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Paper 14
Date: March 16, 2021

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BOSTON SCIENTIFIC CORP., AND BOSTON SCIENTIFIC NEUROMODULATION CORP.,
Petitioner,

v.

NEVRO CORP.,
Patent Owner.

IPR2020-01562
Patent 9,002,460 B2

Before BARRY L. GROSSMAN, MITCHELL G. WEATHERLY, and JAMES A. WORTH, *Administrative Patent Judges*.

WORTH, *Administrative Patent Judge*.

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

I. INTRODUCTION

A. Background and Summary

On September 8, 2020, Boston Scientific Corp. and Boston Scientific Neuromodulation Corp. (collectively, "Petitioner") filed a Petition (Paper 1, "Pet.") requesting an *inter partes* review of claims 1–24 (the "challenged

claims") of U.S. Patent No. 9,002,460 B2 (Ex. 1001, "the '460 patent"). On December 17, 2020, Nevro Corp. ("Patent Owner") filed a Preliminary Response (Paper 6, "Prelim. Resp."). With authorization, the parties filed further pre-institution briefing related to the issue of discretion under 35 U.S.C. § 314(a), as follows. On January 13, 2021, Petitioner filed a reply to the Preliminary Response (Paper 11, "Prelim. Reply"). On January 21, 2021, Patent Owner filed a sur-reply (Paper 13, "Prelim. Sur-Reply").

Institution of an *inter partes* review is authorized by statute when "the information presented in the petition filed under [35 U.S.C. §] 311 and any response filed under [35 U.S.C. §] 313 shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a) (2018). For the reasons set forth below, we determine that Petitioner has demonstrated that there is a reasonable likelihood that at least one of claims 1–24 is unpatentable, and we institute an *inter partes* review of claims 1–24 based on the grounds set forth in the Petition.

B. Real Parties in Interest

Petitioner identifies Boston Scientific Corp. and Boston Scientific Neuromodulation Corp. as real parties-in-interest. *See* Pet. 2. Patent Owner identifies Nevro Corp. as a real-party-in-interest. Paper 4, 1.

C. Related Matters

The parties note as related litigation in federal district court, *Boston Scientific Corp. et al v. Nevro Corp.*, Nos. 16-cv-1163, 18-cv-00644 (consolidated) (D. Del. 2018). *See* Pet. 3; Paper 4, 1. Petitioner has filed a petition for *inter partes* review challenging U.S. Patent No. 10,076,665 (IPR2020-01563) and U.S. Patent No. 9,002,461 (IPR2021-00295). *See* Pet. 3; Prelim. Resp. 12–13. According to Patent Owner, the '460 patent is

related to the following other patents and applications: 61/619,358, 8,676,331, 9,604,059, and 16/128,276. Paper 4, 1.

D. The '460 Patent

The '460 patent is titled "Devices for Controlling Spinal Cord Modulation for Inhibiting Pain, and Associated Systems and Methods, Including Controllers For Automated Parameter Selection" and relates "to devices for controlling spinal cord modulation for inhibiting pain, and associated systems and methods, including simplified controllers." Ex. 1001, 1:21–24.

The '460 patent describes that then-existing pulse generator devices applied electrical pulses to electrodes, which altered a patient's responsiveness to sensory stimuli and/or altered the patient's nervous system's motor-circuit output. *Id.* at 1:43–47. The '460 patent describes that many patients reported tingling or paresthesia that was perceived as less uncomfortable than the patients' underlying pain sensation, but many other patients reported less beneficial effects and/or results. *Id.* at 1:47–54. The '460 patent thus describes a need for improved techniques and systems for addressing pain. *Id.* at 1:55–56.

In particular embodiments embodiment, the '460 patent discloses the use of waveforms having high frequency elements or components that generally produce reduced or eliminated side effects. *Id.* at 2:65–3:2. In this manner, the disclosed waveforms reduced or eliminated unwanted motor stimulation or blocking, and/or interference with sensory functions other than the targeted pain. *See id.* at 3:1–4. The '460 patent discloses that in many embodiments, therapy-induced paresthesia is not a prerequisite to achieving pain reduction, unlike standard spinal cord stimulation (SCS) techniques. *Id.* at 3:32–35; *see also id.* at 1:35 (defining SCS).

The ’460 patent discloses that its embodiments may variously modulate the dorsal column, dorsal horn, dorsal root, dorsal root entry zone, and/or other particular regions of the spinal column to control pain, and may also modulate other neurological structures and/or target neural populations of the spinal cord and/or other neurological tissues. *Id.* at 3:11–18. The therapeutic effect can be produced by inhibiting, suppressing, downregulating, blocking, preventing, or otherwise modulating the activity of the affected neural population. *Id.* at 3:29–32.

Figure 1A of the ’460 patent is reproduced below:

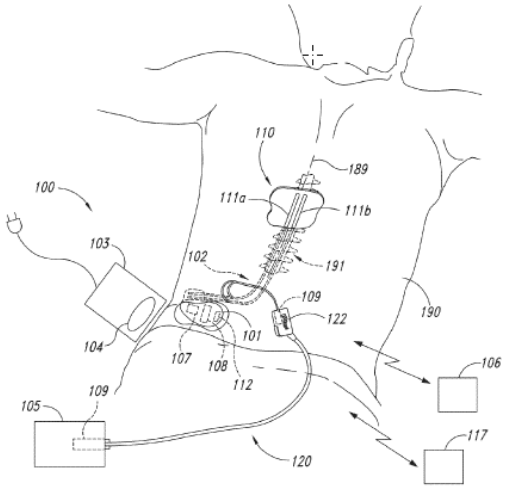

Fig. 1A

Figure 1A is a partially schematic illustration of an implantable spinal cord modulation system positioned at the spine to deliver therapeutic signals in accordance with several embodiments of the disclosure. *See* Ex. 1001, 1:60–63. Overall patient system 100 can include one or more signal delivery devices 110, which may be implanted within patient 190, typically at or near patient’s spinal cord midline 189, coupled to implantable pulse generator 101. *Id.* at 4:6–10. Signal delivery devices 110 carry features for delivering therapy to patient 190 after implantation. *Id.* at 4:10–12. Pulse

generator 101 can be connected directly to signal delivery devices 110, or it can be coupled to signal delivery devices 110 via signal link or lead extension 102. *Id.* at 4:12–15. In a further representative embodiment, signal delivery devices 110 can include one or more elongated lead(s) or lead body or bodies 111 (identified individually as first lead 111a and a second lead 111b). *Id.* at 4:15–18.

Pulse generator 101 can include a machine-readable (e.g., computer-readable) medium containing instructions for generating and transmitting suitable therapy signals. *Id.* at 4:35–38. Pulse generator 101 and/or other elements of system 100 can include one or more processor(s) 107, memory unit(s) 108 and/or input/output device(s) 112. *Id.* at 4:38–41. Accordingly, the process of providing electrical signals, providing guidance information for positioning signal delivery devices 110, and/or executing other associated functions can be performed by computer executable instructions contained by computer-readable media located at pulse generator 101 and/or other system components. *Id.* at 4:42–47.

In one embodiment, the ’460 patent discloses receiving a first input indicating a location of a signal delivery device implanted in a patient, relative to at least one of the patient’s vertebrae; establishing a positional relationship between the implanted signal delivery device and the at least one vertebra; and receiving a second input corresponding to a medical indication of the patient. *Id.* at 35:45–51. The method can include accessing a database of patient information correlating signal delivery parameters and medical indications for other patients, and automatically identifying a signal delivery parameter—in accordance with which a pulsed electrical signal is delivered to the patient via the signal delivery device—based at least in part on the positional relationship, the medical indication, and information

contained in the database. *Id.* at 35:51–58. The signal delivery parameter can include an identity of an electrode to which the pulsed electrical signal is delivered, with the electrode being carried by the signal delivery device. *Id.* at 35:58–61.

The '460 patent discloses that the 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, e.g., to change an axial length of a computer-based image of a vertebra. *Id.* at 35:62–65. The signal delivery parameter can include the identity of a first electrode, and the method can further include identifying a second electrode, e.g., when the circuit containing the first electrode has an impedance that is higher or lower than a target value. *Id.* at 35:66–36:3.

An embodiment illustrated in Figure 13F is reproduced below:

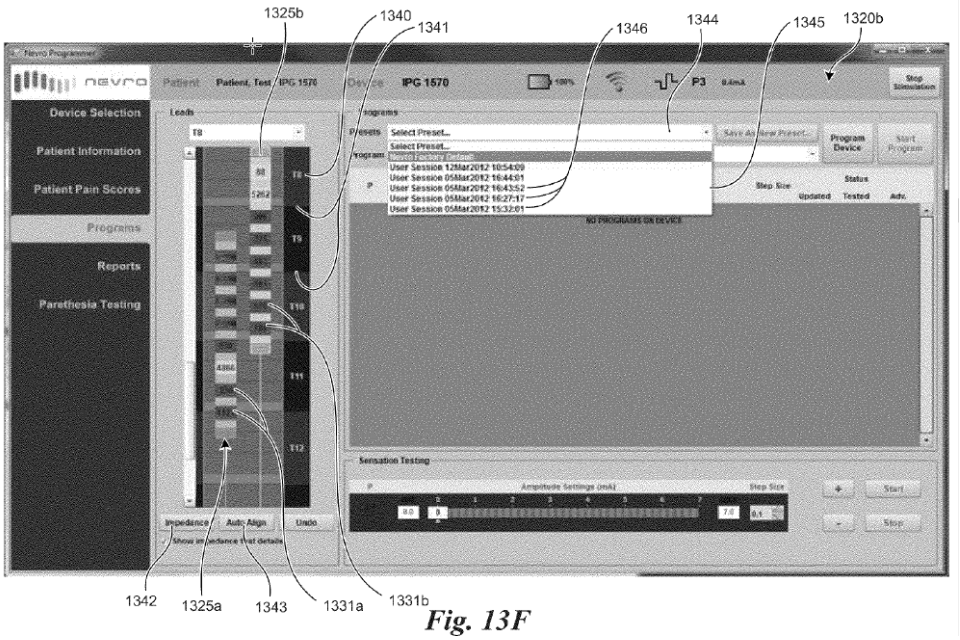

Fig. 13F

Figure 13F illustrates representative display presentations in accordance with particular embodiments of the disclosure. *Id.* at 2:53–55.

