

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*.

Opinion for the Board filed by *Administrative Patent Judge* WEATHERLY

Opinion Dissenting-in-part filed by *Administrative Patent Judge*
WORTH

WEATHERLY, *Administrative Patent Judge*.

DECISION
Final Written Decision
Determining All Challenged Claims Unpatentable
35 U.S.C. § 318(a)

I. INTRODUCTION

This is a Final Written Decision in an *inter partes* review that addresses claims 1–24 of U.S. Patent No. 9,002,460 B2 (Ex. 1001, “the ’460 patent”). We have jurisdiction under 35 U.S.C. § 6(b). This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a). Having reviewed the arguments of the parties and the supporting evidence, we find that Petitioner has demonstrated by a preponderance of the evidence that claims 1–24 are unpatentable.

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 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”).

On March 16, 2021, we instituted an *inter partes* review of claims 1–24 of the ’460 patent. Paper 14 (“Dec. Inst.”).

On July 2, 2021, Patent Owner filed a Response to the Petition. Paper 24 (“PO Resp.”). On September 20, 2021, Petitioner filed a Reply.

Paper 29. On November 5, 2021, Patent Owner filed a Sur-reply. Paper 37.¹

On December 14, 2021, an oral argument was held in the proceeding, a transcript of which has been entered in the record. Paper 47 (“Tr.”).

On January 5, 2022, we issued an Order (Paper 49) inviting supplemental briefing on claim construction for claim 1, and in particular, on the antecedent basis of “the positional relationship,” whether the limitations must follow a temporal sequence, and whether the “third input” clause is a required element of the claim even if there is no “requested change.” *Id.* at 4.

On January 13, 2022, Petitioner filed a supplemental brief on claim construction. Paper 48 (“Pet. Supp. Br.”). On January 21, 2022, Patent Owner filed a supplemental brief on claim construction. Paper 49 (“PO Supp. Br.”).

Petitioner relies on the declaration of Richard T. Mihran, Ph.D. Ex. 1002. Patent Owner relies on the declaration of Robert T. Stone, Ph.D. Ex. 2033.

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.

¹ Patent Owner also filed a Contingent Motion to Amend (Paper 25) to which Petitioner filed an Opposition (Paper 30) and for which the panel issued Preliminary Guidance (Paper 32). However, Patent Owner subsequently withdrew its Contingent Motion to Amend (Paper 36). Accordingly, the motion is moot, and we do not consider any issue presented in the motion.

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 each of 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, 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:

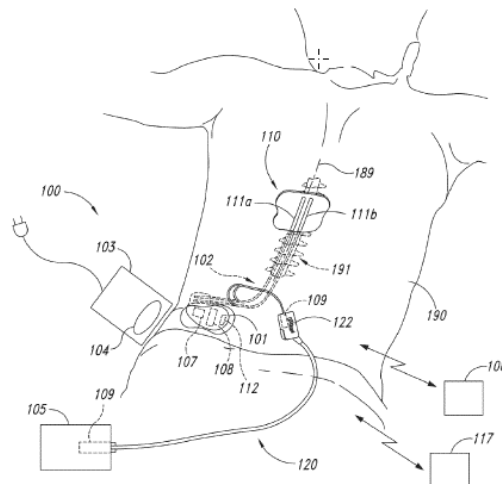


Fig. 1A

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:

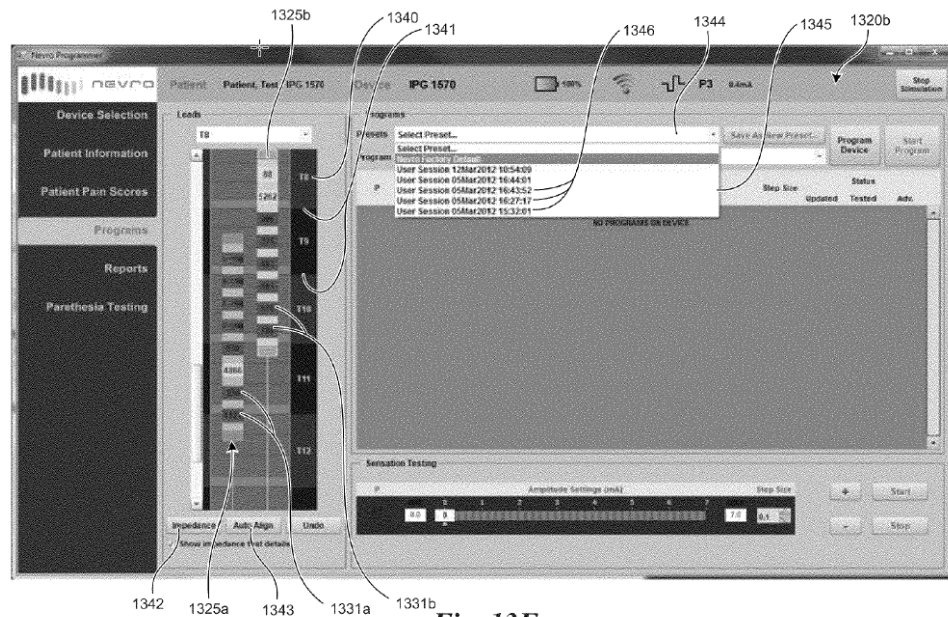


Fig. 13F

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 [the “positional relationship” clause];

receive a second input corresponding to ***a medical indication*** of the patient [the “medical indication” clause];

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*** [the “third input” clause]; 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 [the “based . . . in part” clause].

Ex. 1001, 37:21–39 (all emphases added).

F. Prior Art and Asserted Grounds

Petitioner asserted that claims 1–24 are unpatentable on the following grounds (Pet. 35²):

Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1–14, 18–21	103 ³	Bradley, ⁴ Polefko ⁵
2, 3	103	Bradley, Polefko, Zhu ⁶

² 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. The order in which the references is listed does not change our analysis. *See, e.g., In re Bush*, 296 F.2d 491, 496 (CCPA 1961) (“[i]n a case of this type where a rejection is predicated on two references each containing pertinent disclosure which has been pointed out to the applicant, we deem it to be of no significance, but merely a matter of exposition, that the rejection is stated to be on A in view of B instead of B in view of A, or to term one reference primary and the other secondary.”); *see also In re Cook*, 372 F.2d 563, 566 n.4 (CCPA 1967).

³ 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* Dec. Inst. 9. Because the ’460 patent was filed before the effective date of the relevant amendment, the pre-AIA version of § 103 applies.

⁴ Bradley, US 2012/0083857 A1, pub. Apr. 5, 2012 (Ex. 1004, “Bradley”).

⁵ Polefko, US 9,358,390 B2, iss. June 7, 2016 (Ex. 1025, “Polefko”).

⁶ Zhu, US 2011/0054551A1, pub. Mar. 3, 2011 (Ex. 1024, “Zhu”).

Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
15–17, 22–24	103	Bradley, Polefko, Alataris ⁷
1–14, 18–21	103	Bradley, Davis ⁸
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(a) 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(a); *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 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).

At this final stage, we determine whether a preponderance of the evidence of record shows that the challenged claims would have been

⁷ Alataris, US 2010/0274316 A1, pub. Oct. 28, 2010 (Ex. 1005, “Alataris”).

⁸ Davis, US 2011/0093051A1, pub. Apr. 21, 2011 (Ex. 1027, “Davis”).

rendered obvious in view of the asserted prior art. We analyze the asserted grounds of unpatentability in accordance with these principles.

B. Level of Ordinary Skill in the Art

Petitioner argues that a person of ordinary skill in the art (POSA) at the relevant time 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. PO Resp. 20 (citing Ex. 2033 ¶¶ 69–71).

We adopt Petitioner’s undisputed definition. *See In re NuVasive*, 841 F.3d 966, 974 (Fed. Cir. 2016).

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*).

In its Petition, Petitioner asserts that the claims do not require construction. Pet. 19. Patent Owner requests construction of the term “computer-based image.” PO Resp. 20–24.

Also, the panel *sua sponte* solicited post-hearing submissions on three issues of claim construction:

[1] whether the proper antecedent basis for “the positional relationship” recited in the “based . . . in part” clause of claim 1 is the positional relationship resulting from the “positional relationship” clause or the positional relationship resulting from the “requested change” from the “third input” clause.

