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. 9,002,460
Filing Date: January 29, 2014
Issue Date: April 7, 2015

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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IPR2020-01562

PETITION FOR *INTER PARTES* REVIEW

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1003	Richard T. Mihran CV
1004	U.S. Publication 2012/0083857 ("Bradley857")
1005	U.S. Publication No. 2010/0274316 ("Alataris316")
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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)
1024	U.S. Publication No. 2011/0054551 ("Zhu")
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1026	U.S. Publication No. 2011/0307032 ("Goetz032")
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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 (Patent Owner'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 1-24 (the "Challenged Claims") of Nevro Corp.'s ("Nevro" or "Patent Owner") U.S. Patent No. 9,002,460 (the "'460 Patent") (Ex. 1001).

The '460 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 Examiner recognized as much during prosecution, rejecting as obvious the originally-filed claims that recited this functionality. And although it was not before the Examiner, Bradley857—the primary reference at issue here—is a BSC publication that discloses the limitations of the originally-filed claims virtually word-for-word.

The Challenged Claims issued only after Nevro's amendments that require displaying images of a patient's vertebra and an implanted lead, and receiving a user input to adjust the length of the image of the vertebra, i.e., to scale the anatomical image to the particular patient. But there was nothing new about displaying images of vertebrae and leads, or appropriately sizing the vertebral images. Because the

dimensions of anatomical structures vary between patients, it was well-known to change the dimensions of vertebral images to reflect actual patient anatomy.

The Challenged Claims, as issued, use unconventional terms to recite this conventional functionality. In Ground 1, Bradley857 is combined with Polefko, which teaches that changing the length of vertebral images to match patient anatomy improves SCS accuracy and efficacy. In Ground 4, Bradley857 is combined with Davis, which discloses a different technique for adjusting the length of a vertebral image to generate an anatomically-correct model of lead locations. Grounds 2-3 and 5-6 address dependent claims that recite similarly well-known functionality.

This Petition is part of a stream of disputes that spans three district court proceedings and sixteen IPR petitions filed by Nevro. The parties are close competitors and make (and will continue to make) competing products.

The Challenged Claims would have been obvious at the time of invention. 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. 10,076,665 (the "'665 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

A Power of Attorney accompanies this Petition pursuant to 37 C.F.R. § 42.10(b). Please address all correspondence to:

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Petitioner consents to electronic service by email at:

AG-BSC-NEVROIPR@akingump.com

E. Certification of Grounds for Standing

Petitioners certify that the '460 Patent is eligible for IPR and that Petitioners are not barred or estopped from challenging the claims of the '460 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. 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.[1] The Board

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

instituted three of those IPRs (covering two patents), and, upon Nevro's motion, the court stayed the case. Ex. 1009.[2]

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. Ex. 1018. Nevro moved to dismiss that complaint. While Nevro's motion was pending, the Board issued decisions in the IPRs challenging 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.[3]

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 '460 Patent. 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

[2] 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.

[3] IPR2019-01284, IPR2019-01313, IPR2019-01318, IPR2019-01341, IPR2019-01340, IPR2019-01216, and IPR2019-01315.

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. 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 '460 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 scheduled to close on February 18, 2021, with expert discovery 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 '460 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 in the Litigation 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 issue. 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 '460 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 24 claims of the '460 Patent. On July 16, Nevro identified only 7 claims—1-3, 6-7, and 11-12 (the "Asserted Claims")—as those it intended to pursue in the Litigation. Accordingly, the IPR will resolve the validity of 17 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 '460 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 35 U.S.C. § 103 based on work by BSC, Nevro, and other competitors in the SCS market.

Second, as noted in §IV.D, above, there are efficiency reasons that suggest the Board should resolve validity of all of the '460 Patent's claims at one time.

Third, 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.[4] The subject matter of some of those patents is similar to the subject matter at issue here. *See, e.g.*, IPR2019-01341 (U.S. Patent No. 8,682,447).

Finally, BSC filed this Petition approximately three months before the one-year deadline. BSC prefers to challenge the '460 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.[5] 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

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

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

instituting review. *See Apple v. Seven Networks*, IPR2020-00266, Paper No. 12, at 9-21.

V. OVERVIEW OF THE '460 PATENT

A. Disclosure

The '460 Patent relates to systems for controlling spinal cord stimulation for inhibiting pain (Ex. 1001 at 1:21-24; 4:29-35) by applying electrical signals to specific areas of the spinal cord (*id.* at 1:28-56, 34:25-67). Ex. 1002 ¶¶51-52. This had long been accomplished by traditional 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. Ex. 1001 at 1:43-52; Ex. 1002 ¶53. The '460 Patent further discusses, but does not claim, the use of stimulation signals to treat pain without producing paresthesia. *See, e.g.*, Ex. 1001 at 2:63-3:39, 6:6-11:16, 29:8-23, Fig. 6C.

The disclosed systems use the same hardware components as standard prior-art SCS systems (Ex. 1002 ¶¶54-60), as depicted in Figure 1A:

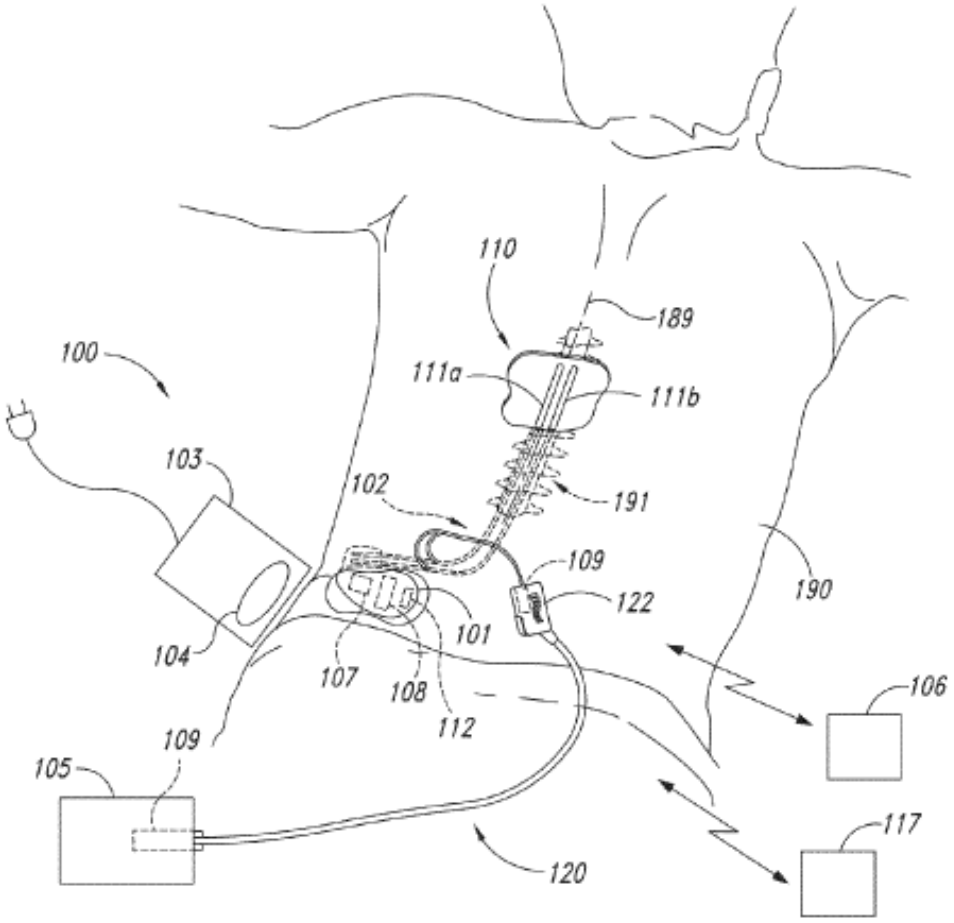

Fig. 1A

Ex. 1001 Fig. 1A; *see also* Ex. 1004 Fig. 2; Ex. 1025 Fig. 1; Ex. 1027 Fig. 2. 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 4:3-28. Those leads can include electrodes for delivering electrical signals to target tissue. *Id.* at 4:21-35. The electrical signals are defined by stimulation parameters (or "signal delivery

parameters"), including the combination of electrodes that deliver the signal, and the frequency, amplitude, and pulse width of the electrical signal itself. *Id.* at 5:1-4, 5:45-55. A physician can update the parameters wirelessly via programmer 117. *Id.* at 5:38-44.

The programmer comprises a display, input devices, memory, and a processor. *Id.* at 3:40-57, 26:34-27:3. Figure 13D shows an exemplary display:

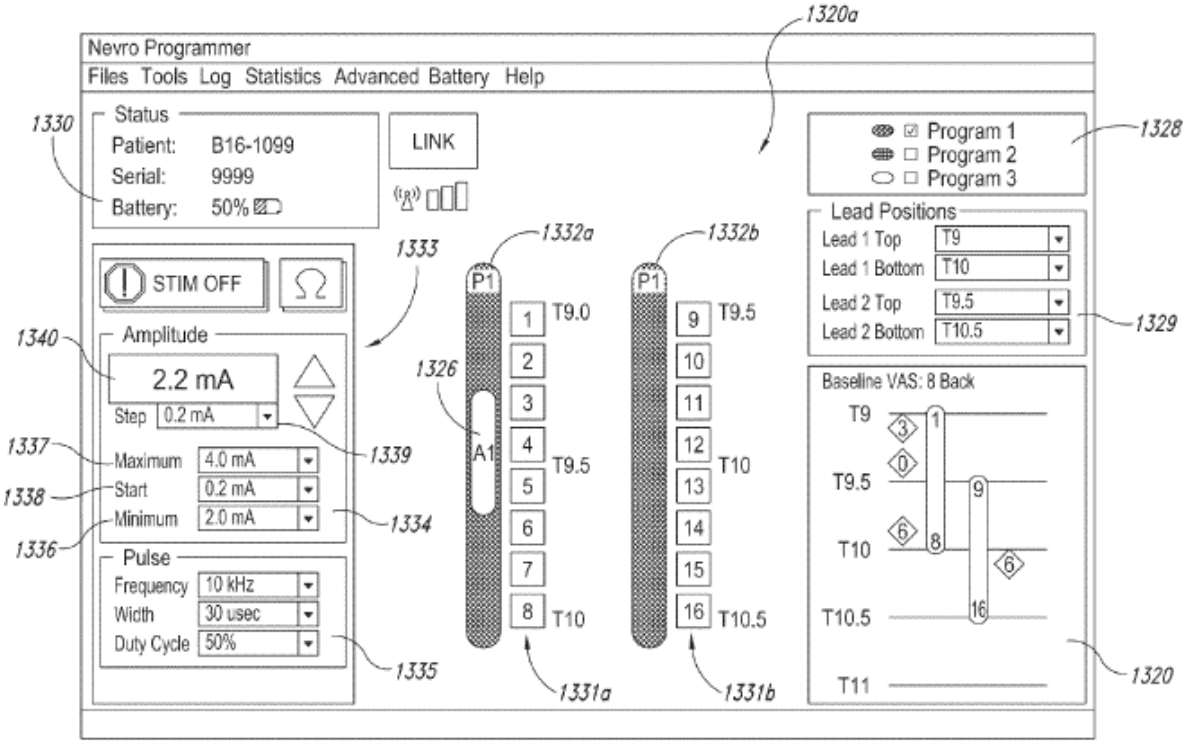

Fig. 13D

Id. Fig. 13D; *see also id.* at 27:4-28:23, Figs. 13B-C and 13F-G; Ex. 1002 ¶¶61-63. The display shows the electrode octet (1331) associated with each implanted lead (Ex. 1001 at 28:10-14), a "lead position summary 1329" (*id.* at 28:6-10), and a

"therapy location indicator 1326" that a clinician can use to identify the target spinal location (*id.* at 28:17-23).

Figure 13F depicts another exemplary display:

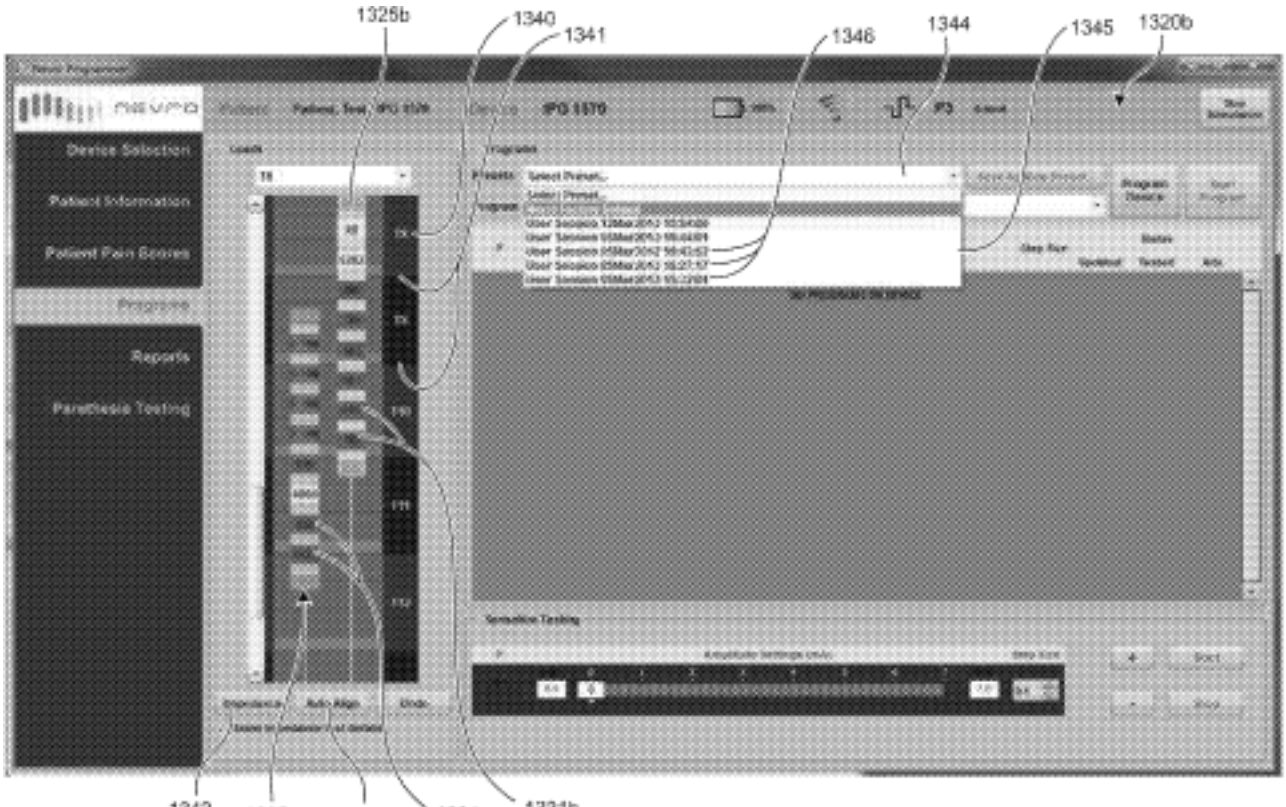

Fig. 13F

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 30:26-32. A user can also adjust the relative dimensions of the leads and vertebrae: "[i]f the patient's vertebral levels do not have the axial dimensions illustrated at the display 1320b, the practitioner can alter these dimensions." *Id.* at 30:32-35. To adjust the vertebral dimensions, "the practitioner can drag and drop individual boundaries 1341 between adjacent

vertebral level identifiers 1340 to adjust the axial extent of each vertebral level identifier 1340," or "the practitioner can scale all the vertebral levels simultaneously with a single control." *Id.* at 30:35-40; *see* Ex. 1002 ¶¶64-66.

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." Ex. 1001 at 32:3-7.