According to the ’460 patent, the practitioner can adjust the relative location between the leads and the illustrated vertebral levels to match or closely correspond to the actual relative locations of the leads in the patient's body, using any of a number of suitable methods. *Id.* at 30:26–30. For example, the practitioner can “drag and drop” one of lead identifiers 1325a, 1325b so that that it is properly aligned with adjacent vertebral level identifiers 1340. *Id.* at 30:30–32. If the patient’s vertebral levels do not have the axial dimensions illustrated at display 1320b, the practitioner can alter these dimensions. *Id.* at 30:32–35. For example, 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. *Id.* at 30:35–38. In addition to or in lieu of the foregoing, the practitioner can scale all the vertebral levels simultaneously with a single control. *Id.* at 30:38–40. The practitioner can move lead identifier 1325a, 1325b and/or manipulate boundaries 1341 between vertebrae based on viewing an image of the implanted lead(s) via an x-ray or other imaging protocol. *Id.* at 30:40–43.

Once the practitioner has properly located one of lead identifiers 1325a, 1325b relative to adjacent vertebral level identifiers 1340, the practitioner can request that the program automatically adjust the location of the other lead identifier relative to the first by activating “auto align button” 1343. *Id.* at 30:44–49. The program can automatically align one lead identifier relative to the other based upon measured data, for example, the impedance data associated with contacts on one or both leads. *Id.* at 30:49–52.

E. Illustrative Claim

Claims 1, 11, and 18 are the independent claims challenged in the Petition. Claim 1, reproduced below, is illustrative of the subject matter:

> 1. A patient treatment system, comprising:
>
> a computer-readable medium having instructions that when executed:
>
> receive a first input corresponding to a location of a signal delivery device implanted in a patient;
>
> 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;
>
> receive a second input corresponding to a medical indication of the patient;
>
> 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; and
>
> 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.

Ex. 1001, 37:21–39.

F. Prior Art and Asserted Grounds

Petitioner asserts that claims 1–24 would have been unpatentable on the following grounds (Pet. 35[1]):

[1] Petitioner's formulation of the grounds lists the references in a different order elsewhere in the Petition. For example, on page 35, Petitioner asserts obviousness of claims 2 and 3 over Bradley, Polefko, and Zhu and over Bradley, Davis, and Zhu, but on pages 67 and 81 of the Petition, the Petitioner asserts obviousness over Bradley, Zhu, and Polefko, and over Bradley, Zhu, and Davis. For purposes of this Decision, the order in which the references is listed does not change our analysis on the merits.

Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1–14, 18–21	103[2]	Bradley,[3] Polefko[4]
2, 3	103	Bradley, Polefko, Zhu[5]
15–17, 22–24	103	Bradley, Polefko, Alataris[6]
1–14, 18–21	103	Bradley, Davis[7]
2, 3	103	Bradley, Davis, Zhu
15–17, 22–24	103	Bradley, Davis, Alataris

II. ANALYSIS

A. Legal Standards

A patent claim is unpatentable under 35 U.S.C. § 103 if the differences between the claimed subject matter and the prior art are such that the subject matter, as a whole, would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. 35 U.S.C. § 103; *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). "[W]hen a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, the combination must do more than yield a predictable result." *KSR*, 550 U.S. at 416 (citing *United States v. Adams*, 383 U.S. 39, 50–51 (1966)). The question of obviousness is resolved based on underlying factual determinations including: (1) the scope and content of

[2] The Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112-29, 125 Stat. 284, 287–88 (2011), amended 35 U.S.C. § 103. It is undisputed on this record that the priority date of the '460 patent is April 2, 2012. *See* Prelim. Resp. 6. Because the '460 patent was filed before the effective date of the relevant amendment, the pre-AIA version of § 103 applies.
[3] Bradley, US 2012/0083857 A1, pub. Apr. 5, 2012 (Ex. 1004, "Bradley").
[4] Polefko, US 9,358,390 B2, iss. June 7, 2016 (Ex. 1025, "Polefko").
[5] Zhu, US 2011/0054551A1, pub. Mar. 3, 2011 (Ex. 1024, "Zhu").
[6] Alataris, US 2010/0274316 A1, pub. Oct. 28, 2010 (Ex. 1005, "Alataris").
[7] Davis, US 2011/0093051A1, pub. Apr. 21, 2011 (Ex. 1027, "Davis").

the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) objective evidence of non-obviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

In an *inter partes* review, a petition must identify "with particularity, each claim challenged, the grounds on which the challenge to each claim is based, and the evidence that supports the grounds for the challenge to each claim." 35 U.S.C. § 312(a)(3) (2018); *see also* 37 C.F.R. § 42.104(b) (2018) (requiring a petition for *inter partes* review to identify how the challenged claim is to be construed and where each element of the claim is found in the prior art patents or printed publications relied upon).

B. Level of Ordinary Skill in the Art

Petitioner argues that a person of ordinary skill in the art (POSA) at the relevant times would have had a degree in 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, or greater than 5 years for a Bachelor's degree) researching or developing neural stimulation systems or other implantable medical devices. Pet. 19–20 (citing Ex. 1002 ¶ 21). Petitioner argues that a person of ordinary skill alternatively would have had an M.D. and experience practicing as a neurologist, neurosurgeon or anesthesiologist, with 2–3 years of experience in neural stimulation. *Id.* at 20 (citing Ex. 1002 ¶ 21). Petitioner argues that the person would have had general knowledge of implantable medical devices and various related technologies as of April 2, 2012. *Id.*

Patent Owner does not contest Petitioner's definition of the ordinary level of skill at this time but reserves the right to challenge Petitioner's formulation should trial be instituted. Prelim. Resp. 7.

On the record at this stage of the proceeding, we adopt Petitioner's undisputed definition.

C. Claim Construction

We construe each claim "in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent." 37 C.F.R. § 42.100(b) (2019). Under this standard, claim terms are generally given their plain and ordinary meaning as would have been understood by a person of ordinary skill in the art at the time of the invention and in the context of the entire patent disclosure. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) (*en banc*).

Petitioner asserts that the claims do not require construction. Pet. 19. Patent Owner does not propose any constructions but reserves the right to propose constructions should trial be instituted. Prelim. Resp. 7.

Given the lack of dispute on this record, we need not construe the claims at this time. *See Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) (claims are construed only to the extent necessary to resolve a dispute).[8]

D. Patent Owner's Arguments Regarding 35 U.S.C. § 314(a)

Patent Owner contends that the Board should deny institution under 35 U.S.C. § 314(a) because institution would be an inefficient use of Board resources. Prelim. Resp. 13. As detailed above, we authorized additional briefing from the parties on the issue of discretion under 35 U.S.C. § 314(a). We address Patent Owner's arguments as follows.

[8] We note that the Specification provides an express definition of some terms, e.g., "computer" and "controller." *See* Ex. 1001, 3:49–55.

1. Applicable Precedent[9]

Institution of an *inter partes* review under 35 U.S.C. § 314(a) is discretionary. *See Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2140 (2016) ("[T]he agency's decision to deny a petition is a matter committed to the Patent Office's discretion."). In exercising that discretion, the Board may consider the advanced state of a related district court proceeding, among other considerations, as a "factor that weighs in favor of denying the Petition under § 314(a)." *NHK Spring Co. v. Intri-Plex Techs., Inc.*, IPR2018-00752, Paper 8 at 20 (PTAB Sept. 12, 2018) (precedential); *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 at 5–6 (PTAB Mar. 20, 2020) (precedential) ("the *Fintiv* Order").

The precedential *Fintiv* Order identifies several factors to be considered in analyzing § 314(a) issues, with the goal of balancing efficiency, fairness, and patent quality. *See Fintiv* Order, Paper 11 at 5–6. These factors include: 1) whether a stay exists or is likely to be granted if a proceeding is instituted; 2) proximity of the court's trial date to the Board's projected statutory deadline; 3) investment in the parallel proceeding by the court and parties; 4) overlap between issues raised in the petition and in the parallel proceeding; 5) whether the petitioner and the defendant in the parallel proceeding are the same party; and 6) other circumstances and considerations that impact the Board's exercise of discretion, including the merits.

[9] This statement of applicable precedent is excerpted from *Supercell Oy v. Gree, Inc.*, IPR2020-00513, Paper 11 at 5–6 (PTAB June 24, 2020).

2. Procedural Background

The following facts are undisputed on this record. *See* Prelim. Resp. 8–13.

In May 2015, Boston Scientific Neuromodulation Corp. filed two petitions for *inter partes* review challenging the validity of Patent Owner's U.S. Patent No. 8,359,102 ("the '102 patent"). *See* IPR2015-01203, Paper 1; IPR2015-01204, Paper 1. The Board denied institution on both petitions. IPR2015-01203, Paper 10, 2; IPR2015-01204, Paper 10, 2.

In November 2016, Patent Owner sued Petitioner for patent infringement of six patents, including the '102 patent, in the U.S. District Court for the Northern District of California. Ex. 1012, 31. Petitioner did not file any petitions for *inter partes* review for Patent Owner's five other asserted patents.

Less than two weeks later, Petitioner sued Patent Owner for infringement of ten patents in the U.S. District Court for the District of Delaware ("first Delaware lawsuit"). *Boston Scientific Corp. and Boston Scientific Neuromodulation Corp. v. Nevro Corp.*, Case No. 1:16-cv-01163-UNA (D. Del., filed Dec. 9, 2016) (Ex. 1013, 1).

Five months later, Patent Owner began filing petitions for *inter partes* review of Petitioner's then-remaining eight asserted patents. In November 2017, Patent Owner moved to stay the case in view of the pending *inter partes* review proceedings. The Court denied the motion without prejudice. Ex. 2017. The Board subsequently instituted review of every asserted claim of two of Petitioner's patents, including U.S. Patent No. 6,895,280 ("the '280 patent"). Patent Owner Nevro renewed its motion to stay, which the Court granted. Ex. 2016.

The Board reached a final written decision on the claims for the two challenged patents, finding certain claims unpatentable, and the Federal Circuit subsequently affirmed. *See Boston Sci. Neuromodulation Corp. v. Nevro Corp.*, 813 F. App'x 572 (Fed. Cir. 2020); *Boston Sci. Neuromodulation Corp. v. Nevro Corp.*, 813 F. App'x 543 (Fed. Cir. 2020).

