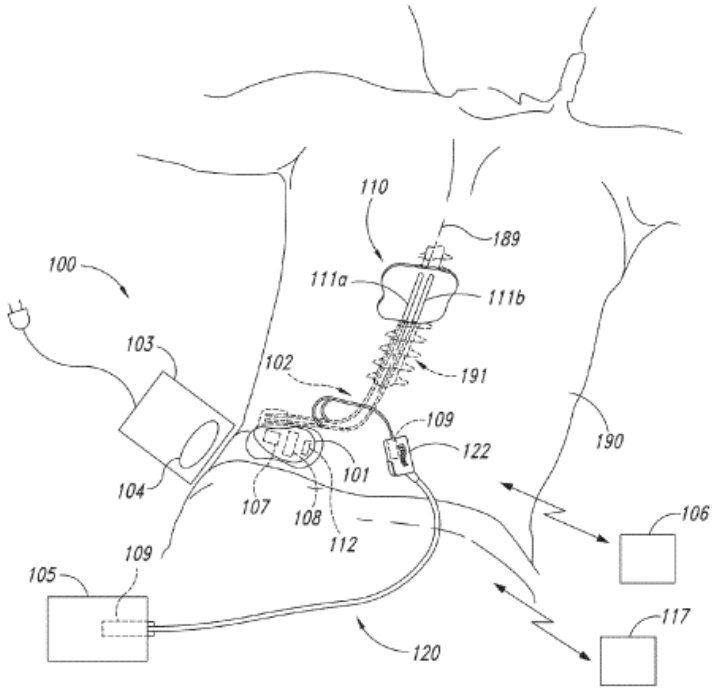

Fig. 1A

Ex. 1001 at Fig. 1A; *see also* Ex. 1004 Fig. 2, Ex. 1006 Fig 2B. Figure 1A depicts an implantable pulse generator (IPG) (101) and signal delivery devices 110, which can have one or more leads (111)—e.g., a first lead 111a and a second lead 111b—implanted within a patient. Ex. 1001 at 4:12-37. Those leads can include electrodes for delivering electrical signals to target tissue. *Id.* at 4:31-44. The electrical signals are defined by signal delivery parameters, including identification of electrodes that deliver the signal, and the frequency, amplitude, and pulse width of the electrical signal itself. *Id.* at 5:10-13, 5:57-67. A physician can update the parameters wirelessly via programmer 117. *Id.* at 5:50-54.

The programmer comprises a display, input devices, memory, and a processor. *Id.* at 27:36-53; Ex. 1002 ¶¶59-64. Figure 13D shows an exemplary display:

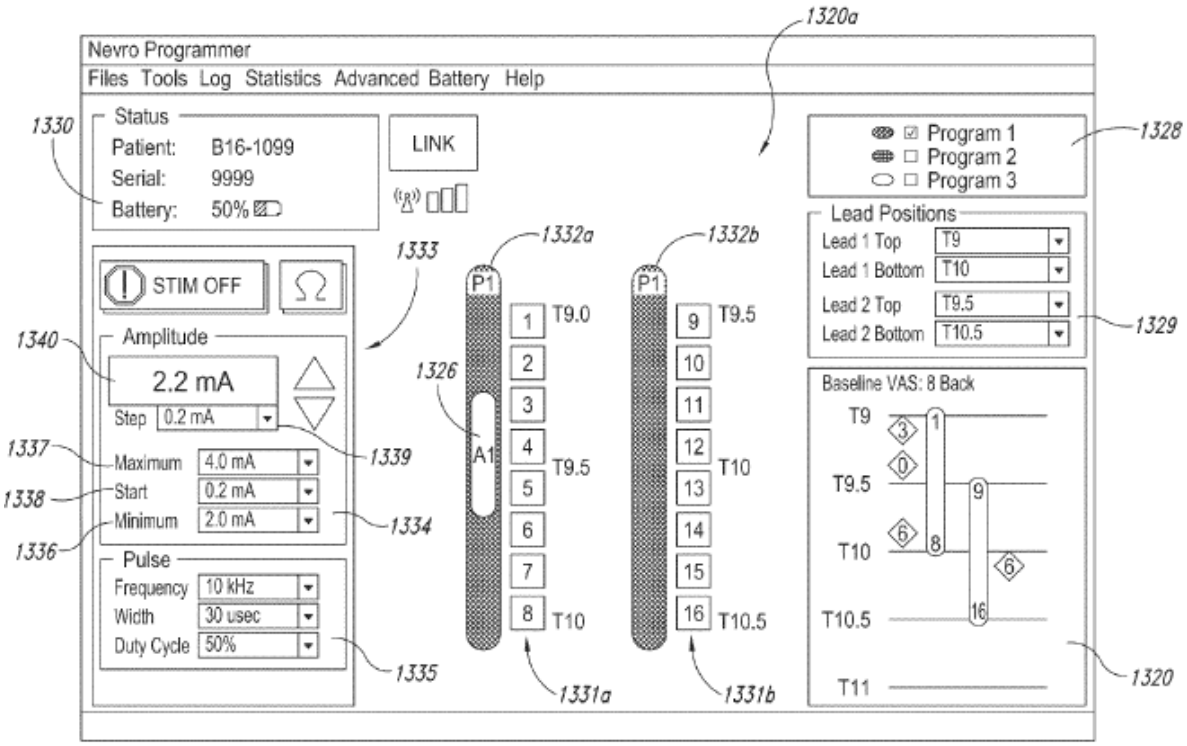

Fig. 13D

Id. Fig. 13D; *see also id.* at 27:54-29:6, Figs. 13B-C and 13F-G. The display shows the electrode octet (1331) associated with each implanted lead (*id.* at 28:60-64), a "lead position summary 1329" (*id.* at 28:59), and a "therapy location indicator 1326" that a practitioner can use to identify the target spinal location (*id.* at 28:67-29:6). The programmer can automatically select electrodes to deliver stimulation energy. *Id.* at 29:7-10.

Figure 13F depicts another exemplary display:

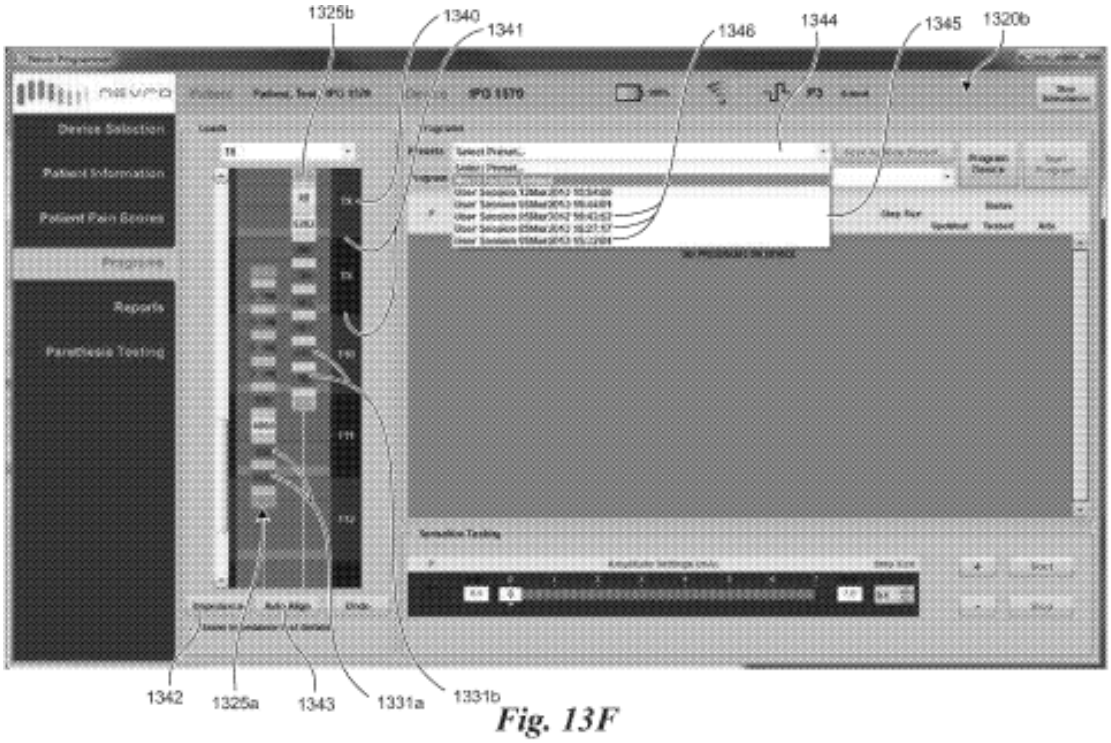

Fig. 13F

Id. at Fig. 13F. On this display, a user can drag and drop a lead identifier 1325a onto the screen so that it is aligned with a patient vertebral level identifier 1340, indicating the location of the lead in a patient's body. *Id.* at 31:9-16. The program can then use measured electrical data (e.g., impedance data) to align an image of the second lead relative to an image of the first lead. *Id.* at 31:28-36. The programmer can also measure the impedance at each individual electrode and reject any electrodes not within a pre-established range. *Id.* at 30:65-31:8. This display includes a "preset window 1344," with a drop-down menu of patient indications that may be addressed by one or more of the electrodes at the identified vertebral levels. Alternatively, as shown in Figure 13B, the user can enter pain score identifiers relating to a patient's indication. *Id.* at 28:6-29, Fig. 13B.

Finally, Figure 13H depicts a "technique for automatically selecting signal delivery parameters based . . . on the patient indication and the location of a signal delivery device implanted in the patient." *Id.* at 32:57-61; Ex. 1002 ¶¶65-68.

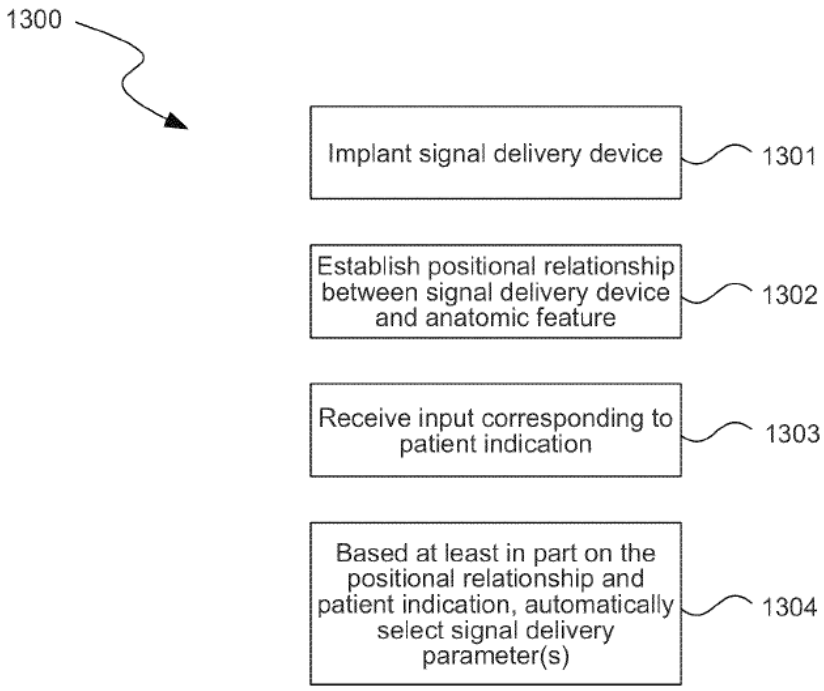

Fig. 13H

Ex. 1001 Fig. 13H. The programmer automatically selects signal delivery parameters based on the positional relationship of the leads (step 1302) (*id.* at 33:16-20) and a patient indication (step 1303) (*id.* at 33:41-50). *Id.* at 33:53-57. "For example, the process can include automatically identifying which electrodes should be activated . . . ." *Id.* at 33:57-58. "To identify the electrodes, the program can access one or more databases containing information (e.g., aggregated data obtained

from similarly treated patients) which establish correlations between electrode location and patient indication." *Id.* at 33:61-65.