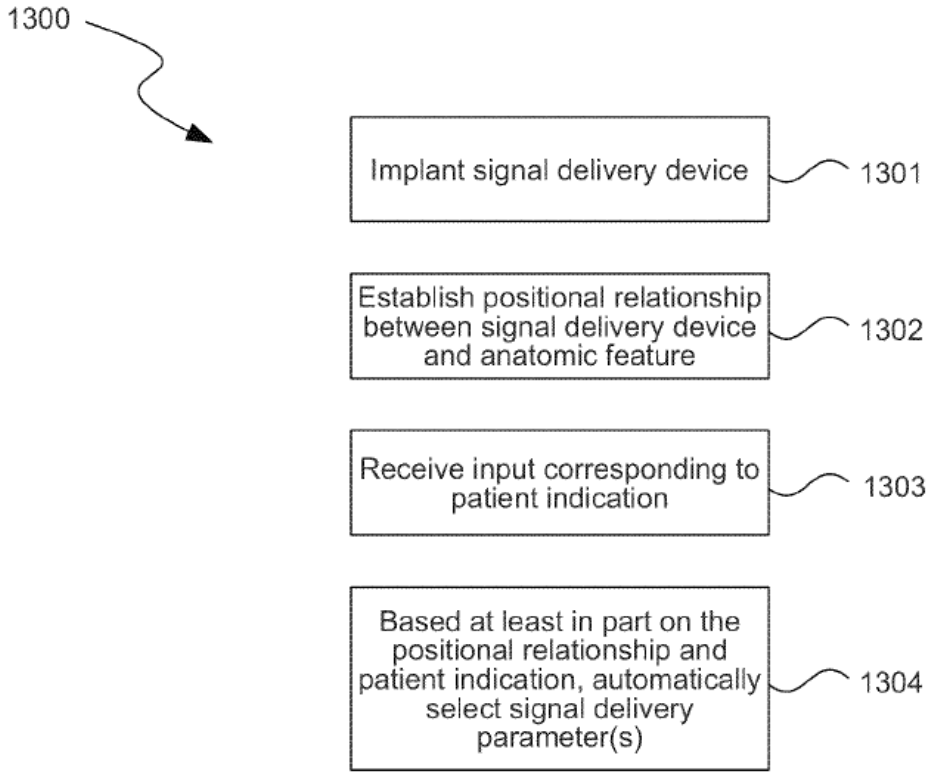

Fig. 13H

Id. Fig. 13H. In step 1302, the programmer establishes a "positional relationship" between the implanted lead and an anatomical feature (e.g., a vertebra). *Id.* at 32:11-18. For example, the user can provide an input to establish this "positional

relationship" by positioning images of implanted leads on a spinal image, as described in Figure 13F, or by correlating leads to vertebral locations using the pulldown menu of lead position summary 1329 in Figure 13D. *See id.* at 30:26-32, 32:28-52, 35:62-65; Ex. 1002 ¶¶67-68. In step 1303, the programmer receives an "input corresponding to a patient indication." Ex. 1001 at 32:53-64. For example, the user can identify a patient's area of pain using preset identifier 1346 in Figure 13F. *Id.* at 30:53-67, 32:53-64; Ex. 1002 ¶69. And in step 1304, the programmer automatically identifies a stimulation parameter (e.g., which electrodes to activate) based on the inputs in steps 1302 and 1303. Ex. 1001 at 32:65-33:10; Ex. 1002 ¶70. To identify the electrodes, the programmer can access databases correlating patient indications and electrode locations. Ex. 1001 at 33:6-10.

B. Priority Date and Prosecution History

The '460 Patent's application was filed on January 29, 2014, and the Patent issued on April 7, 2015. The Patent claims priority to provisional application No. 61/619,358, filed April 2, 2012.

Originally-filed Claim 3, which issued as Claim 1, recited a system for programming stimulation using the process described above in Figure 13H. *See* Ex. 1015 at 62. The Examiner rejected originally-filed Claim 3 (and dependent claims covering similar subject matter), finding that each limitation was disclosed or

rendered obvious by Nevro's prior-art Alataris316 publication in view of additional prior art. *Id*. at 164-170.

The Examiner allowed Claim 44, which was added in a preliminary amendment and issued as claim 11. *Id*. at 170; *see also id.* at 123. Claim 44 did not recite the programming functionality of originally-filed Claim 3/Figure 13H—instead, it claimed (i) presenting a computer-based image of a vertebra and a lead, (ii) "receiv[ing] an input provided by a user and corresponding to a requested change in axial length of the computer-based image of the vertebra" (referred to herein as the "Axial Length Limitation"), and (iii) updating the image of the vertebra in response. *Id.* at 123. The Examiner allowed claim 44 and its dependent claims, and also indicated that other dependent claims reciting the Axial Length Limitation would be allowable if re-written in independent form. *Id.* at 170-173. Nevro subsequently amended the pending claims so that they all include the Axial Length Limitation, and the claims issued. *Id.* at 199-208.

VI. CLAIM CONSTRUCTION

BSC does not believe that 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 '460 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 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 '460 Patent

SCS has been used to treat chronic pain since 1967. Ex. 1023 at 1; Ex. 1028; Ex. 1002 ¶31. By 2012, both the hardware and software components of SCS therapy were well-known. Ex. 1002 ¶32. The hardware components generally include an implantable pulse generator (IPG), implanted electrode leads, and an external programmer. *See, e.g.*, Ex. 1004 ¶¶4, 37-43, Figs. 1-2; Ex. 1025 at 3:58-4:42, Fig. 1; Ex. 1024 ¶3; Ex. 1002 ¶¶32-33. Programming an SCS system typically includes determining the locations of implanted leads, selecting a vertebral area to stimulate, and automatically identifying the parameters (e.g., electrode combination, frequency, amplitude, and pulse width) of electrical pulses to deliver through the

electrodes to the target tissue. *See, e.g.*, Ex. 1004 ¶¶65-75, 79; Ex. 1025 at 11:5-15; Ex. 1014 at 1:38-55, 8:7-31; Ex. 1002 ¶¶34-48.

1. U.S. No. 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 '460 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, and a clinician programmer 18 ("CP") with a display. *Id.* ¶¶18, 38, 40-41, 54, Fig. 1.

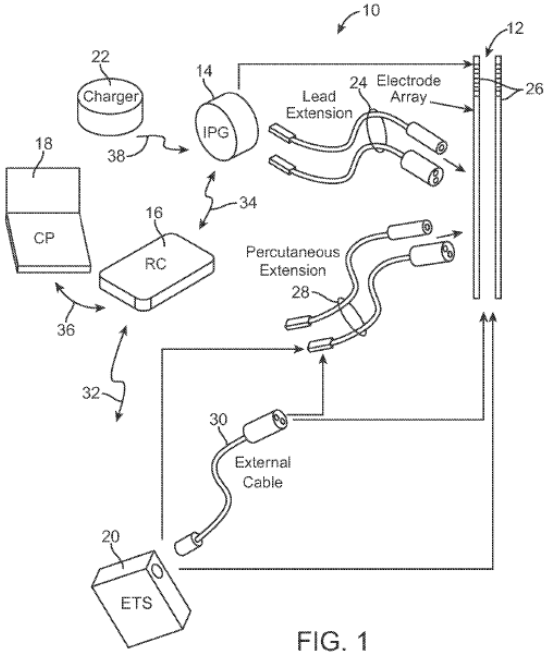

FIG. 1

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

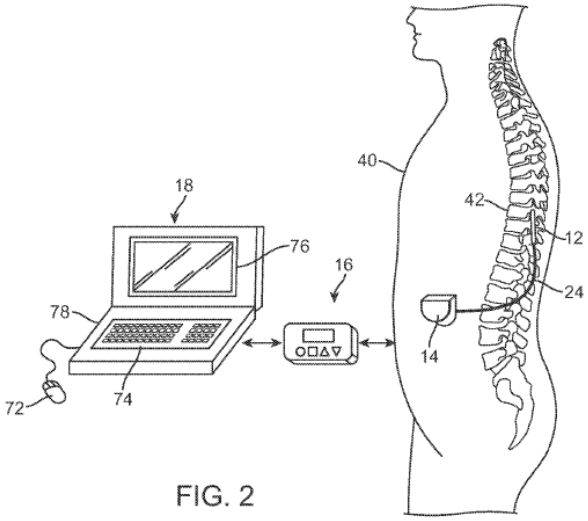

FIG. 2

Id. Fig. 2; *see also id.* ¶¶14-18, 37-38, 52-55, Fig. 1. 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. 1004 ¶¶53-55; Ex. 1002 ¶¶82-89.

Figure 11 shows a process for programming the system:

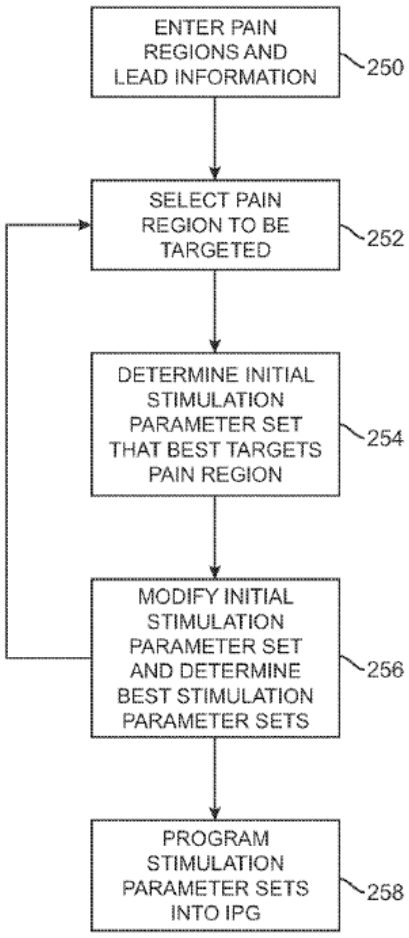

FIG. 11

Ex. 1004 Fig. 11, ¶79.

First, Bradley857's CP can generate screen 100(1), which includes a pain map of the human body 104. *Id.* ¶58. There, the clinician can input information about the location (the shaded areas) and severity (the VAS score) of the patient's pain:

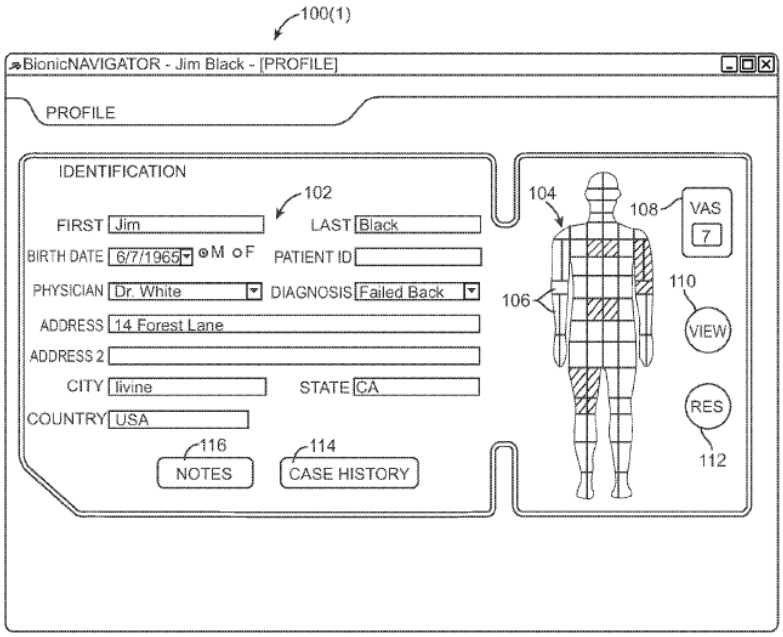

FIG. 7

Id. Fig. 7, ¶58.

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, "lead configuration screen 100(2)" allows selection of a specific configuration of the implanted leads:

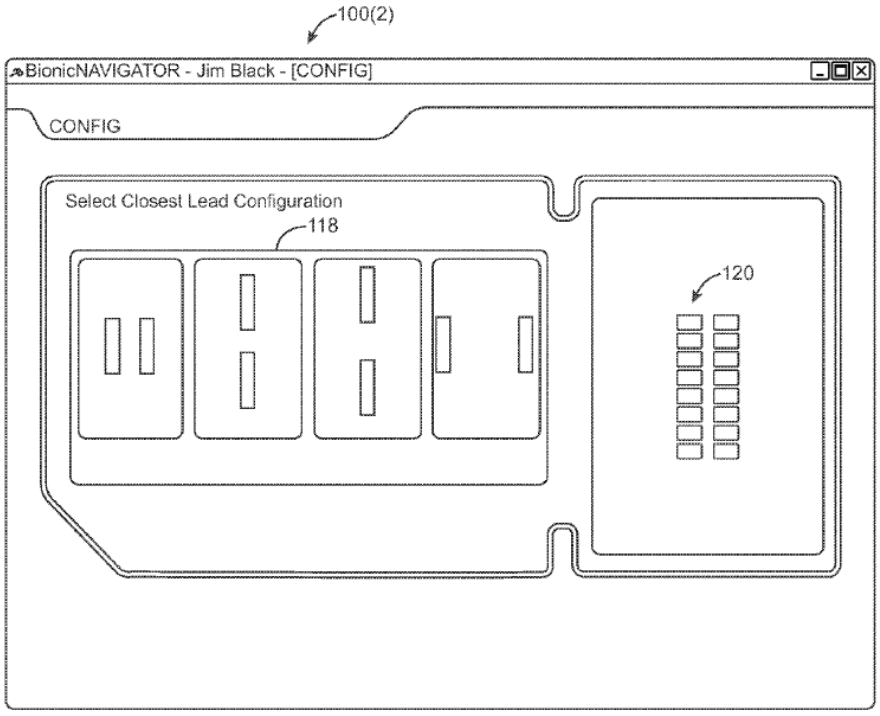

FIG. 8

Id. Fig. 8, ¶59. If the user does not select the configuration manually, "the positions of the tissue stimulation leads 12 relative to each other can be determined based on the measured electrical parameters" described in, e.g., U.S. Patent Pub. No. 2011/005455 ("Zhu," Ex. 1024), which Bradley857 incorporates by reference. Ex. 1004 ¶61 (incorporating U.S. App. No. 12/550,136).

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

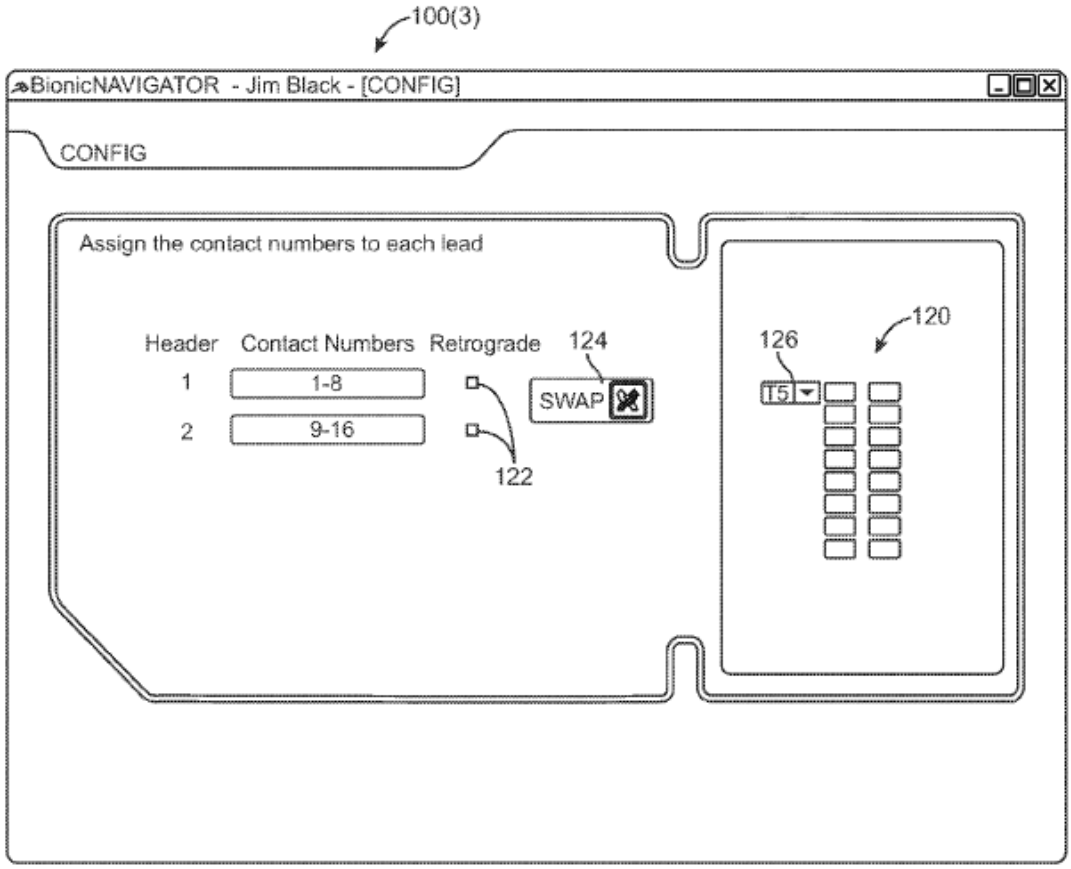

FIG. 9

Id. Fig. 9.