Petitioner filed a second lawsuit in April 2018 against Patent Owner in the District of Delaware ("second Delaware lawsuit") alleging infringement of four patents, trade secret misappropriation, and tortious interference. *Boston Scientific Corp. and Boston Scientific Neuromodulation Corp. v. Nevro Corp.*, Case No. 1:16-cv-00644-GMS (D.Del., filed Apr. 27, 2018) (Ex. 2018). Nearly three months later, Petitioner filed a First Amended Complaint dropping three of the originally asserted patents and adding eight other asserted patents. Ex. 1018. Patent Owner filed a motion to dismiss Petitioner's First Amended Complaint. Ex. 2019. In November 2019, the Court granted Patent Owner's motion to dismiss Petitioner's direct infringement claims as to eight of the nine asserted patents, indirect infringement and willful infringement claims as to all patents, and tortious interference claim. Ex. 2020, 27.

On December 9, 2019, Patent Owner answered the claims that were not dismissed and asserted counterclaims for infringement of five of its own patents, including the '460 patent. Ex. 1019. Petitioner subsequently filed a Second Amended Complaint, and Patent Owner filed its Answer and Counterclaims to Petitioner's Second Amended Complaint.

Patent Owner filed petitions for *inter partes* review of seven of Petitioner's nine originally asserted patents. *See* IPR2019-01216; IPR2019-01284; IPR2019-01313; IPR2019-01315; IPR2019-01318; IPR2019-01340;

IPR2019-01341. In January 2020, the Board instituted review of all seven patents.

After the Board instituted review of Petitioner's seven patents, Patent Owner moved to stay Petitioner's patent infringement and trade secret claims. Ex. 2021.

On June 22, 2020, the Court stayed Petitioner's patent infringement claims from the second Delaware lawsuit, and consolidated Petitioner's remaining patent claims from the first Delaware lawsuit with its trade secret claim and Patent Owner's counterclaims. Ex. 1010, 21:7–11, 22:13–20, 34:7–17.

Petitioner has now filed the petition in this proceeding against the '460 patent as well as petitions for *inter partes* review against the '665 patent (IPR2020-01563) and the '461 patent (IPR2021-00295) (i.e., three of the five patents alleged to be infringed in Patent Owner's counterclaims from the second Delaware lawsuit).

The District Court has scheduled a jury trial for October 18, 2021. Ex. 1020, 21. The jury trial would encompass Petitioner's remaining patent claims from the first Delaware lawsuit as well as Petitioner's trade secret claim and Patent Owner's counterclaims from the second Delaware lawsuit. *See* Ex. 1010, 21:7–11, 22:13–20, 34:7–17. The District Court's *Markman* hearing was postponed from January 6, 2021, to February 11, 2021. Prelim. Reply 3 (citing Ex. 1037); Prelim. Sur-reply 3.

Petitioner has submitted a stipulation that if an *inter partes* review is instituted, Petitioner will not pursue in the District Court any grounds that Petitioners raised or reasonably could have raised in the *inter partes* review. Prelim. Reply 3 (citing Ex. 1011).

In summary, the dispute between the parties has an extended history of considerable litigation. Thus far, the parties have been involved in three District Court proceedings (two of which have been consolidated into the present parallel proceeding in the District of Delaware and a portion of which has been stayed pending *inter partes* review proceedings) and multiple *inter partes* reviews and appeals therefrom.

3. Analysis

With this background, we consider each of the factors set forth in the precedential *Fintiv* Order.

a) Factor 1: whether the court granted a stay or evidence exists that one may be granted if a proceeding is instituted.

Petitioner asserts that "[t]here is ample evidence that the court will stay Nevro's counterclaims if the Board institutes review here." Pet. 9. Petitioner argues that because Petitioner's affirmative patent claims from the 2018 litigation are currently stayed, there will be another as-of-yet unscheduled trial over at least some of Petitioner's stayed claims, and therefore the court has a readily-available option to stay Patent Owner's counterclaims. *Id.* at 8–9.

Patent Owner argues that the court's prior grants of stays were under different circumstances in which an *inter partes* review had been instituted on the '280 patent, which comprised 84% of Petitioner's damages claim and after the soon-to-retire Judge Sleet expressed concerns over the availability of the next judge who would preside over the case. Prelim. Resp. 9 (citing Ex. 1022, 7:13–8:24), 14. Patent Owner also argues that Petitioner ignores evidence that strongly suggests the court will not stay Patent Owner's counterclaims. *Id.* Patent Owner asserts that Judge Connolly cautioned Petitioner to "think about it" when Petitioner informed the court that it

planned to move for a stay of Patent Owner's counterclaims. *Id.* at 15 (citing Ex. 1010, 34:19–35:2)[10]. Patent Owner also argues that the case will be at a late stage because it is likely that by the time an institution decision issues, there will have been a claim construction hearing conducted, a claim construction order issued, fact discovery will have closed, and the parties will be working on preparing expert reports. *Id.* at 15–16 (citing, e.g., Ex. 1020, 20–21; *HIP, Inc. v. Hormel Foods, Corp.*, No. 18-615-CFC, 2019 WL 7667104, at *1 (D. Del. May 16, 2019) (denying motion to stay pending IPR where parties have engaged in "substantial amount of discovery" and claim construction already completed). Subsequent to the Preliminary Response, the District Court held a *Markman* hearing and issued a *Markman* Order. *See* Ex. 3001. Patent Owner argues that the timing of these *inter partes* reviews is accordingly different from the previous *inter partes* reviews that resulted in a stay.

Petitioner responds that Patent Owner has twice successfully moved for stays in the district court proceedings based on parallel *inter partes* reviews. Prelim. Reply 5. Petitioner adds that in the January 6, 2021, hearing, the court stated: "I'm also worried about spending court time trying

[10] The colloquy with the Court was as follows:

> MR. WOLF: Your Honor, just to put our cards on the table, we expect to file a similar motion to stay once we get the IPRs on file consistent with the Court's jurisprudence, but we have not --
>
> THE COURT: Yes. Just think about it. I mean, one of the disturbing things of this case is there seemed like a lot of dilatory tactics, and it's hard to figure out who the bad actor is with respect to certain tactics, so think about it.

Ex. 1010, 34:19–35:2 (*quoted in* Prelim. Resp. 15).

to resolve these issues when everything could change come March if there's an institution of an IPR, and I don't want to waste time on Markmans unnecessarily." *Id.* (citing Ex. 1038, 75:8–76:13).

Patent Owner replies that "[t]he Court's statement that it was worried about spending time on *Markman* when things could change if these IPRs are instituted is irrelevant in view of the fact that the Court decided to proceed with claim construction on February 11, 2021." Prelim. Sur-reply 5 (citing Ex. 1038, 84:3–9). Patent Owner's argument is bolstered by the fact that the Court not only held the *Markman* hearing, but also entered a *Markman* order. Ex. 3001.

Although the District Court previously issued a stay as to certain of Petitioner's patent claims, we agree with Patent Owner that it is difficult to extrapolate to Patent Owner's counterclaims because the court's stay decision was based in part on Judge Sleet's uncertainty at the time as to a next judge's availability. *See* Ex. 1022, 8:17–20. We decline to speculate on how the District Court would rule on a stay motion for Patent Owner's counterclaims.

We decline to speculate based on the record in this case, which is ambiguous, as to whether the District Court will grant a stay pending this *inter partes* review. For these reasons, we determine that the facts underlying this factor are neutral.

b) Factor 2: proximity of the court's trial date to the Board's projected statutory deadline for a final written decision

A jury trial in District Court is currently scheduled for October 18, 2021. Ex. 1020, 21. Should *inter partes* review be instituted, the statutory deadline for the final written decision will be one year from the date of our

Decision in March of 2022. Thus, the jury trial is scheduled to commence approximately 5 months before the statutory deadline.

Patent Owner asserts that there is no evidence that the court's trial date will not hold. Prelim. Resp. 17 (citing *Fintiv*, Paper 15, 13). Patent Owner's Preliminary Response stated that neither Petitioner nor Patent Owner have sought or been granted an extension of any date (Prelim. Resp. 17), although the court did reschedule the *Markman* hearing from January 6, 2021, to February 11, 2021 (Prelim. Reply 3 (citing Ex. 1037)).

Petitioner asserts that, during a motions hearing on January 6, 2021, the District Court and parties addressed broader case management issues, including whether Patent Owner's counterclaims (including infringement of the '460 Patent) should be tried in October 2021 or stayed. Prelim. Reply 3 (citing Ex. 1038, 80:12–81:25, 83:11–84:9). Petitioner asserts that Patent Owner has disclosed its intent to move to amend its theories in its counterclaims, and the District Court has commented, at hearings on January 6 and 13, 2021, that allowing Patent Owner to amend its counterclaims "may affect whether or not the October trial date would include the "[460 Patent] counterclaims" and that Patent Owner "runs the risk that it loses its trial date." Prelim. Reply 3–4 (citing Ex. 1038, 83:11–84:2; Ex. 1039, 11:16–12:8).

Patent Owner replies that the District Court, on January 6 and January 13, 2021, declined to extend the discovery and trial schedule for Patent Owner's counterclaims, and that the District Court only delayed the *Markman* hearing by a few weeks so that the parties could narrow the number of disputed terms from 29 to 10. Prelim. Sur-reply 4–5 (citing Ex. 1038, 83:9–14, 84:3–9; Ex. 1039, 16:9–24), *id*. at 4 n.1 (citing Ex. 1037).

In the absence of more concrete evidence, we decline to speculate as to whether the District Court would delay the trial on Patent Owner's counterclaims in the event that Patent Owner seeks to amend its counterclaims. Rather, because the jury trial date has not been delayed and is set five months before the final written decisions would be due, this factor weighs in favor of the exercise of our discretion to deny institution in this proceeding. *NHK Spring*, Paper 8 at 20; *Fintiv Order*, Paper 11 at 5–6. Nevertheless, we consider all factors holistically and do not rely upon this factor in isolation. *Fintiv Order*, Paper 11 at 6.

c) *Factor 3: investment in the parallel proceeding by the court and the parties*

Petitioner asserted in the Petition that this factor weighs in favor of institution based on the investment in the litigation, which was in early stages of fact discovery at the time of the Petition. Pet. 10 (citing *Sand Revolution II, LLC v. Continental Intermodal Grp.—Trucking LLC*, IPR2019-01393, Paper No. 24 (PTAB June 16, 2020) (informative)).