. . . [2] whether the limitations in claim 1 must follow a temporal sequence, or whether the “positional relationship” clause can occur both before and after “the requested change,” as argued by Petitioner. . . .

. . . [and 3] whether the “third input” clause is a required element of the claim even if there is no “requested change,” i.e., if there is no change to be made, does the user need to enter a “zero” or “none” as a positive step required by the claim?

Paper 46, 4.

For purposes of this final written decision, we address the construction of “computer-based image” and the three issues for which the panel solicited briefing.

“computer-based image”

Patent Owner proposes that that the term “computer-based image” be construed to mean “schematic illustration generated by a computer.” PO Resp. 21 (citing Ex. 2033 ¶¶ 72–73). Patent Owner argues that its proposed construction is supported by the plain language of the claims because the claims recite an “input provided by a user and corresponding to a requested

change in axial length of [a/the] computer-based image of the [vertebra/anatomical feature].” *Id.* (citing Ex. 1001, 37:32–34, 38:22–24, 38:60–62). Patent Owner argues that this means that the axial lengths must be able to be manipulated or changed and that this is not possible for an image of the patient’s actual spine in the manner contemplated by the ’460 patent’s preferred “drag and drop” embodiment. *Id.*

Patent Owner also argues that this interpretation is further supported by dependent claim 4, which specifies that the practitioner’s input adjusts “computer-based data identifying the dimension” of the vertebra requested to be changed. *Id.* at 21 (citing Ex. 1001, 37:50–55; Ex. 2033 ¶ 74). Patent Owner argues that this claim language makes clear that the “computer-based data” identifying the dimension requested to be changed—i.e., the axial length of a vertebra—is manipulatable data that, when changed, updates the computer-based image of the illustrated spinal cord displayed in the GUI. *Id.* (citing Ex. 2033 ¶ 74). Patent Owner argues that this data is associated with schematic illustrations, not actual medical images. *Id.* at 21–22.

Patent Owner argues that the patent Specification also supports the proposed construction because, according to Patent Owner, the ’460 patent describes a GUI that displays a computer-based image of a spinal column depicting what are unambiguously illustrated vertebrae 1340 and vertebral boundaries 1341 (rather than a medical image of actual vertebrae and vertebral boundaries). *Id.* at 22 (citing Ex. 1001, FIG. 13F, 30:9-15; Ex. 2033 ¶ 75; Ex. 2034, 137:7–12). Patent Owner argues that Petitioner’s expert agreed that Figure 13F is “certainly” not an image of an actual patient’s spine and argues that the patent describes this image as an “illustration.” *Id.* (citing, e.g., Ex. 2034, 137:7–12; Ex. 1001, 30:8–10, 30:32–38). Patent Owner argues that the ’460 patent describes how to

manipulate the axial length so that the vertebrae more closely approximate the patient's actual anatomy, i.e., only "if the patient's vertebral levels do not have the axial dimensions illustrated at the display." *See id.* at 22–23 (citing, e.g., Ex. 1001, 30:32–38; Ex. 2033 ¶ 75; Ex. 2034, 144:9–146:3) (emphasis omitted). Patent Owner argues that the '460 patent discloses that the practitioner can drag and drop individual boundaries 1341 between adjacent vertebral level identifiers 1340 to adjust the axial extent of vertebral level identifier 1340. *See id.* (citing, e.g., Ex. 1001, 36:60–65).

Patent Owner acknowledges that the '460 patent describes an embodiment in which "the practitioner can use a touch-screen or other graphical user interface (GUI) that presents one or more fluoroscopy or other image(s), and can touch the screen to correlate particular electrodes or other markers on the signal delivery device with one or more vertebrae." *Id.* at 23 (citing Ex. 1001, 32:36–41; Ex. 2033 ¶ 76). However, Patent Owner argues that the usage in the Specification of the term "fluoroscopy or other image(s)" in this place, as opposed to the term "computer-based image," evidences that the patentee intended to distinguish these terms. *Id.* at 24 (citing *CAE Screenplates Inc. v. Heinrich Fiedler GmbH & Co. KG*, 224 F.3d 1308, 1317 (Fed. Cir. 2000); *Roche Diagnostics Operations, Inc. v. Lifescan Inc.*, 660 F. App'x 932, 938 (Fed. Cir. 2016)).

Petitioner responds that the claims use "computer-based" to modify "image" (claim 1), "data" (claim 4), and "display" (claim 5), that claim terms are normally used consistently, and that Patent Owner's arguments do not make sense when applied to "data" or "display," e.g., because nothing in the claim makes clear that they require "a generic spinal column." Pet. Reply 2–3 (citing *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005); PO Resp. 21). Petitioner also asserts that its position is consistent

with the District Court’s finding in the related litigation that “[t]he plain meaning of computer-based image is the physical image displayed by the computer.” *Id.* (citing Ex. 1041, 120:2–4, 125:11–19; Ex. 2037, 4).

Petitioner asserts that the Specification defines “computer” to “refer to any data processor,” and states that “[i]nformation handled by these computers can be presented at any suitable display medium.” *Id.* at 3 (citing Ex. 1001, 3:40–57). Petitioner asserts that the only mention of “computer-based” in the Specification refers to “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.* (citing Ex. 1003, 35:62–65). Petitioner argues that there is no indication that the applicant intended to disavow computer-based versions of “actual” images and claim only “generic” computer-generated schematics. *Id.*

Petitioner argues that the ’460 patent did not refer to Figure 13F (with vertebral identifiers 1340 and boundaries 1341) as a “computer-based image” but rather as a “schematic illustration of a display 1320*b*,” as for other figures. *Id.* at 3–4 (citing 1:60–2:47, 11:28, 20:40, 23:20, 24:40, 25:20, 29:24, 30:8). Petitioner argues that the ’460 patent teaches using such actual images for “additional precision.” *Id.* at 4 (citing Ex. 1001, 32:34–41).

Petitioner also responds to Patent Owner’s argument that the argued “drag and drop” embodiment would serve no purpose if the computer displayed an image of an actual spine and the apparent argument that it would only make sense to permit image adjustment if it were a schematic and not an image of the actual spine. Pet. Resp. 4. Petitioner argues that Patent Owner successfully argued to the District Court in the related litigation that the claims cover “zooming” in on an image which would scale

all images simultaneously. *Id.* (citing Ex. 1041, 120:5–121:25). Petitioner argues that zooming would be useful for any type of image, not just for schematic images, and that in any event, the claims are not limited to this “drag and drop” embodiment. *Id.* (citing Ex. 2034, 235:19–237:12).

Analysis

There is no definition of “computer-based image” in the claim or in the Specification. Patent Owner acknowledges that it is not arguing for a disclaimer or implied disclaimer, Tr. 22:23–23:2, and neither party presents an argument based on the prosecution history. We therefore assess the plain and ordinary meaning of the term in the context of the Specification.

The issue as framed by the parties appears to be what it means for an image to be “based” on a computer, and whether a “computer-based image” includes a photographic image (e.g., a fluoroscopic image) that is displayed on a computer and can be enlarged or shrunk on the computer, or whether a “computer-based image” is limited to a schematic image that is generated by a computer. However, the claim could have recited a “computer-generated image” or a “computer-drawn image” instead of a “computer-based image” and did not do so. Further, dependent claim 5 uses the term “graphical representation” which appears to be narrower than “computer-based image” in claim 1, although claim 5 might use a different term because the “graphical representation” is of the vertebra and the signal delivery device, and not just of the vertebra. *See* Ex. 1001, 37:56–58.⁹

We agree with Petitioner that the term “computer-based” should be read to have the same meaning in “computer-based image” (claim 1),

⁹ Further, an “image” would seem to naturally include the result of a medical imaging procedure, such as an X-ray or a fluoroscope.

“computer-based data” (claim 4), and “computer-based display” (claim 5). In all three of these instances, in context, “computer-based” appears to mean “on a computer.”

The only instance of the term in the Specification is: “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.” Ex. 1001, 35:62–65. This embodiment occurs in a passage in column 35 of the Specification labeled “Additional Embodiments.” *See id.* at 35:1. The Specification does not define the term “computer-based image.”