The programmer also provides "drag-and-drop lead screen 100(4)," in which a user can model the locations of implanted leads by placing images of leads on an image of a spine with vertebral level identifiers:

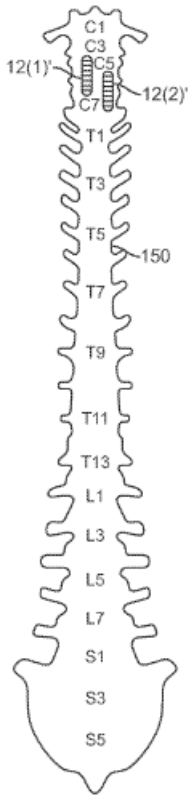

FIG. 10

Id. Fig. 10, ¶63.

Bradley857's CP analyzes the information about the patient's indication and the implanted lead location to automatically generate a set of stimulation parameters. *Id.* ¶¶65, 79. The CP accesses a database that includes known indications (e.g., areas of pain), 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 ¶¶90-91.

2. U.S. No. 9,358,390 (Ex. 1025) ("Polefko")

Polefko issued on June 7, 2016 from an application filed on September 7, 2011. Polefko qualifies as prior art under 35 U.S.C. § 102(e) and was not considered during prosecution of the '460 Patent.

Polefko describes systems and methods for programming an SCS system. Ex. 1025 at 1:40-44. The system includes an IPG 115, leads 110, and clinician's programmer CP 130 (e.g., a tablet):

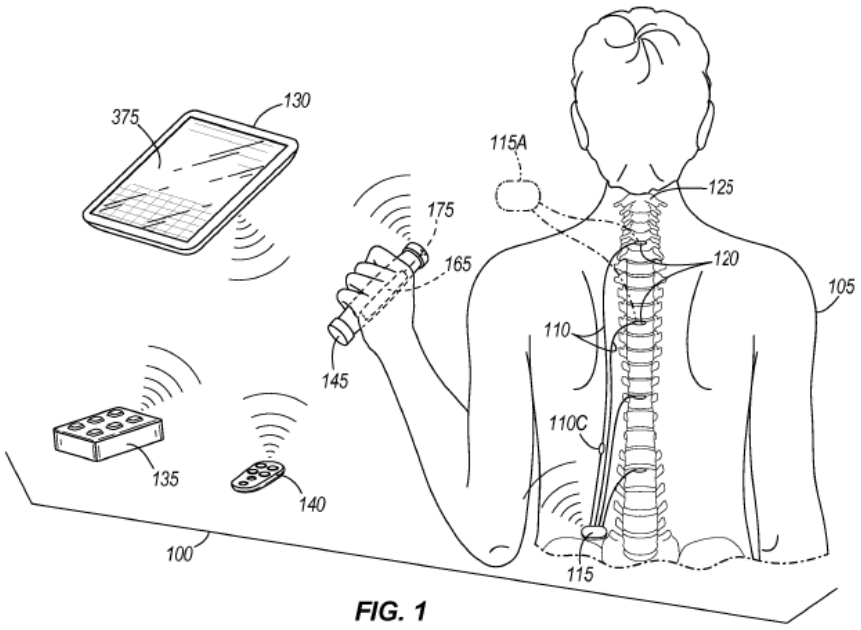

FIG. 1

Id. at 3:58-4:42, 10:23-26, Fig. 1. The CP includes a processor and memory configured to perform the disclosed programming functionality. *Id.* at 8:49-63; *see also id.* at 2:34-57 (computer-readable medium); Ex. 1002 ¶95.

Figure 7 depicts a process for programming an SCS system by identifying a target stimulation area based on a patient's area of pain (step 505) and modeling the locations of implanted leads relative to the patient's vertebrae (step 510). Ex. 1025 at 11:5-13.

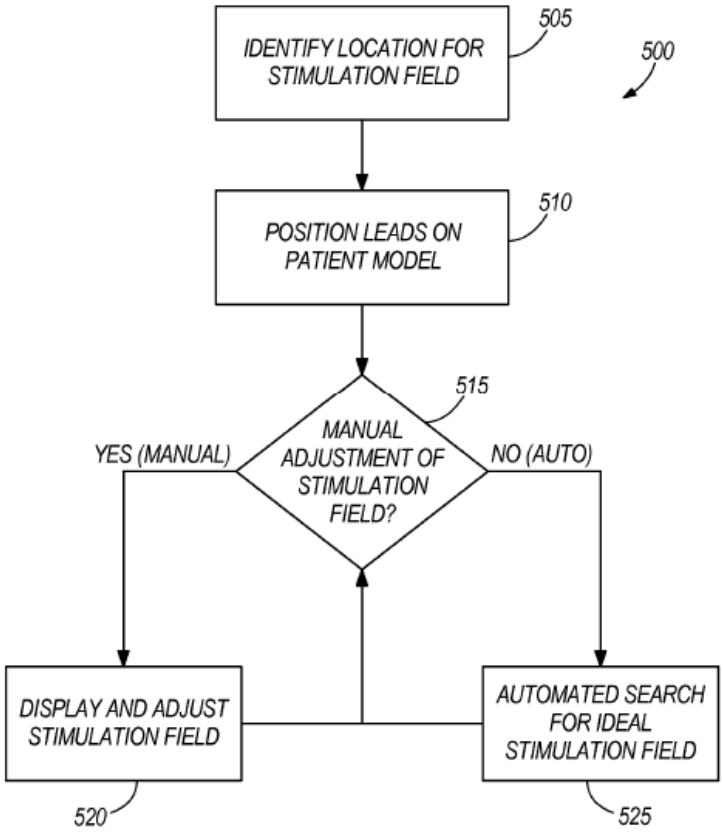

FIG. 7

Id. at Fig. 7.

During programming, Polefko displays an image of vertebrae:

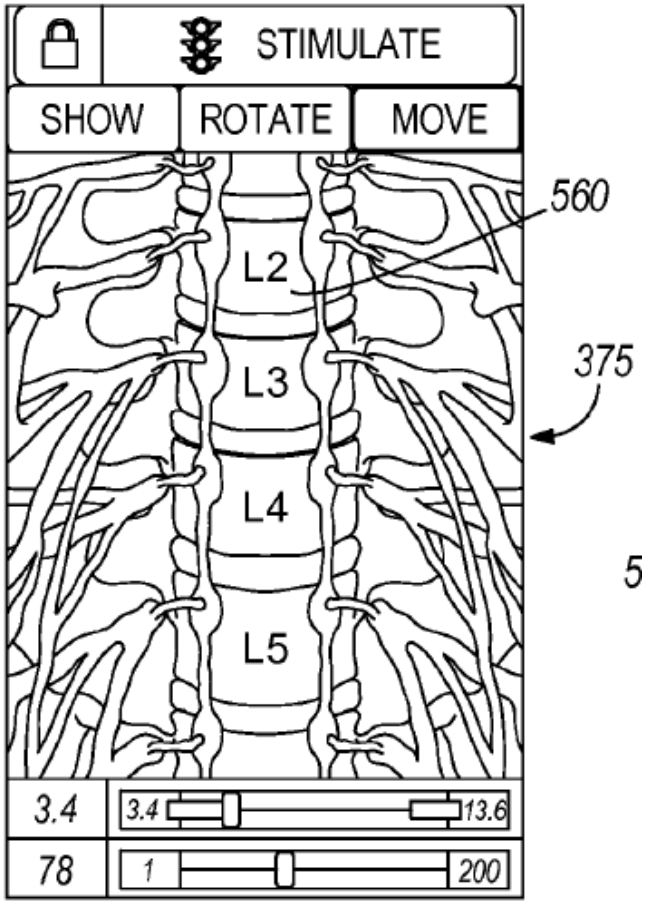

FIG. 12A

Id. Fig. 12A. The vertebral image is used to model the locations of implanted leads (*id.* at 12:53-13:19), and to display a target stimulation area (*id.* at 12:32-44); Ex. 1002 ¶98. Polefko teaches that the vertebral image should be "anatomically correct." Ex. 1025 at 12:32-44, 13:8-10. To generate an anatomically correct image, the user inputs anatomical information (e.g., height and weight) to create a "scaling parameter" that is used to change the axial dimensions of the vertebrae to match the patient's anatomy. *See id.* at 12:32-44,

12:53-13:10, 14:64-15:8; Ex. 1002 ¶¶99-100. Figure 13 "illustrates an original image and a scaled image of a spinal column":

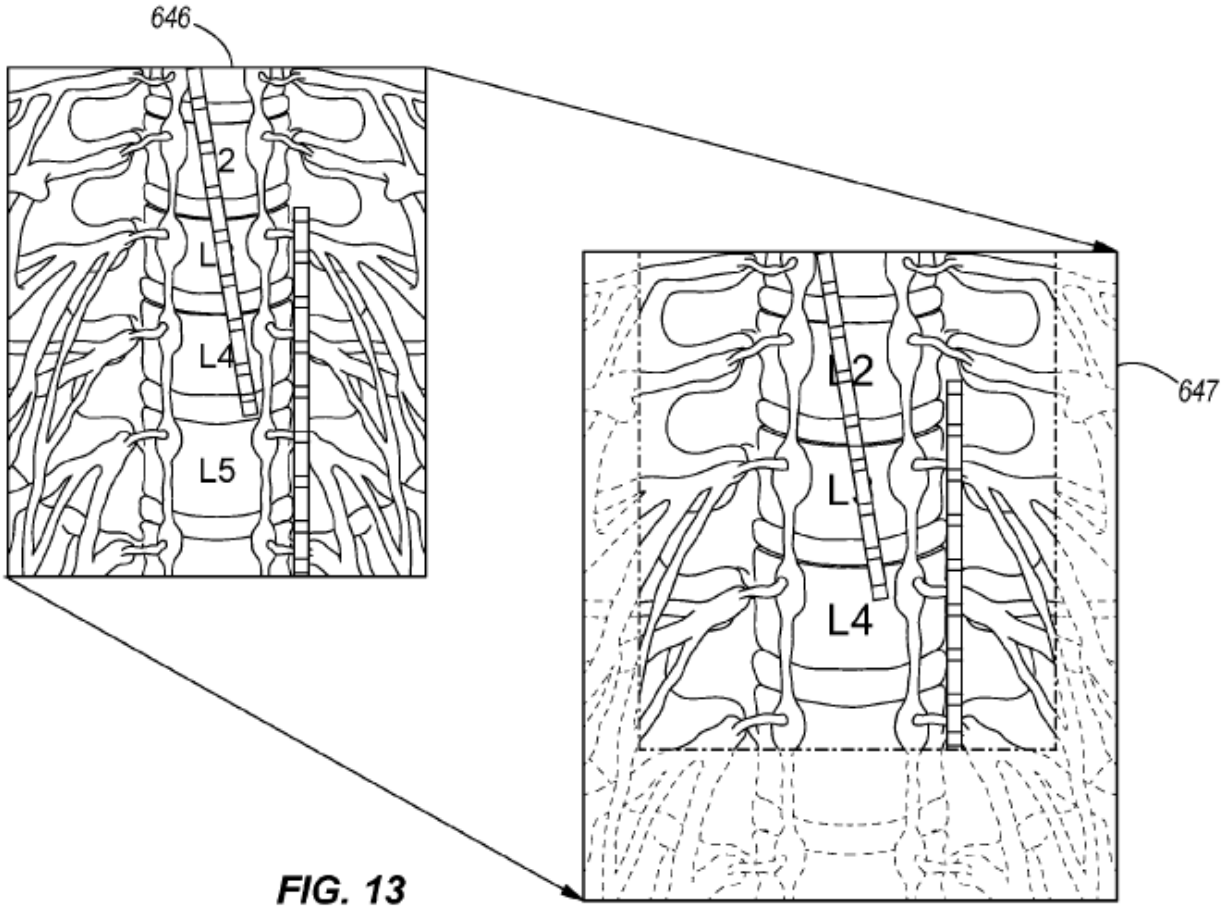

FIG. 13

Id. Fig. 13, 3:22-23.

3. U.S. No. 2011/0093051 (Ex. 1027) ("Davis")

Davis published on April 21, 2011, based on an application filed on April 30, 2010, and claims priority to six provisional applications filed on either October 21 or November 12, 2009. Davis is prior art under 35 U.S.C. §§ 102(a) and (e), but was not considered during prosecution of the '460 Patent.

Davis discloses techniques for programming an SCS system. Ex. 1027 ¶¶6-7. Davis's systems include an implantable stimulator 34, electrode leads 32, and programmer 40:

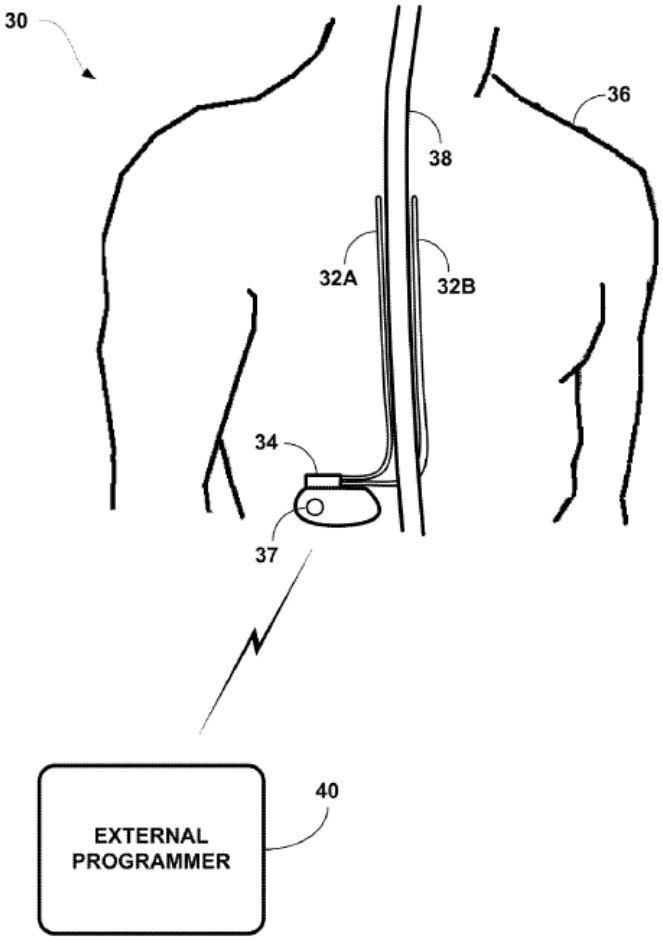

FIG. 2

Id. Fig. 2, ¶¶37, 42-44. The programmer includes a processor, memory, input devices, and a display. *Id.* ¶¶64-66; *see also* ¶119 (disclosed functionality embodied as instructions on computer-readable medium); Ex. 1002 ¶106. The user inputs information into the programmer to configure leads and determine stimulation parameters. Ex. 1027 ¶82.