Patent Owner asserts that the parties have each already served and responded to over 20 interrogatories and hundreds of document requests, and each produced over 450,000 pages of documents. Prelim. Resp. 19. Patent Owner asserts that the document production deadline passed on November 20, 2020, that the parties have already completed claim construction briefing (i.e., opening, responsive, reply, and sur-reply briefs) on 29 terms related to Patent Owner's counterclaim patents, that Patent Owner submitted the declaration of its expert in support of claim construction, and that Petitioner took the deposition of Patent Owner's expert. Prelim. Resp. 19 & n.6 (citing Ex. 1020, 20; Ex. 2010; Ex. 2011). Patent Owner also asserts that each party's expert has spent multiple days

reviewing the other party's source code. Patent Owner asserts that the District Court, in consolidating the first and second Delaware lawsuits, stated that "[t]he parties and this Court have already invested substantial resources in setting schedules, conducting discovery, construing claims and engaging in motion practice for both of these cases." Prelim. Resp. 20 (citing Ex. 1010, 24:7–10) (emphasis omitted). Patent Owner asserts that by the time of an institution decision, the claim construction hearing will have been held, a claim construction order likely issued,[11] the parties will have completed fact discovery, made their final elections of asserted claims and asserted prior art, and be just days away from serving opening expert reports. *Id.* (citing Ex. 1020, 20–21). Patent Owner's predictions about the progress in the litigation have been accurate. *See, e.g.*, Ex. 3001. Further, according to the District Court's scheduling order, the cut off for fact discovery will have been February 18, 2021, and opening expert reports will be due on March 19, 2021. *See* Ex. 1020, 21.

We determine that the District Court and the parties have invested substantial resources in the parallel proceeding through claim construction and fact discovery, and will have invested some resources in expert discovery. The parties have briefed claim construction, the Court has held a *Markman* hearing, and the Court has issued a *Markman* Order. *See* Ex. 3001. We accept Patent Owner's undisputed representation that the parties have each already served and responded to over 20 interrogatories and hundreds of document requests, and each produced over 450,000 pages of documents. *See* Prelim. Resp. 19. We have not been directed, however, to any persuasive evidence that the totality of this discovery concerns the

[11] A claim construction order has since issued. *See* Ex. 3001.

validity or patentability of the '460 patent, which is the only issue in the proceeding before us. Further, Patent Owner has filed a motion to dismiss Petitioner's counterclaim for inequitable conduct. *See* Ex. 3002.

We further note that the dispute between the parties has a long history spanning almost six years, with three District Court proceedings (two of which have been consolidated into the present parallel proceeding in the District of Delaware) and multiple *inter partes* reviews and appeals therefrom, as detailed in the background section above.

For the reasons above, we find that this factor weighs in favor of exercising discretion to deny institution under 35 U.S.C. § 314(a).

d) Factor 4: overlap between issues raised in the petition and in the parallel proceeding

Petitioner initially asserts that it has stipulated that if the Board institutes review, Petitioner will not pursue district court invalidity challenges on the same grounds raised in this proceeding. Pet. 10 (citing Ex. 1011). Petitioner argues that this narrow stipulation lessens concerns of duplicative efforts and conflicting decisions. *Id.* (citing *Sand Revolution*, IPR2019-01393, Paper No. 24, at 11–12; *Apple v. Seven Networks*, IPR2020-00266, Paper 12, at 15). Petitioner asserts that any further AIA challenges to the '460 patent are now barred under 35 U.S.C. 315. *Id.* at 11.

Patent Owner responds that Petitioner's narrow stipulation was unlike the broader stipulation in *Sotera* for grounds that could reasonably have been raised. Prelim. Resp. 22 n.8 (citing *Sotera Wireless, Inc. v. Masimo Corp.*, IPR2020-01019, Paper 12, 18-19 (PTAB Dec. 1, 2020) (precedential)). Patent Owner also argues that Petitioner's challenges here largely overlap with Petitioner's invalidity contentions in District Court, as follows: Bradley and Polefko like Grounds 1–3 (Ex. 2002, 9 (ground vii)); Polefko

and Zhu like Ground 2 (*id.* (ground viii.)); Polefko and Alataris like Ground 3 (*id.* (ground ix.)); Bradley and Davis like Grounds 4–6 (*id.* ground x.)); Davis and Zhu like Ground 5 (*id.* (ground xi.)); Davis and Alataris like Ground 6 (*id.* (ground xii.)); and Bradley and Alataris (*id.* (ground vxii.)). *Id.* at 22–23. Patent Owner also argues Petitioner's challenges to the '665 patent in IPR2020-01563 also overlap with Petitioner's invalidity contentions for that patent in District Court. *Id.* at 23 (citing Ex. 1002, 7–8 (grounds ii–iv, vi–ix, xii–xix, xxii)).

With its reply, Petitioner submitted a broader stipulation that it will forgo in District Court any grounds that Petitioner raised or reasonably could have raised in the *inter partes* review. Prelim. Reply 2 (citing Ex. 1036).

Patent Owner responds that Petitioner's invalidity grounds in the litigation, which overlap with the challenges raised here, include nine obviousness grounds based on a combination of a prior art system (e.g., Boston Scientific's PrecisionTM Plus SCS System) and the same prior art references used here. Although Petitioner cannot allege the grounds of invalidity from the District Court in this proceeding, i.e., because they include a prior art system, those invalidity grounds, nevertheless, substantially overlap with the grounds of unpatentability asserted here. *See* Prelim. Sur-reply 2. Patent Owner argues that Petitioner thereby "aims to both avoid its stipulation while also pursuing the same invalidity arguments before the Board and the district court." *Id.* at 3.

Under the *Fintiv* Order, "if the petition includes materially different grounds, arguments, and/or evidence than those presented in the district court, this fact has tended to weigh against exercising discretion to deny institution under [*NHK Spring*]." *Fintiv* Order, Paper 11 at 12–13; *see also Sotera*, Paper 12, at 18–19 ("Petitioner's stipulation here mitigates any

concerns of duplicative efforts between the district court and the Board, as well as concerns of potentially conflicting decisions.").

Considering that Petitioner has agreed to be bound by a stipulation that is substantively the same as the stipulation addressed in *Sotera*, we follow the *Sotera* precedent in finding that this factor weighs strongly against discretionary denial. *See Sotera Wireless, Inc. v. Masimo Corp.*, IPR2020-01019, Exhibit 1038, 7–8. We decline Patent Owner's invitation to look behind Petitioner's stipulation and weigh similarities and differences of the invalidity arguments here and in the District Court. Accordingly, we consider the stipulation to address any concerns about overlap between the issues presented in the two fora.

e) Factor 5: whether Petitioner and the defendant in the parallel proceeding are the same party

This *Fintiv* Order factor suggests that "[i]f a petitioner is unrelated to a defendant in an earlier court proceeding, the Board has weighed this fact against exercising discretion to deny institution under *NHK*." *Fintiv* Order, Paper 11 at 13–14. Here, Petitioner is a party in the present parallel proceeding in District Court. The fact that the Petitioner here is the same as the defendant in the parallel proceeding weighs in favor of the exercise of discretion to deny institution.

f) Factor 6: other circumstances that impact the Board's exercise of discretion, including the merits

Based on our review of the arguments and evidence on the merits, we determine that the merits in this case do not weigh so strongly in either direction that it would affect our analysis under *Fintiv*. We simply determine that Petitioner has demonstrated a reasonable likelihood that it

would prevail at trial. Accordingly, this factor is neutral in exercising discretion.

g) Holistic Analysis of Fintiv Order Factors

As noted in the *Fintiv* Order, we consider six factors when taking "a holistic view of whether efficiency and integrity of the system are best served by denying or instituting review." *Fintiv* Order, Paper 11 at 6. We recognize that the parties and the District Court have invested substantial time and resources in the related litigation. The District Court trial is scheduled for five months before a final written decision would occur in this proceeding. Nevertheless, in view of Petitioner's stipulation not to pursue grounds in the District Court that Petitioner raised or reasonably could have raised in this *inter partes* review, and after weighing the factors together, we decline to exercise discretion to deny the Petition under 35 U.S.C. § 314.

E. Obviousness of Claims 1–14 and 18–21 over Bradley and Polefko

Petitioner contends that claims 1–14 and 18–21 are obvious over Bradley and Polefko. Pet. 36–67. Petitioner relies on the declaration of Richard T. Mihran, Ph.D. Ex. 1002. Patent Owner disagrees. *See* Prelim. Resp. 30–39.

1. Bradley

Bradley is titled "Tissue Stimulation System and Method with Anatomy and Physiology Driven Programming" and relates "to tissue stimulation systems, and more particularly, to tissue stimulation systems for programming tissue stimulation leads." Ex. 1004, code (54), ¶ 2. Bradley was assigned to Boston Scientific Neuromodulation Corp. *See id.*, code (73).

Bradley describes that then-existing tissue stimulation systems may have had sixteen or thirty-two electrodes, with millions of stimulation

parameter sets available for programming. *See id.* ¶ 8. To facilitate selection of parameters, the clinician generally would program the neurostimulator through a computerized programming system. *See id.* ¶ 9. Bradley identified a drawback in one of the useful existing programming systems, i.e., that targeting specific regions could be challenging to inexperienced users who might be unsure as to the set of stimulation parameters, and who might require an extended amount of time to find an effective set of stimulation parameters, or who might not find an effective set of stimulation parameters. *See id.* ¶ 13.

Bradley discloses an external control device for use with a tissue stimulation device and at least one tissue stimulation lead having a plurality of electrodes implanted within a patient. *Id.* ¶ 14. The external control device comprises a user interface configured for allowing a user to enter first information defining a therapeutic indication (e.g., chronic pain) and second information defining the location of the tissue stimulation lead relative to an anatomical reference (e.g., a verterbral level and/or mediolateral location relative to the spine) and optionally the type and number of the tissue stimulation leads and the positional information of the tissue stimulation leads to each other. *See id.* ¶ 15. The external control device further comprises circuitry for analyzing the information and generating a stimulation parameter set and output circuitry (e.g., telemetry circuitry) for transmitting the set to the tissue stimulation device. *Id.* ¶ 16.