Elsewhere in the Specification, in a passage in column 30 describing Figure 13F, there is an embodiment (or set of embodiments) in which the user can “drag and drop individual boundaries 1341 between adjacent vertebral level identifier 1340 to adjust the axial extent of each vertebral level identifier 1340” and “[i]n addition to or in lieu of” that, the user can “scale all the vertebral levels simultaneously.” Ex. 1001, 30:26–43. In this passage of column 30 of the Specification, the disclosure that a user can scale the vertebral levels is presented as an alternative to (i.e., “in lieu of”) the drag and drop feature. Further, the embodiment of column 35 that refers to a “computer-based image,” is presented as an “alternative embodiment.” *See* Ex. 1001, 35:1. For these two reasons, the “drag and drop” embodiment of column 30 does not appear to limit the construction of “computer-based image.”

As to Patent Owner’s argument that claim 1 requires that the computer-based image must be capable of a change in axial length based on a third input (PO Resp. 21; *see also* Ex. 2033 ¶ 72), the parties appear to agree that a change in axial length can be accomplished by zooming the

image and does not require dragging and dropping the boundaries. Pet. Supp. Br. 2 (“e.g., zooming”); Tr. 25:4–6 (counsel for Patent Owner agrees that zooming in or out on a computer-based image satisfies the axial length limitation).¹⁰ For the same reason, zooming can also accomplish the adjustment of a dimension of the vertebra relative to a dimension of the signal delivery device recited in dependent claim 4. As an example, the Specification appears to present scaling all the vertebral levels, as a way that the practitioner can adjust the relative location between the leads and the illustrated vertebral levels. *See* Ex. 1001, 30:26–43.

Dependent claim 4 contains an additional limitation, “wherein the computer-readable medium has instructions that, when executed adjust computer-based data identifying the dimension, in response to the third input.” Ex. 1001, 37:53–55.¹¹ Although Patent Owner relies on this limitation to argue that “computer-based image” is not an actual image, this limitation does not mention “computer-based image” and instead only refers to “computer-based data.” The computer-based data is not necessarily part of the computer-based image. On the face of the limitation, the computer-readable medium has instructions that adjust the computer-based data when

¹⁰ We acknowledge that, as discussed above, Patent Owner still maintains that only a schematic image is a computer-based image and that Patent Owner maintains that only a schematic image is capable of the claimed change in axial length.

¹¹ Although the claim has two possible antecedent bases for “the dimension,” i.e., “a dimension of the vertebra” and “a dimension of the signal delivery device,” the antecedent basis of “the dimension” appears to be “a dimension of the vertebra” because it is in response to the third input, which corresponds to a requested change in the axial length of a computer-based image of the vertebra.

there is a requested change to the axial length of the computer-based image. Although it is possible that the computer-based image has associated data that relates to a length or dimension of the vertebra, claim 4 does not say that the computer-based data is part of the computer-based image.¹² Even if claim 4 were limited to a schematic image (with which we do not agree), claim 4 would not necessarily narrow the scope of independent claim 1, from which it depends.

Further, the Specification describes certain embodiments, including embodiments that use fluoroscopic images and/or image recognition techniques to automatically identify vertebral levels as follows:

In still further embodiments, the active electrode selection process can be further automated and/or can be performed with additional precision. For example, the practitioner can use a touch-screen or other graphical user interface (GUI) that presents one or more fluoroscopy or other image(s), and can touch the screen to correlate particular electrodes or other markers on the signal delivery device with one or more vertebrae. In still further embodiments, the system can use image recognition techniques to automatically identify markers on the electrode and/or automatically identify particular vertebral levels. Based on this information, the system can automatically identify the positional relationship between one or more of the electrodes and one or more corresponding vertebrae. The practitioner can verify or confirm the positional relationship established automatically by the program, based on the practitioner's view of the same image or a different image (or, in complex cases, several images, e.g., obtained in different planes), and/or based on the practitioner's background knowledge or other data.

¹² Petitioner argues with respect to the obviousness of claim 4, that Davis stores data regarding the image after zooming and in this way meets the limitation. *See* Pet. 78 (Ex. 1027 ¶¶ 93, 103-105; Ex. 1002 ¶ 237).

Ex. 1001, 32:34–52. This passage follows a passage explaining that a practitioner can move the lead identifiers or the vertebral boundaries to align the contacts with the vertebral levels. *See* Ex. 1001, 32:28–33. We note that the ’460 patent explicitly discloses that fluoroscopic images may be used, that the ’460 patent does so in the context of an example to provide “additional precision,” and discloses that image recognition techniques can automatically identify vertebral levels. Because there would be no reason to use automatic identification techniques to identify vertebral levels if the levels were already programmed, it appears that these image recognition techniques would be used for fluoroscopic images.^{13,14} Importantly, the ’460 patent discloses that these image recognition techniques are used to automatically identify the positional relationship between one or more of the electrodes and one or more corresponding vertebrae, which is essentially a relationship recited in claim 1 (“establish a positional relationship . . .”). This is additional evidence that the “computer-based image” of claim 1 does not exclude fluoroscopic images.

Although Patent Owner argues that a “computer-based image” should be read in contradistinction to the term fluoroscopic image, we have seen that the “computer-based image” (Ex. 1001, 35:62–63) is marked as a separate embodiment from both the “drag and drop” embodiment and the scaling embodiment which are part of the discussion of a “schematic

¹³ Patent Owner asserts that Dr. Mihran agreed that there would “likely” be no reason to modify an image if it is already accurate. PO Sur-reply 13 (citing Ex. 2034, 146:11–148:4, 154:5–12).

¹⁴ Dr. Stone averred that an actual image is not manipulable in the manner contemplated by the drag and drop embodiment (Ex. 2033 ¶ 73), but did not explain why it cannot be scaled.

illustration of a display” (Ex. 1001, 30:8, 30:35–38), and the discussion of the use of “fluoroscopy or other image” (Ex. 1001, 32:34–38) to increase precision. In other words, Patent Owner’s argument proves too much because by the same logic, the “computer-based image” embodiment of column 35 would be separate also from a “schematic illustration” embodiment of column 32.¹⁵

The cases that Patent Owner relies on are inapplicable to the situation at hand. Patent Owner cites *CAE Screenplates* for the proposition that the use of different terms connotes different meanings. PO Resp. 24 (citing *CAE Screenplates Inc. v. Heinrich Fiedler GmbH & Co. KG*, 224 F.3d 1308, 1317 (Fed. Cir. 2000)). However, in *CAE Screenplates*, the different terms were terms used in the claims, and were not just terms used in the Specification. *See id.*, 224 F.3d at 1317. Patent Owner also cites *Roche Diagnostics* for the proposition that an embodiment may be unclaimed. PO Resp. 24 (citing *Roche Diagnostics Operations, Inc. v. Lifescan Inc.*, 660 F. App’x 932, 938 (Fed. Cir. 2016)). However, in *Roche Diagnostics*, the Specification explained that capillary depth of at least 100 μm was necessary for blood but examples used 62 μm , whereas in the case at hand the Specification did not make this distinction. *See id.*, 660 F. App’x at 938.

Patent Owner also argues that the phrase “computer-based” in “computer-based image” would be redundant over the term “computer” in “computer-readable medium” unless “computer-based image” meant something more than an actual image. PO Sur-reply 12. However, the

¹⁵ We further note that the “schematic illustration” in the Specification is a “schematic illustration of a display” as opposed to a schematic illustration of a spine. *See* Ex. 1001, 30:8.

computer-readable medium refers to that which houses the set of instructions whereas the computer-based image refers to that which is acted upon by the set of instructions.

Patent Owner argues that the only mention of computer-based image in the Specification is consistent with Figure 13F of the Specification, which Dr. Mihran acknowledged is not an actual image of the patient's spine. PO Sur-reply 12 (citing Ex. 2034, 137:7–12). In context, Dr. Mihran agreed that Figure 13F of the '460 patent was not an actual image of a patient's spine, but did not connect Figure 13F to the term “computer-based image” and did not agree that the only mention of “computer-based image” in the '460 patent was not an actual image of a patient's spine. *See* Ex. 2034, 137:7–12.