Davis's techniques "provide the user with the ability to accurately define a lead image relative to an anatomical target, which may be helpful in accurately programming stimulation fields." *Id.* ¶19. A user defines lead locations by dragging-and-dropping lead images onto a background anatomical image, which can be a fluoroscopic or graphical representation of vertebrae (*id.* ¶¶20, 86-90, 100-101):

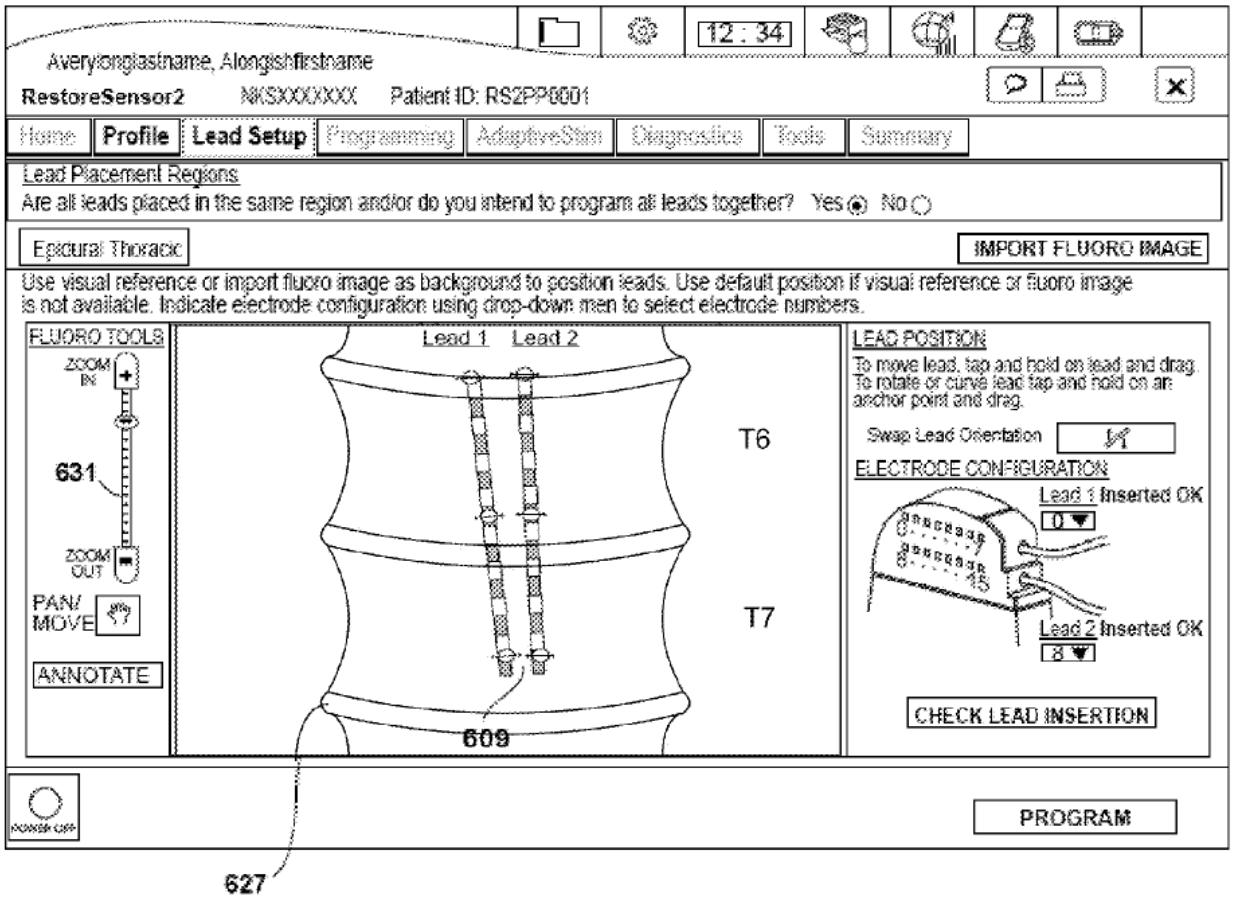

FIG. 6G

Id. Fig. 6G. The user can move and scale the images of leads and vertebrae to align them in their anatomically-correct positions. *Id.* ¶¶87-90. The user can adjust the

dimensions of the vertebrae relative to the leads by "scal[ing]" the anatomical image separately from the leads. *Id.* ¶92; Ex. 1002 ¶¶107-109.

4. U.S. No. 2011/0054551 (Ex. 1024) ("Zhu")

Zhu published on March 3, 2011, and is prior art to the Challenged Claims under 35 U.S.C. § 102(b). Zhu was not considered during prosecution of the '460 Patent.

Zhu describes systems and methods for determining the relative locations of implanted leads. Ex. 1024 ¶1. Zhu recognizes that leads can migrate after implantation, moving away from their stimulation target and decreasing the efficacy of programmed stimulation. *Id*. ¶¶8-9. To address that problem, Zhu's clinician's programmer ("CP") measures electrical properties across electrodes to determine the relative positioning or "stagger" of the leads. *Id.* ¶¶14-16, 61-62; Ex. 1002 ¶¶113-115. Zhu's system can determine when a lead location has changed by detecting a change in lead stagger. Ex. 1024 ¶87. This allows the CP to take "corrective action," including automatically reprogramming stimulation by changing which electrodes are activated. *Id.* ¶¶87-89; Ex. 1002 ¶115.

5. U.S. No. 2010/0274316 (Ex. 1005) ("Alataris316")

Nevro's Alataris316 application published on October 28, 2010, and is prior art under 35 U.S.C. § 102(b).

Alataris316 discloses providing what Nevro refers to as "high-frequency" SCS—e.g., with frequencies above 1.5 kHz—that can treat pain without producing paresthesia. Ex. 1005 at Abstract, ¶23; Ex. 1002 ¶117-118. Substantial portions of Alataris316 are identical to the '460 Patent. *Compare* Ex. 1001 at 1:21-2:52, 2:60-3:39, 5:45-29:60, 34:24-67, 36:42-37-18, Figs. 1A-13E *with* Ex. 1005 ¶¶2-23,31-112, Figs. 1A-13E. As described in §V.B, the Examiner rejected all pending claims that did not recite the Axial Length Limitation (expressly or by dependence) as obvious over Alataris316 alone or in view of additional prior art. The Examiner did not, however, consider Alataris316 in combination with any of the references described herein.

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

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

Ground	Claims	Obvious under 35 U.S.C. § 103
1	1-14, 18-21	Bradley857 in view of Polefko
2	2-3	Bradley857 in view of Polefko and Zhu
3	15-17, 22-24	Bradley857 in view of Polefko and Alataris316
4	1-14, 18-21	Bradley857 in view of Davis
5	2-3	Bradley857 in view of Davis and Zhu
6	15-17, 22-24	Bradley857 in view of Davis and Alataris316

X. Each Challenged Claim of the '460 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: Claims 1-14 and 18-21 are Obvious over Bradley857 in View of Polefko

1. A POSA would have been motivated to combine Bradley857 with Polefko

As shown in §§X.A.2-19, below, Bradley857 discloses every element of claims 1-14 and 18-21 except for the Axial Length Limitation. Polefko's disclosures of vertebral scaling, i.e., changing the size of the vertebral image relative to the size of the lead images, disclose the claimed Axial Length Limitation. These references, and others in the prior art, teach, suggest, and motivate a POSA to combine them with a reasonable expectation of success.

a. A POSA would have applied Polefko's technique of scaling images of vertebrae to improve Bradley857 with predictable results

Bradley857 teaches various ways to program an SCS system, including by modeling the anatomical locations of implanted leads. Ex. 1004 ¶¶57-63; Ex. 1002 ¶¶120-125. For example, Bradley857's CP displays a generic image of a spine on which a user can superimpose images of leads at their implanted locations. Ex. 1004 ¶63. As described below, a POSA would have recognized that incorporating a technique for changing the dimensions of the vertebral images to match the patient's

anatomy (as disclosed in Polefko) would improve the system's accuracy and efficacy. Ex. 1002 ¶¶123-130. Accordingly, a POSA would have been motivated to combine these two references. *See* MPEP 2143 (Rationale I.D); *see also, e.g.*, *In re Nilssen*, 851 F.2d 1401 (Fed. Cir. 1988).

Specifically, Bradley857 begins by explaining the basic principle that effective stimulation parameters will stimulate target spinal tissue while minimizing stimulation of non-target tissue. Ex. 1004 ¶7; Ex. 1002 ¶124. Bradley857's CP determines such stimulation parameters by, *inter alia*, analyzing information about the locations of leads implanted within the patient's body. Ex. 1004 ¶¶65-71, 79. One way the CP receives lead location information is the graphical interface on screen 100(4). *Id.* ¶63. That screen displays an image of a spine and allows the user to "drop the respective virtual lead 12' at the vertebra corresponding to the location of the actual lead 12 relative to the spine":

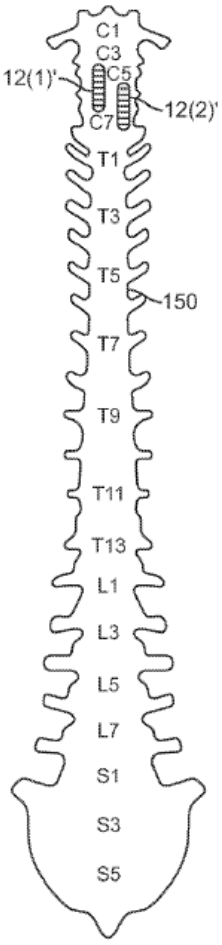

FIG. 10

Id. Fig. 10, ¶63; *see also id.* ¶79 ("the user first enters the . . . location of the tissue stimulation leads *relative to . . . the spine of the patient*") (emphasis added). However, screen 100(4) uses a generic image of a spine, and Bradley857 does not describe whether or how the user can adjust the vertebral dimensions to match the patient's anatomy and/or to maintain proportional dimensions between vertebrae and leads. *See id.* ¶63; Ex. 1002 ¶125.

Other prior-art references disclosed similar techniques for modeling lead locations on a graphical interface to aid in stimulation programming. *See, e.g.*, Ex.

1016 at 9:61-11:47; Ex. 1025 at 13:5-60; Ex. 1026 ¶¶233-236; Ex. 1027 ¶¶20, 82-92; Ex. 1002 ¶126. The art recognized that generating an anatomically-correct lead location model—i.e., one that accurately represents the dimensions of the specific patient's anatomy and the locations of the implanted leads relative to the vertebrae—improves the programmer's ability to determine effective stimulation parameters. *See, e.g.*, Ex. 1016 at 9:61-10:18; Ex. 1025 at 12:32-44, 12:53-63; Ex. 1027 ¶19; Ex. 1002 ¶126. For example, in systems like Bradley857 where the CP analyzes lead location information to identify parameters that will stimulate a target vertebral area, an accurate model of where implanted leads are located relative to the patient's vertebrae (and to other leads) improves the programmer's ability to identify which electrodes to activate and other characteristics of the stimulation signal. *See, e.g.*, Ex. 1004 ¶¶63, 65, 70-71, 79; Ex. 1025 at 12:53-13:60, 17:19-29; Ex. 1027 ¶19; Ex. 1002 ¶126. Stimulation parameters generated without an accurate model "may be inaccurate and ineffective in treating [a] patient." Ex. 1007 ¶87; Ex. 1002 ¶126.

The art disclosed various techniques for generating anatomically-correct lead location models. Ex. 1002 ¶¶127-128. For example, Polefko teaches that "[a]ccurately modeling the actual placement of the medical leads [] within the patient [] assists a user in stimulation programming." Ex. 1025 at 12:58-60. Polefko, like Bradley857, models lead locations by displaying an image of a spine and allowing a user to position images of leads in their "anatomically correct position":

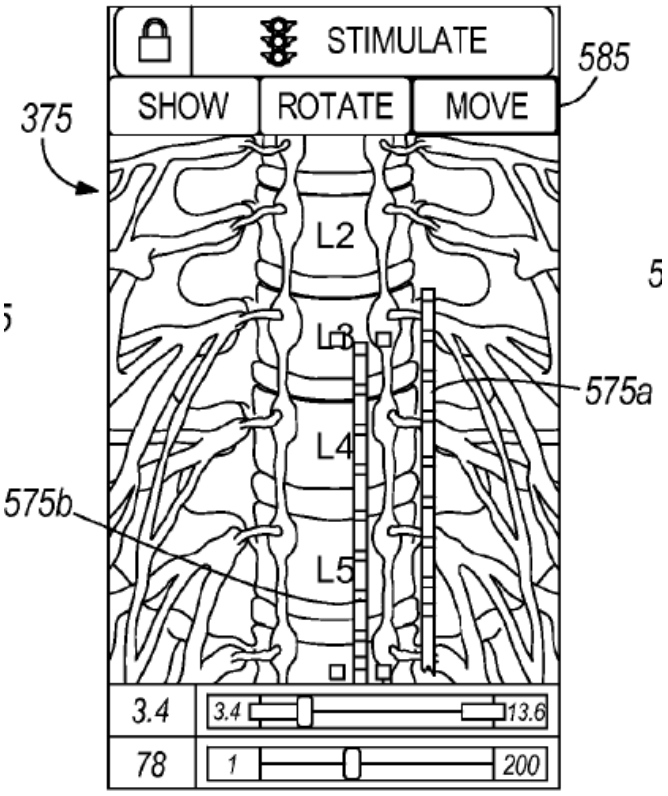

FIG. 12B

Id. Fig. 12B; *see also id.* at 13:5-60; *compare id.* Fig. 12B *with* Ex. 1004 Fig. 10. Polefko teaches that "[t]he user may specify patient information, such as height, weight, etc., such that the image of the spinal column 560 is scaled to be anatomically correct." Ex. 1025 at 13:8-10; *see infra* §X.A.2.1[f]. "The term 'anatomically correct' means a generally realistic representation of the particular patient's anatomy or an actual image (e.g., x-ray image) of the patient, rather than a generic image applicable to patients with significantly different anatomies." Ex. 1025 at 12:36-40. In Polefko, the patient's information is used to generate a vertebral "scaling parameter" that changes the dimensions of the spinal images to

match that patient's actual anatomy. *Id.* at 13:8-10, 14:64-15:8. In general, a taller patient's scaling parameter will increase the axial length of a generic spinal image and a shorter patient's scaling parameter will decrease the axial length of the generic spinal image. "Thus, an anatomically correct image is scaled to a patient to accommodate differently sized patients or is otherwise customized to a particular patient or to particular characteristics associated with the patient." *Id.* at 12:40-44; *see also id.* at 14:66-15:1.

A POSA could have applied Polefko's vertebral scaling technique to Bradley857 through routine software programming. Ex. 1002 ¶129. As described above, Bradley857's CP already models lead locations by displaying images of leads on a spinal image at locations corresponding to the anatomical location of the leads. Ex. 1004 ¶¶58, 63; Ex. 1002 ¶129. And Polefko explains exactly how to perform the technique—displaying an image of a spinal column and creating a scaling parameter based on patient anatomical information. Ex. 1025 at 13:8-10; Ex. 1002 ¶129.

A POSA would have recognized that applying Polefko's vertebral scaling techniques to Bradley857's screen 100(4) would predictably improve the accuracy of programming taught by Bradley857. Ex. 1002 ¶130. Bradley857 explains that lead images are placed "at a location matching the location of the anatomical region at which the actual lead(s) 12 are implanted." Ex. 1004 ¶63; *see also id.* ¶79 (defining

lead locations "relative to . . . the spine of the patient"). A POSA would have understood that scaling the vertebral dimensions so they match the particular patient's anatomy would make the model more accurate. *See* Ex. 1025 at 12:33-44, 12:53-60, 13:5-10, 14:64-15:8; Ex. 1002 ¶130. And because Bradley857's CP identifies stimulation parameters based in part on lead location information (Ex. 1004 ¶65), a more-accurate lead location model would improve the CP's ability to identify parameters that will stimulate the target spinal tissue while minimizing stimulation of non-target tissue (Ex. 1004 ¶7). Ex. 1002 ¶130. The results of this modification would have been predictable given the similarities between the two systems, the detailed teachings of Bradley857 and Polefko, and the knowledge of a POSA. Ex. 1002 ¶130.

b. A POSA would have been motivated to apply Polefko's teaching of creating anatomically-correct models of implanted lead locations to Bradley857

Even if there was not a need to "improve" Bradley857, the prior art taught the benefits of adjusting vertebral dimensions to create accurate models of lead locations. Ex. 1002 ¶131. Bradley857 relies on a generic spinal image to model lead locations. *See* Ex. 1004 ¶63, Fig. 10. Polefko teaches the benefits of generating a scaled spinal image that matches a patient's anatomy, "rather than a generic image applicable to patients with significantly different anatomies." Ex. 1025 at 12:32-44,

12:53-60, 14:66-15:8. Polefko itself motivates a POSA to combine the references. Ex. 1002 ¶131; MPEP 2143 (Rationale I.G).

Additional prior art confirms the motivation to modify Bradley857 to allow the user to scale vertebral dimensions. Ex. 1002 ¶132. For example, Davis teaches that accurately defining the location of a lead relative to an anatomical target aids in accurately programming stimulation fields. Ex. 1027 ¶19. Like Bradley857 and Polefko, Davis's programmer allows a user to position images of leads on an image of vertebrae. *Id.* ¶¶86-92, 95-100. To achieve proper alignment between leads and vertebrae, Davis's programmer allows the user to "scale" the relative size of the vertebral image *separately* from the lead images. *Id.* Ex. ¶¶90, 92, 100-101; Ex. 1002 ¶132. U.S. Patent No. 8,913,804 (Blum) discloses different techniques for modeling lead locations that involve a "transformation" of a generic spinal image or "atlas" to match a radiological image of the patient's spine. Ex. 1014 at 6:52-7:13 Ex. 1002 ¶133. These teachings would have further motivated a POSA to combine Polefko's scaling technique with Bradley857. Ex. 1002 ¶134.