B. Priority Date and Prosecution History

The '665 Patent's application was filed on March 22, 2017, and the '665 Patent issued on September 18, 2018, claiming priority to provisional application, No. 61/619,358, filed April 2, 2012.

During prosecution, the examiner rejected the pending claims as anticipated and obvious. Relevant here, Nevro amended the pending claims to require lead alignment based, at least in part, on "impedance values of one or more of the second plurality of contacts." Ex. 1015 at 195. Nevro argued that one of the references disclosed only reconfiguration of electrodes to direct or steer current for stimulation—not to align lead images. *Id.* at 204. Nevro also distinguished another reference, Butson (US2011/0066407) (Ex. 1014), which used impedance values for selecting stimulation parameters, as not using impedance to "align[]" images. Ex. 1015 at 205; *see also* Ex. 1014 ¶156. On July 26, 2018, the examiner allowed the claims. Ex. 1002 ¶69.

VI. CLAIM CONSTRUCTION

BSC does not believe any terms require construction for the Board to find all Challenged Claims unpatentable.

VII. LEVEL OF ORDINARY SKILL IN THE ART

A person of ordinary skill in the art ("POSA") at the time of the earliest priority application of the '665 Patent would have a degree in electrical engineering, biomedical engineering, or a related discipline, along with relevant experience (at least 2-3 years for a Ph.D., 3-5 years for a Master's, and 5+ years for a Bachelor's degree) researching or developing neural stimulation systems or other implantable medical devices. Ex. 1002 ¶21. Alternatively, the POSA would have an M.D. and experience practicing as a neurologist, neurosurgeon or anesthesiologist, with 2-3 years of experience in neural stimulation. *Id.* The person would have had general knowledge of implantable medical devices and various related technologies as of April 2, 2012. *Id.*

VIII. SUMMARY OF PRIOR ART

A. State of the Art Prior to the '665 Patent

SCS has been used to treat chronic pain since 1967. Ex. 1023 at 1; Ex. 1028; Ex. 1002 ¶31. By 2012 SCS systems were in widespread use and both the hardware and software components of SCS therapy were well-known. *Id.* ¶¶31-47. The hardware components generally include an implantable pulse generator (IPG), implanted electrode leads, and an external programmer. *See, e.g.*, Ex. 1004 ¶4, Figs. 1 & 2; Ex. 1006 at 2:44-64, 11:19-22; Ex. 1024 ¶3; Ex. 1002 ¶¶32-33. And the software in the programmer is typically used to program the IPG with information

about a patient and their implanted leads, and then to automatically determine the parameters (e.g., electrode combination and polarity, frequency, amplitude, and pulse width) of effective electrical pulses to deliver through the electrodes to target patient tissue. Ex. 1004 ¶45, 65-75; Ex. 1002 ¶¶33-47.

1. U.S. 2012/0083857 (Ex. 1004) ("Bradley857")

Bradley857 published on April 5, 2012 based on an application filed on September 24, 2011 and claims priority to provisional application 61/390,112, filed October 5, 2010. Bradley857 is prior art under 35 U.S.C. § 102(e) and was not considered during prosecution of the '665 Patent.

Bradley857 discloses systems for programming tissue stimulation leads (Ex. 1004 ¶2) during initial setup or if the leads later move (*id.* ¶11). Bradley857's system includes an IPG 14, two leads 12 with a plurality of electrodes 26, a remote controller 16, and a clinician programmer 18 ("CP") with a display. *Id.* ¶¶18, 38, 40-41, 54, Fig. 1.

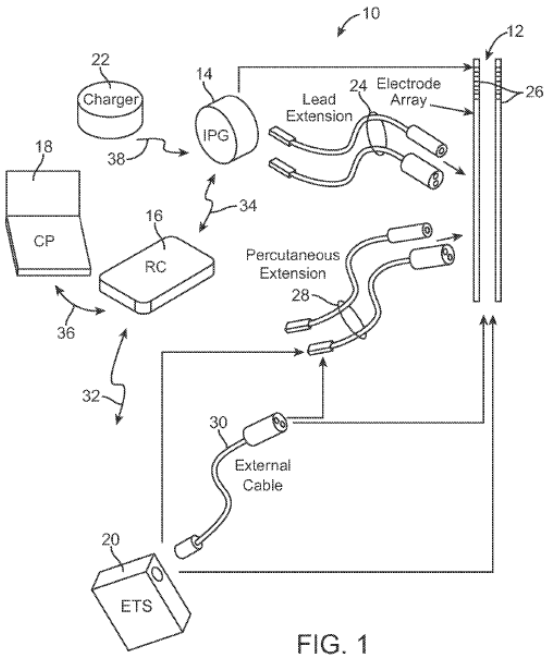

FIG. 1

Id. Fig. 1. The IPG and leads can be implanted into a patient with the leads extended along the patient's spine:

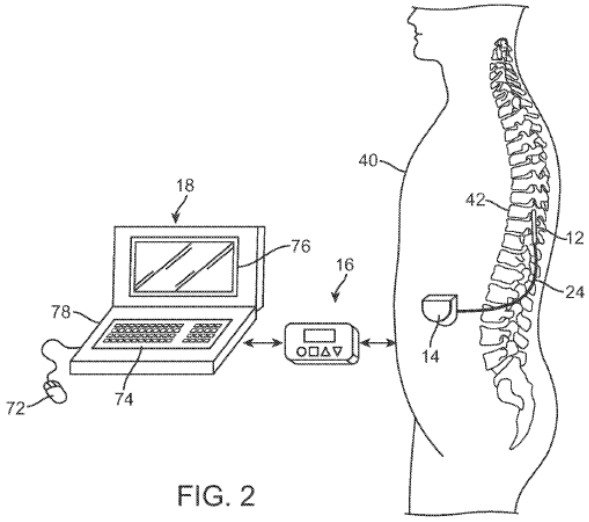

FIG. 2

Id. Fig. 2; *see also id.* ¶43.

The CP can execute program 86, which provides several displays that the clinician can use to input information about a patient and the implanted leads. Ex. 1002 ¶¶77-84.

First, Bradley857's CP can generate screen 100(1), which includes a pain map of the human body. Ex. 1004 ¶58. There, the clinician can input information about the location (the shaded areas) and severity (the VAS score) of the patient's pain. *Id.*

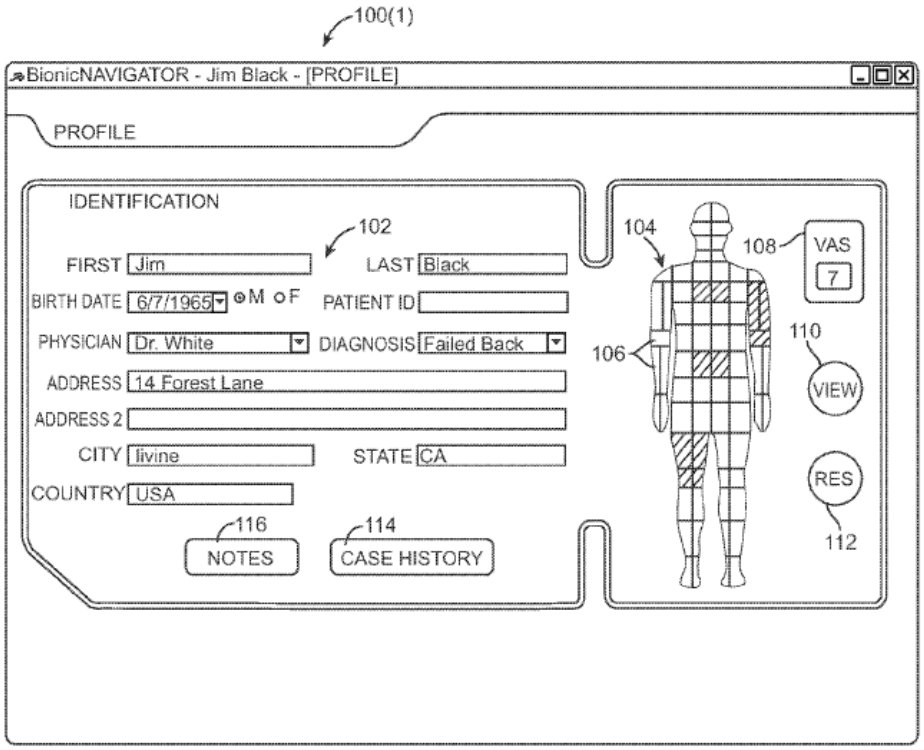

FIG. 7

Id. Fig. 7.

The CP also provides a number of display screens for inputting information about the implanted leads. First, a user can enter information about lead type and

number. *Id.* ¶59. Second, a "lead configuration screen 100(2)" allows selection of a specific lead configuration of the implanted leads.

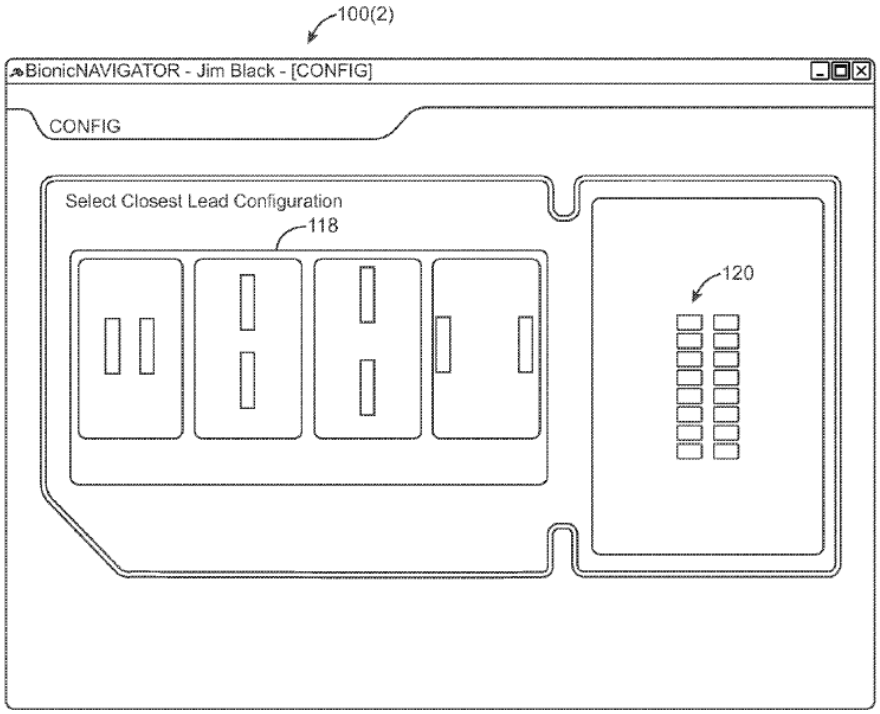

FIG. 8

Id. Fig. 8, ¶59.

Alternatively, rather than inputting the lateral spacing between the leads, "the positions of the tissue stimulation leads 12 relative to each other can be determined based on the measured electrical parameters," as described in, for example, U.S. Patent No. 6,993,384 (Ex. 1005) ("Bradley384"), which Bradley857 specifically incorporates by reference. Ex. 1004 ¶61.