Patent Owner argues that Dr. Mihran conceded at the deposition that if an actual image of the vertebrae were accurate, a practitioner would likely not change the axial length thereof unless there were another reason. PO Sur-reply 13 (citing Ex. 2034, 146:11–148:4, 154:5–12.) However, Dr. Mihran did not address whether a user might scale an image of the vertebrae as a means to change the relative relationship between leads and vertebral levels to match the patient. *See* Ex. 1001, 30:26–29. Further, we give this extrinsic evidence less weight than the intrinsic language of the claims and the Specification in our claim construction analysis. A court should discount any expert testimony “that is clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history, in other words, with the written record of the patent.” *Phillips*, 415 F.3d at 1318.

We agree with Petitioner that the claims of the '460 patent and the Specification of the '460 patent do not limit the term “computer-based image” to exclude actual images (fluoroscopic images) of the patient. Thus,

we construe “computer-based image” to mean “an image displayed on a computer.”

We also address the claim construction issues in the post-hearing briefing as follows:

[1] whether the proper antecedent basis for “the positional relationship” recited in the “based . . . in part” clause of claim 1 is the positional relationship resulting from the “positional relationship” clause or the positional relationship resulting from the “requested change” from the “third input” clause.

We posed this question to the parties in our Order soliciting additional briefing on claim construction because the “third input” clause recites a change in axial length and we were inquiring whether the change in axial length resulted in a change in the positional relationship, i.e., where the positional relationship resulting from the “third input” clause” would be a possible antecedent basis for “the positional relationship,” instead of “a positional relationship” in the “positional relationship” clause. *See* Paper 46, 3 (citing Ex. 1001, 30:26–43).

The parties agree that the antecedent basis of “the positional relationship” is “a positional relationship” in the “positional relationship clause.” *See* Pet. Supp. Br. 1–4; PO Supp. Br. 1–3. We agree that as a matter of grammar and syntax, this is the antecedent basis of “the positional relationship.”

Petitioner argues that the result of the third input, i.e., changing the axial length, does not necessarily change the positional relationship between the leads and the vertebral levels if the image is zoomed. Pet. Supp. Br. 2 (“e.g., zooming”). Patent Owner agrees that zooming is a possibility, Tr. 25:4–6, and also argues that the positional relationship may be updated at a later time. *See* PO Supp. Br. 3.

Because the change in axial length does not necessarily change the positional relationship between the leads (signal delivery device) and the vertebra (anatomical feature of the patient), we agree with the parties that the “third input” clause does not change our analysis that the antecedent basis of “the positional relationship” is “a positional relationship.”

[2] whether the limitations in claim 1 must follow a temporal sequence, or whether the “positional relationship” clause can occur both before and after “the requested change,” as argued by Petitioner

Petitioner argues that the claim language is agnostic as to when “a requested change” is received, and in the single embodiment of this limitation in the specification, the “requested change” occurs before establishing a positional relationship. Pet. Supp. Br. 4 (citing Ex. 1001, 32:18–33, 35:62–65). Petitioner argues that the claim limitation describes a type of input and is not intended to be a temporal limitation. *Id.* at 5. Petitioner argues that this is not a method claim and that the Board has previously rejected the argument that an antecedent basis implies a temporal relationship. *Id.* at 6 (citing *Apple Inc. v. Seven Networks, LLC*, IPR2020-00156, 2020 WL 3249313, at *13–16 (PTAB June 15, 2020) (Paper No. 10 at 30–37)). Petitioner further argues that claim 2 presents a different situation because claim 2 requires updating the parameter after a lead has migrated. *Id.* (citing Ex. 1001, 33:66–34:5).

Patent Owner argues that the plain language and structure of the claim indicates a temporal order. PO Supp. Br. 3–4. Patent Owner argues, *inter alia*, that in order for there to be a “change,” there has to be something preexisting that is subject to the change. *Id.* at 4.

Patent Owner argues that the Specification describes adjusting the relative location between the leads and the illustrated vertebral levels to

allow the system to establish a positional relationship and thereafter altering the dimensions of the vertebral levels. *Id.* at 5 (citing, e.g., Ex. 1001, 30:26–38, 32:7–33, 35:62–65).

Patent Owner argues that Dr. Stone testified that the claimed order of operations allows the practitioner to “establish[] an anchor point for ... the leads” so the system can effectively “tag” the stimulus area before changing axial length. *Id.* (citing Ex. 1040, 150:16–154:6).

We determine that the claimed “third input” refers only to an action by the user to change the shape of the displayed image of the vertebra. This input can be provided by the user with or without knowing the “positional relationship between the [electrodes] and [the vertebra].” Further, as detailed in the preceding section, the third input is not used or needed for the system to be able to perform the last, “based-in-part” step. Rather, the third input is not used until dependent claim 4.

Therefore, we conclude that claim 1 does not require a temporal order. Instead, the plain meaning of claim 1 is that there is a computer with three inputs, and there is no required order for receiving the three inputs.

[3] whether the “third input” clause is a required element of the claim even if there is no “requested change,” i.e., if there is no change to be made, does the user need to enter a “zero” or “none” as a positive step required by the claim?

Petitioner argues that claim 1 requires software instructions that will receive the claimed input when a user provides it, but the claim, as written, does not require the software to prompt the user for an input or that the user perform some positive step if no change is to be made. Pet. Supp. Br. 7. Petitioner argues that the claim cannot require a user action without being invalid for improperly mixing a method step in an apparatus claim. *Id.*

(citing *IPXL Holdings, L.L.C. v. Amazon.com, Inc.*, 430 F.3d 1377, 1383–84 (Fed. Cir. 2005)).

Patent Owner argues that the clause unconditionally requires the system to receive an input, and that input must “correspond to a requested change” in axial length. PO Supp. Br. 6. Patent Owner argues that if the applicant had intended for the limitation to require receiving an input only if a change is needed, there would have been myriad ways to write the claim to achieve that objective, including by simply using the modifier “if.” *Id.* (citing, e.g., *Ex parte Schulhauser*, 2016 WL 6277792, at *3-4 (PTAB Apr. 28, 2016) (precedential)). Patent Owner argues that the Board’s obviousness determination cannot turn on a hypothetical scenario in which a change would be unnecessary. *Id.* (citing *Lincoln Nat’l Life Ins. Co. v. Transam. Life Ins. Co.*, 609 F.3d 1364, 1370 (Fed. Cir. 2010)).

We need not reach this issue to resolve the parties’ dispute. Further, as detailed above, there can be a change in axial length by zooming even without a change in the positional relationship between a lead and a vertebra. *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).¹⁶

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

Petitioner contends that claims 1–14 and 18–21 would have been obvious over Bradley and Polefko. Pet. 36–67. Patent Owner disagrees. *See* PO Resp. 25–45, 57–59.

¹⁶ We note that the Specification provides an express definition of some terms, e.g., “computer” and “controller.” *See* Ex. 1001, 3:49–55.

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.*, at 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 vertebral 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:

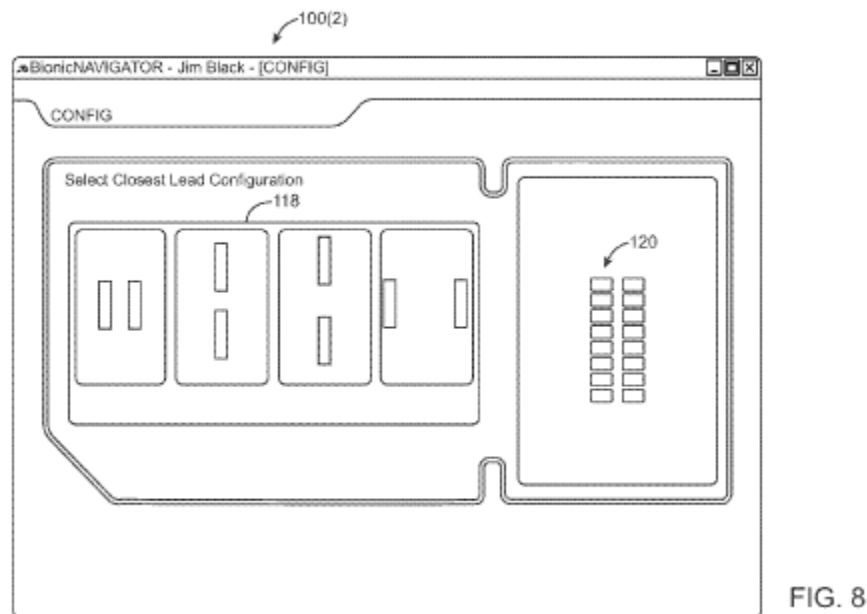


Figure 8 is a lead configuration screen that can be displayed by the clinician's programmer. *Id.* ¶¶ 30, 32. In the conventional case where a pair of percutaneous leads are to be used, lead configuration screen 100(2) generated by clinician's programmer 18 includes four different graphical configurations 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:

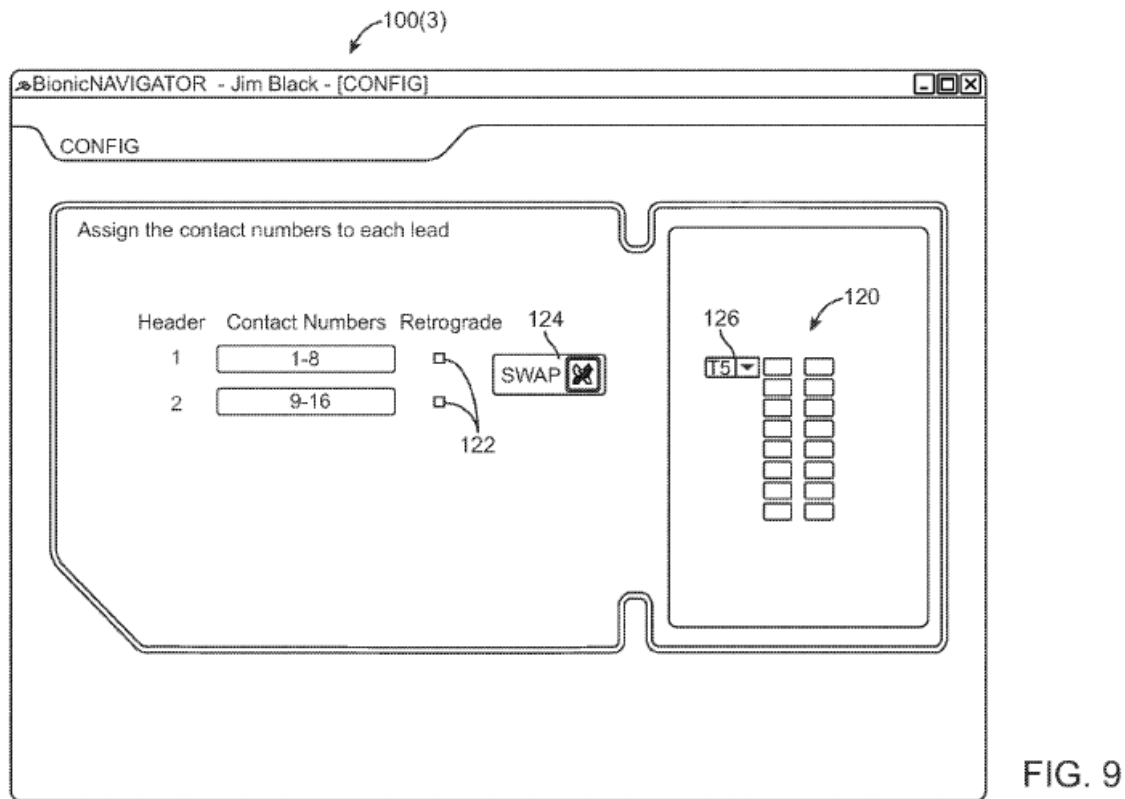


Figure 9 is a lead orientation screen that can be displayed by the clinician's programmer. *Id.* ¶ 33. As shown in Figure 9, a lead orientation screen 100(3) generated by clinician's programmer 18 allows the clinician to select the lead direction, assign the electrode numbers to each lead, and the vertebral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

Figure 10 of Bradley is reproduced below:

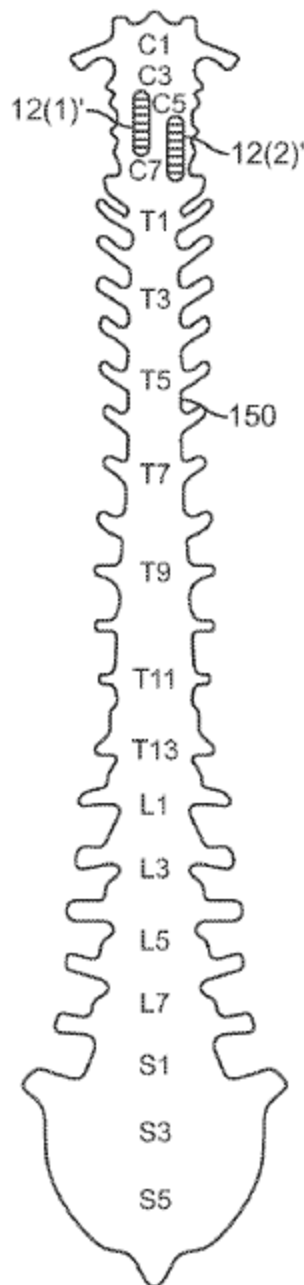


FIG. 10

Figure 10 is a drag-and-drop lead screen that can be displayed by the clinician's programmer (of Figure 6, not shown here). *Id.* ¶ 34. In an optional embodiment, one or more virtual leads 12' can be dragged and

dropped from a lead generation icon (not shown) over a graphical representation of an 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 drag-and-drop lead screen 100(4). *Id.* ¶ 63. Each vertebra of spine 150 is labeled with the corresponding level, so that the user can drop the respective virtual lead 12' at the vertebra corresponding to the location of the actual lead 12 relative to the spine.

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 stimulation 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:

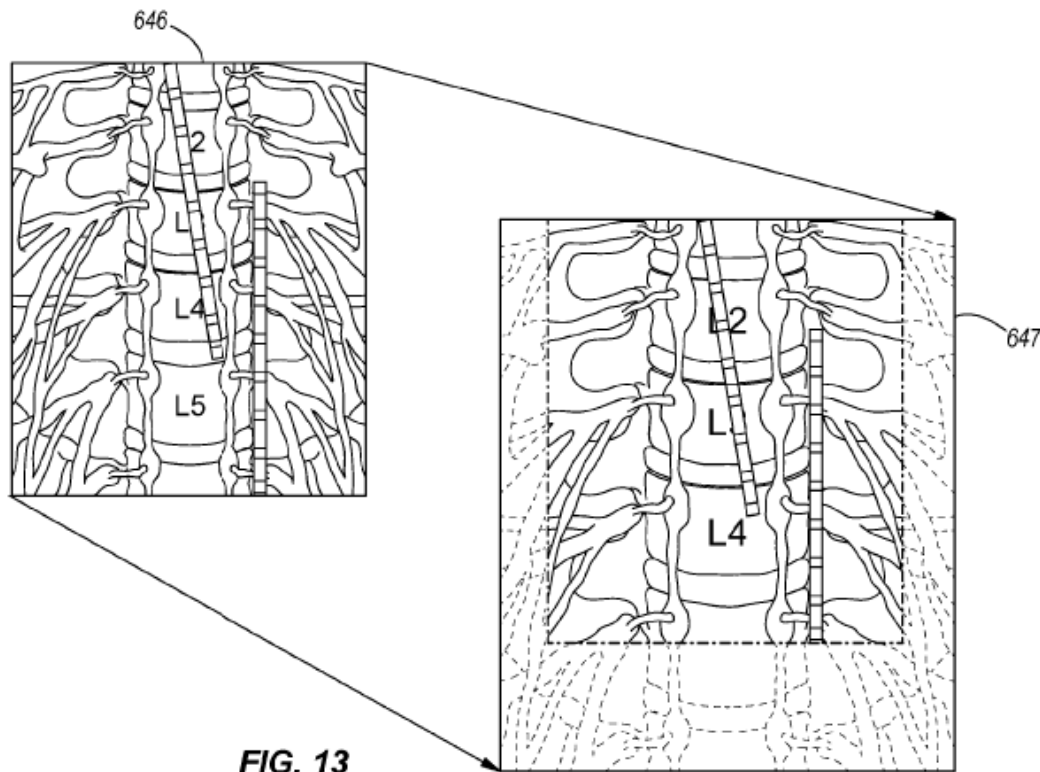


FIG. 13

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*¹⁷

Zhu is titled “Method and Apparatus for Determining Relative Positioning 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 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.