A POSA would have had a reasonable expectation of success combining Bradley857 and Polekfo. Ex. 1002 ¶135. Bradley857 and Polefko use substantially the same hardware components (Ex. 1004 ¶37; Ex. 1025 at 3:58-4:42), and both systems model lead locations by displaying an image of a spine and dragging-and-dropping images of leads (Ex. 1004 ¶63; Ex. 1025 at 13:5-60). Ex. 1002 ¶135.

Modifying Bradley857 to use a vertebral scaling parameter with its spinal image, as taught by Polefko, would have been a routine matter of software programming. Ex. 1002 ¶135.

2. Claim 1

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

To the extent the preamble is a limitation, Bradley857 discloses "tissue stimulation systems" for treating a patient. Ex. 1004 ¶¶2, 14; Ex. 1002 ¶137.

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

Bradley857's 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 user to program the IPG 14 and RC." Ex. 1004 ¶55; Ex. 1002 ¶¶138-140. Execution of programming package 86 performs the functions described below. *See* Ex. 1004 ¶¶26, 56-65, 71; Ex. 1002 ¶139.

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

The '460 Patent claims a "signal delivery device." For all relevant purposes here, disclosures of a "lead" with "electrodes" in the prior art refer to the same "signal delivery device" with "contacts" as used in the '460 Patent. Ex. 1001 at 4:15-24; Ex. 1002 ¶¶55, 141. Accordingly, the terms (signal delivery device/lead and contact/electrode) will be used interchangeably throughout the petition.

Bradley857 uses "electrode leads 12 [that] are implanted within the spinal column 42 of a patient 40" and can be used to deliver an electrical signal to the patient's tissue. Ex. 1004 ¶43; *see also id.* ¶38, Figs. 2, 3; Ex. 1002 ¶142.

The CP provides a number of user interfaces that allow it to receive the claimed first input. Ex. 1004 ¶57; Ex. 1002 ¶143. For example, "lead configuration screen 100(2)" allows the user to identify the location of a first lead relative to a second lead using pre-set configurations or by measuring electrical parameters. Ex. 1004 ¶¶59-61; Ex. 1002 ¶143. Additionally, "[l]ead 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.

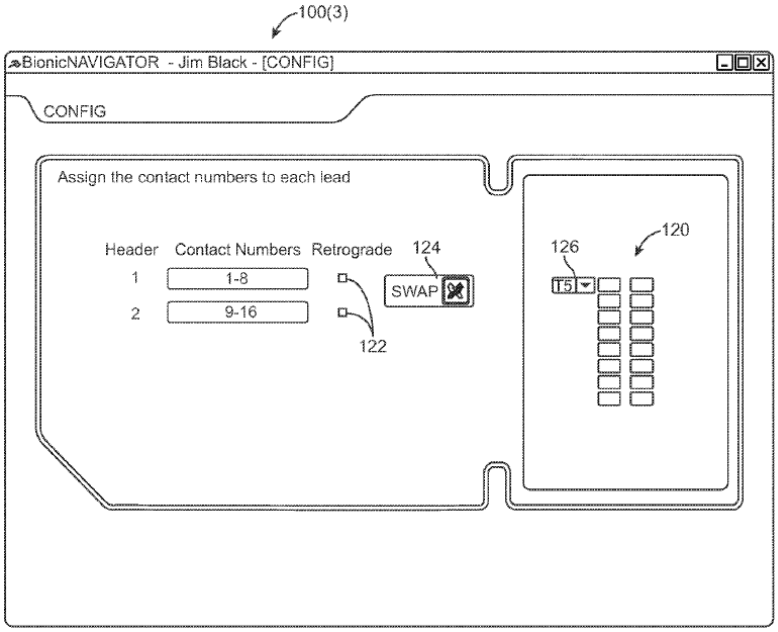

FIG. 9

Id. Fig. 9; *see also id.* ¶62 (user can move electrode octets relative to one another, defining relative locations of leads); Ex. 1002 ¶144. And "drag-and-drop lead screen 100(4)" allows the user to drop virtual lead images onto a graphical image of a spine at locations corresponding to the vertebral locations of the implanted leads. Ex. 1004 ¶63; Ex. 1002 ¶145.

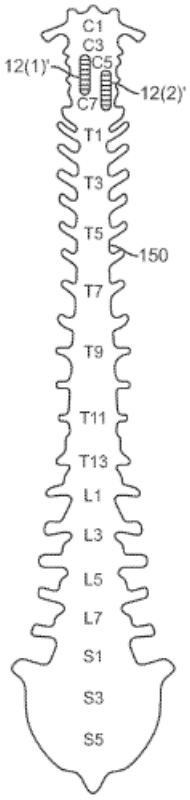

FIG. 10

Ex. 1004 Fig. 10. This input is nearly identical to the '460 Patent's description of inputting location information—"[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 35:62-65; Ex. 1002 ¶¶145-146.

1[d]. ***"establish a positional relationship between the implanted signal delivery device and an anatomical feature of the patient, wherein the anatomical feature includes a vertebra of the patient"***

The '460 Patent explains that the programmer "establishes" the claimed positional relationship once the anatomical location of the lead has been defined. *See* Ex. 1001 at 32:11-54; Ex. 1002 ¶147. For example, the user can "move the lead identifiers 1325a, 1325b and/or manipulate the vertebral boundaries 1341 to properly align the contacts with corresponding vertebral levels" to define the lead location and establish the positional relationship. Ex. 1001 at 32:11-32; *see also id.* at 28:3-10, Fig. 13D (lead position summary 1329 with vertebral pull-down menus); Ex. 1002 ¶147.

In Bradley857, execution of programming package 86 allows the user to enter "information defining a location of the tissue stimulation lead or leads 12 relative to an anatomical reference (in this case, a vertebral location…)," establishing the claimed positional relationship. Ex. 1004 ¶57; *see also id.* ¶¶15, 65, 79; §X.A.2.1[c]; Ex. 1002 ¶¶147-149. Specifically, the selected vertebral level from drop-down menu 126 (¶62), or the lead image placed "at the vertebra corresponding to the location of the actual lead 12 relative to the spine" (¶63), establishes the claimed positional relationship. §X.A.2.1[c]); Ex. 1002 ¶¶148-149.

The remainder of Bradley857's disclosure confirms that the processor establishes the claimed positional relationship. Ex. 1002 ¶¶150-153. Bradley857's

CP "analyz[es]" the positional relationship to identify stimulation parameters. Ex. 1004 ¶65; *see also id.* ¶79. The CP "is further configured for selecting the electrodes 26 adjacent the desired stimulation target based on the user-defined location of the stimulation leads 12." *Id.* ¶70. The CP could not determine the electrodes adjacent the target vertebra if it did not first establish the position of the leads relative to the target vertebra. Ex. 1002 ¶150-151.

1[e]. ***"receive a second input corresponding to a medical indication of the patient"***

Bradley857 teaches that that the CP can receive inputs identifying patient medical indications such as areas of pain. Ex. 1004 ¶57 ("[E]xecution of the programming package 86 provides a user interface that allows the user to enter information defining a therapeutic indication of the patient (e.g., any of a plurality of different tissue regions associated with chronic pain)."); Ex. 1002 ¶¶154-155; *see also* Ex. 1001 at 32:53-64 (receiving inputs corresponding to patient indications, including areas of pain). Screen 100(1) allows the clinician to input a patient's diagnosis and "provides a pain map of the human body 104 divided into several regions 106. Clicking on one or more of these regions 106 allows the clinician to record the regions of pain experienced by the patient." Ex. 1004 ¶58; *see also* ¶¶65, 79, Figs. 7, 11; Ex. 1002 ¶¶154-155.

1[f]. ***"receive a third input provided by a user and corresponding to a requested change in axial length of a computer-based image of the vertebra"***

Bradley857 teaches receiving an input provided by a user on screen 100(4) to position images of leads onto a computer-based image of a spine (including vertebrae). Ex. 1004 ¶63, Fig. 10; §X.A.2.1[c]-[d]; Ex. 1002 ¶156.

Polefko teaches that the CP receives a third input from a user corresponding to a requested change in axial length of a computer-based image of the vertebra. *See* §VIII.A.2; Ex. 1002 ¶¶157-159. During stimulation programming, Polefko's computer-based display presents images of a spinal column and leads. Ex. 1025 at 13:5-6, Figs. 12A-I; *see also id.* at 12:32-36, 13:6-14:7, Fig. 10. "The user may specify patient information, such as height, weight, etc., such that the image of the spinal column 560 is scaled to be anatomically correct." *Id.* at 13:8-10. Specifically, the user-entered patient information is used to create a "scaling parameter" that changes the dimensions (including axial length) of the displayed vertebrae relative to the leads to generate an anatomically-correct image of the patient's anatomy:

> [A] scaling parameter is sent along with the identifier of the spinal column representation or actual image used in the positioning process. Scaling an image enables a particular image to be used to represent patients of various sizes. For instance, Fig. 13 illustrates an original image 646 at 100% and a scaled image 647 at 125%. While the scaled image 647 is larger, a corresponding smaller area of the image is

> presented in the display 375 [(]shown in the dashed rectangle) and the leads are not scaled.

Id. at 14:64-15:8; *see also id.* at 12:36-44 ("an anatomically correct image is scaled to a patient to accommodate differently sized patients or is otherwise customized to a particular patient or to particular characteristics associated with the patient."), 15:9-23 (CP "scales and displays the image according to the scaling parameter"), claims 1, 15; Ex. 1002 ¶157. Figure 13 shows how the system updates the computer-based image to reflect the user's requested change:

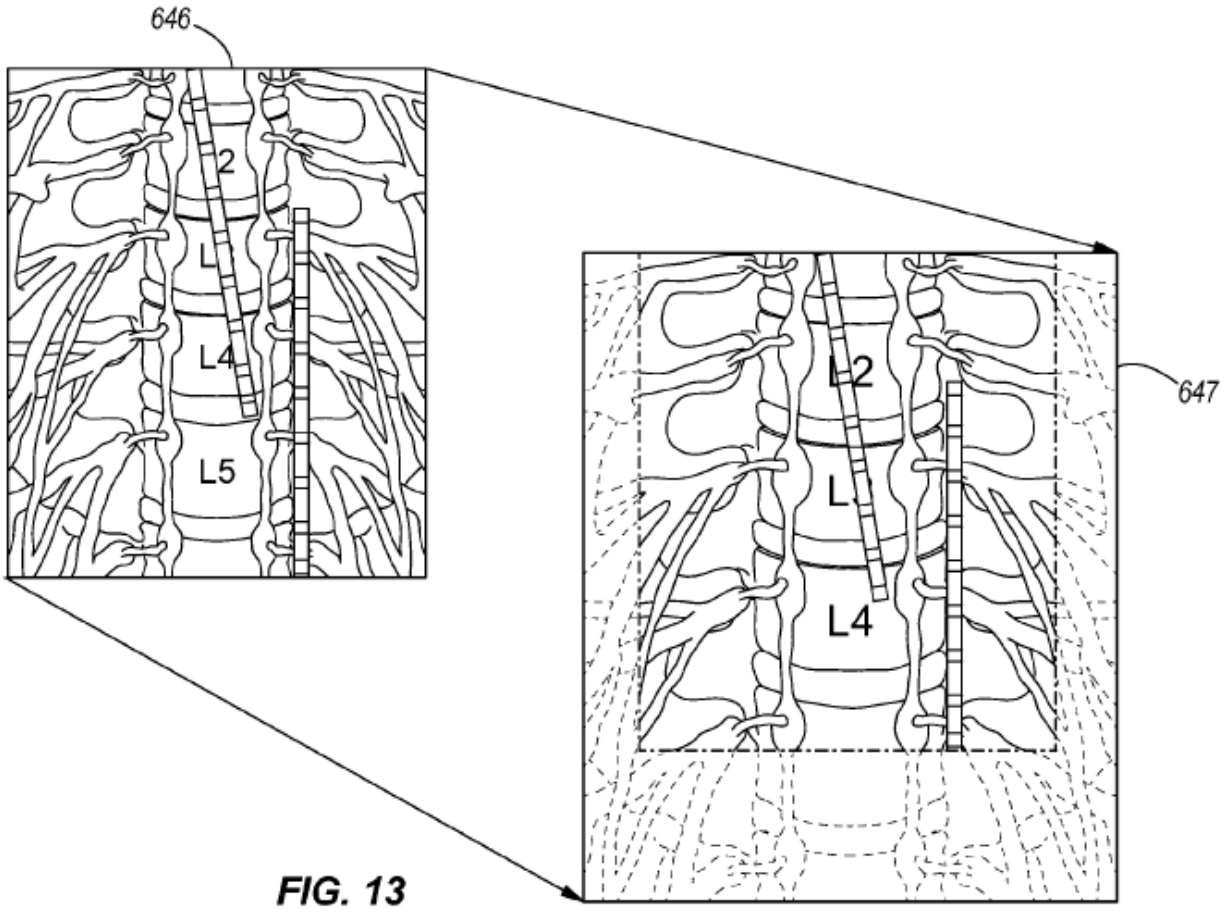

FIG. 13

Ex. 1025 at Fig. 13, 3:22-23, 15:1-5; *see also id.* claim 15. Ex. 1002 ¶¶157-159.

1[g]. ***"based at least in part on the positional relationship and the indication, automatically identify a signal delivery parameter in accordance with which a pulsed electrical signal is delivered to the patient via the signal delivery device"***

As explained above, a user can enter a patient indication and define the positional relationship between leads and vertebrae using Bradley857's CP. Ex. 1004 ¶¶57, 65; Ex. 1002 ¶¶141-155, 160; §X.A.2.1[c]-[e]. "By analyzing this information, the CP 18 can automatically generate a set of stimulation parameters" including active electrode combination and pulse width for delivering a pulsed electrical signal through the leads. Ex. 1004 ¶¶65, 71, 79, Fig. 11; Ex 1002 ¶160.

Specifically, the CP can automatically identify stimulation parameters by accessing a database correlating "reference therapeutic indications" (e.g., pain regions) with "stimulation targets" (e.g., vertebral levels), lead positions, and stimulation parameters known to treat the reference indications. Ex. 1004 ¶¶66-68; Ex. 1002 ¶161. That database can include detailed information about lead positions and effective parameters in other patients. Ex. 1004 ¶67. The CP matches the patient's indication with a reference indication to determine a stimulation target, and then selects electrodes adjacent the stimulation target based on the positional relationship between the patient's vertebrae and implanted leads. *Id.* ¶¶59-64 (entering lead location information), ¶¶69-71 (selecting electrodes); Ex. 1002 ¶161. The CP may also select a cathode-anode pattern and pulse width corresponding to

treatment at the target location. Ex. 1004 ¶71. Accordingly, based on the patient's indication and positional relationship between the lead and the vertebra, the CP identifies where stimulation is needed, which electrodes are closest to the target location, and which electrode pattern and pulse width will effectively stimulate the target location. Ex. 1002 ¶162.

After the CP automatically identifies stimulation parameters, it causes the IPG to "deliver[] electrical stimulation energy in the form of a pulsed electrical waveform (i.e., a temporal series of electrical pulses) to the electrode array 26 in accordance with [the] set of stimulation parameters." Ex. 1004 ¶38; Ex. 1002 ¶163.

3. Claim 2—"The system of claim 1 wherein the instructions, when executed: receive a fourth input corresponding to an updated location of the signal delivery device; and in response to the fourth input, automatically update the signal delivery parameter"

Bradley857 recognizes that leads can "gradually or unexpectedly move" after implantation, requiring reprogramming to redirect stimulation to the target area. Ex. 1004 ¶11. Leads can also break, requiring replacement. Ex. 1002 ¶164. The same disclosures of Bradley857 described in limitations 1[c]-[d] allow a user to update the locations of leads if they move or are replaced, or if a user adjusts the lead location to refine stimulation programming. *See* §§X.A.2.1[c]-[d]; Ex. 1002 ¶165. Thus, if leads move, execution of Bradley857's instructions causes the CP to receive a fourth input from the user of an updated lead location to update signal delivery parameters.