Lead orientation screen 100(3) allows the clinician to assign electrode numbers and the vertebral position (entered in box 126) to each lead. *Id.* ¶62, Fig. 9.

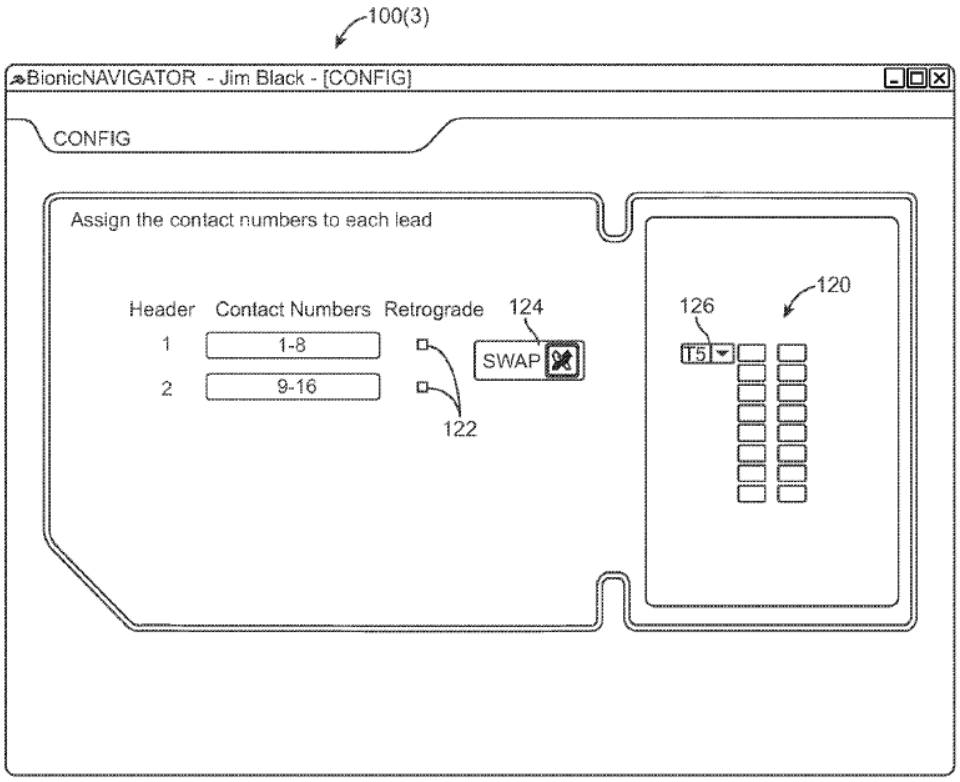

FIG. 9

Id. Fig. 9.

A clinician can also use drag-and-drop screen 100(4) to place a graphic of each lead on a computer-based image of a spine. *Id.* ¶63, Fig. 10. Specifically, the user can drag and drop an object from the lead generation icon to create virtual lead 12(1)'—an image representing the first lead. *Id.* ¶63. The user can then drag a second object to create virtual lead 12(2)'—an image of the second lead, at a location relative to the first lead. *Id.*

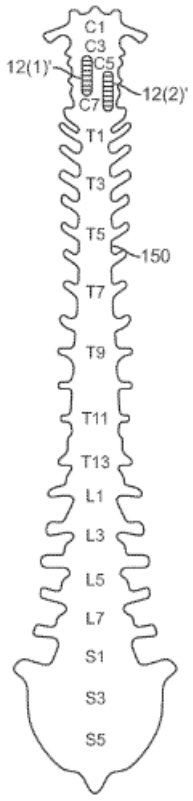

FIG. 10

Finally, Bradley857's CP analyzes information about the patient's indication and the implanted lead location to automatically generate a set of stimulation parameters. *Id.* ¶65. The processor accesses a database that includes known indications and their corresponding vertebral level stimulation targets and other stimulation parameters. *Id.* ¶¶66, 67 (database can be based on other patient's data and include data about specific electrode positions). The CP's processor compares the patient's information to the database to determine the desired stimulation target (*id.* ¶69), and then "select[s] the electrodes 26 adjacent the desired stimulation target" (*id.* ¶70). The processor then generates "a set of stimulation parameters,

including the selected active electrode combination and pulse width." *Id.* ¶71. Ex. 1002 ¶85-86.

2. Bradley384 (Ex. 1005)

Bradley384 issued on January 31, 2006 and is prior art to the Challenged Claims under 35 U.S.C. § 102(b). It was cited on an IDS during prosecution of the '665 Patent, but was not relied on by the examiner. Bradley384, which BSC asserted in the Litigation, claims priority to provisional application 60/338,331, filed December 4, 2001. BSC's '447 Patent (Ex. 1007), also asserted in the Litigation and challenged by Nevro in IPR2019-01341 (Ex. 1008), is a continuation of Bradley384 and shares a common specification.

Bradley384 was expressly incorporated by reference into Bradley857. *See* Ex. 1004 ¶61. Bradley384 discloses an SCS system where either interelectrode impedance or field potential is used "to determine the relative orientation of one electrode on an implanted lead to other electrodes on the implanted lead or adjacent implanted leads in the spinal column." Ex. 1005 at 3:10-17; Ex. 1002 ¶¶89-97. Impedance is a measure of the effective resistance to the flow of electric current between two points. Ex. 1031 at 3; Ex. 1005 at 6:61-7:1; Ex. 1002 ¶93.

Bradley384 teaches that by measuring (1) the monopolar impedances for all electrodes; and (2) bipolar impedances between each electrode on opposing leads, a user can create an impedance "map." Ex. 1005 at 7:8-22. Specifically, the

monopolar impedance values may be used to "correct" the bipolar impedance values, which are then used to determine the relative orientation of the leads. *Id.* at 7:8-43. Ex. 1002 ¶90, 94-96. That information "may then be loaded into a programmer, which can then provide a graphic display of the assumed relative lead positions." Ex. 1005 at 7:43-46. That graphic of the two aligned leads can be compared to stored graphics of earlier measurements to track lead orientation and migration. *Id.* 7:46-50. If necessary, corrective action, including reprogramming, can be taken. *Id.* at 10:1-50. The impedance techniques disclosed in Bradley384 "may be used as an automated or assistive method" for programming a system for spinal cord stimulation. *Id.* at 10:56-61.

3. U.S. Patent No. 6,516,227 ("Meadows") (Ex. 1006)

Meadows is a foundational BSC patent that issued on February 4, 2003 and is prior art to the Challenged Claims under 35 U.S.C. § 102(b). Meadows was not considered during prosecution of the '665 Patent. Meadows ultimately claims priority to provisional application 60/145,829, filed July 27, 1999. Meadows was expressly incorporated by reference into both Bradley384 and Bradley857. *See* Ex. 1004 ¶47; Ex. 1005 at 1:65-67 (citing the then-pending application that issued as Meadows).

Meadows is directed to a spinal cord stimulation system that can, *inter alia*, map current fields and take electrode impedance measurements. Ex. 1006 at 1:9-

18, 10:57-67, 20:32-54. Ex. 1002 ¶¶99-101. Meadows includes an IPG 100, lead extensions 120 having an electrode array 110, and a clinician programmer 204. Ex. 1006 at 8:28-37 9:3-5, 9:44-10:12, 10:57-60, 32:61-65, Figs. 1, 2A, 2B.

In Meadows, "[a]n important feature included with the IPG 100 is its ability to measure electrode impedance, and to transfer the impedance thus measured back to a remote programmer, or other processor." *Id.* at 20:5-8. The impedance is measured for each electrode when the programmer is initially connected (*id.* at 32:35-39), and, for "a spinal cord implantation, the electrode impedance will typically range between about 400 ohms and 1000 ohms" (*id.* at 20:13-14, 18-22). If "the impedance is too high, that suggests the connector and or leads which connects with the electrode may be open or broken. If the impedance is too low, that suggest there may be a short circuit somewhere in the connector/lead system. In either event (too high or too low impedance), the device may be unable to perform its intended function." *Id.* at 46:55-61. Only electrodes with impedance values within a certain threshold will be available for programming. *Id.* at 32:35-39, 34:55-59, 38:32-43, 40:14-18; Ex. 1002 ¶102-104.

IX. STATEMENT OF PRECISE RELIEF REQUESTED AND REASONS THEREFOR UNDER 37 C.F.R. §§ 42.104(B)(1) AND (2)

Petitioner requests review of the Challenged Claims under 37 C.F.R. § 42.108 and cancellation of these claims as unpatentable on the following grounds:

Ground	'665 Patent Claims	Unpatentable under 35 U.S.C. §§ 102/103
1	1-21	Anticipated by Bradley857 (35 U.S.C. § 102)
2	1-21	Obvious over Bradley857 in view of Bradley384 and Meadows (35 U.S.C. § 103)

X. EACH CHALLENGED CLAIM OF THE '665 PATENT IS UNPATENTABLE

Pursuant to 37 C.F.R. § 42.104(b)(4)-(5), the Challenged Claims are unpatentable for the reasons set forth in detail below.

A. GROUND 1: Bradley857 anticipates Claims 1-21

1. Principles of Anticipation

A patent claim is anticipated if every element of the claimed invention is described either expressly or inherently within the four corners of a single, prior art document. *Callaway Golf Co. v. Acushnet Co.*, 576 F.3d 1331, 1346 (Fed. Cir. 2009). "Material not explicitly contained in the single, prior art document may still be considered for purposes of anticipation if that material is incorporated by reference into the document" by a clear identification of the subject matter incorporated and where it is found. *Id.*; *see also Paice LLC v. Ford Motor Co.*, 881 F.3d 894, 909 (Fed. Cir. 2018).

In *Paice*, the clause "is incorporated herein by this reference" incorporated the entire disclosure of a patent because it stated the reference "is" incorporated, without qualification, and identified the patent number where the material could be found.

Paice, 881 F.3d at 909. In *Harari v. Lee*, a reference stated that "[o]ptimized erase implementations have been disclosed in two co-pending U.S. applications." 656 F.3d 1331, 1335 (Fed. Cir. 2011). The reference identified those applications and indicated that their disclosures "are hereby incorporate[d] by reference." *Id.* The Federal Circuit held that language incorporated the entire disclosure of the applications, and not just the portions describing optimized erase implementations.

Bradley857 expressly incorporates the disclosures of both Bradley384 and Meadows. *See* Ex. 1004 ¶47 (Bradley384, Meadows), ¶61 (Bradley384); Ex. 1002 ¶¶81-82, 100, 138. Bradley857 indicates those references "are" incorporated and specifically identifies them. *See* Ex. 1004 ¶47 ("Further details discussing the detailed structure and function of IPGs are described more fully in [Meadows] and [Bradley384], which are expressly incorporated herein by reference."); ¶61 (stating that Bradley384 and others "are expressly incorporated herein by reference"). Like in *Paice* and *Harari*, language that the references "are" incorporated and the identification of the references is sufficient to incorporate the disclosures of Bradley384 and Meadows into Bradley857 in their entirety. *See Paice*, 881 F.3d at 909; *Harari*, 656 F.3d at 1335; Ex. 1002 ¶¶81-82, 100, 138. Those disclosures are therefore properly considered together in an anticipation analysis. *Callaway*, 576 F.3d at 1346; *Harari*, 656 F.3d at 1335.

In addition to the broad language incorporating the entirety of both Bradley384 and Meadows, Bradley857 also makes more-specific incorporations of precisely the disclosures necessary to anticipate the claims of the '665 Patent. For example, Bradley857 incorporates the disclosures from Bradley384 about using electrical parameters such as impedance to align leads, and the disclosures from Meadows about the functions of the IPG. Ex. 1004 ¶¶47, 61; Ex. 1002 ¶¶128, 138, 143. With those incorporated disclosures, Bradley857 discloses each and every claim limitation, arranged as in the claims.