¹⁷ Although this ground is based on Bradley and Polefko, Petitioner argues that *Zhu*’s teaching is incorporated by reference into Bradley. Pet. 53.

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 separately dispute Petitioner’s contention. See PO Resp. 25–45.

We determine that Bradley discloses the limitation. In particular, Bradley discloses tissue stimulation leads 12(1) and 12(2), 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 separately dispute Petitioner’s contention. See PO Resp. 25–45.

We determine that Bradley discloses the limitation. Bradley discloses that its 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. Ex. 1004 ¶ 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 ¶¶ 143–145). Patent Owner does not separately dispute Petitioner’s contention. *See* PO Resp. 25–45.

We determine that Bradley discloses the limitation. 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 separately dispute Petitioner’s contention. *See* PO Resp. 25–45.

We determine that Bradley discloses the limitation. 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 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 separately dispute Petitioner’s contention. *See* PO Resp. 25–45.

We determine that Bradley discloses the limitation. 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). Petitioner argues that Polefko teaches that

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. *Id.* at 49–50 (citing, e.g., Ex. 1025, 12:36–44, 14:64–15:23; Ex. 1002 ¶¶ 157–159).

Petitioner argues that a person of ordinary skill would have recognized that applying Polefko’s vertebral scaling techniques to Bradley’s screen 100(4) would predictably improve the accuracy of programming taught by Bradley. Pet. 41 (citing Ex. 1002 ¶ 130).

Patent Owner argues, *inter alia*, that Polefko’s patient height and weight input does not “correspond to” a “requested change” in axial length. PO Resp. 34 (citing Ex. 2033 ¶ 101). Patent Owner also argues that Polefko’s scaling is based on the patient’s height and weight information, which cannot reliably be used as a proxy for a patient’s actual anatomy. PO Resp. 35 (citing Ex. 2039, 37). Patent Owner argues that height and weight can only be used, at best, for an approximately correct image of a patient’s spine and not for an anatomically correct image. *See id.* at 36.

Petitioner replies that the claims do not require any level of precision and that Patent Owner has argued that the image of the spine must be generic, not actual. Pet. Reply 8 (citing Ex. 1040, 143:24–144:12).¹⁸

¹⁸ Patent Owner also argues that Polefko discloses creating a pre-scaled image, not an input corresponding to a requested change, and Polefko requires the scaling of the image to occur before the user manipulates the image. *See* PO Resp. 31–33. Petitioner responds that the claims do not exclude establishing a relationship after receiving an input and Polefko does not require scaling before a user manipulates an image. Pet. Reply 7–9.

We agree with Patent Owner that Polefko’s image is created in response to the input of height and weight based on the disclosure in Polefko

We determine that Petitioner has not established that a person of ordinary skill would have modified Bradley’s computer model with Polefko’s input of height and weight in order to scale the image. The burden of persuasion rests with Petitioner. *See* 35 U.S.C. § 316(e). Polefko discloses that in its method, “[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.”¹⁹ Ex. 1025, 13:8–10. Dr. Mihran relies on Polefko for this disclosure (Ex. 1002 ¶ 100 (citing Ex. 1025, 13:8–10)), but neither Petitioner nor Dr. Mihran addresses Patent Owner’s assertion that height and weight do not reliably improve the accuracy of the model. Patent Owner adduces evidence that height and weight cannot be reliably used as a proxy for a patient’s actual anatomy. *See* Ex. 2039, 37.²⁰ In particular, Ko states that “the size of the spinal cord is not necessarily correlated with body height, body weight, or length of the vertebral column.” *Id.* Petitioner has not shown that adding height and weight would increase the accuracy of Bradley’s computer model of the spine. Although Polefko is evidence of the knowledge of a person of ordinary skill in the art at the relevant time, Ko is also. Petitioner’s failure to rebut Patent Owner’s evidence sufficiently erodes Petitioner’s primary rationale for modifying Bradley in view of Polefko, i.e., to improve accuracy. *See* Pet. 42 (“a more-accurate lead

describing the step of displaying an image and explaining that the input is such that the image “is scaled” to be correct. *See* Ex. 1025, 13:5–10. However, based on our claim construction, *supra*, we determine that the claim limitations do not require a temporal sequence.

¹⁹ Polefko does not define the subject matter indicated by “etc.”

²⁰ H-Y Ko et al., *Gross quantitative measurements of spinal cord segments in human*, 42 Spinal Cord 35–40 (2004) (Ex. 2039, “Ko”).

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"). This deficiency also erodes Petitioner's secondary rationale for modifying Bradley in view of Polefko, i.e., that the modification would have been predictable. *See* Pet. 42.

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 by analyzing a patient indication and defining the positional relationship between leads and vertebrae using Bradley's clinician programmer (CP), the CP can automatically generate a set of stimulation parameters including active electrode combination and pulse width for delivering a pulsed electrical signal through the leads. Pet. 51 (citing Ex. 1004 ¶¶ 65, 71, 79, Fig. 11; Ex 1002 ¶ 160).

Patent Owner does not separately dispute that Bradley discloses this recitation. *See* PO Resp. 25–67.

We adopt Petitioner's undisputed assertions as factual findings. *See generally In re NuVasive*, 841 F.3d at 974.

h) Summary of Claim 1

For the reasons given in Section II.D.4.f., *supra*, we determine that Petitioner has not shown by a preponderance of the evidence that claim 1 would have been obvious over Bradley and Polefko.

5. Analysis of Dependent Claims 2–10

Petitioner sets forth argument and evidence for its assertions that claims 2–10 would have been obvious over Bradley and Polefko. Pet. 52–62.

We determine that Petitioner has not established that claims 2–10 would have been obvious over Bradley and Polefko for the same reasons as for claim 1, from which they depend.

6. Analysis of Independent Claim 11

Independent claim 11 contains 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.

Petitioner’s contentions for claim 11 are similar to those for claim 1. *See* Pet. 62–63. We determine that Petitioner has not established that claim 11 would have been obvious over Bradley and Polefko for the same reasons as for claim 1.

7. 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 a computer-based 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 its response addressing the specific merits of Petitioner’s contentions, separately from Patent Owner’s arguments as to claim 11. *See* PO Resp. 25–67. We determine that Petitioner has not established that claim 18 would have been obvious over Bradley and Polefko for the same reasons as for claim 11.

8. Analysis of Claims 12–14 and 19–21

Petitioner sets forth argument and evidence for its assertions that claims 12–14 and 19–21 would have been obvious over Bradley and Polefko. Pet. 62–64, 65–67.

We determine that Petitioner has not established that claims 12–14 and 19–21 would have been obvious over Bradley and Polefko for the same reasons as for claims 11 and 18, from which they depend.

E. 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, which depend ultimately from claim 1.

Pet. 66–69. Petitioner does not rely on Zhu to remedy the above-identified deficiency in the asserted ground of obviousness of independent claim 1 over Bradley and Polefko. Therefore, we determine that Petitioner has not shown that claims 2 and 3 would have been obvious over the combination of Bradley, Zhu, and Polefko for the same reason as for Petitioner’s assertion that claim 1 would have been obvious over Bradley and Polefko.

F. 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 disagrees. See PO Resp. 62–67.

1. Alataris

Alataris is titled “Devices for Controlling High Frequency Spinal Cord Modulation for Inhibiting Pain, and Associated Systems and Methods, Including Simplified 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 reduce pain without creating paresthesia. *See id.* ¶¶ 37, 45.

2. Analysis of Claims 15–17 and 22–24

Claims 15–17 depend ultimately from claim 11, and claims 22–24 depend ultimately from claim 18. Petitioner does not rely on Alataris to remedy the above-identified deficiency in the asserted ground of obviousness of independent claims 11 and 18 over Bradley and Polefko. Therefore, we determine that Petitioner has not shown that claims 15–17 and 22–24 would have been obvious over the combination of Bradley, Polefko, and Alataris for the same reason as for Petitioner’s assertion that claims 11 and 18 would have been obvious over Bradley and Polefko.

G. 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* PO Resp. 45–62.

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.