Ex. 1002 ¶165. The same disclosures identified in limitation 1[g] for automatically identifying stimulation parameters based on the leads' vertebral locations apply equally to an updated lead location. *See* §X.A.2.1[g]; Ex. 1002 ¶165. For example, the CP automatically "select[s] the electrodes 26 adjacent the desired stimulation target based on the user-defined location of the tissue stimulation leads 12." Ex. 1004 ¶¶70-71; *see also* ¶¶76-77 (changing electrode combinations during "current steering"). If the CP receives updated location information such that a different electrode is adjacent the target area, the CP would update the stimulation parameters by selecting the now-adjacent electrode. Ex. 1002 ¶165.

Moreover, in the context of identifying lead positioning, Bradley857 incorporates the disclosure of Zhu. Ex. 1004 ¶61 (incorporating U.S. App. No. 12/550,136). Material not explicitly contained in a single prior art document can be considered part of that document if it is incorporated by reference. *See Callaway Golf Co. v. Acushnet Co.*, 576 F.3d 1331, 1346-47 (Fed. Cir. 2009). To incorporate by reference, the document must clearly identify 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) (holding that the clause "which is incorporated herein by this reference" sufficiently incorporated the entire disclosure of the patent). As in *Paice*, Bradley857 identifies where the incorporated techniques are found (Zhu) and states

that Zhu and others "are expressly incorporated herein by reference." Ex. 1004 ¶61. Accordingly, Zhu is incorporated in its entirety. Ex. 1002 ¶¶87, 166.

Zhu discloses receiving an updated lead location and, in response, automatically updating a stimulation parameter such as the active electrode combination. Ex. 1002 ¶¶167-168. Zhu's CP is "configured for automatically determining the relative positioning (e.g., the stagger, separation and/or tilt angle) of the percutaneous leads 12 by taking one or more cross-lead electrical field measurements and comparing these measurements to reference electrical field measurements of known lead configuration to determine the relative position between two leads." Ex. 1024 ¶61. The CP can continuously monitor lead migration. *Id.* ¶89. "If the stagger between the leads 12 indicates that the relative positioning between the leads 12 has moved from an optimal position or is otherwise not in an optimal position, corrective action may be taken." *Id.* ¶87. This corrective action can include changing stimulation parameters, including the active electrode combination. For example, if the CP detects that a lead has moved such that the previously-activated electrodes are no longer optimally positioned relative to the target vertebra, the CP can "substitut[e]" new active electrodes to redirect stimulation. *Id.* ¶88; Ex. 1002 ¶168. "Reprogramming may be performed automatically or by a clinician." Ex. 1024. ¶89.

4. Claim 3—"The system of claim 2 wherein identifying the signal delivery parameter includes identifying a first electrode, and wherein updating the signal delivery parameter includes identifying a second electrode different than the first electrode"

The same disclosures of Bradley857 identified regarding claim 2 also disclose claim 3. Specifically, the user inputs described in limitations 1[c]-[d] allow a user to update the locations of leads. *See* §§X.A.2.1[c]-[d], X.A.3; Ex. 1004 ¶¶11, 59-63; Ex. 1002 ¶169. And the functionality described in limitation 1[g] for automatically identifying stimulation parameters (including active electrodes) based on lead locations would update the active electrodes in response to an updated lead location if, e.g., the new location meant that a different electrode is adjacent the target stimulation area. *See* §§X.A.2.1[g], X.A.3; Ex. 1004 ¶¶70-71, 76-77; Ex. 1002 ¶169.

Bradley857 also incorporates Zhu in the context of identifying lead positioning, which teaches techniques for detecting updated lead locations and, in response, automatically updating the active electrode combination. *See* §X.A.3; Ex. 1024 ¶¶87-89; Ex. 1002 ¶170. If the leads have migrated far enough, different electrodes will be selected to deliver the energy. Ex. 1024 ¶88; Ex. 1002 ¶¶168, 170.

5. Claim 4—"The system of claim 1 wherein the third input corresponds to a requested adjustment of a dimension of the vertebra relative to a dimension of the signal delivery device, and wherein the computer-readable medium has instructions that, when executed adjust computer-based data identifying the dimension, in response to the third input"

Bradley857 teaches receiving user inputs to position images of leads onto an image of vertebrae at locations that match the actual anatomical regions where the leads are implanted. *See* §X.A.2.1[f]; Ex. 1002 ¶171.

And, as described in limitation 1[f], Polefko teaches that the CP (which includes a processor and memory) receives user inputs of patient information to create a "scaling parameter" that adjusts the dimensions of vertebral images relative to the dimensions of lead images. Ex. 1025 at 15:2-5 (leads are not scaled); *see also id.* at 12:32-44, 13:8-10, 14:64-15:8, claims 1, 15; Ex. 1002 ¶¶172-173. The scaling parameter adjusts the computer-based data defining the dimensions of the vertebrae. *See* Ex. 1025 at 15:2-5; Ex. 1002 ¶173. Figure 13 shows how the scaling parameter adjusts the dimensions of the vertebrae relative to the leads in the computer-based image presented on the display:

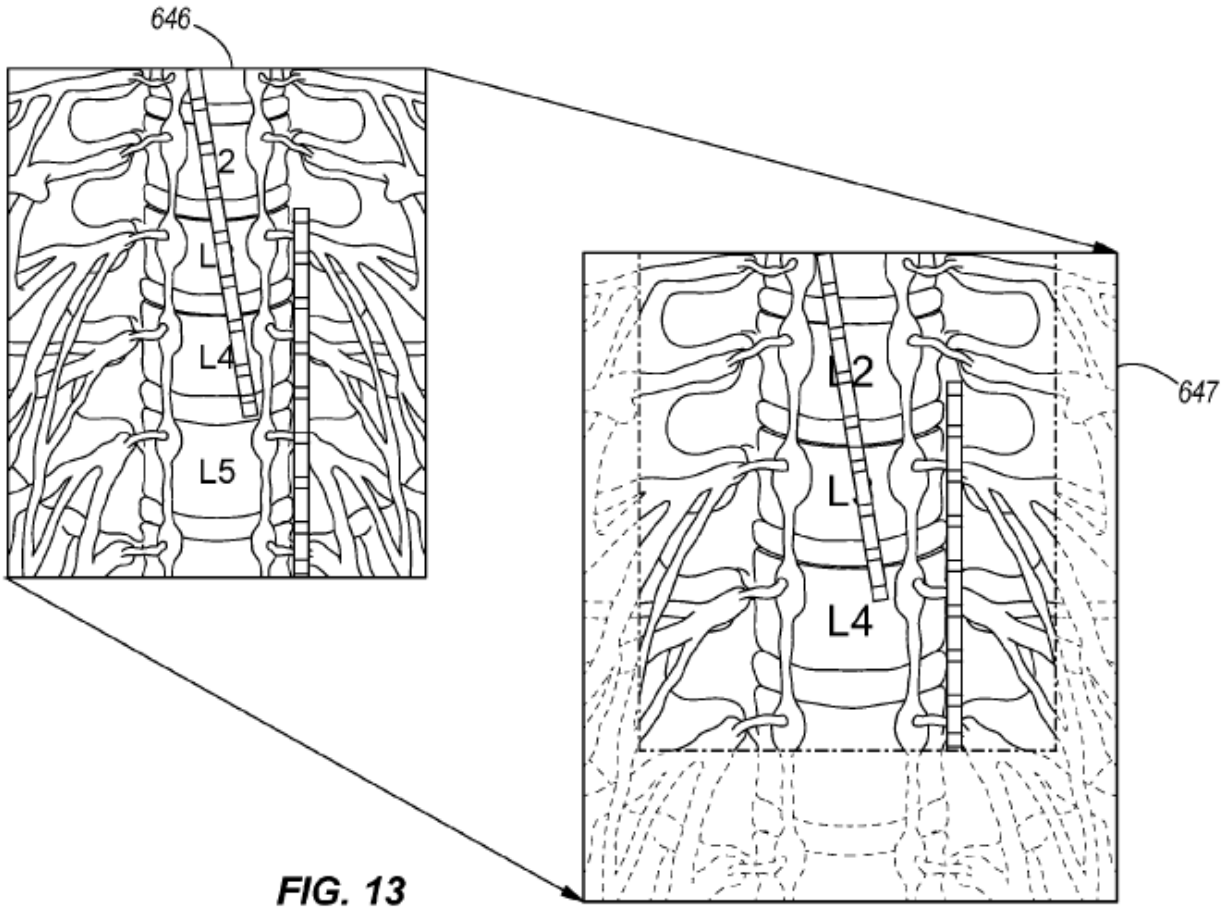

FIG. 13

Ex. 1025 Fig. 13, 3:22-23, 15:1-4. In original image 646, the left lead extends to the top of vertebra L5; but with the vertebrae scaled to 125% in image 647, the left lead only extends to the middle of vertebra L4. Ex. 1002 ¶173.

6. Claim 5—"The system of claim 4, further comprising presenting a graphical representation of the vertebra and the signal delivery device at a computer-based display"

Bradley857 and Polefko both teach presenting graphical representations of vertebrae and leads on the CP's computer-based display. *See* §§X.A.2.1[f], X.A.5; Ex. 1004 Fig. 10; Ex. 1025 Fig. 13; Ex. 1002 ¶¶174-175.

7. Claim 6—"The system of claim 1 wherein establishing a positional relationship includes establishing a positional relationship between an electrode of the signal delivery device and the vertebra"

As explained in limitation 1[d], Bradley857's CP establishes a positional relationship between a lead and vertebra. "The 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; *see also id.* (user can assign electrode numbers to each lead). The vertebral position is determined, for example, with respect to the first electrode on the first lead:

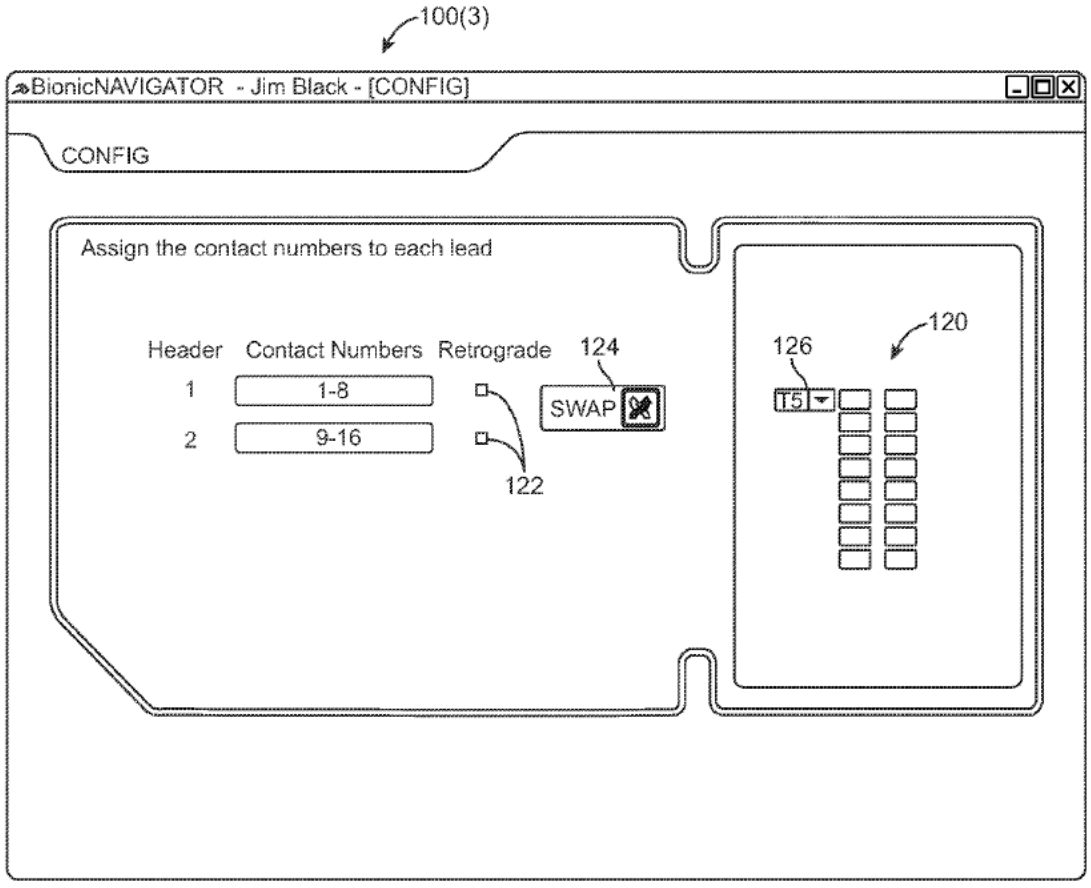

FIG. 9

Id. Fig. 9, ¶62. Based on the user's inputs—here, associating the first electrode of the left octet with the T5 vertebra—the CP establishes a positional relationship between the electrode and the vertebra. *See* §§X.A.2.1[c]-[d]; Ex. 1002 ¶176.

The user can also enter the position of a lead (with the electrode octet depicted) on screen 100(4), allowing the CP to establish the positional relationship of each electrode with a vertebra:

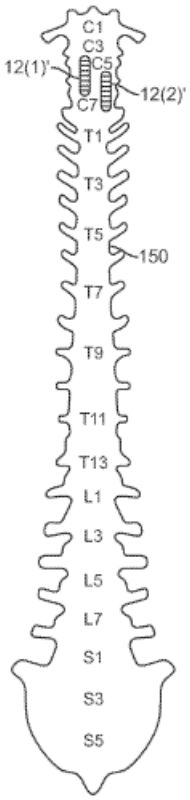

FIG. 10

Ex. 1004 Fig. 10, ¶62; Ex. 1002 ¶177.

Both techniques correlate specific electrodes to vertebral positions as claimed. Ex. 1002 ¶¶176-178. Bradley857 confirms that the CP establishes this positional relationship 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[.]" Ex. 1004 ¶¶70-71; Ex. 1002 ¶178.

8. Claim 7—"The system of claim 1 wherein the computer-readable medium has instructions that when executed: access a database of patient information correlating signal delivery parameters and medical indications for other patients and wherein automatically identifying the signal delivery parameter is based at least in part on the information contained in the database"

Bradley857 teaches automatically identifying stimulation parameters by accessing a "database containing a plurality of reference therapeutic indications (in this case, a plurality of pain regions) and a plurality of desired stimulation targets respectively corresponding to the therapeutic indications." Ex. 1004 ¶66; *see* §X.A.2.1[g]; Ex. 1002 ¶179. The database can "be generated or further refined using empirical data acquired from previous patients" that correlates specific areas of pain with stimulation parameters such as active electrode combinations and pulse widths. Ex. 1004 ¶¶67-68; Ex. 1002 ¶179. The CP automatically identifies stimulation parameters based on the information in the database. Ex. 1004 ¶¶69-71; *see* §X.A.2.1[g]; Ex. 1002 ¶179.

9. Claim 8—"The system of claim 7 wherein the patient is one of multiple patients presenting with the medical indication, and wherein the computer-readable medium has instructions that when executed update the database with data from the patient"

Bradley857 teaches accessing a database correlating stimulation parameters and patient indications. Ex. 1004 ¶67; Ex. 1002 ¶180; §X.A.8. The database is stored in memory 84 of the CP. Ex. 1004 ¶¶55, 66, 69. As additional patients enter treatment information into the database, the database may be updated and refined to reflect that new data. *Id.* ¶67 ("This database can alternatively be generated or further refined using empirical data acquired from previous patients."); Ex. 1002 ¶180. Data from the patient—including regarding the efficacy of treatment—may be entered through patient profile screen 100(1). Ex. 1004 ¶58, Fig. 7; Ex. 1002 ¶180.

10. Claim 9—"The system of claim 7 wherein the instructions for accessing the database include instructions for accessing a correlation between the medical indication and a vertebral level, and wherein the instructions for automatically identifying a signal delivery parameter include instructions for selecting an electrode carried by the signal delivery device and positioned proximate to the vertebral level"

Bradley857's CP automatically identifies stimulation parameters by accessing a database that correlates reference indications (e.g., pain areas) with stimulation targets that include vertebral levels. Ex. 1004 ¶66; Ex. 1002 ¶181; §X.A.2.1[g]. "Thus, for each pain region stored within the database, a corresponding vertebral

and mediolateral location, as well as other information from which a set of stimulation parameters can be derived, to optimize stimulation for the current patient is provided." Ex. 1004 ¶68; *see also id.* ¶¶66-69 (correlations between pain areas and vertebral levels). Based on the information in the database, the CP automatically "select[s] the electrodes 26 adjacent the desired stimulation target based on the user-defined location of the tissue stimulation leads 12[.]" *Id.* ¶¶70-71; Ex. 1002 ¶181.