2. Claim 1

The '665 Patent uses the terms "signal delivery device" and "contacts." For all relevant purposes here, disclosures of a "lead" with "electrodes" in the prior art is a "signal delivery device" with "contacts" as used in the '665 Patent. Ex. 1001 at 4:24-34; Ex. 1002 ¶¶54-55. Accordingly, these terms (signal delivery device/lead and contact/electrode) will be used interchangeably throughout the petition.

1[a]. ***"A patient treatment system, comprising:"***

To the extent the preamble is a limitation, Bradley857 discloses "tissue stimulation systems" for use within a patient. Ex. 1004 ¶¶2, 14; Ex. 1002 ¶107.

1[b]. ***"a non-transitory computer-readable medium having instructions that, when executed:"***

Bradley857's Clinician Programmer (CP) "generally includes a processor 82 . . . and memory 84 that stores a stimulation programming package 86, which can be executed by the processor 82 to allow the clinician to program the IPG 14 and RC." Ex. 1004 ¶55; Ex. 1002 ¶108 (identifying non-transitory computer-readable medium). The CP communicates either directly with the IPG, or indirectly with the IPG via the remote controller (RC 16), via an RF link. Ex. 1004 ¶¶41, 52, Fig. 1; *see also id.* ¶51 (RC circuitry), ¶55 (CP circuitry). Execution of programming package 86 performs the functions described below. Ex. 1002 ¶109-110.

1[c]. ***"receive a first input corresponding to a location of a first signal delivery device implanted in a patient, the first signal delivery device including a first plurality of contacts"***

Bradley857 uses "electrode leads 12 [that] are implanted within the spinal column 42 of a patient 40." Ex. 1004 ¶43; Figs. 2, 3. "[T]he tissue stimulation leads 12, which carry a plurality of electrodes 26," are connected to an implantable pulse generator (IPG). Ex. 1004 ¶38; *see also id.* ¶44; Fig 3 (showing electrodes on both leads). Thus, lead 12(1) is a first signal delivery device that includes a plurality of contacts, implanted in a patient, and information about the contacts can be entered into Bradley857's CP. Ex. 1004 ¶¶59, 71; Ex. 1002 ¶111-112.

The CP provides a number of user interfaces that allow it to receive the claimed first input. For example, "[t]he lead orientation screen 100(3) has a vertebral location pull down menu 126 next to the graphical electrode representation 120 that a clinician can use to indicate the vertebral position of the leads." Ex. 1004 ¶62; Fig. 9.

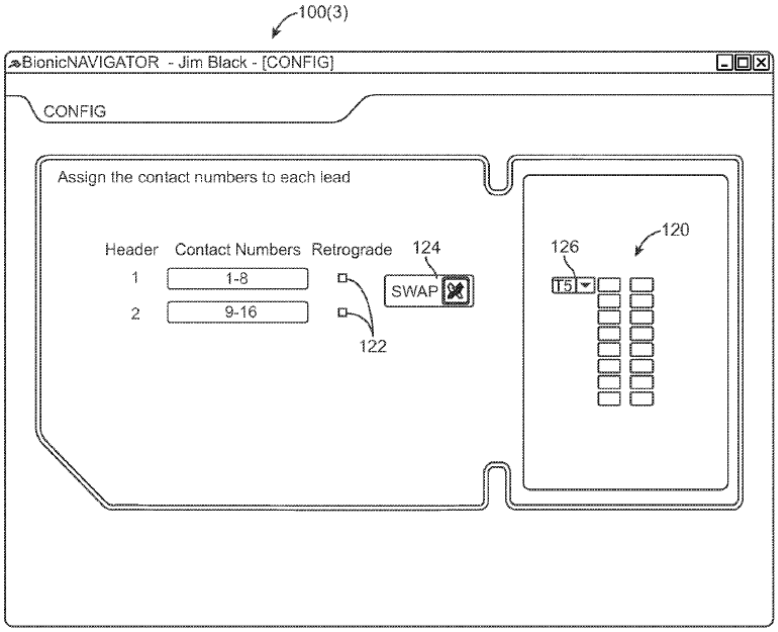

FIG. 9

Id. Fig. 9 (showing that lead 1 (electrodes 1-8) is located at vertebral position T5). Ex. 1002 ¶112-113.

Drag-and-drop lead screen 100(4) allows a clinician to input the location of each implanted lead, including lead 12(1), onto a graphical image of a spine. Ex. 1004 ¶63, Fig. 10. Ex. 1002 ¶¶114-116.

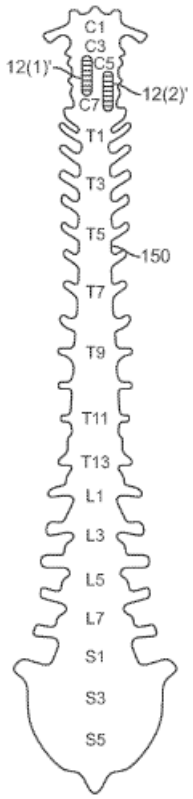

FIG. 10

Here, the user drags an image of a virtual lead "over a graphical representation of an anatomical region 150 (in this case, a spine)." Ex. 1004 ¶63. Ex. 1002 ¶¶115-117. This input is nearly identical to the '665 Patent's description of providing the "first input"—"[t]he first input can be provided by a user moving a computer-based image of the lead relative to a computer-based image of the at least one vertebra . . . ." Ex. 1001 at 36:52-55.

There were a number of well-known ways a user could determine the anatomical location of the leads to input this information. *See* Ex. 1004 ¶10; Ex. 1030 ¶53; Ex. 1002 ¶114.

1[d]. ***"establish a first positional relationship between the location of the first signal delivery device and an anatomical feature of the patient;"***

A system "establishes" the claimed positional relationship once the position of the leads within a patient's body has been defined. *See* Ex. 1001 at 32:66-33:40; Ex. 1002 ¶118. For example, the practitioner can "move the lead identifiers 1325a, 1325b and/or manipulate the vertebral boundaries 1341 to properly align the contacts with corresponding vertebral levels" to establish the positional relationship. Ex. 1001 at 32:66-33:20.

In Bradley857, execution of programming package 86 allows the clinician to define "a location of the tissue stimulation lead or leads 12 relative to an anatomical reference"—a vertebral location—establishing the claimed first positional relationship. Ex. 1004 ¶57; *see also id.* ¶¶15, 65, § X.A.2.1[c]. Specifically, the selected vertebral level from drop down menu 126 (¶62), or the virtual lead placed at "the location of the actual lead 12 relative to the spine" (¶63) establishes the claimed positional relationship. §X.A.2.1[c]; Ex. 1002 ¶¶118-124.

The remainder of Bradley857 confirms that it has established the claimed positional relationship. The CP "analyz[es]" the positional relationship to generate a set of stimulation parameters and to determine which electrodes are adjacent the stimulation target. Ex. 1004 ¶¶65, 70 (processor selects electrodes based on user defined location of leads); *see also id.* ¶71 ("The processor 82 may obtain the actual

electrode spacing of the implanted leads 12 . . . ."); Ex. 1002 ¶121. The CP could not determine the electrodes adjacent a stimulation target if it had not first established the position of the leads relative to the anatomy. Ex. 1002 ¶¶121-124.

1[e]. ***"receive a second input corresponding to a location of a second signal delivery device implanted in the patient, the second signal delivery device including a second plurality of contacts;"***

For the reasons explained above, Bradley857's second lead 12(2) is the claimed "second signal delivery device including a second plurality of contacts" that is "implanted in the patient." *See* §X.A.2.1[c]; Ex. 1002 ¶125.

Bradley857 discloses several ways the CP receives a second input corresponding to location information of a second signal delivery device.

First, the clinician can input the lateral spacing between the leads on the "lead configuration screen 100(2)" (Ex. 1004 ¶¶59, 61, Fig. 8), or, alternatively, use measured electrical parameters to determine the lead positions relative to each other (*id.* ¶61). Bradley384, incorporated into Bradley857, teaches using impedance—a measured electrical parameter—as a type of electrode location information that can be input to determine the relative spacing of leads and to align the images of the two leads to reflect that spacing. *Id.* ¶61; Ex. 1002 ¶¶127-128; Ex. 1005 at 6:57-67 (impedance varies linearly with distance between leads), 6:43-7:51 (process for aligning leads using impedance values); *see also* §X.A.2.1[i].

Once a user has determined lead spacing, screen 100(3), which depicts a graphic of the two leads, allows the clinician to input the vertebral level in box 126 and adjust the longitudinal stagger between the leads, moving the second lead relative to box 126. Ex. 1004 ¶62; Ex. 1002 ¶129.

Finally, if a user knows the positions of the tissue stimulation leads relative to each other (e.g., based on impedance measurements), they can drag a second virtual lead 12(2)' to a location "relative to the previously generated virtual lead 12(1)'" on screen 100(4). Ex. 1004 ¶63; Fig. 10; Ex. 1002 ¶130.

1[f]. ***"establish a second positional relationship between the location of the second signal delivery device and at least one of the location of the first signal delivery device or the anatomical feature of the patient;"***

A "positional relationship" is established when the system defines the position of the leads within the patient's body. *See* §X.A.2.1[d]. The second positional relationship can be between two leads and/or between the second lead and the patient anatomy.

Bradley857 teaches establishing a second positional relationship. Specifically, the user can define the location of the leads relative to each other and relative to the patient anatomy, allowing the system to establish the position of the electrodes and the leads. Ex. 1004 ¶¶65, 70-71. For example, once the user has defined the lead spacing on lead configuration screen 100(2) (*id.* ¶59) or determined the relative position of the two leads using measured electrical parameters, like

impedance (*id.* ¶61), and/or defined the vertebral level in pull-down 126, the second positional relationship is established. Ex. 1002 ¶132. Once the second virtual lead is located on the drag-and-drop screen 100(4) (*id.* ¶63) at the appropriate location relative to the first virtual lead, the second positional relationship is established. Ex. 1002 ¶¶132-133.

1[g]. ***"identify one or more contacts of the first plurality of contacts for delivering therapy to the patient, wherein the identified one or more contacts are (a) located at a target vertebral level of the patient, and"***

Bradley857 explains that "[b]y analyzing [information about indication and lead location], the CP 18 can automatically generate a set of stimulation parameters" (Ex. 1004 ¶65), including the identity of electrodes used to deliver stimulation energy to specific portions of the patient anatomy (*id.* ¶¶45, 70-71). "Electrical stimulation will occur between two (or more) activated electrodes," which can be on separate leads (including the first lead). *Id.* ¶46; Fig. 3. The IPG can individually control the current flowing through each of the electrodes. *Id.* ¶47. Those electrodes can deliver therapy to a patient. Ex. 1002 ¶134.

Bradley857 further teaches the use of a database containing reference therapeutic indications, their corresponding stimulation targets (Ex. 1004 ¶66), which correspond to known vertebral levels (e.g., C3, C4-C5, T1, L1-L2, S5) (*id.* ¶¶67, 70), and other stimulation parameters (*id.* ¶¶67, 71). *Id.* ¶68 (database

providing vertebral and mediolateral location and other information from which stimulation parameters can be derived for each pain region); Ex. 1002 ¶135.