Figure 6D of Davis is reproduced below:

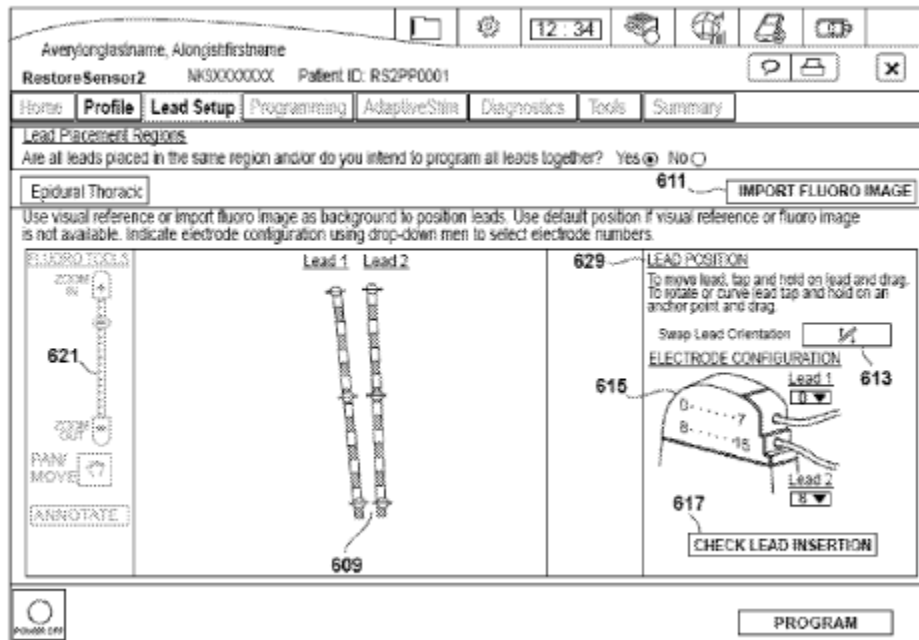


Figure 6D illustrates a programming screen in an exemplary sequence. *See Ex. 1027* ¶ 17. In Figure 6D, the graphical representation of leads 609 may be displayed on the screen. *Id.* ¶ 86. The user may be presented with an option to import an image for the lead region being programmed, where the image may be, for example, a fluoroscopic image of the region in which therapy is applied. *Id.*

Figure 6G of Davis is reproduced below:

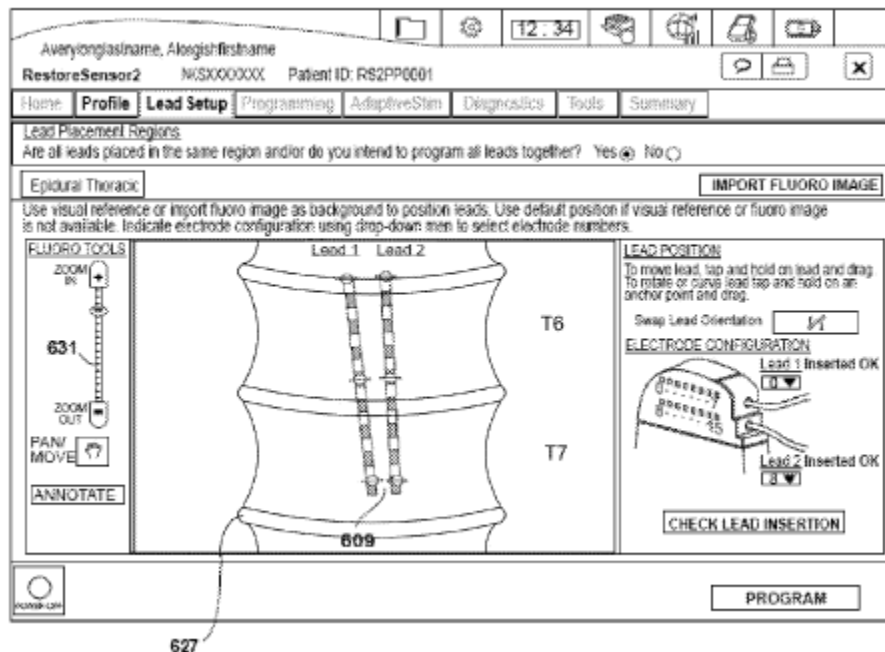


Figure 6D illustrates another programming screen in an exemplary sequence. *See* Ex. 1027 ¶ 17. The representation of leads 629 may be superimposed on fluoroscopic image 627 of the leads. *Id.* ¶ 89. In one example, the representation of leads 609 may not be initially aligned with the leads in fluoroscopic image 629. *Id.* ¶ 90. To get the representation of leads 609 to more accurately align with leads in fluoroscopic image 627, the representation of the leads 609 may be scaled, stretched, bent, moved, or rotated to match the actual leads shown in the background imported image. *Id.*

Davis discloses with respect to another screen that the user may scale fluoroscopic image 627 and the representation of the leads 609 together or separately. *Id.* ¶ 92.

Davis discloses that for each group of one or more leads assigned to a lead region, the user may select which leads will be programmed together and which will be programmed separately. *Id.* ¶ 97. The user may then

label or name the region. *Id.* ¶ 98. The regions may be for example labeled according to the anatomical name of the region, such as, for example, “lumbar spine” or “cervical spine.” *Id.*

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”*;

Petitioner’s contentions as to these 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 addressing the specific merits of Petitioner’s contentions. *See* PO Resp. 25–67.

We determine that Petitioner has shown that Bradley discloses these limitations for the same reasons as for the ground of obviousness based on Bradley and Polefko. *See* Section II.D.4.a–c. *supra*.

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 argues that Davis does not disclose that its background image contains any metadata or other information identifying vertebrae that the system can use to establish a positional relationship between a vertebra and the leads overlaid on that image, or to update the positional relationship. *See* PO Resp. 51–53. However, Bradley discloses that the user may

establish the positional relationship by entering the vertebral level in screen 100(3). Ex. 1004 ¶ 62.

We thus determine that Bradley discloses the limitation in two ways. 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.

As we discuss *infra*, in the combination of Bradley and Davis, Petitioner can assign vertebral levels in screen 100(3) after performing Davis’s technique for aligning a representation of a lead with the actual image of the lead on a fluoroscopic image.

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

Petitioner’s contentions as to this limitation 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. 75–77. Patent Owner does not present arguments in its 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* PO Resp. 25–67.

We determine that Petitioner has shown that Bradley discloses these limitations for the same reasons as for the ground of obviousness based on Bradley and Polefko. *See* Section II.D.4.e. *supra*.

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 Bradley 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). *See* Pet. 75 (citing Ex. 1002 ¶ 229; Pet. § X.A.2.1[f] [Pet. 49–50] (citing Ex. 1004 ¶ 63, Fig. 10; Pet. § X.A.2.1[c]–[d]; Ex. 1002 ¶156)). Patent Owner does not separately dispute that Bradley discloses this recitation. *See* PO Resp. 25–67.

Petitioner also argues that Davis teaches that “[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.” Pet. 76 (citing Ex. 1002 ¶ 231 (citing Ex. 1027 ¶ 92)). Petitioner argues that this scaling can also be applied when using a graphical representation. *Id.* (citing, e.g., Ex. 1027 ¶¶ 100–101). Petitioner also refers to Davis’s “Fluoro Tool,” and asserts that the programmer provides a resizing input so that the user can change the dimensions of the vertebral image relative to the leads. *Id.* at 76–77 (citing, e.g., Ex. 1027 ¶¶ 90, 101, 113, 115, Fig. 6H).

Patent Owner does acknowledge that “[a]ligning graphical leads with imaged leads is the principal method Davis describes for accurately modeling the implanted lead location.” PO Resp. 50 (citing Ex. 2033 ¶ 128). Patent Owner argues that Davis’s fluoroscopic image is not a “computer-based image” within the meaning of the claims. PO Resp. 48–53 However, applying our claim construction of “computer-based image” (*see*

supra), we determine that Davis’s fluoroscopic image is a “computer-based image.”²¹

*Whether and how a person of ordinary skill would have combined
Bradley and Davis*

Before we review Petitioner’s contentions regarding whether and how a person of ordinary skill would have combined Bradley and Davis, we make the following factual findings to provide context. Bradley discloses, in the embodiment of screen 100(4), placing a schematic representation of the leads on a schematic image of the vertebrae. *See* Ex. 1002 ¶ 89 (citing Ex. 1004 ¶ 63, Fig. 10). Davis discloses, in one embodiment, displaying a schematic representation of the leads on a fluoroscopic image of the spine. *See id.* ¶ 107 (citing Ex. 1027 ¶¶ 85, 99, Fig. 6D). In Davis, the fluoroscopic image of the spine also contains an actual fluoroscopic image of the leads.