11. Claim 10—"The system of claim 9 wherein the selected electrode is the electrode closest to the vertebral level"

Bradley857's CP is "configured for selecting the electrodes 26 adjacent the desired stimulation target" (Ex. 1004 ¶70), which is the vertebral level identified by the database (*id.* ¶¶66-71). *See* §X.A.10; Ex. 1002 ¶182.

12. Claim 11

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

See §X.A.2.1[a]; Ex. 1002 ¶183.

11[b]. ***"a computer-readable medium having instructions that when executed:"***

See §X.A.2.1[b] ; Ex. 1002 ¶184.

11[c]. ***"present a computer-based image of an implanted signal delivery device and a vertebra of a patient;"***

Both Bradley857 and Polefko disclose presenting a computer-based image of an implanted lead and a patient's vertebra. *See* §§X.A.2.1[f], X.A.5-6; Ex. 1004 ¶63, Fig. 10; Ex. 1025 at 13:28-30, 15:1-8, Figs. 12B and 13; Ex. 1002 ¶185.

11[d]. ***"receive an input provided by a user and corresponding to a requested change in axial length of the computer-based image of the vertebra and;"***

See §X.A.2.1[f]; Ex. 1002 ¶186.

11[e]. ***"update the computer-based image of the vertebra to reflect the requested change"***

Polefko teaches updating the computer-based image of the vertebra according to the scaling parameter to reflect the user's requested change in axial length. *See* §§X.A.2.1[f], X.A.5; Ex. 1025 at 13:8-10, 14:64-15:8, Fig. 13; Ex. 1002 ¶187.

13. Claim 12

12[a]. ***"The system of claim 11 wherein the input is a first input and wherein the computer-readable medium further includes instructions that, when executed:"***

Bradley857 discloses a computer-readable medium having instructions that are executed to perform the functions below. *See* §X.A.2.1[b]; Ex. 1004 ¶¶53-56; Ex. 1002 ¶188. The input recited in limitation 11[d] is a first input. Ex. 1002 ¶188.

12[b]. ***"receive a second input corresponding to a medical indication of the patient; and"***

See §X.A.2.1[e] ; Ex. 1002 ¶189.

12[c]. ***"based at least in part on the indication and a positional relationship between the signal delivery device and the vertebra, automatically identify a signal delivery parameter in accordance with which a pulsed electrical signal is delivered to the patient via the signal delivery device"***

Bradley857 discloses establishing a positional relationship between a lead and a vertebra. *See* §X.A.2.1[d]; Ex. 1004 ¶¶57-65; Ex. 1002 ¶190. Bradley857 also discloses, based on the patient's indication and the positional relationship, automatically identifying a stimulation parameter in accordance with which a pulsed electrical signal is delivered via the lead. *See* §X.A.2.1[g]; Ex. 1004 ¶¶38, 65-71; Ex. 1002 ¶190.

14. Claim 13—"The system of claim 12 wherein the signal delivery device includes multiple electrodes and wherein the identifying the signal delivery parameter includes identifying which of the electrodes receives the pulsed electrical signal"

Bradley857 discloses systems having implanted leads with multiple electrodes: "the 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); Ex. 1002 ¶191; §X.A.2.1[c]. Identifying the stimulation parameter includes identifying active electrodes. *See* §§X.A.2.1[g], X.A.4; Ex. 1004 ¶¶70-71, ¶¶76-77; Ex. 1002 ¶191.

15. Claim 14—"The system of claim 11 wherein the computer-readable medium has instructions that when executed deliver a pulsed electrical signal to the patient"

Bradley857 discloses that the computer-readable medium has instructions that, when executed (limitation 1[b]), deliver a pulsed electrical signal to the patient. *See* §X.A.2.1[g]; Ex. 1004 ¶38 (describing delivery of pulse by IPG); Ex. 1002 ¶192.

16. Claim 18

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

See §X.A.2.1[a]; Ex. 1002 ¶193.

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

See §X.A.2.1[b]; Ex. 1002 ¶194.

18[c]. ***"present a computer-based image of an implanted signal delivery device and an anatomical feature of the patient, wherein the anatomical feature includes at least one of a vertebra and a disk of a patient;"***

Bradley857 discloses presenting images of implanted leads and patient vertebrae (Ex. 1004, Fig. 10), and Polefko discloses presenting images of leads, vertebrae, and discs (Ex. 1025, Fig. 13). *See* §§X.A.2.1[f], X.A.5-6; Ex. 1002 ¶195.

18[d]. ***"receive an input provided by a user and corresponding to a requested change in axial length of the computer-based image of the anatomical feature; and"***

Polefko discloses receiving an input provided by a user corresponding to a requested change in axial length of the computer-based image of the vertebra. *See* §X.A.2.1[f]; Ex. 1025 at 13:8-10, 14:64-15:8; Ex. 1002 ¶196.

18[e]. ***"update the computer-based image of the anatomical feature to reflect the requested change."***

Polefko discloses updating the computer-based image of the vertebra according to the scaling parameter to reflect the user's requested change in axial length. *See* §§X.A2.1[f], X.A.5; Ex. 1025 at 13:8-10, 14:64-15:8, Fig. 13; Ex. 1002 ¶197.

17. Claim 19—"The system of claim 18 wherein the input is a first input and wherein the computer-readable medium further includes instructions that, when executed: receive a second input corresponding to a medical indication of the patient; and based at least in part on the indication and a positional relationship between the signal delivery device and the anatomical feature, automatically identify a signal delivery parameter in accordance with which a pulsed electrical signal is delivered to the patient via the signal delivery device"

Bradley857 discloses a computer-readable medium having instructions (*see* §X.A.2.1[b]; Ex. 1004 ¶¶53-56) that, when executed, receive a second input corresponding to a patient's indication (*see* §X.A.2.1[e]; Ex. 1004 ¶¶57-58); establish a positional relationship between a lead and a vertebra (*see* §X.A.2.1[d];

Ex. 1004 ¶¶57-65); and based on those factors, automatically identify a stimulation parameter in accordance with which a pulsed electrical signal is delivered via the lead (*see* §X.A.2.1[g]; Ex. 1004 ¶¶38, 65-71). Ex. 1002 ¶198.

18. Claim 20—"The system of claim 19 wherein the signal delivery device includes multiple electrodes and wherein identifying the signal delivery parameter includes identifying which of the electrodes receives the pulsed electrical signal"

See §X.A.14; Ex. 1002 ¶199.

19. Claim 21—"The system of claim 18 wherein the computer-readable medium has instructions that, when executed, deliver a pulsed electrical signal to the patient"

See §X.A.15; Ex. 1002 ¶200.

B. GROUND 2: Claims 2-3 are Obvious over Bradley857 in View of Zhu and Polefko

As shown in Ground 1, Bradley857 and Polefko disclose every limitation of claims 1-3. For dependent claims 2-3, Petitioners rely in part on disclosures of Zhu, which is incorporated by reference into the specification of Bradley857. *See* §§X.A.3-4. To the extent the Board determines that Bradley857 does not sufficiently incorporate the cited disclosures of Zhu, a POSA would nonetheless be motivated to combine the references and claims 2-3 would be obvious over Bradley857 in view of Polefko and Zhu.

1. A POSA would have been motivated to combine Bradley857, Zhu, and Polefko

A POSA would have been motivated to combine Bradley857 with Zhu. Ex. 1002 ¶¶201-202. First, Bradley857 directs a POSA to incorporate the lead alignment techniques described in Zhu. *See* §§VIII.A.4, X.A.3; Ex. 1004 ¶61; Ex. 1002 ¶203. Bradley857's CP relies on lead location information to identify stimulation parameters (Ex. 1004 ¶¶57, 65), and teaches using electrical parameters such as those described in Zhu to determine locations of leads relative to one another. Ex. 1004 ¶61; Ex. 1024 ¶61; Ex. 1002 ¶203; *see also* MPEP §2143, I.G.

Additionally, Zhu's teaching of taking "corrective action" after detecting a lead has migrated—e.g., by updating stimulation parameters to re-focus stimulation energy on the target area (Ex. 1024 ¶¶87-89)—would motivate a POSA to include this functionality in Bradley857 as well. Ex. 1002 ¶204. Zhu and Bradley857 both recognize that lead migration reduces the efficacy of SCS, and that reprogramming may be necessary to re-focus stimulation on the target area. Ex. 1004 ¶11, Ex. 1024 ¶¶8-9. Zhu expressly provides a solution to this problem. Ex. 1024 ¶¶87-89. Because Bradley857's CP relies on lead location information to identify stimulation parameters (*id.* ¶¶57-65), a POSA would understand that incorporating Zhu's teaching of automatically updating stimulation parameters upon receiving an updated lead location would improve the accuracy and efficacy of Bradley857's stimulation programming. Ex. 1002 ¶204. A POSA would further have been

motivated to combine Bradley857/Zhu with Polefko for the same reasons described in Ground 1. *See* §X.A.1; Ex. 1002 ¶204.

A POSA would have had a reasonable expectation of success in incorporating Zhu's techniques for monitoring lead locations and updating stimulation parameters because Bradley857 and Zhu use substantially the same hardware components, Bradley857 teaches the use of the electrical parameters disclosed in Zhu, and Bradley857 already is configured to automatically identify stimulation parameters based in part on lead location. Ex. 1002 ¶205. In view of the detailed instructions provided by Zhu, pointed to by the disclosure of Bradley857, applying the combined teaching of Bradley857 and Zhu in further combination with Polefko would have been a routine matter of software programming for a POSA. Ex. 1002 ¶205.

2. Bradley857, Polefko, and Zhu disclose claims 2-3

As shown in Ground 1, Bradley857, Zhu, and Polefko disclose claims 2 and 3. *See* §§X.A.3-4; Ex. 1002 ¶206.

C. GROUND 3: Claims 15-17 and 22-24 are Obvious over Bradley857 in View of Polefko and Alataris316

Claims 15-17 depend from claim 14, and recite frequency ranges for the stimulation signal provided to the patient. Claims 22-24 depend from claim 21, and are otherwise identical to claims 15-17. Bradley857 and Polefko disclose claims 14 and 21, as shown in Ground 1, and Nevro's prior-art Alataris316 publication explicitly discloses the claimed frequency ranges. Because a POSA would have

been motivated to use Bradley857/Polefko to provide stimulation in the frequency ranges taught by Alataris316, claims 15-17 and 22-24 are obvious.

1. A POSA would have been motivated to program Bradley857/Polefko in the frequency ranges taught by Alataris316

As shown in Ground 1, a POSA would have been motivated to combine Bradley857 with Polefko. *See* §X.A.1. Bradley857 is directed to programming an SCS system to treat pain. Ex. 1004 ¶¶2-3, 14-15. Alataris316 describes "standard" SCS as providing what it refers to as "low frequency" stimulation, below 1.5 kHz, to produce paresthesia where a patient feels pain. Ex. 1005 ¶¶4, 36, 83. Alataris316 states that some patients receive minimal benefits from paresthesia, and "there remains a need for improved techniques and systems for addressing patient pain." *Id.* ¶4. Alataris316 purports to meet that need by providing what it refers to as "high frequency" stimulation, above 1.5 kHz, to treat pain without producing paresthesia. *Id.* ¶¶22-23, 37. Alataris316 describes studies purportedly showing the efficacy of its "high frequency" SCS in treating pain. *Id.* ¶¶33-62. These teachings would have motivated a POSA to program Bradley857/Polefko to provide "high frequency" stimulation for patients who, according to Alataris316, received fewer benefits from "low frequency" stimulation. Ex. 1002 ¶¶207-211.

A POSA would have had a reasonable expectation of success in programming Bradley857/Polefko at the frequencies disclosed by Alataris316. Ex. 1002 ¶212.

Bradley857, Polefko, and Alataris316 use substantially the same hardware, and no software modification would be necessary—the only change would be programming stimulation at a different frequency. Ex. 1002 ¶212; Ex. 1004 ¶50 ("Pulse Rate Adjustment Mode"). Alataris316 provides detailed instruction of how to program SCS systems at these frequencies—e.g., by identifying correlations between patient indications, target vertebral levels, and stimulation parameters. *See, e.g.*, Ex. 1005 ¶¶36-37, 48, 82-111; Ex. 1002 ¶212.

2. Bradley857, Polefko, and Alataris316 Disclose Claims 15-17 and 22-24

a. Claims 15/22—"The system of claim [14/21] wherein the pulsed electrical signal has a frequency in a frequency range of from about 1.5 kHz to about 100kHz"

Claims 16/23—"The system of claim [14/21] wherein the pulsed electrical signal has a frequency in a frequency range of from about 1.5 kHz to about 50 kHz"

Claims 17/24—"The system of claim [14/21] wherein the pulsed electrical signal has a frequency in a frequency range of from about 3 kHz to about 20 kHz"

As shown in Ground 1, Bradley857/Polefko discloses claims 14 and 21. *See* §§X.A.15, X.A.19; Ex. 1002 ¶213. Alataris316 discloses treating patients using stimulation signals in the exact frequency ranges recited in claims 15-17 and 22-24: "the frequency of the signal (or at least a portion of the signal) can be from about 1.5 kHz to about 100 kHz, or from about 1.5 kHz to about 50 kHz, or from about 3 kHz to about 20 kHz[.]" Ex. 1005 ¶48; Ex. 1002 ¶214.

D. GROUND 4: Claims 1-14 and 18-21 are Obvious over Bradley857 in View of Davis

1. A POSA would have been motivated to combine Bradley857 with Davis

Bradley857 discloses every limitation of claims 1-14 and 18-21 except for the Axial Length Limitation. *See* §§X.A.2-19. As described in Ground 1, there was teaching, suggestion, and motivation in the prior art to generate an anatomically-correct model of patient vertebrae to model implanted lead locations when programming stimulation. *See* §§X.A.1.a-b. Davis discloses additional techniques for generating an anatomically-correct model. A POSA would have been motivated to apply Davis's techniques to Bradley857, and would have done so with a reasonable expectation of success.

a. A POSA would have applied Davis's technique of scaling images of vertebrae to improve Bradley857 with predictable results

As described in Ground 1, a POSA would have recognized that Bradley857's lead location modeling could be improved by allowing a user to adjust the dimensions of vertebral images to match the patient's anatomy. *See* §§X.A.1.a-b; Ex. 1002 ¶¶215-216.

Davis discloses techniques that "provide the user with the ability to accurately define a lead image relative to an anatomical target, which may be helpful in accurately programming stimulation fields." Ex. 1027 ¶19; *see also id.* at Abstract.

Davis teaches that its programmer can display an image of a patient's vertebrae, and the user can drag-and-drop images of leads on top of the vertebral image. *Id.* ¶¶86-92; Ex. 1002 ¶217. Davis also teaches that the user can manipulate the vertebral image so the lead images reflect their correct locations and dimensions in relation to the vertebrae. Ex. 1027 ¶¶90, 92, 101; Ex. 1002 ¶217. Unlike the "scaling parameter" used in Polefko that is generated from patient anatomical information, Davis teaches that the user can resize or "scale" a vertebral image relative to the leads by clicking buttons or "tools" presented on the programmer's display. Ex. 1027 ¶¶90, 92, Figs. 6G-H; Ex. 1002 ¶217; *infra* §X.D.2.1[f]. Resizing vertebrae *separately* from leads changes the axial lengths of the vertebrae relative to the leads (as opposed to zooming in or out on an image of vertebrae and leads together, which does not change their relative alignment or dimensions). Ex. 1002 ¶217.