In one embodiment, Bradley discloses that the external control device further comprises memory storing a database, which may further contain a plurality of pulsewidth values respectively corresponding to the reference therapeutic indications. *Id.* ¶ 17–18. The selecting pulse width value will then be included within the generated stimulation parameter set(s). *Id.* ¶ 18.

Figure 8 of Bradley is reproduced below:

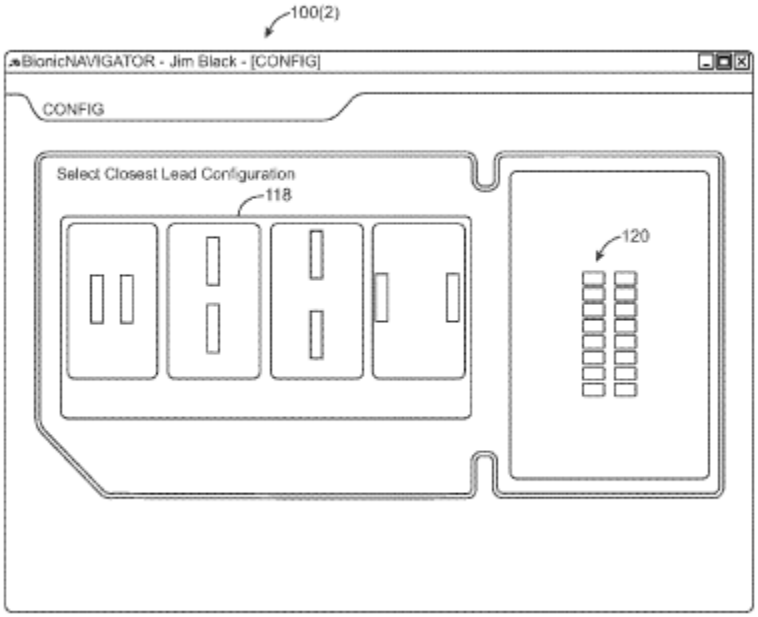

FIG. 8

Figure 8 is a lead configuration screen that can be displayed by the clinician's programmer. *Id.* ¶ 30, 32. In the conventional case where a pair of percutaneous leads are to be used, lead configuration screen 100(2) generated by clinician's programmer 18 includes four different graphical configurations 118 that can be clicked on to select a specific lead configuration (e.g., a closely spaced side-by-side configuration, a closely spaced top-bottom configuration, a widely spaced top-bottom configuration, or a widely spaced side-by-side configuration) that best matches the actual configuration of implanted leads 12. *Id.* ¶ 59.

Alternatively, rather than inputting the lateral spacing between the leads 12 using the lead configuration screen 100(2), the positions of the tissue stimulation leads 12 relative to each other can be determined based on the measured electrical parameters in a conventional manner. *Id.* ¶ 61.

Figure 9 of Bradley is reproduced below:

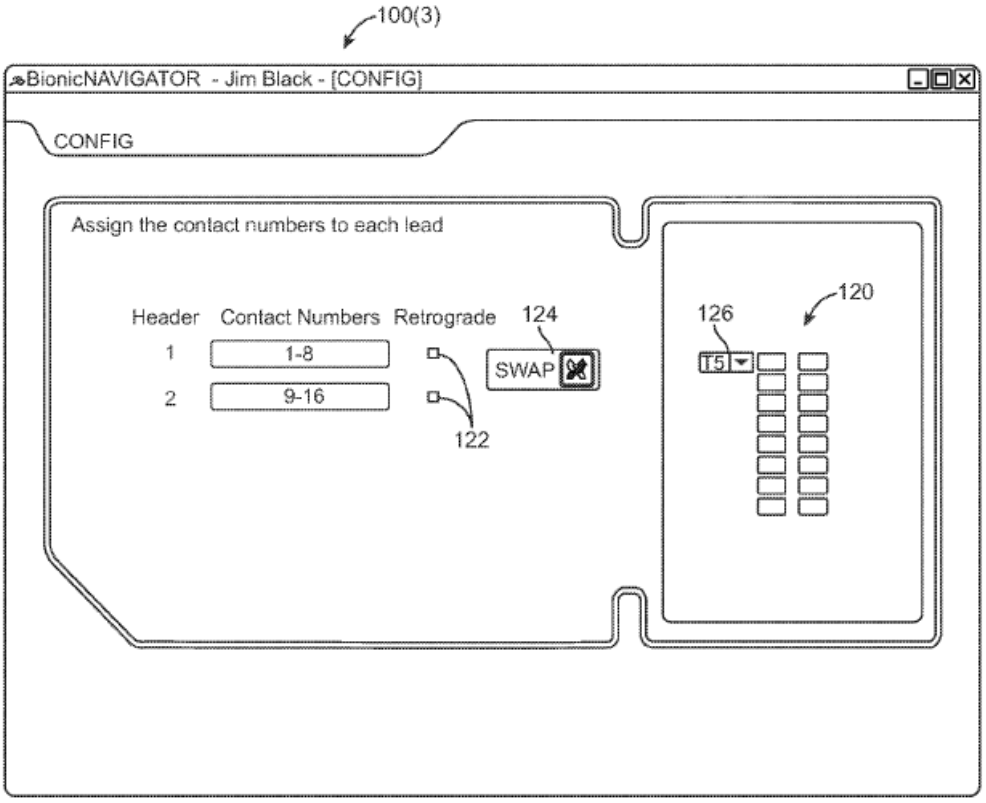

FIG. 9

Figure 9 is a lead orientation screen that can be displayed by the clinician's programmer. *Id.* ¶ 33. As shown in Figure 9, a lead orientation screen 100(3) generated by clinician's programmer 18 allows the clinician to select the lead direction, assign the electrode numbers to each lead, and the vertebral position of the leads. *Id.* ¶ 62.

2. Polefko

Polefko is titled "Configuring Electrical Stimulation to Treat a Patient" and relates to "a stimulation system, such as a spinal cord stimulation (SCS) system, having a tool for programming an electrical stimulation generator, such as an implantable pulse generator (IPG)." Ex. 1025, code (54), 1:6–9. Polefko also relates to "a method for developing a program for the system." *Id.* at 1:9–11.

Polefko describes a similar problem in the art as Bradley described, i.e., the large number of electrode and parameter combinations required a substantial amount of time by clinicians for establishing a manually created program for providing therapeutic spinal cord stimulation. *See id.* at 1:31–34. Polefko concluded that a manual approach for creating a program was not an optimal solution for a spinal cord stimulation system (SCS) system. *Id.* at 1:34–36.

Polefko discloses a stimulation system including an electrical stimulation generator, an implanted medical lead implanted in the patient and coupled to the electrical stimulation generator, and a programmer with a display screen. *Id.* at 1:46–49. The method includes displaying an image of a tissue (such as a spinal column) on the display screen of the programmer and determining a position of the implanted medical lead with respect to the tissue. *Id.* at 1:49–53.

According to Polefko, the initial stimulation field has an initial boundary depicted on the display screen and the initial target stimulation area has an initial target boundary depicted on the display screen. *Id.* at 2:44–47. The programmer further receives graphical manipulations of the initial boundary and the initial target boundary to define an altered stimulation field and an altered target stimulation area. *Id.* at 2:47–50. The programmer then determines stimulation parameters to drive the implanted medical lead to generate the altered stimulation field and the altered target stimulation area. *Id.* at 2:52–55.

Method 510 begins in step 510a with displaying an image of spinal column 560, as illustrated in Figure 12A (not reproduced here). *Id.* at 13:5–6. According to Polefko, "the user may specify patient information,

such as height, weight, etc. such that the image of spinal column 560 is scaled to be anatomically correct." *Id.* at 13:8–10.

Figure 13 of Polefko is reproduced below:

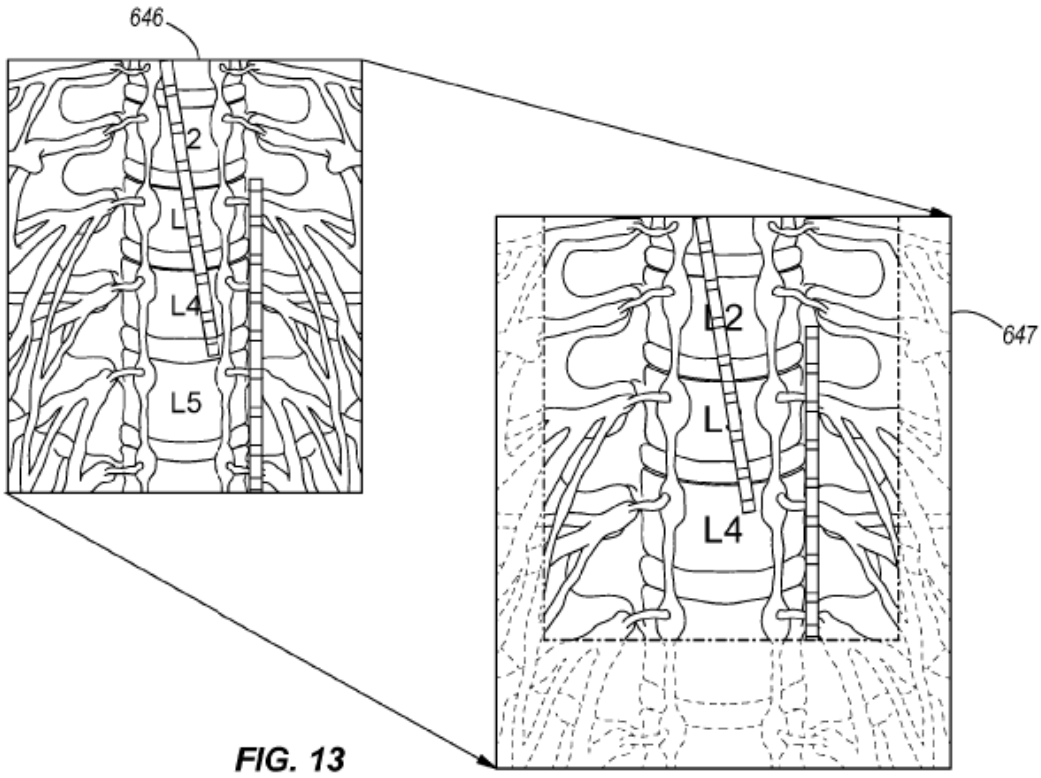

FIG. 13

Figure 13 illustrates an original image and a scaled image of a spinal column. *Id.* at 3:22–23. Polefko discloses that scaling an image enables a particular image to be used to represent patients of various sizes. *Id.* at 14:66–15:1. The scaling parameter can be sent with an identifier to IPG (implantable pulse generator) 115. *See id.* at 1:9, 14:41, 14:64–65.