The processor is configured for accessing the database and comparing a patient's indication with reference indications in the database to determine the stimulation target. Ex. 1004 ¶69. The processor then selects electrodes "adjacent the desired stimulation target" based on the positional information of the lead. *Id.* ¶70; *see also id.* ¶71 (electrode combination and pulse width), ¶¶73-74 (describing generating stimulation parameter values like specific pulse width (¶73) and electrode combination (¶74)). Ex. 1002 ¶¶136-137.

1[h]. ***"(b) have impedance values within a pre-established range;"***

Meadows, incorporated into Bradley857, discloses that "an important feature included within the IPG 100 is its ability to measure electrode impedance." Ex. 1006 at 20:5-8; Ex. 1002 ¶¶138-140. Meadows provides a pre-established range—"[f]or a spinal cord implantation, the electrode impedance will typically range between about 400 ohms and 1000 ohms." Ex. 1006 at 20:18-20. Hardware recognition occurs once the clinician programmer is connected to the system and "the system identifies the stimulator, the patient programmer, ***and electrode availability (through electrode impedance measurements)***." *Id.* at 32:35-39 (emphasis added); *see also id.* at 47:7-49:47 (explaining voltage sweep to determine impedance values).

Impedance values that are too high suggest an open or broken electrode; impedance values that are too low suggest a short circuit. *Id*. at 46:55-65.

Those monopolar electrode impedance measurements are used to determine whether an electrode is "available" for use. *Id*. at 32:35-39, 34:55-59, 38:32-36; Ex. 1002 ¶140-142. Electrodes can be displayed on a screen, and "available" electrodes can receive programming data. Ex. 1006 at 38:32-54, 40:16-18; Ex. 1002 ¶142. Accordingly, Meadows teaches that the electrodes for delivering therapy that are located at the target vertebral level must have impedance values within a pre-established range to be available for programming. Ex. 1002 ¶142.

1[i]. ***"based at least in part on impedance values of one or more of the second plurality of contacts, align a computer-based image of the second signal delivery device relative to a computer-based image of the first signal delivery device; and"***

Bradley857 teaches that the relative positions of implanted leads can be determined based on "measured electrical parameters." Ex. 1004 ¶61. With respect to using such "measured electrical parameters," Bradley857 specifically points to and incorporates Bradley384. *Id.*; Ex. 1002 ¶¶81-82. Bradley384, in turn, teaches the use of impedance, a "measured electrical parameter" to align images of leads. Ex. 1005 at 6:43-7:60; Ex. 1002 ¶144.

Bradley857 discloses an embodiment that uses screen 100(3) to depict computer-based images of two leads aligned either by input of lead orientation

information (Ex. 1004 ¶59) or measured electrical parameters (i.e., impedance) (*id.* ¶61). *Id.* ¶62, Fig. 9. The user then enters the vertebral level identifier with pull-down menu 126 (*id.* ¶62, Fig. 9). Ex. 1002 ¶145.

Bradley857 also discloses an embodiment where the user enters lead location information onto a graphical interface showing an image of a spine. Ex. 1002 ¶146; Ex. 1004 ¶63 (screen 100(4)). That lead location information includes the location of the first lead relative to the patient's spine, and "if multiple tissue stimulation leads are used, the positional [sic] of the tissue stimulation leads relative to each other." *Id.* ¶15; *see also id.* ¶57. As explained above, Bradley384, incorporated into Bradley857, explains that a user can use impedance measurements at each electrode (including the electrodes on the second lead) to create a graphical display of the tissue stimulation leads relative to each other. *Id.* ¶63; Ex. 1005 at 6:43-7:60. Ex. 1002 ¶146.

On screen 100(4), the user can define the lead position by dragging and dropping an image of the second lead (virtual lead 12(2)') "***relative*** to the previously generated virtual lead 12(1)'," the image of the first lead. Ex. 1004 ¶63 (emphasis added). In other words, these disclosures from Bradley857 teach that the CP can depict a graphical display of the relative position of the leads based on measured impedance values (Bradley384) on screen 100(4). Ex. 1002 ¶¶146-147. Bradley384 confirms that its method could be used for such a purpose. Ex. 1005 at 10:56-61;

Ex. 1002 ¶146. And other prior art references also confirm this reading of Bradley857. *See* Ex. 1030 ¶53 (describing a drag-and-drop screen where the configuration is defined by imaging or electrical means as described in e.g., Bradley384). Indeed, Bradley857 incorporates by reference provisional application 61/333,673 (Ex. 1032), to which Ex. 1030 claims priority, and which provides "[f]urther details discussing the dragging and dropping of virtual leads 12' onto a screen," directly linking these disclosures to Bradley857. Ex. 1004 ¶64; Ex. 1032 at 27-30 (¶¶53-58); Ex. 1030 ¶¶53-58; Ex. 1002 ¶147. Accordingly, Bradley857 discloses an embodiment where screen 100(4) displays computer-based images of the leads aligned, in part, using impedance values. *Id.* ¶¶145, 148, 150.

Finally, Bradley857 incorporates Bradley384, which itself discloses a display showing a computer-based image of the first lead aligned with a computer-based image of the second lead. *Id.* ¶149. Bradley384 explains that the bipolar impedance values measured between each electrode pair are "corrected" with monopolar impedance values. Ex. 1005 at 6:43-7:43. The corrected bipolar impedance values are used to generate an electrode map. *Id.* "Th[at] information may then be loaded into a programmer, which can then provide a graphic display of the assumed relative lead positions." *Id.* at 7:43-46. That image can be compared to future alignments to determine whether the leads have migrated. *Id.* at 7:46-51. Using the methods of

Bradley384, each subsequent impedance measurement will be used to align or re-align the computer-based images of the leads. *Id.*

Nevro is very familiar with the disclosures from Bradley384. In the Litigation, BSC accused Nevro of infringing claims of Bradley384. As described above, Bradley384 shares a specification with BSC's '447 Patent, which Nevro is challenging in IPR2019-01341. Nevro readily argued in the course of its arguments to render BSC's claims unpatentable that prior art as of 2001 "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." Ex. 1008 at 3.

1[j]. ***"automatically identify a signal delivery parameter value for a pulsed electrical signal that is to be delivered to the patient via at least one of the first signal delivery device or the second signal delivery device, wherein the signal delivery parameter value has a predetermined correlation with at least one of the first positional relationship or the second positional relationship."***

In Bradley857, once a clinician enters a patient's indication and lead location information, the CP automatically accesses a stored database and identifies signal delivery parameter values (e.g., pulse width values and cathode-anode patterns (Ex. 1004 ¶¶18, 21, 71) for use in the patient. Ex. 1004 ¶¶65-68; *see also* §X.A.2.1[g]; Ex. 1002 ¶151. The electrical pulse can then be delivered to the patient by two or

more activated electrodes, which can be on different leads (Ex. 1004 ¶46), and the IPG can control the current at each individual electrode (*id.* ¶47). Ex. 1002 ¶152.

Specifically, the CP accesses a database that includes a predetermined correlation between reference indications, desired stimulation locations, lead positions, cathode-anode patterns, and effective pulse width values. Ex. 1004 ¶66-69. For example, that database can include empirical data from other patients, including information about lead and electrode position—the claimed first or second positional relationships (e.g., two cathodes separated by 5mm along the midline of the spinal cord and an anode laterally separated by 10mm)—and signal delivery parameter values (pulse width values and cathode-anode pattern used). *Id.* ¶67; Ex. 1002 ¶152. The processor matches a patient's indication to a reference indication (and corresponding stimulation location). Ex. 1004 ¶69 (providing example selecting parameters in ¶67, mentioned above); Ex. 1002 ¶¶151-152. Then, the processor selects the available electrodes adjacent the desired stimulation target based on the established positional relationships of the leads in the patient. Ex. 1004 ¶70; *see also* ¶¶59-63 (describing the location information that the CP uses to establish positional information). The processor then selects values for the cathode-

anode pattern[7] and pulse width that correspond to the target treatment based on the predetermined correlation between electrode position and stimulation parameter values in the database. *Id.* ¶71. Bradley857 teaches this "automatically determining" limitation. Ex. 1002 ¶155.

Bradley857 also teaches that the CP can use a set of heuristic rules to select specific signal delivery parameter values. *Id.* ¶153. Those parameter values have a predetermined correlation with lead position. *See* Ex. 1004 ¶73 (providing exemplary pulse width (50-300 μs) for use with cathodes that are located medially relative to the midline of the spine); ¶74 (providing exemplary anode-cathode separation (<8mm) to selectively stimulate midline dorsal column fibers). In short, based on the patient's indication, and the established positional relationship of the leads, the CP determines where treatment is needed, which available electrodes are at that location, and the electrode pattern and pulse width of the electrical signal that is transmitted to that location. Ex. 1002 ¶153. That determination is based on a predetermined correlation—found in a database or set of heuristic rules—between the signal delivery parameter values and the positional relationships of leads. *Id.* .

[7] The cathode-anode pattern is defined by various electrodes being identified as cathode (-), anode (+), or off (0). Ex. 1004 ¶¶5, 45.

Moreover, the second positional relationship may be the relationship between the locations of the second lead and the first lead. *See* §X.A.2.1[f]; Ex. 1002 ¶154. Bradley384, incorporated into Bradley857, teaches updating signal delivery parameter values based on this second positional information alone. For example, Bradley384 teaches monitoring relative orientation of the leads to track lead migration. Ex. 1005 at 7:38-51, 9:25-30, Fig. 10. The clinician can then take "correcti[ve] action" if needed. Ex. 1005 at 10:4-7. Such corrective action can include manual changes to the parameters or "automatically adjusting the stimulation energy to a previously-defined optimal potential field." *Id.* at 10:46-50; *see also* 10:17-45, 56-61; Ex. 1002 ¶154. The optimal stimulation energy can include the parameter values described in Bradley857, such as electrode combination and pulse width. Ex. 1002 ¶154. Accordingly, Bradley857, incorporating the disclosure from Bradley384, teaches a predetermined correlation between lead position and signal delivery parameter values and taking corrective action to move the field based on that correlation. *Id.* ¶¶151-155.

3. Claim 2: "The system of claim 1 wherein the predetermined correlation is further based at least in part on patient database information correlating signal delivery parameters and indications for other patients."

The database described in limitation 1[j] can "be generated or further refined using empirical data acquired from previous patients," correlating stimulation of

certain spinal segments and parameter values (such as pulse width) to treatment of certain indications. Ex. 1004 ¶¶67, 71; Ex. 1002 ¶156.

4. Claim 3: "The system of claim 1 wherein the instructions, when executed: receive a third input corresponding to an updated location of at least one of the first signal delivery device or the second signal delivery device; and in response to the third input, automatically update the signal delivery parameter value."

Bradley857 recognizes that leads can "gradually or unexpectedly move" (Ex. 1004 ¶11), and describes automatically determining signal parameters based on lead position (*Id.* ¶¶66-71). Ex. 1002 ¶157.

Bradley384, incorporated into Bradley857, specifically describes using subsequent impedance measurements to monitor relative lead orientation. These subsequent, "updated" inputs concerning the updated location of the first or second implanted lead disclose the claimed third inputs. *Id.* ¶158; Ex. 1005 at 7:45-51. Lead migration may require corrective action, including refitting the system to the patient. Ex. 1005 at 10:1-45. As described above (§X.A.2.1[i]), once the updated lead location indicates that the leads have shifted, corrective action can be taken, including automatically adjusting stimulation energy to previously-defined parameters. Ex. 1002 ¶¶159-160; Ex. 1005 at 10:46-50; *see also id.* at 9:25-30.[8]

[8] This is disclosed for different types of electrical measurements, including field potential and impedance values. *Id.* at 3:10-17, 10:51-65; Ex. 1002 ¶159.