A POSA could apply Davis's techniques to Bradley857 through routine software programming. Ex. 1002 ¶218. Bradley857's CP is already configured to model lead locations by placing leads on an image of a spine. Ex. 1004 ¶63. Davis explains exactly how to perform its scaling technique—by resizing a vertebral image separately from the leads. Ex. 1027 ¶¶90, 92. Applying Davis's techniques would not change the principle of operation of either system. Ex. 1002 ¶218. And a POSA would have understood that applying Davis's scaling would predictably improve the accuracy of Bradley857's lead location modeling—and the effectiveness of the

programmed stimulation—for the same reasons as described above regarding Polefko's scaling parameter. *See* §X.A.1.a; Ex. 1002 ¶219. The results of this modification would have been predictable because Bradley857 and Davis use substantially the same hardware and drag-and-drop functionality, and Davis provides explicit instructions for scaling vertebrae relative to leads. Ex. 1002 ¶219.

b. A POSA would have been motivated to apply Davis's teaching of creating anatomically-correct models of implanted lead locations to Bradley857

As described in Ground 1, the prior art taught that generating an accurate model of implanted leads aids in programming stimulation. *See* §X.A.1.a-b. Davis echoes that teaching, and would have motivated a POSA to apply its own scaling techniques even without a need to "improve" Bradley857. Ex. 1027 ¶19; Ex. 1002 ¶¶220-221; §X.A.1.b (Polefko and Blum provide additional motivation to combine).

A skilled artisan would have had a reasonable expectation of success in incorporating Davis's scaling techniques into Bradley857. Ex. 1002 ¶222. Bradley857 and Davis use substantially the same hardware components, and both systems model lead locations by dragging-and-dropping images of leads onto an image of vertebrae. *Id*. Modifying Bradley857 to use Davis's resizing input to scale the background vertebral image relative to the leads would have been a routine matter of software programming. *Id.* This scaling functionality would operate the same way and for the same purpose in the combined system as it does in Davis. *Id.*

2. Claim 1

The disclosures of Bradley857 cited in Ground 1 (§§X.A.2-19) apply equally in Ground 4. Davis discloses the Axial Length Limitation and related limitations. Ex. 1002 ¶223.

1[a].

See §X.A.2.1[a]; Ex. 1002 ¶224.

1[b].

See §X.A.2.1[b]; Ex. 1002 ¶225.

1[c].

See §X.A.2.1[c]; Ex. 1002 ¶226.

1[d].

See §X.A.2.1[d]; Ex. 1002 ¶227.

1[e].

See §X.A.2.1[e]; Ex. 1002 ¶228.

1[f].

Bradley857 teaches receiving an input provided by a user to position images of leads onto a computer-based image of a spine (including vertebrae). *See* §X.A.2.1[f]; Ex. 1002 ¶229.

Davis discloses various "programmer screens" for programming stimulation. Ex. 1027 ¶82, Figs. 6A-L; Ex. 1002 ¶230. The leads are displayed on the programmer's screen, and the user imports a background anatomical image (e.g., a

fluoroscopic image) for the area being programmed. Ex. 1027 ¶¶86, 89; *see also id.* ¶53. Alternatively, the imported image may be a "graphical representation of the region, e.g., an anatomical image of the spinal cord." *Id.* ¶100; *see also id.* ¶86. "[T]he user may manipulate the fluoroscopic image (627) and the representation of the leads (609) so that they align. The user may then scale fluoroscopic image (627) and the representation of the leads (609) together or separately." *Id.* ¶92; Ex. 1002 ¶231. This scaling can similarly be applied when using a graphical representation of the spine. *See* Ex. 1027 ¶¶100-101, Figs. 6G-H; Ex. 1002 ¶231. For example, the programmer provides a resizing input so that the user can change the dimensions of the vertebral image relative to the leads:

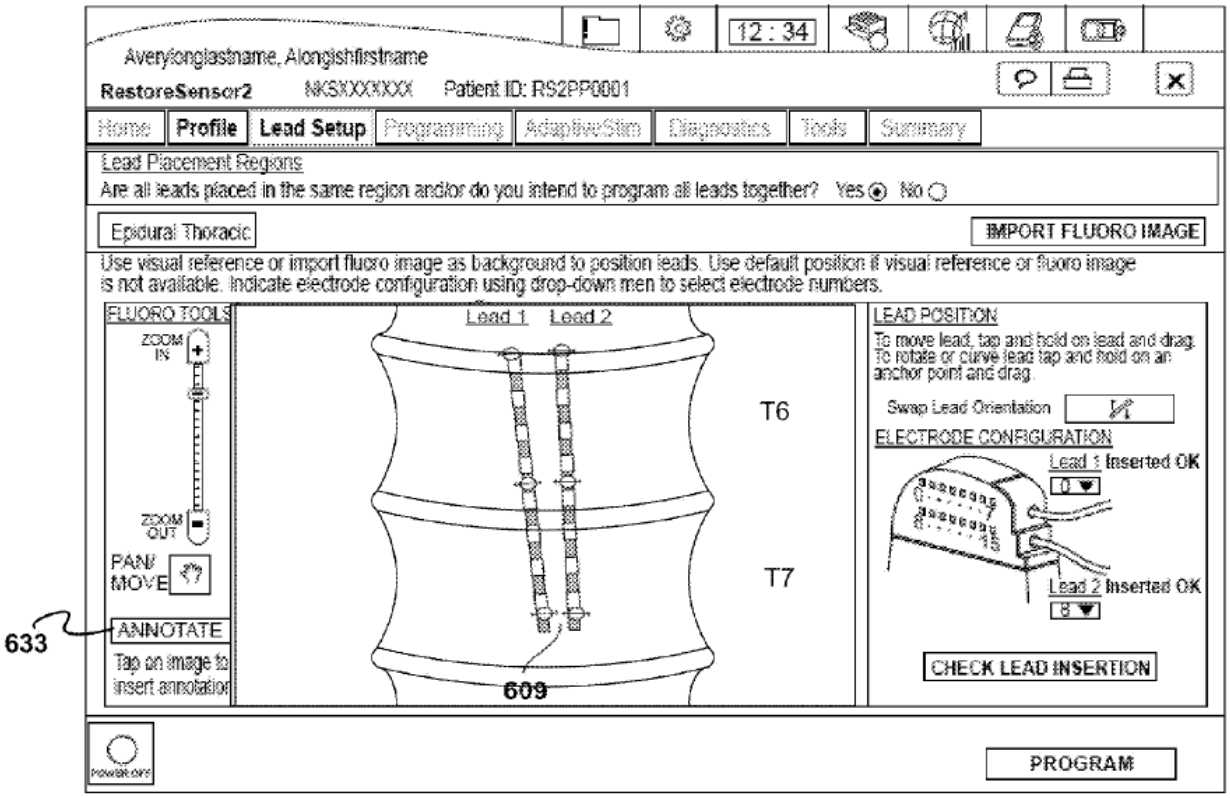

FIG. 6H

Ex. 1027 Fig. 6H ("Fluoro Tools"); *see also id.* ¶¶90, 101, 113, 115 (describing manipulation of vertebral image), Fig. 6G; Ex. 1002 ¶231. "The user may manipulate both the drawn graphical representations of the leads and the imported image until the desired placement is achieved[.]" Ex. 1027 ¶101. Accordingly, Davis discloses receiving a user input to change the axial length of a computer-based vertebral image. Ex. 1002 ¶231.

1[g].

See §X.A.2.1[g]; Ex. 1002 ¶232.

3. Claim 2

See §X.A.3; Ex. 1002 ¶233.

4. Claim 3

See §X.A.4; Ex. 1002 ¶234.

5. Claim 4

Bradley857 teaches receiving user inputs to position images of leads onto an image of a spine. *See* §§X.A.2.1[f], X.A.5; Ex. 1002 ¶235.

Davis teaches that the user can "scale" the background vertebral image and the images of leads "together or separately." Ex. 1027 ¶92; *see also id.* ¶¶90, 101, 113, 115; Ex. 1002 ¶236; §X.D.2.1[f]. When the user scales the vertebral image separately from the leads (e.g., by resizing the background image), the dimensions of the displayed vertebrae change relative to the dimensions of the leads. Ex. 1002 ¶237. After the user changes the dimensions of the background image, the image is compressed and stored in the device, and is used to identify stimulation parameters. Ex. 1027 ¶¶93, 103-105; Ex. 1002 ¶237.

6. Claim 5

Bradley857 and Davis both disclose presenting graphical representations of vertebrae and leads on the programmer's display. *See* §§X.D.2.1[f], X.D.5; Ex. 1004 Fig. 10; Ex. 1027 Figs. 6G-I; Ex. 1002 ¶¶238-239.

7. Claim 6

See §X.A.7; Ex. 1002 ¶240.

8. Claim 7

See §X.A.8; Ex. 1002 ¶241.

9. Claim 8

See §X.A.9; Ex. 1002 ¶242.

10. Claim 9

See §X.A.10; Ex. 1002 ¶243.

11. Claim 10

See §X.A.11; Ex. 1002 ¶244.

12. Claim 11

11[a].

See §X.A.12.11[a] ; Ex. 1002 ¶245.

11[b].

See §X.A.12.11[b] ; Ex. 1002 ¶246.

11[c].

Both Bradley857 and Davis disclose presenting a computer-based image of an implanted lead and a patient's vertebra. *See* §§X.D.2.1[f], X.D.5-6; Ex. 1004 Fig. 10; Ex. 1027 Figs. 6G-I; Ex. 1002 ¶247.

11[d].

See §X.A.2.1[f]; Ex. 1002 ¶248.

11[e].

Davis teaches updating the computer-based image of the vertebra to reflect the user's request to resize the vertebral image. *See* §§X.D.2.1[f], X.D.5; Ex. 1027 ¶¶90, 92, 101, 113, 115, Figs. 6G-I; Ex. 1002 ¶249.

13. Claim 12

12[a].

See §X.A.13.12[a]; Ex. 1002 ¶250.

12[b].

See §X.A.13.12[b]; Ex. 1002 ¶251.

12[c].

See §X.A.13.12[c]; Ex. 1002 ¶252.

14. Claim 13

See §X.A.14; Ex. 1002 ¶253.

15. Claim 14

See §X.A.15; Ex. 1002 ¶254.

16. Claim 18

18[a].

See §X.A.16.18[a]; Ex. 1002 ¶255.

18[b].

See §X.A.16.18[b]; Ex. 1002 ¶256.

18[c].

Bradley857 discloses presenting images of implanted leads and vertebral levels (Ex. 1004, Fig. 10), and Davis discloses presenting images of leads, vertebrae, and discs (Ex. 1027 Figs. 6G-I). *See* §§X.D.2.1[f], X.D.5-6; Ex. 1002 ¶257.

18[d].

Davis discloses receiving an input provided by a user corresponding to a requested change in axial length of the computer-based image of the vertebra. *See* §X.D.2.1[f]; Ex. 1027 ¶¶90, 92, 101, 113, 115, Figs. 6G-I; Ex. 1002 ¶258.

18[e].

Davis discloses updating the computer-based image of the vertebra according to the scaling parameter to reflect the user's requested change in axial length. *See* §§X.D.2.1[f], X.D.5; Ex. 1027 ¶¶90, 92, 101, 113, 115, Figs. 6G-I; Ex. 1002 ¶259.

17. Claim 19

See §X.A.17; Ex. 1002 ¶260.

18. Claim 20

See §X.A.18; Ex. 1002 ¶261.

19. Claim 21

See §X.A.19; Ex. 1002 ¶262.

E. GROUND 5: Claims 2-3 are Obvious over Bradley857 in View of Zhu and Davis

As shown in Ground 4, Bradley857 and Davis disclose every limitation of claims 1-3. For claims 2-3, Petitioners rely in part on disclosures of Zhu, which is

incorporated by reference into the specification of Bradley857. To the extent Nevro argues Bradley857 does not sufficiently incorporate the cited disclosures of Zhu, a POSA would nonetheless be motivated to combine the references and claims 2-3 would be obvious in view of Davis and Zhu.

1. A POSA would have been motivated to combine Bradley857 Zhu, and Davis

A POSA would have been motivated to combine Bradley857 and Zhu based on Bradley857's teaching of determining relative lead positions using the techniques of Zhu. *See* §X.B.1; Ex. 1004 ¶61; Ex. 1002 ¶¶263-265. Bradley857's CP relies on the locations of implanted leads to identify stimulation parameters (Ex. 1004 ¶57), and teaches using measured electrical parameters such as those described in Zhu to determine relative lead orientation. Ex. 1004 ¶61; Ex. 1024 ¶61; Ex. 1002 ¶265.

Additionally, Zhu's teaching of taking "corrective action" after detecting a lead has migrated—e.g., by updating stimulation parameters to re-focus stimulation energy on the target area (Ex. 1024 ¶¶87-89)—would motivate a POSA to include this functionality in Bradley857 as well. Ex. 1002 ¶266. Zhu teaches that lead migration reduces the efficacy of SCS, and that reprogramming may be necessary to re-focus stimulation on the target area. Ex. 1024 ¶¶8-9. Bradley857 also recognizes that leads can migrate after implantation. Ex. 1004 ¶11. Because Bradley857's CP relies on lead location information to identify stimulation parameters, a POSA would understand that incorporating Zhu's teaching of automatically updating stimulation

parameters upon receiving an updated lead location would improve the accuracy and efficacy of Bradley857's stimulation programming. Ex. 1002 ¶266. A POSA would further have been motivated to combine Bradley857/Zhu with Davis for the same reasons described in Ground 4. *See* §X.D.1.

A POSA would have had a reasonable expectation of success in incorporating Zhu's techniques for monitoring lead locations and updating lead parameters because Bradley857 and Zhu use substantially the same components, Bradley857 teaches the use of the electrical parameters disclosed in Zhu, and Bradley857 already is configured to automatically identify stimulation parameters based in part on lead location. Ex. 1002 ¶267. In view of the detailed instructions provided by Zhu, pointed to by Bradley857, applying the combined teaching of Bradley857 and Zhu in further combination with Davis would have been a routine matter of software programming for a POSA. Ex. 1002 ¶267.

2. Bradley857, Davis, and Zhu disclose claims 2-3

As shown in Ground 4, Bradley857, Davis, and Zhu disclose claims 2 and 3. *See* §X.D.3-4; Ex. 1002 ¶268; *see also* §X.A.3-4.

F. GROUND 6: Claims 15-17 and 22-24 are Obvious over Bradley857 in View of Davis and Alataris316

As described in Ground 3, claims 15-17 depend from claim 14, and claims 22-24 depend from claim 21 but are otherwise identical. *See* §X.C. Bradley857 and Davis disclose claims 14 and 21, and Alataris316 discloses the exact frequency

ranges recited in claims 15-17 and 22-24. Because a POSA would have been motivated to provide stimulation at these frequency ranges, claims 15-17 and 22-24 are obvious.

1. A POSA would have been motivated to program Bradley857/Davis in the frequency ranges taught by Alataris316

A POSA would have been motivated to combine Bradley857 with Davis. *See* §X.D.1; Ex. 1002 ¶¶269-270. And as described in Ground 3, Alataris316 states that some patients do not benefit from SCS at frequencies below 1.5 kHz. Ex. 1005 ¶4. Alataris316 instructs that those patients may benefit from stimulation above 1.5 kHz, and provides a detailed explanation of how to provide such stimulation using conventional hardware. *Id.* ¶¶22-23, 37; Ex. 1002 ¶¶272-273. Alataris316's teaching would have motivated a POSA to program Bradley857/Davis at the frequencies taught by Alataris316 for patients who received minimal benefits from low-frequency stimulation. Ex. 1002 ¶¶271-273; *see* §X.C.1.

A POSA would have had a reasonable expectation of success in programming Bradley857/Davis at the frequencies taught by Alataris316. *Id*. ¶274. All three systems use substantially the same hardware, and no software modification would be necessary—the only change would be programming stimulation at a different frequency. *Id*. Alataris316 provides detailed instruction of how to provide

stimulation at these frequencies. *See, e.g.*, Ex. 1005 ¶¶36-37, 48, 82-111; Ex. 1002 ¶274; §X.C.1.

2. Bradley857, Davis, and Alataris316 disclose claims 15-17 and 22-24

As shown in Ground 4, Bradley857 and Davis disclose claims 14 and 21. Alataris316 discloses treating patients using stimulation in the exact frequency ranges recited in claims 15-17 and 22-24 (*see* §X.C.2): "the frequency of the signal (or at least a portion of the signal) can be from about 1.5 kHz to about 100 kHz, or from about 1.5 kHz to about 50 kHz., or from about 3 kHz to about 20 kHz[.]" Ex. 1005 ¶48; Ex. 1002 ¶¶275-276.

XI. CONCLUSION

Petitioners respectfully requests that *inter partes* review of the '460 Patent be instituted and 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 13,981 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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