In step 510b, the user inputs lead positioning input, and the user selects one or more leads. *Id.* at 13:20–27. Once the one or more leads are selected, in step 510c, they are overlaid on the image of the spinal column 560. *Id.* at 13:28–30.

In some instances, when an actual image of the patient, such as an X-ray or fluoroscope image, is received by CP 130 in step 510a, CP 130 may use image processing in step 510b to analyze the received image to identify the actual lead position, orientation, and size. *Id.* at 13:61–65. Thereafter, in step 510c, spinal column 560 and leads 575a and 575b, as identified, are displayed on the screen 375. *Id.* at 13:65–14:2.

3. Zhu[12]

Zhu is titled "Method and Apparatus for Determining Relative Positoning between Neurostimulation Leads" and relates to "tissue stimulation systems, and more particularly, to apparatus and methods for determining the position of neurostimulation leads." Ex. 1024, code (54), ¶ 1.

Zhu discloses a then-existing problem in the art of implanted SCS systems. In particular, when lead migration occurs, reprogramming the IPG requires knowledge of the relative positions between the leads in order to properly place the poles of the generated electrical field. *See id.* ¶¶ 8–9. Such information was not readily available to the programmer unless fluoroscopic imaging is performed, which involves ionizing radiation, adds time and cost, and requires bulky instrumentation, which limited its use in the clinical setting and effectively prevented its use outside of the clinical setting. *Id.* ¶ 9.

Zhu discloses a method whereby CP 18 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

[12] Although this ground is based on Bradley and Polefko, Petitioner argues that Zhu's teaching is incorporated by reference into Bradley. Pet. 53; *see* discussion of claims 2 and 3, *infra*.

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. *Id.* ¶ 61.

4. Analysis of Independent Claim 1

a) preamble

Petitioner argues that Bradley discloses "tissue stimulation systems" for treating a patient. Pet. 44 (citing Ex. 1004 ¶¶ 2, 14; Ex. 1002 ¶ 137). Patent Owner does not present arguments in the Preliminary Response addressing the specific merits of Petitioner's contention. *See* Prelim. Resp. 29–39.

On the record at this stage of the proceeding, we determine that Petitioner has made an adequate showing. In particular, Bradley discloses tissue stimulation leads 12(1), with eight electrodes each, and IPG 14 that delivers the electrical stimulation energy in the form of a pulsed electrical waveform to electrode array 26 in accordance with a set of stimulation parameters programmed into IPG 14. Ex. 1004 ¶¶ 44–45.

b) "a computer-readable medium having instructions that when executed"

Petitioner argues that Bradley discloses a computer-readable medium having instructions. Pet. 44 (citing Ex. 1004 ¶ 55; Ex. 1002 ¶ 138–140). Patent Owner does not present arguments in the Preliminary Response addressing the specific merits of Petitioner's contention. *See* Prelim. Resp. 29–39.

On the record at this stage of the proceeding, we determine that Petitioner has made an adequate showing. Bradley discloses that its Bradley's CP 18 generally includes a processor 82 and memory 84 that stores a stimulation programming package 86, which can be executed by

processor 82 to allow the user to program the IPG 14 and RC [remote control] 16. *Id.* ¶ 55.

c) *"receive a first input corresponding to a location of a signal delivery device implanted in a patient"*

Petitioner argues that Bradley's CP provides a number of user interfaces that allow it to receive the claimed first input. Pet. 44–46 (citing Ex. 1004 ¶ 57, 59–63; Ex. 1002 ¶ 143). Patent Owner does not present arguments in the Preliminary Response addressing the specific merits of Petitioner's contention. *See* Prelim. Resp. 29–39.

On the record at this stage of the proceeding, we determine that Petitioner has made an adequate showing. In particular, Bradley discloses that lead configuration screen 100(2) generated by clinician's programmer 18 includes four different graphical configurations 118 that can be clicked on to select a specific lead configuration (e.g., a closely spaced side-by-side configuration, a closely spaced top-bottom configuration, a widely spaced top-bottom configuration, or a widely spaced side-by-side configuration) that best matches the actual configuration of implanted leads 12. Ex. 1004 ¶ 59. Additionally, lead orientation screen 100(3) generated by clinician's programmer 18 allows the clinician to select the lead direction, assign the electrode numbers to each lead, and the vertebral position of the leads. *Id.* ¶ 62. Lead orientation screen 100(3) has vertebral location pull down menu 126 next to graphical electrode representation 120 that a clinician can use to indicate the vertebral position of the leads (e.g., C1–C7.5, T1–T12.5, L1–L5.5, S1–S5). *Id.* Additionally, drag-and-drop lead screen 100(4) allows the user to drop the respective virtual lead 12′ at the representation of the vertebra corresponding to the location of the actual lead 12 relative to the spine. *See id.* ¶ 63.

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"

Petitioner argues that the selected vertebral level from Bradley's 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. Pet. 47 (citing, e.g., Ex. 1004 ¶¶ 62, 63, 70; Ex. 1002 ¶¶ 148–149). Patent Owner does not present arguments in the Preliminary Response addressing the specific merits of Petitioner's contention. *See* Prelim. Resp. 29–39.

On the record at this stage of the proceeding, we determine that Petitioner has made an adequate showing. Bradley discloses that, with lead orientation screen 100(3), "CP 18 allows the clinician to select the lead direction, assign the electrode numbers to each lead, and the vertebral position of the leads." Ex. 1004 ¶ 62. Bradley also discloses that, with lead orientation screen 100(4), the user can drop the respective virtual lead 12′ at the representation of the vertebra corresponding to the location of the actual lead 12 relative to the spine. *See id.* ¶ 63.

e) "receive a second input corresponding to a medical indication of the patient"

Petitioner argues that Bradley teaches that that the CP can receive inputs identifying patient medical indications such as areas of pain. Pet. 48 (citing Ex. 1004 ¶ 57–58, 65; Ex. 1002 ¶ 154–155). Patent Owner does not present arguments in the Preliminary Response addressing the specific merits of Petitioner's contention. *See* Prelim. Resp. 29–39.

On the record at this stage of the proceeding, we determine that Petitioner has made an adequate showing. In particular, Bradley discloses that execution of 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. 1004 ¶ 57.

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"

Petitioner argues that 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 by inputting the patient's height and weight. Pet. 49 (citing, e.g., Ex. 1025, 12:32–36, 13:5–14:7, Figs. 10, 12A–I; Ex. 1002 ¶¶ 157–159). Patent Owner argues that Polefko's disclosure fails to satisfy the claim because Polefko does teach that a user can input a "*requested change in axial length*" because the user does not request to change the axial length. Prelim. Resp. 34 (citing Ex. 1025, 13:8–10).

On the record at this stage of the proceeding, we determine that Petitioner has made an adequate showing. The claim does not require a "requested change in axial length" but rather requires an input "*corresponding to* a requested change in axial length." Polefko discloses that 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. Ex. 1025, 12:36–44. Polefko discloses 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." *Id.* at 13:8–10. On this record, we determine that a person of ordinary skill reading Polefko would understand the input height and weight data to correspond to a requested change in axial length.

Petitioner argues that it would have been obvious to a person of ordinary skill to combine the teachings of Polefko and Bradley because 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. Pet. 36–44 (citing, e.g., Ex. 1025, 12:33–44, 12:53–60, 13:5–10, 14:64–15:8; Ex. 1002 ¶¶ 123–130). Petitioner also argues that U.S. Patent No. 8,913,804 to 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, which would have further motivated a person of ordinary skill to combine Polefko's scaling technique with Bradley. Pet. 43 (citing Ex. 1014, 6:52–7:13; Ex. 1002 ¶ 134).[13]

Patent Owner argues that Petitioner has not articulated an adequate reason to combine the teachings of Bradley with Polefko, that Petitioner's arguments are based on improper hindsight, and that it would not have been necessary to look to Polefko to create effective stimulation of target spinal tissue and to minimize non-target stimulation. Prelim. Resp. 30 (citing Pet. 37). Patent Owner argues that in Bradley's paresthesia-based system, the clinician can get feedback from the patient about where they feel the paresthesia and whether the paresthesia is being applied to the right area, and there is no need for the programmer to precisely align the leads with the computer-based image of the vertebra. Prelim. Resp. 30–31 (citing Ex. 1004

[13] We note that the section of the Petition asserting a motivation to combine Bradley with Polefko also asserts that Davis teaches that accurately defining the location of a lead relative to an anatomical target aids in accurately programming stimulation fields. Pet. 43 (citing, e.g., Ex. 1027 ¶ 19).

¶¶ 9–11). Patent Owner argues that the '460 patent, by contrast, teaches paresthesia-free therapy. Pet. 31 (citing, e.g., Ex. 1001, 29:12–15, 3:32–35).

On the record at this stage of the proceeding, we determine that Petitioner has made an adequate showing. In particular, Polefko teaches that 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. Ex. 1025, 12:40–44. Polefko teaches that accurately modeling the actual placement of the medical leads within the patient assists a user in stimulation programming. Ex. 1025, 12:58–60.

Although Patent Owner argues that Bradley discloses other mechanisms of ensuring accuracy, on this record we determine that Petitioner has established a reasonable likelihood that a person of ordinary skill would have looked to an additional mechanism to increase the locational accuracy. *Cf. In re Ethicon*, 844 F.3d 1344, 1351 (Fed. Cir. 2017) ("The normal desire of artisans to improve upon what is already generally known can provide the motivation to optimize variables . . . .") (citing *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007) ("A person of ordinary skill is also a person of ordinary creativity, not an automaton.")). Patent Owner argues that the '460 patent teaches paresthesia-free therapy, but the '460 patent itself teaches in one embodiment that "paresthesia testing can be used to correlate the location of the signal delivery device . . . even if higher frequency signals are used during therapy." Ex. 1001, 32:23–28. Thus, we are not persuaded that the use of paresthesia for identifying the location of electrodes is incompatible with the '460 patent.