That stimulation energy is based on the signal delivery parameter values described in Bradley857. Ex. 1002 ¶159. Accordingly, Bradley857/Bradley384 discloses receiving a third input corresponding to updated lead location, and automatically updating the signal delivery parameter value. *Id.* ¶161.

5. Claim 4: "The system of claim 1, wherein establishing the first positional relationship includes establishing a positional relationship between the anatomical feature of the patient and one or more of the first plurality of contacts."

As explained in limitation 1[d], the CP establishes a first positional relationship when it has a defined anatomical position of the first lead. *See* §X.A.2.1[d]. Lead orientation screen 100(3) depicts the specific electrodes in the electrode octets found on the leads and includes a drop-down menu 126 to associate vertebral level with the first electrode of the first lead (Ex. 1004 ¶62):

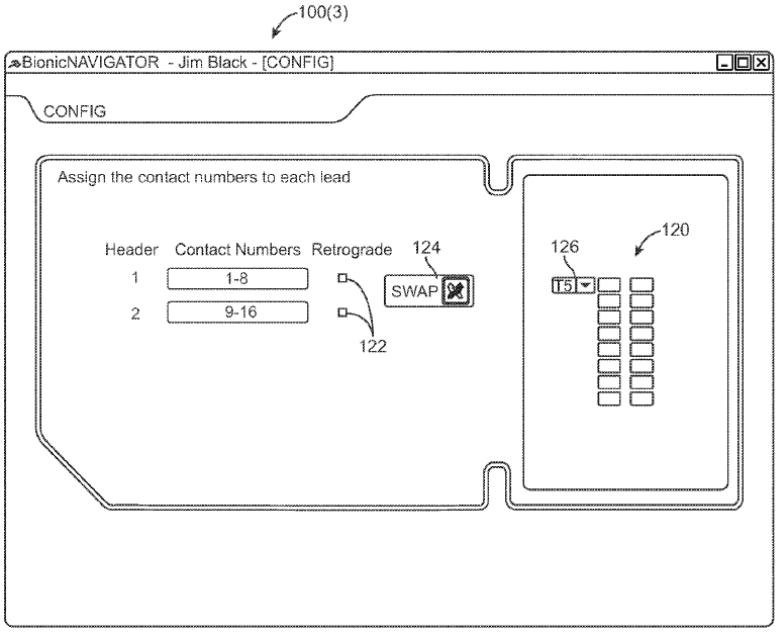

FIG. 9

Id. Fig. 9; ¶62; Ex. 1002 ¶¶162-163.

The clinician can also enter the location of the first lead, with the electrode octet depicted, on the drag and drop screen, allowing the CP to establish the positional relationship of each electrode with its vertebral position (Ex. 1002 ¶164):

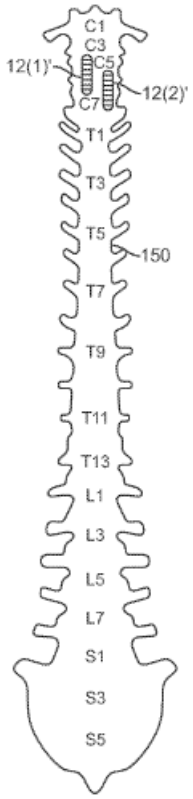

FIG. 10

Ex. 1004 Fig. 10.

Both techniques correlate specific electrodes to vertebral position and teach the added limitation of claim 4. Bradley857 confirms that the CP establishes the positional relationship of individual electrodes by teaching that the CP is "configured for selecting the electrode 26 adjacent the desired stimulation target based on the user-defined location of the stimulation leads[.]" *Id.* ¶¶70-71; Ex. 1002 ¶165.

6. Claim 5: "The system of claim 1 wherein the first plurality of contacts and the second plurality of contacts are operable to deliver the pulsed electrical signal to the patient."

Bradley857 discloses that "[e]lectrical stimulation energy may be delivered from the neurostimulator to the electrodes in the form of an electrical pulsed waveform . . . to stimulate neural tissue," disclosing this claim. Ex. 1004 ¶5, 46; Ex. 1002 ¶166. Bradley857 discloses electrodes on each lead, which make up the first plurality of contacts and the second plurality of contacts. *See* §§§X.A.2.1[c], [e].

7. Claim 6: "The system of claim 1, wherein the computer-based image of the first signal delivery device and the computer-based image of the second signal delivery device are displayed on a display, and wherein the display further includes vertebral level identifiers corresponding to the anatomical feature of the patient, and lead identifiers corresponding to the first signal delivery device and second signal delivery device."

As described in limitation 1[i], Bradley857 discloses lead orientation screen 100(3), which displays computer-based images of the leads (lead identifiers), and includes a pull-down menu with vertebral level identifiers from which the user can select the identifier of the anatomical feature at which the lead is positioned. Ex. 1004 ¶62; Ex. 1002 ¶167. Bradley857 also discloses a screen 100(4) that displays the computer-based images of the leads aligned on a display showing a computer-based image of the patient vertebrae. *See* §X.A.2.1[i]; Ex. 1004 ¶¶61, 63. For example, screen 100(4) includes vertebral level identifiers corresponding to the patient's spine, and two virtual leads, which are lead identifiers corresponding to

first and second leads. *Id.* ¶63, Fig. 10; Ex. 1001 at 31:13-16, Fig. 13F; Ex. 1002 ¶168-169.

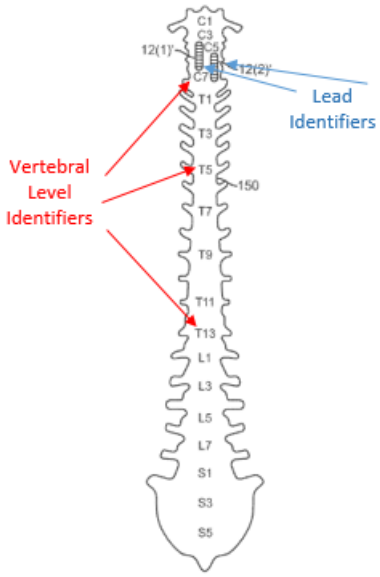

FIG. 10

Ex. 1004 Fig. 10 (annotated); Ex. 1002 ¶168.

8. Claim 7: "The system of claim 6, wherein the instructions, when executed: receive a third input to adjust the location of one or more of the lead identifiers relative to the vertebral level identifiers."

Bradley384, incorporated into Bradley857, teaches displaying lead orientation on a display and comparing that orientation to previously determined orientations to determine if the leads have migrated. Ex. 1005 at 7:43-51. If a lead has migrated, a clinician can detect and display such migration by taking subsequent impedance measurements, which are then input (the "third input") to align or re-align the computer-based images of the leads as described in Bradley857. *Id.* at

7:43-51, 10:1-50, 10:56-65; Ex. 1004 ¶¶11, 61, 63; Ex. 1002 ¶170; §X.A.7 (Claim 6).

9. Claim 8: "The system of claim 6, wherein each lead identifier includes a contact lead identifier, and wherein automatically identifying a signal delivery parameter value is based at least in part on impedance indicated at the contact lead identifier."

As explained in section X.A.5 (claim 4), screen 100(3) depicts a graphical representation of the electrodes (contact lead identifiers) associated with each lead. Ex. 1004 ¶62, Fig. 9; Ex. 1002 ¶171. Drag-and-drop screen 100(4) also depicts the individual electrodes associated with each virtual lead. Ex. 1004 ¶63, Fig. 10; Ex. 1002 ¶172. Thus, the lead identifiers (virtual leads) each include contact lead identifiers (individual electrode identifiers). Ex. 1002 ¶171-172. Moreover, Bradley857 expressly incorporates the description of CP display screens in U.S. Patent Application 12/614,942 (Ex. 1033). Ex. 1004 ¶56. That application describes and shows display screens with the individual electrodes enumerated. *See* Ex. 1033 at Figs. 7-10, ¶¶92-96; *see also* Ex. 1030 at Figs. 7-9, ¶¶54-58; Ex. 1032 at 27-30, 44-46 (incorporated into Bradley857 paragraph 64).

Section X.A.2.1[h] explains how the incorporated disclosure from Meadows uses monopolar impedance values at each electrode to determine electrode availability. If that electrode is unavailable, it is omitted from programming (Ex. 1006 at 32:35-39, 34:55-59, 38:32-36, 40:14-18), and cannot be used in a cathode-

anode pattern (Ex. 1004 ¶¶5, 67, 71) to deliver the electrical pulse (thus, no pulse width) as described in Bradley857. Ex. 1002 ¶173.

Moreover, sections X.A.2.1[e], [f] explain how Bradley857, including the disclosure of Bradley384, discloses using impedance values measured at each electrode and each electrode pair to determine relative lead orientation. That determination is used to establish the positional relationship of the leads, which the CP uses when accessing the database of indications, lead positions, and signal delivery parameter values to generate signal delivery parameters for the patient, including pulse width values and cathode-anode pattern. Ex. 1004 ¶¶66-71; Ex. 1002 ¶174. Accordingly, automatically identifying a signal delivery parameter value (including pulse width) is based at least in part on the alignment of the two leads, which Bradley857 teaches can be based on impedance values at each contact (and therefore at each contact lead identifier). Ex. 1002 ¶174.

Finally, as noted in §X.A.2.1[j], Bradley384 itself teaches that a clinician can use impedance values at each electrode to monitor lead migration. Ex. 1005 at 7:38-51, 9:25-30, Fig. 10. If the leads have migrated, the programmer can take corrective action, including "automatically adjusting the stimulation energy to a previously-defined optimal potential field." *Id.* at 10:4-7, 46-50. Returning that stimulation energy to a previously-defined optimal field includes identifying signal delivery

parameter values, including for the parameters described in Bradley857. Ex. 1004 ¶67 (electrode combination and pulse width); Ex. 1002 ¶175.

10. Claim 9: "The system of claim 1 wherein aligning the computer-based image of the second signal delivery device is further based on the impedance values of one or more of the first plurality of contacts."

Section X.A.2.1[i] explains how Bradley857 (with the incorporated disclosures of Bradley384) teaches aligning a computer-based image of the leads. That alignment is performed by measuring bipolar impedance at each electrode pair, which includes the electrodes on the first lead and the second lead. Ex. 1005 at 7:6-50; Ex. 1002 ¶176.

11. Claim 10: "The system of claim 1 wherein the instructions, when executed, prevent one or more of the first plurality of contacts from being used to deliver therapy to the patient, wherein the prevented one or more contacts have impedance values outside the pre-established range."

Meadows, which Bradley857 expressly incorporates, explains that the IPG measures impedance at each electrode to determine which electrodes are "available" for use. *See* §X.A.2.1[h]. The circuitry of the handheld programmer only allows programming available electrodes. Ex. 1006 at 40:14-18. Accordingly, if an individual electrode does not have an impedance value within the pre-established range, it is not available and cannot be used for stimulation. Ex. 1002 ¶177.

12. Claim 11: "The system of claim 1 wherein the instructions, when executed, receive a third input corresponding to a medical indication of the patient, and wherein the predetermined correlation is between the indication and at least one of the first positional relationship or the second positional relationship."

Bradley857 teaches that the CP allows a clinician to input information corresponding to a medical indication of a patient and the location of leads in that patient's body. Ex. 1004 ¶65; *see also id.* ¶¶15, 57.

The patient's indication and lead position are the bases for identifying the stimulation target (*id.* ¶¶66-68), and the positional relationship of the leads is the basis for specifically identifying the electrodes adjacent that target (*id.* ¶¶69-70). The stimulation parameter values for treatment are based on known effective treatments for patients correlated to similar indications and lead positions. *Id.* ¶¶67, 70-71; Ex. 1002 ¶¶178-179.

13. Claim 12:

12[a]: ***"A patient treatment system, comprising"***

See limitation 1[a]. Ex. 1002 ¶180.

12[b]: ***"an implantable signal generator;"***

Bradley857 discloses an implantable pulse generator (IPG). Ex. 1004 ¶¶37-38. The IPG is implanted in the patient's body (*id.* ¶43), generates the stimulation signals used in the system (*id.* ¶45), and is therefore an implantable signal generator. Ex. 1002 ¶181.

12[c]: ***"a first elongated signal delivery lead coupled to the implantable signal generator and positioned proximate to a patient's spinal cord, the first lead including a first plurality of contacts;"***

As explained in limitation 1[c], Bradley857 teaches "electrode leads 12 [that] are implanted within the spinal column 42 of a patient 40." Ex. 1004 ¶43; Figs. 2, 3. An implanted pulse generator (IPG) is connected to "the tissue stimulation leads 12, which carry a plurality of electrodes 26." Ex. 1004 ¶38; *see also id.* ¶44; Fig 3 (showing elongated leads with electrodes 26 on both first lead 12(1) and second lead 12(2)); Ex. 1002 ¶182.

12[d]: ***"a second elongated signal delivery lead coupled to the implantable signal generator and positioned proximate to the patient's spinal cord, the second lead including a second plurality of contacts; and"***

See supra limitation 12[c]. Ex. 1002 ¶183.

12[e]: ***"a programmer in wireless communication with the implantable signal generator, the programmer having a computer-readable medium with instructions that, when executed:"***

Bradley857 teaches a CP 18, which includes processor 82, memory 84, and programming package 86. Ex. 1004 ¶55; *see also* limitation 1[b]. The CP communicates with the IPG wirelessly via RF connections either directly or through the RC. *See* Ex. 1004 ¶¶40-41, §X.A.2.1[b]. Ex. 1002 ¶184.

12[f]: ***"receive a first input indicating a location of the first lead;"***

Limitation 1[c], *supra*, explains where Bradley857 discloses inputting the location of a first lead. Ex. 1004 ¶¶62-63, Figs. 9&10. Ex. 1002 ¶185.

12[g]: "***receive a second input indicating a location of the second lead;"***

Limitation 1[e], *supra*, explains where Bradley857 discloses inputting the location of a second lead. Ex. 1004 ¶¶59, 61-63, Figs. 8-10. Ex. 1002 ¶186.

12[h]: ***"establish a first positional relationship between the first lead and a vertebra of the patient;"***

Bradley857 discloses this limitation for the reasons explained in §X.A.2.1[d]. Ex. 1002. ¶187.

12[i]: ***"establish a second positional relationship between the second lead and at least one of the first lead or the vertebra of the patient;"***

Bradley857 discloses this limitation for the reasons explained in §X.A.2.1[f]. *Id.* ¶188.

12[j]: ***"identify one or more contacts of the first plurality of contacts for delivering a pulsed electrical signal to the patient, wherein the identified one or more contacts have impedance values within a pre-established range;"***

Bradley857 discloses how the CP "identif[ies] one or more contacts of the first plurality of contacts for delivering a pulsed electrical signal to the patient" for the reasons explained in §X.A.2.1[g]. *See also* Ex. 1004 ¶¶38, 44-47, 65-71; Ex. 1002

¶189. And Bradley 857, through its incorporation of Meadows, discloses that those electrodes have impedance values within a pre-established range. *See* §X.A.2.1[h]; Ex. 1002 ¶190.

12[k]: ***"based at least in part on impedance values of one or more of the second plurality of contacts, align a computer-based image of the second lead relative to a computer-based image of the first lead;"***

Bradley857/Bradley384 discloses this limitation for the reasons explained in §X.A.2.1[i]; Ex. 1002 ¶191.

12[l]: ***"access an established database of patient information, wherein the database includes a predetermined correlation including the first and second positional relationships for other patients; and"***

As explained in §§X.A.2.1[i] and X.A.3, Bradley857 discloses how the CP accesses a database generated "using empirical data acquired from previous patients" that correlates therapeutic indications with stimulation targets and the positional relationships of leads in those other patients. Ex. 1004 ¶67. "For example, it may be known through the stimulation treatment of previous patients that stimulating the spinal cord at the L2 spinal segment level actually provides pain relief for the right thigh, and that an active electrode combination having a cathode-anode pattern consisting of ***two cathodes axially separated from each other by 5 mm along the physiological midline of the spinal cord, and an anode laterally***

separated from these cathodes by 10 mm, and a pulse width of 400 μs provides optimum pain relief for the right thigh." *Id.* (emphasis added). Ex. 1002 ¶¶192-193.

12[m]: ***"based at least in part on the predetermined correlation, automatically identify a value of a signal delivery parameter for a pulsed electrical signal to be delivered to the patient's spinal cord via at least one of the first or second pluralities of contacts."***

Based on the reference information in the database that correlates previous patient indications, lead location and signal delivery parameter values (*see* §§ X.A.2.1[i], X.A.3, X.A.13.12[l]), Bradley857's CP selects electrodes adjacent the desired stimulation target (Ex. 1004 ¶70), and can determine the cathode-anode pattern and pulse width value for the electrical signal is that is delivered by the electrodes (*id.* ¶71). *See also* §X.A.2.1[j] (describing automatic parameter determination based on predetermined correlations stored in the database). That pulsed electrical signal is to be delivered to the patient's spinal cord. Ex. 1004 ¶79; *see also* ¶67 (explaining separation of leads along the midline of the spinal cord), ¶71, Fig. 2. Ex. 1002 ¶194.

14. Claim 13: "The system of claim 12 wherein the instructions, when executed: receive a third input corresponding to an updated location of at least one of the first lead or the second lead; and in response to the third input, automatically update the signal delivery parameter value for delivering the pulsed electrical signal to the patient's spinal cord."

This claim is nearly identical to claim 3. Bradley857/Bradley384 discloses this limitation for the reasons explained in §X.A.4 (Claim 3). Ex. 1002 ¶195.

15. Claim 14: "The system of claim 13 wherein the signal delivery parameter includes at least one of frequency, amplitude or pulse width."

Bradley857 teaches that based on the database information described in paragraph 67, which may include information about pulse width, the processor "generates a set of stimulation parameters, including the selected active electrode combination and pulse width." Ex. 1004 ¶¶67, 71; *see also id.* ¶¶65-71; ¶45 (describing cathode-anode pattern, amplitude, pulse width, and pulse rate (frequency) as stimulation parameters); Ex. 1002 ¶196.

16. Claim 15: "The system of claim 14 wherein the instructions, when executed, automatically update the signal delivery parameter value, in response to the third input."

Bradley384, incorporated into Bradley857, teaches that the CP can receive a third input corresponding to an updated lead position to take corrective action, including automatically adjusting the stimulation parameters. Ex. 1005 at 7:43-51, 9:25-30, 10:46-50; §X.A.4 (claim 3). And Bradley857 teaches how the database

uses the lead position information to generate signal delivery parameter values such as pulse width and cathode-anode pattern. Ex. 1004 ¶¶65, 67, 71; *see also id.* ¶45. Accordingly, Bradley857/Bradley384 discloses updating signal delivery parameter values in response to a third input of updated lead location. Ex. 1002 ¶197.

17. Claim 16: "The system of claim 12 wherein the computer-based image of the first lead and the computer-based image of the second lead are displayed on a display, and wherein the display further includes vertebral level identifiers corresponding to the vertebra of the patient, and lead identifiers corresponding to the first and second leads, and wherein the instructions, when executed: receive a third input to adjust the location of one or more of the lead identifiers relative to the vertebral level identifiers."

Sections X.A.2.1[i] and X.A.7 (limitations 1[i] and Claim 6) explain Bradley857's description of an embodiment where the computer-based lead images are displayed on display 100(4). That display includes both lead identifiers (virtual leads 12(1)' and 12(2)') and vertebral level identifiers. *See* §§X.A.2.1[i] and X.A.7. Section X.A.8 (claim 7) discloses where Bradley857/Bradley384 teaches the claimed third input. *See* Ex. 1002 ¶198-199.

18. Claim 17: "The system of claim 12 wherein the predetermined correlation further includes a medical indication of the patient."

Bradley857's processor is configured to access a database that contains a plurality of desired reference therapeutic indications that are correlated to stimulation targets, cathode-anode patterns, and pulse widths. Ex. 1004 ¶¶65-68,

71; *see also* §X.A.2.1[j]. The processor analyzes the patient's indication and the information in the database that correlates therapeutic indications to stimulation targets and uses the first and second positional relationships to generate a set of stimulation parameters. Ex. 1004 ¶¶69-71. Ex. 1002 ¶200.

19. Claim 18

18[a]: ***"A method of operating a patient treatment system, the method comprising:"***

To the extent the preamble is a limitation, Bradley857 discloses a method of operating a patient treatment system. Ex. 1004 Title, ¶36, ¶65, ¶79 (exemplary method for programming an IPG by performing steps described throughout disclosure); Ex. 1002 ¶201.

18[b]: ***"establishing a first positional relationship between a location of a first signal delivery device and an anatomical feature of a patient, the first signal delivery device including a first plurality of contacts;"***

As described fully in §X.A.2.1[c], Bradley857 teaches using first electrode lead 12(1), which carries a plurality of electrodes 26. Ex. 1004 ¶¶38, 44; Fig 3; Ex. 1002 ¶202. In Bradley857, the clinician can indicate the vertebral position on screen 100(3) via vertebral pull down menu 126 next to the graphical electrode representation 120. Ex. 1004 ¶62; Fig. 9. Or the clinician can input the location of each implanted lead "at a location matching the location of the anatomical region at which the actual lead(s) 12 are implanted" graphically on the drag-and-drop screen.

Id. ¶63; Fig. 10; §X.A.2.1[c]. Section X.A.2.1[d] explains how the system disclosed in Bradley857 uses that location information to establish the claimed first positional relationship. Ex. 1004 ¶¶65, 70-71, 79; Ex. 1002 ¶203.

18[c]: ***"establishing a second positional relationship between a location of a second signal delivery device and at least one of the location of the first signal delivery device or the anatomical feature of the patient;"***

Bradley857's second lead 12(2) is the claimed "second signal delivery device." §X.A.2.1[e] (limitations 1[e]); Ex. 1002 ¶204. A clinician can input location information that is used to establish a second positional relationship between the leads. *See* § X.A.2.1[e]. Section X.A.2.1[f] explains how the claimed second positional relationship is established based on that location information. Ex. 1002 ¶205.

18[d]: ***"identifying one or more contacts for delivering therapy to the patient, wherein the identified one or more contacts have impedance values within a pre-established range; and"***

This method step is nearly identical to system limitation 12[j]. Bradley857 discloses this limitation for the same reasons. *See* §X.A.13.12[j]. Ex. 1002 ¶206.

18[e]: ***"based at least in part on impedance values of one or more of the second plurality of contacts, aligning a computer-based image of the second signal delivery device relative to a computer-based image of the first signal delivery device."***

This method step is nearly identical to limitation 1[i]. Bradley857/Bradley384 discloses this limitation for the reasons explained in §X.A.2.1[i]. Ex. 1002 ¶207.

20. Claim 19: "The method of claim 18, further comprising automatically identifying a value for a signal delivery parameter for a pulsed electrical signal to be delivered to the patient via at least one of the first or second pluralities of contacts, wherein the signal delivery parameter value has a predetermined correlation between a medical indication of the patient and at least one of the first positional relationship or the second positional relationship."