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"

Petitioner argues that Bradley discloses that 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. Pet. 50 (citing, e.g., Ex. 1004 ¶¶ 65, 66–68, 71, 79, Fig. 11; Ex 1002 ¶¶ 160–161).

Patent Owner argues that Bradley's CP 18 automatically generates stimulation parameters that allow the user to more efficiently program the IPG 14 (or ETS 20), but the identified embodiments do not disclose delivery of "a pulsed electrical signal…to the patient" that is "in accordance with" the automatically generated stimulation parameters. Prelim. Resp. 38–39 (citing Ex. 1004 ¶ 65).

Although Patent Owner argues that Bradley does not automatically deliver a pulsed electrical signal to a patient, it is not clear on this record that claim 1 requires that the claimed device automatically deliver the pulsed electrical signal to the patient based on the positional relationship and indication. On this record, claim 1 requires that the device automatically *identify* the signal delivery parameters. The claim appears to allow the clinician to perform some additional programming before delivery of the electrical signal because the electrical signal delivered is only required to be "in accordance with" the automatically-identified signal parameters. *See* Ex. 1001, 37:35–39. The parties are free to brief these issues further at trial.

On the record at this stage of the proceeding, we determine that Petitioner has made an adequate showing. Bradley discloses that by

analyzing the inputted information, i.e., therapeutic indication and information defining the type, number, and vertebral and mediolateral locations of the tissue stimulation leads 12, CP 18 can automatically generate a set of stimulation parameters that serves as a starting point that is close or is as close as possible to the optimum set of stimulation parameters, thereby allowing the user to more efficiently program the IPG 14 (or ETS 20). Ex. 1004 ¶ 65.

h) Summary of Claim 1

On the record at this stage of the proceeding, Petitioner has demonstrated a reasonable likelihood that claim 1 of the '460 patent would have been obvious over Bradley and Polefko.

5. Analysis of Dependent Claim 2

Claim 2 depends from claim 1 and further recites "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." Ex. 1001, 37:40–45.

Petitioner argues that Bradley incorporates Zhu in its entirety. Pet. 53–54 (citing Ex. 1004 ¶ 61; Ex. 1002 ¶¶ 87, 166). Petitioner cites *Paice* for its holding that the patent's language of incorporation in *Paice*, i.e., "which is incorporated herein by this reference," sufficiently incorporated the entire disclosure of the patent. *Id.* at 53 (citing *Paice LLC v. Ford Motor Co.*, 881 F.3d 894, 909 (Fed. Cir. 2018)). Petitioner asserts that Bradley states that Zhu and others "are expressly incorporated herein by reference," and that similar to the language at issue in *Paice*, Bradley's language of incorporation serves to incorporate Zhu's disclosure in its entirety. *Id.* at 54 (citing Ex. 1004 ¶ 61). Patent Owner does not present

arguments in the Preliminary Response addressing the specific merits of Petitioner's contention. *See* Prelim. Resp. 39.

Whether and to what extent material has been incorporated by reference into a host document is a question of law. *Cook Biotech Inc. v. Acell, Inc.*, 460 F.3d 1365, 1376 (Fed. Cir. 2006). A proper incorporation is based on a clear indication of what is being incorporated, with due respect for the particularity voiced by the applicant. *See, e.g.*, *Zenon Envtl., Inc. v. U.S. Filter Corp.*, 506 F.3d 1370, 1378–79 (Fed. Cir. 2007). On this record, and based on our review of paragraph 61 of Bradley, we conclude that Petitioner has made an adequate showing that Bradley intended to incorporate at least Zhu's "manner" of "determin[ing]" "the tissue stimulations leads 12 relative to each other" "based on the measured electrical parameters," based on the full language of incorporation in Bradley. *See* Ex. 1004 ¶ 61.[14]

[14] Paragraph 61 of Bradley states:

> Alternatively, rather than inputting the lateral spacing between the leads 12 using the lead configuration screen 100(2), the positions of the tissue stimulation leads 12 relative to each other can be determined based on the measured electrical parameters in a conventional manner, such as, e.g., any one or more of the manner disclosed in U.S. Pat. No. 6,993,384, entitled "Apparatus and Method for Determining the Relative Position and Orientation of Tissue stimulation leads," U.S. patent application Ser. No. 12/550,136, entitled "Method and Apparatus for Determining Relative Positioning Between Tissue stimulation leads," and U.S. patent application Ser. No. 12/623,976, entitled "Method and Apparatus for Determining Relative Positioning Between Tissue stimulation leads," which are expressly incorporated herein by reference.

Ex. 1004 ¶ 61.

Petitioner asserts that Zhu discloses the automatic updating of the location of the signal delivery device and the updating of the signal delivery parameter. Pet. 54 (citing, e.g., Ex. 1024 ¶¶ 61, 87–89). Patent Owner does not present arguments in the Preliminary Response addressing the specific merits of Petitioner's contention. *See* Prelim. Resp. 39.

On this record, we determine that Petitioner has made an adequate showing. In particular, Zhu discloses that its 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. Zhu discloses that that lead migration is being continuously monitored. *Id.* ¶ 89. Zhu discloses that "[i]f 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," which includes (1) surgical removal or repositioning and (2) reprogramming. *Id.* ¶ 87. Zhu discloses that if it was determined that a lead had moved, the therapeutic regimen may be reprogrammed by substituting new active electrodes. *See id.* ¶ 88; Ex. 1002 ¶ 168. Zhu discloses that "[r]eprogramming may be performed automatically or by a clinician." Ex. 1024 ¶ 89.

6. Analysis of Dependent Claim 3

Claim 3 depends from claim 2 and further recites "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." Ex. 1001, 37:46–49.

Petitioner's contentions as to claim 3 refer back to its contentions as to claim 2. *See* Pet. 55. Patent Owner does not present arguments in the Preliminary Response addressing the specific merits of Petitioner's contention. *See* Prelim. Resp. 39.

On this record, we determine that Petitioner has made an adequate showing for similar reasons as described above for claim 2.

7. Analysis of Independent Claim 11

Independent claim 11 certain requirements that are similar to those described above for independent claim 1, and in addition recites "present a computer-based image of an implanted signal delivery device and a vertebra of a patient" and "update the computer-based image of the vertebra to reflect the requested change." *See* Ex. 1001, 38:20–21, 38:25–26.

a) "present a computer-based image of an implanted signal delivery device and a vertebra of a patient"

Petitioner argues that both Bradley and Polefko disclose presenting a computer-based image of an implanted lead and a patient's vertebra. Pet. 62 (citing Ex. 1004 ¶ 63, Fig. 10; Ex. 1025, 13:28–30, 15:1–8, Figs. 12B and 13; Ex. 1002 ¶ 185; Pet. §§X.A.2.1[f], X.A.5-6). Patent Owner does not present arguments in the Preliminary Response addressing the specific merits of Petitioner's contention, separately from Patent Owner's arguments as to claim 1. *See* Prelim. Resp. 39.

On this record, we determine that Petitioner has made an adequate showing. In particular, Bradley discloses that, in an optional embodiment, "one or more virtual leads 12′ can be dragged and dropped from a lead generation icon over a graphical representation of anatomical region 150 (in this case, a spine) at a location matching the location of the anatomical

region at which the actual lead(s) 12 are implanted, as shown in a drag-and-drop lead screen 100(4) of FIG. 10." Ex. 1004 ¶ 63.

b) "update the computer-based image of the vertebra to reflect the requested change"

Petitioner argues that 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. Pet. 62 (citing Ex. 1025, 13:8–10, 14:64–15:8, Fig. 13; Ex. 1002 ¶187; Pet. §§X.A.2.1[f], X.A.5). Patent Owner does not present arguments in the Preliminary Response addressing the specific merits of Petitioner's contention, separately from Patent Owner's arguments as to claim 1. *See* Prelim. Resp. 39.

On this record, we determine that Petitioner has made an adequate showing. In particular, Polefko discloses that "[t]he user may specify patient information, such as height, weight, etc. such that the image of the spinal column is scaled to be anatomically correct." Ex. 1025, 13:8–10.

8. Analysis of Independent Claim 18

Independent claim 18 contains language and requirements that are substantially similar to those of independent claim 11 with one distinction: while claim 11 refers to an image of a vertebra, claim 18 refers to an image of "an anatomical feature of the patient, wherein the anatomical feature includes at least one of a vertebra and a disk of a patient." *Compare* Ex. 1001, 38:53–64*, with id.* at 38:17–26. Petitioner's contentions for claim 18 are similar to those for claim 11. *See* Pet. 65–66. Patent Owner does not present arguments in the Preliminary Response addressing the specific merits of Petitioner's contention, separately from Patent Owner's arguments as to claim 1. *See* Prelim. Resp. 39. On this record, we

determine that Petitioner has made an adequate showing for similar reasons as for independent claim 11. *See supra* II.E.7.

9. Analysis of Claims 4–10, 12–14, and 19–21

Petitioner sets forth argument and evidence for its assertions that claims 4–10, 12–14, and 19–21 are obvious over Bradley and Polefko. Pet. 56–61, 62–64, 65–67. Patent Owner does not present arguments in the Preliminary Response addressing the specific merits of Petitioner's contention, separately from Patent Owner's arguments as to claim 1. *See* Prelim. Resp. 39.

Based on our independent review of the evidence on this record, we determine that Petitioner has made an adequate showing that claims 4–10, 12–14, and 19–21 are obvious over Bradley and Polefko.

F. Obviousness of Claims 2 and 3 over Bradley, Zhu, and Polefko

In the alternative to its ground of obviousness over Bradley and Polefko, Petitioner presents a ground of obviousness over Bradley, Zhu, and Polefko for claims 2 and 3. Pet. 66–69. Petitioner argues that, to the extent that Bradley does not sufficiently incorporate the teachings of Zhu, a person of ordinary skill would still have combined Zhu with Bradley and Polefko. *See id.* 47. Petitioner argues that Bradley directs a person of ordinary skill to incorporate the lead alignment techniques described in Zhu, and additionally Zhu teaches taking "corrective action" after a lead has migrated by updating the stimulation parameters, which would improve the accuracy and efficiency of Bradley's stimulation programming. Pet. 68 (citing Ex. 1024 ¶¶ 87–89; Ex.1002 ¶ 204).