Bradley857 discloses this method step at the locations identified in sections X.A.2.1[j] and X.A.12. *See also* Ex. 1004 ¶79 (exemplary method step which includes the CP determining an initial set of parameters). Ex. 1002 ¶¶208-209.

21. Claim 20: "The method of claim 19, further comprising delivering the pulsed electrical signal having the signal delivery parameter value to the patient's spinal cord."

Bradley857 describes delivering a pulsed electrical signal having the signal delivery parameter value to the patient's spinal cord. Ex. 1004 ¶¶45, 79 (method to deliver pulse to patient's spine); *see also* ¶67 (position of leads along the spinal cord), ¶71, Fig. 2. Ex. 1002 ¶210.

22. Claim 21: "The method of claim 18, wherein the first positional relationship is established between a location of one or more of the first plurality of contacts and the anatomical feature of the patient, and wherein the second positional relationship is established between a location of one or more of the second plurality of contacts and (a) the anatomical feature of the patient or (b) one or more of the first plurality of contacts."

Bradley857 discloses an exemplary method for programming the IPG. Ex. 1004 ¶79. In that method, the clinician enters the location of the leads relative to an anatomical structure. Section X.A.5 (Claim 4) explains where Bradley857 details establishment of Claim 21's first positional relationship. *See* §X.A.5; Ex. 1002 ¶211.

Section X.A.19.18[c] explains where Bradley857 details establishment of the second position relationship of the second lead. These same disclosures describe establishing the positional relationship of the electrodes on that lead. *See e.g.*, Ex. 1004 ¶61 (incorporating Bradley384's disclosure of determining impedance values at each electrode to determine position of each electrode (and therefore each lead) relative to the other), ¶62 (adjusting second electrode octet relative to first electrode octet to establish positional relationship), Fig. 9, ¶63 (drag-and-drop screen showing anatomical position of electrode octets relative to vertebra and each other), Fig. 10. Ex. 1002 ¶212.

B. GROUND 2: Bradley857 In View Of Bradley384 And Meadows Renders Claims 1-21 Obvious

Ground 1 identifies where each limitation is located in the art. Ground 2 further explains why, to the extent the Board views Bradley384 and Meadows to be separate from and not sufficiently incorporated into Bradley857, there was nonetheless a strong motivation for a POSA to combine the references. A combination of the disclosures from Bradley857, Bradley384, and Meadows teaches each limitation of the Challenged Claims and renders them obvious.

1. A POSA Would Have Been Motivated to Combine Bradley857 with Bradley384 and Meadows

Bradley857 describes inventive SCS systems and methods that incorporate and build upon specific and, as of 2012, well-known approaches developed and patented by BSC. Bradley857 expressly directs a POSA to look to and to incorporate the impedance-based lead alignment techniques disclosed in Bradley384 (Ex. 1004 ¶61), and the IPG of Meadows (*id.* ¶47), which uses impedance to ensure electrode fitness and functionality (Ex. 1006 at 20:5-20; 32:35-39; 34:55-59; 38:32-36; 46:55-47:64). Those disclosures teach and suggest the combination of the disclosure of Bradley857 with the expressly referenced and incorporated disclosures of both Bradley384 and Meadows, and motivated a POSA to combine them. Ex. 1002 ¶214; *see also* MPEP §2143, I.G.

Moreover, each of the references addresses the problem of effectively programming an SCS device initially and over time and uses the same components to do so. Ex. 1002 ¶215. The hardware for SCS systems was well-known by 2012. *Id.* As described in §X.A, the prior art includes each claim limitation. A POSA would have been motivated to, and could have combined the elements by known methods to yield a predictable result, where all of the common components would function the same way as in the individual references. Ex. 1002 ¶¶215-223; *see also* MPEP §2143, I.A.

a. All three references teach, suggest, or motivate a POSA to combine the references

Each of these reference recognizes the same problems and expressly points to the other references for a solution. These references themselves motivate a POSA to combine them.

Bradley857 discloses in detail the issues a POSA faces when developing an effective SCS system. First, Bradley857 recognizes that for an SCS system to be effective, "stimulation energy must be controllably delivered to the electrodes to stimulate neural tissue," and that the electrodes that are capable of delivering that energy should be able to act as anodes, cathodes, or zero (left off). Ex. 1004 ¶5. Second, Bradley857 recognizes that the leads containing the electrodes must be correctly positioned. *Id.* at ¶10 ("If a lead is not correctly positioned, it is possible that the patient will receive little or no benefit from an implanted SCS system.").

"[C]orrect lead placement can mean the difference between effective and ineffective pain therapy." *Id.* And the ability to program or reprogram leads is particularly useful in situations where the leads may have migrated over time. *Id.* ¶11; Ex. 1002 ¶216. Finally, in the context of its description on how to input information about lead orientation (Ex. 1004 ¶¶59-63), Bradley857 explains that one can use measured electrical parameters such as those described in Bradley384, which uses measured impedance values, to define relative lead orientation. *Id.* ¶61; Ex. 1002 ¶216.

Accordingly, Bradley857 would motivate a POSA to ensure that the electrodes are functional and to ensure that leads are properly aligned using measured electrical data. Ex. 1002 ¶217.

Bradley857 and Meadows

Meadows also teaches that a POSA would want to ensure that the electrodes intended to deliver stimulation energy are suitable, and therefore available, to deliver energy. Ex. 1006 at 46:55-64 (explaining problems if impedance is too high or too low); Ex. 1002 ¶218. Meadows solves that problem by determining which electrodes are available (i.e., they have monopolar impedance values within an appropriate range). Ex. 1006 at 32:35-39; 34:55-59; 38:32-43, 40:14-18. Bradley857 and Meadows both explain why a POSA would be motivated to ensure the electrodes function properly—to deliver the appropriate and intended stimulation energy—and Meadows expressly teaches a standard technique as of 2012 for how

to do so. Ex. 1006 at 47:7-49:48; Ex. 1002 ¶218. Bradley857 includes the same components that Meadows uses to measure impedance values (IPG, electrodes, processor) and points to the foundational Meadows's IPG as a starting point. Ex. 1004 ¶37, ¶47 (incorporating Meadows and citing its IPG), Fig. 1; e.g., Ex. 1006 at 5:25-6:3; 6:37-63. Meadows details how one can measure impedance values and assess electrode availability using those components. Ex. 1006 at 47:7-49:48; *see also id.* at 32:35-39; 34:55-59; Ex. 1002 ¶¶218-219. Accordingly, a POSA would be motivated to combine these references and would have a reasonable expectation of success in doing so.

Bradley857 and Bradley384

Like Bradley857, Bradley384 recognizes the value in using measured electrical parameters to determine the relative orientation of two leads, including during initial implantation, programming, and as leads migrate over time. *See* Ex. 1004 ¶¶10-11, 61 (teaching to use measured electrical parameters to determine lead orientation and expressly incorporating Bradley384 to do so); Ex. 1005 at 1:17-18, 1:24-25, 56-60; 2:3-22 (noting benefits to impedance based alignment over manually aligning using imaging); Ex. 1002 ¶¶220-221. Each reference describes using those electrical parameters to align computer-based images of leads (Ex. 1004 ¶61-63; Ex. 1005 at 7:43-46) and Bradley384 further includes a detailed discussion as to how a POSA would use the measured bipolar impedance values between sets of two

contacts to determine lead orientation and to align images of leads. Ex. 1005 at 7:7-51. Ex. 1002 ¶¶221-222. Accordingly, both Bradley857 and Bradley384 would motivate a POSA to use measured electrical parameters in the course of aligning computer-based images of leads as disclosed in Bradley857, and a POSA would be motivated to combine them to take advantage of Bradley384's detailed instructions in Bradley857's system. Ex. 1002 ¶222.

For the same reasons, a POSA would have a reasonable expectation of success in combining those references because they both use the same components and Bradley857 expressly teaches to use the technique disclosed in Bradley384. Ex. 1004 ¶61; Ex. 1002 ¶223. Bradley384 details how to set up an IPG (Ex. 1005 at 3:16-6:10), how to measure impedance values (*id.* at 6:43-7:17), and how to implement a mathematical technique using impedance to determine lead alignment (*id.* at 7:18-43). Ex. 1002 ¶223.

b. A POSA would use known methods to combine these references to yield predictable results where all of the components function the same way

The prior art includes each element of the Challenged Claims (§X.A), and a POSA would have been motivated to combine that art (*see* §X.B.1.a).

A POSA not only would have been motivated to, but also easily could have combined these elements by known methods. Ex. 1002 ¶¶225-226. The devices each have the same relevant hardware. Each has an IPG connected to leads with a

plurality of electrodes. Ex. 1004 ¶¶37-38; Ex. 1005 at 3:27-38; Ex. 1006 at 4:11-20. Each is programmed by an external programmer. Ex. 1004 ¶¶52-63; Ex. 1005 at 3:61-4:9; Ex. 1006 at 32:50-65. This was standard hardware at the time of the invention. *See* Ex. 1025 at 3:58-4:48; Ex. 1026 ¶¶43-48; Ex. 1027 ¶¶21-24; Ex. 1002 ¶225. It was well-known at the time of invention that one could measure the impedance at each electrode using an IPG to determine whether the electrode was functional. Ex. 1006 at 32:35-39; §X.A.2.1[h]; Ex. 1002 ¶225. A POSA could have programmed the IPG in Bradley857 the same way as in Meadows or Bradley384. *See* Ex. 1004 ¶¶41, 47 (pointing to IPGs in Meadows and Bradley384); Ex. 1005 at 3:16-6:29; Ex. 1006 at 47:7-49:47; Ex. 1002 ¶225. Similarly, by 2012 a POSA could have used routine impedance measurements in the context of aligning leads in Bradley857. Ex. 1002 ¶226. Bradley857 teaches to use the conventional electrical measurements detailed in Bradley384, *e.g.*, impedance values, to determine the relative orientation of the leads. Bradley384 expressly discloses that a computer-based representation of leads aligned using impedance values can be displayed using the programmer, just like Bradley857's CP can display a number of screens for aligning computer-based images of leads and vertebrae. Ex. 1005 at 7:43-47; Ex. 1004 ¶¶62, 63. Accordingly, each of the combined elements would perform the same function in Bradley857's system as it does in Meadows or Bradley384's similar and incorporated systems. Ex. 1002 ¶226.

Finally, such a combination would yield predictable results. *Id.* ¶227. As explained above, a POSA could use the same hardware used in each reference to measure impedance values and to ensure that "available" electrodes are all within a certain predetermined impedance range and to align the leads. Ex. 1004 ¶47; Ex. 1002 ¶227. The results of actually using impedance to align leads as described in Bradley384 would be predictable because both references use the same equipment and Bradley384 and Meadows each explain how to program the equipment to measure and use the impedance values. Ex. 1002 ¶227.

XI. CONCLUSION

Petitioner respectfully requests that the Challenged Claims be cancelled as unpatentable pursuant to 35 U.S.C. § 318(b).

Respectfully submitted,

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CERTIFICATION UNDER 37 CFR § 42.24(d)

Under the provisions of 37 CFR § 42.24(d), the undersigned hereby certifies that the word count for the foregoing Petition for *Inter Partes* Review totals 13,668, which is less than the 14,000 allowed under 37 CFR § 42.24(a)(i).

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing Petition for *Inter Partes* Review was served on counsel of record on September 8, 2020 by filing this document through the End-to-End System, as well as delivering a copy via Priority Mail Express to the counsel of record for the Patent Owner at the following address:

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