Patent Owner does not present arguments in the Preliminary Response addressing the specific merits of Petitioner's contentions, separately from Patent Owner's arguments as to claim 1. *See* Prelim. Resp. 40.

On this record, we determine that Petitioner has made an adequate showing. In particular, Zhu discloses that automatic reprogramming, which is especially useful when lead migration is being continuously monitored, could be truly automatic (i.e., it would happen without the patient's knowledge). Ex. 1024 ¶ 89. For this reason, we agree that a person of ordinary skill would have sought to combine the teachings of Bradley and Polefko with Zhu.

G. Obviousness of Claims 15–17 and 22–24 over Bradley, Polefko, and Alataris

Petitioner contends that claim 15–17 and 22–24 would have been obvious over Bradley, Polefko, and Alataris. Pet. 69–71. Patent Owner does not present arguments in the Preliminary Response addressing the specific merits of Petitioner's contentions, separately from Patent Owner's arguments its arguments as to the ground of obviousness of claim 1 over Bradley and Polefko. *See* Prelim. Resp. 40.

1. Alataris

Alataris is titled "Devices for Controlling High Frequency Spinal Cord Modulation for Inhibiting Pain, and Associated Systems and Methods, Including Simplifed Controllers" and relates to "devices for controlling high frequency spinal cord modulation for inhibiting pain, and associated systems and methods, including simplified controllers." Ex. 1005, code (54), ¶ 2.

Alataris describes a problem with existing systems, i.e., in many cases, patients reported a tingling or paresthesia that is perceived as more pleasant and/or less uncomfortable than the underlying pain sensation, but many other patients reported less beneficial effects. *Id.* ¶ 4. Alataris discloses a spinal cord modulation system that provides high frequency

therapeutic signals that reduced pain without creating paresthesia. *See id.* ¶¶ 37, 45.

2. Analysis of Claim 15

Claim 14 depends from independent claim 11 and further recites "wherein the computer-readable medium has instructions that when executed deliver a pulsed electrical signal to the patient." Ex. 1001, 38:41–43. Claim 15 depends from claim 14 and further recites "wherein the pulsed electrical signal has a frequency in a frequency range of from about 1.5 kHz to about 100 kHz." Ex. 1001, 38:44–46.

Petitioner argues that Alataris discloses that "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[.]" Pet. 71 (citing Ex. 1005 ¶ 48; Ex. 1002 ¶ 214). On this record, Petitioner has made an adequate showing. Alataris discloses the frequency range of about 1.5 kHz to 100 kHz, which is the range recited in claim 15. Ex. 1005 ¶ 48.

Petitioner argues that a person of ordinary skill would have modified the device of Bradley/Polefko to provide "high frequency" stimulation for patients who, according to Alataris, received fewer benefits from "low frequency" stimulation but who were treated with efficacy by Alataris's device and without producing paresthesia. *See* Pet. 70 (citing, e.g., Ex. 1005 ¶¶ 22–23, 33–62; Ex. 1002 ¶¶ 207–211). Patent Owner does not present arguments in the Preliminary Response addressing the specific merits of Petitioner's contentions, separately from Patent Owner's arguments as to claim 1. *See* Prelim. Resp. 40. On this record, Petitioner has made an adequate showing. Alataris discloses that patients treated with its high

frequency therapy obtained no sensation rather than pain or paresthesia. *See* Ex. 1005 ¶ 45.

3. Analysis of Claims 16, 17, and 22–24

Petitioner sets forth argument and evidence for its assertions that claims 16, 17, and 22–24 are obvious over Bradley, Polefko, and Alataris. Pet. 69–71. Patent Owner does not present arguments in the Preliminary Response addressing the specific merits of Petitioner's contention, separately from Patent Owner's arguments as to claim 1. *See* Prelim. Resp. 40.

Based on our independent review of the evidence on this record, we determine that Petitioner has made an adequate showing that claims 16, 17, and 22–24 are obvious over Bradley, Polefko, and Alataris.

H. Obviousness of Claims 1–14 and 18–21 over Bradley and Davis

Petitioner contends that claims 1–14 and 18–21 would have been obvious over Bradley and Davis. Pet. 72–81. Patent Owner disagrees. *See* Prelim. Resp. 40–42.

1. Davis

Davis is titled "Assignment and Manipulation of Implantable Leads in Different Anatomical Regions with Image Background" and "relates to medical devices and, more particularly, to medical devices that deliver electrical stimulation therapy." Ex. 1027, code (54), ¶ 2.

Davis describes techniques for creating, assigning, and manipulating implanted leads in different anatomical regions utilizing a graphical view of the leads and an image of the regions to which the leads are to deliver electrical stimulation therapy. *Id.* ¶ 6.

2. Analysis of Independent Claim 1

a) Preamble; b) "a computer-readable medium having instructions that when executed"; c) "receive a first input corresponding to a location of a signal delivery device implanted in a patient"; 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"; e) "receive a second input corresponding to a medical indication of the patient"

Petitioner's contentions as to these recitations and limitations for the ground of obviousness based on Bradley and Davis are the same as Petitioner's contentions as to the ground of obviousness based on Bradley and Polefko. *See* Pet. 75–78. Patent Owner does not present arguments in the Preliminary Response addressing the specific merits of Petitioner's contentions, separately from Patent Owner's arguments as to the ground based on Bradley and Polefko. *See* Prelim. Resp. 40–42.

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"

Petitioner asserts that Davis teaches that its programmer can display an image of a patient's vertebrae, and the user can manipulate images of leads on top of the vertebral image. *See* Pet. 73, 75–77 (citing Ex. 1027 ¶¶ 86–92; Ex. 1002 ¶ 217). Petitioner asserts that Davis also 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 so the lead images reflect their correct locations and dimensions in relation to the vertebrae. *Id.* at 73, 76 (citing Ex. 1027 ¶¶ 90, 92, 101, Figs. 6G-H; Ex. 1002 ¶ 217). Patent Owner does not present arguments in the Preliminary Response addressing the specific merits of Petitioner's contentions. *See* Prelim. Resp. 40–42.

On this record, we determine that Petitioner has made an adequate showing. In particular, Davis discloses that the user may manipulate both the drawn graphical representations of the leads and the imported image until the desired placement is achieved, e.g., a placement in which the graphical lead representations are generally aligned with the corresponding imaged leads. Ex. 1027 ¶ 101. Davis discloses that the user may manipulate the imported images by moving or rotating the image or zooming. *Id.*

Petitioner's argument for its asserted motivation to combine Bradley with Davis refers back to its arguments for the ground based on Bradley and Polefko, and Petitioner states by way of a parenthetical that "Polefko and Blum provide additional motivation to combine." *See* Pet. 74 (citing *id.* § X.A.1.b). Patent Owner argues that Petitioner advances no unique reasons for modifying Bradley based on Davis. Prelim. Resp. 41. On this record, we determine that Petitioner made an adequate showing for similar reasons as for the ground based on Bradley and Polefko, i.e., Polefko teaches that accurately modeling the actual placement of the medical leads within the patient assists in matching patients of different sizes. Ex. 1025, 12:32–44, 12:53–60, 14:66–15:8.

We further note that Petitioner's argued motivation to combine Bradley and Polefko also relied on Davis's disclosure that accurately defining a lead image relative to an anatomical target (as taught in Davis's examples) may be helpful in accurately programming stimulation fields. *See* Pet. 43 (citing Ex. 1027 ¶ 19). Although Petitioner does not repeat this argument for the ground based on Bradley and Davis, we understand Petitioner's reference to its previous argument to incorporate this teaching from Davis as well. *See* Pet. 74.

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"*

Petitioner's contentions as to this limitation for the ground of obviousness based on Bradley and Davis is the same as Petitioner's contentions as to the ground of obviousness based on Bradley and Polefko. *See* Pet. 77. Patent Owner's argument in response is similar to its argument based on the ground of obviousness based on Bradley and Polefko (*see* Prelim. Resp. 41–42), and we are unpersuaded for similar reasons.

h) *Summary of Claim 1*

On the record at this stage of the proceeding, Petitioner has demonstrated a reasonable likelihood that claim 1 of the '460 patent would have been obvious over Bradley and Davis.

3. Analysis of Claims 2–14 and 18–21

Petitioner sets forth argument and evidence for its assertions that claims 2–14 and 18–21 are obvious over Bradley and Davis. Pet. 78–81. Patent Owner does not present arguments in the Preliminary Response addressing the specific merits of Petitioner's contentions, separately from its arguments as to claim 1. *See* Prelim. Resp. 42–43.

Based on our independent review of the evidence on this record, we determine that Petitioner has made an adequate showing that claims 2–14 and 18–21 are obvious over Bradley and Davis.

I. Obviousness of Claim 2 and 3 over Bradley, Zhu, and Davis; Obviousness of Claims 15–17 and 22–24 over Bradley, Davis, and Alataris

Petitioner's contentions regarding the remaining grounds of obviousness based on Bradley and Davis (over Bradley, Zhu, and Davis and

over Bradley, Davis, and Alataris) are similar to its contentions regarding the corresponding grounds of obviousness based on Bradley and Polefko (over Bradley, Zhu, and Polefko and over Bradley, Polefko, and Alataris). *See* Pet. 81–85. Patent Owner's opposes the remaining grounds for similar reasons as for the corresponding grounds based on Bradley and Polefko. *See* Prelim. Resp. 43. On this record, we determine that Petitioner has demonstrated a reasonable likelihood of prevailing on its contentions as to the remaining ground of obviousness based on Bradley and Davis, for similar reasons set forth above with respect to the corresponding grounds based on Bradley and Polefko. *See supra* II.F., II.G.

III. CONCLUSION

We conclude, on the present record, that Petitioner has demonstrated a reasonable likelihood of prevailing on its assertion that claims 1–24 of the '460 patent are unpatentable.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 314(a), an *inter partes* review of claims 1–24 of the '460 patent is instituted with respect to all grounds set forth in the Petition (*see* Section I.F., *supra*); and

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

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