²¹ Petitioner also argues that Davis discloses graphical representations or schematic images of the spine. Pet. 76; Pet. Reply 21 (citing Ex. 1027 ¶¶ 20, 100). Patent Owner acknowledges that Davis discloses that a “user may import an anatomical image, e.g., fluoroscopy image, X-ray image, MRI image, graphical representation of the anatomical region or the like.” PO Resp. 48–49 (citing Ex. 1027 ¶¶ 20, 100). Patent Owner argues, *inter alia*, that a person of ordinary skill would interpret “graphical representation” in this context as being an image that depicts the patient’s actual spinal column because it is listed alongside other images that represent the actual anatomy, i.e., fluoroscopy image, X-ray image, MRI image. *Id.* at 49 (citing Ex. 2033 ¶¶ 126–127; *United States v. Williams*, 553 U.S. 285, 294 (2008)). Patent Owner also argues that Davis’s technique of aligning a graphical image of the leads with a background image would not work with a schematic background image, which lacks a reference point for the leads. *Id.* at 51. We agree with Patent Owner because Petitioner has not established that Davis’s disclosure of a “graphical representation” necessarily refers to a schematic diagram. *See, e.g., In re Oelrich*, 666 F.2d 578, 581 (CCPA 1981) (“inherency may not be established by mere possibilities or probabilities”).

See Ex. 1002 ¶ 108; Ex. 2033 ¶ 128 (citing Ex. 1027 ¶ 90). Davis discloses, *inter alia*, that a user can scale the actual fluoroscopic image of the spine to align the schematic representation of the leads with the actual fluoroscopic image of the leads in a background fluoroscopic image. *See* Ex. 1002 ¶¶ 108–109 (citing Ex. 1027 ¶¶ 87, 89, 90, 101); Ex. 2033 ¶ 128.

Petitioner presents two alternative theories on how a person of ordinary skill would have combined Bradley and Davis. *See generally* Tr. 5:19–8:6 (“Those are alternative arguments . . .”).

First, Petitioner argues that a person of ordinary skill would have scaled Bradley’s background image based on the teachings of Davis. In particular, Petitioner argues that Bradley discloses every limitation except for the “axial length” limitation (Pet. 72), and that a person of ordinary skill would have used Davis’s technique of scaling images to improve Bradley by scaling the background vertebral image in Bradley (*see* Pet. 72–74), i.e., by scaling the background image in Bradley’s screen 100(4). *See* Pet. Reply 21.

Second, Petitioner argues that a person of ordinary skill would also have scaled Davis’s background image. In particular, Petitioner also argues that Davis discloses the limitation “present a computer-based image of an implanted signal delivery device and a vertebra of a patient” in the first instance (*see supra* § II.G.2.d. (discussing Pet. 79)), and that a person of ordinary skill would have combined the image of the leads with an image of an “actual” spine, e.g., as taught by Davis. *See* Pet. Reply 23–24.

Patent Owner argues that only this second theory is advanced in the Petition and that Petitioner has waived the first theory because Petitioner did not argue in the Petition that Bradley’s image is a computer-based image. PO Sur-Reply 10–12. We determine that it is sufficiently clear from the

Petition that Petitioner was asserting in the Petition that each of Bradley and Davis discloses the limitation “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” (*see* Pet. 75–76), and therefore, it is sufficiently clear from the Petition that either Bradley’s image or Davis’s image could be subject to a change in axial length based on the teachings in Davis.

As to Petitioner’s first theory, i.e., that a person of ordinary skill would have merely used the concept of scaling, as taught by Davis, to modify the background schematic image from Bradley, we agree with Patent Owner that a person of ordinary skill would not have been able to do so and/or doing so would have conflicted with the Davis’s purpose. *See* PO Resp. 50 (citing Ex. 1027 ¶ 90; Ex. 2033 ¶ 128). Davis discloses aligning the schematic representation of the leads with the fluoroscopic image of the leads in a background fluoroscopic image.²² Ex. 1002 ¶¶ 108–109 (citing Ex. 1027 ¶¶ 87, 89, 90, 101, 113, 115); Ex. 2033 ¶ 128 (citing Ex. 1027 ¶ 90). In the absence of a fluoroscopic image of the patient’s spine which contains an actual image of the position of the leads, a person of ordinary skill would not have been able to perform Davis’s technique of scaling by aligning the actual fluoroscopic image of the leads with the schematic representation of the leads. *See id.*

At the hearing, counsel for Petitioner appeared to have a new argument that a person of ordinary skill could have scaled Bradley’s schematic vertebrae by looking at a picture of the fluoroscopy, which is not

²² In other words, the fluoroscopic image of the patient contains both an image of the spine and an actual image of the leads. *See* Ex. 1027 ¶¶ 86, 89, 90.

a background image (as in Davis) but which is side-by-side with Bradley's screen. *See* Tr. 10:10–12:8. Because this argument was not in Petitioner's briefing, we find that it has been waived. *See* Paper 38, 4 (Hearing Order). Further, we agree with Dr. Stone that Petitioner's alternative way of scaling Bradley's schematic image as argued by Petitioner would fundamentally alter Davis's stated theory of operation. *See* Ex. 2033 ¶ 128.

Petitioner also argues that a person of ordinary skill could have zoomed in to scale both the schematic background image of the spine and the representation of the leads in Bradley based on the teaching in Davis that they could be scaled separately or together. *See* Ex. 1002 ¶ 231 (citing Ex. 1027 ¶ 92); Tr. 12:2–3. However, contrary to Petitioner's underlying rationale for combining Davis and Bradley, it is unclear how scaling both the schematic background image of the spine and the representation of the leads would have improved anatomical accuracy because there is no evidence that it would change the positional relationship of the leads to the vertebrae.

As to Petitioner's second theory, i.e., that a person of ordinary skill would have imported a fluoroscopic image of the patient's spine to perform the aligning technique, as taught by Davis, we are persuaded by Petitioner that a person of ordinary skill in the art would have done so to improve the accuracy of the displayed image of the representation of the leads. *See* Ex. 1027 ¶ 19 (“The examples of this disclosure may 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.”); Pet. Reply 22 (citing Pet. 73–77).

Indeed, Dr. Stone concedes that Davis is directed to combining a representation of the leads with a fluoroscopic image of the spine in which actual leads are implanted so that the practitioner can align the

representation of the leads with the actual fluoroscopic image of the leads. *See* Ex. 2033 ¶ 128 (citing Ex. 1027 ¶¶ 90, 92, 101). Dr. Stone quotes Davis for the proposition that Davis scales the leads “to more accurately align with leads in the fluoroscopic image.” *Id.* (citing Ex. 1027 ¶ 90).

Patent Owner argues that Davis does not disclose any metadata or other information identifying vertebrae that the system can use to establish a positional relationship between a vertebra and the leads. PO Resp. 51. However, claim 1 does not mention metadata. Nevertheless, a person of ordinary skill could enter metadata for the vertebral level at which each lead is positioned after a user performs the alignment of the images, e.g., using Bradley’s screen 100(3). *See* Tr. 13:14–22. For example (as discussed above), Petitioner argues, *inter alia*, that the selected vertebral level from Bradley’s drop-down menu 126 (¶ 62) establishes the claimed positional relationship. Pet. 47 (citing, e.g., Ex. 1004 ¶¶ 62, 63, 70; Ex. 1002 ¶¶ 148, 149).²³

Petitioner argues that a person of ordinary skill art would have combined the teachings of Bradley and Davis with predictable results because an ordinarily skilled artisan would have 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. Pet. 39 (citing Ex. 1016, 9:61–10:18; Ex. 1025, 12:32–44, 12:53–63; Ex. 1027 ¶ 19; Ex. 1002

²³ The placement of Petitioner’s arguments in its Petition is consistent with Petitioner’s argument that the steps of claim 1 need not be performed in a sequential order, with which we agree. *See supra*, Section II.C.

¶ 126). Patent Owner argues that Bradley discloses a paresthesia-based system in which stimulation parameters are determined, in part, based on patients indicating that they are experiencing paresthesia, and a skilled artisan would have had no reason to turn to techniques for accurately modeling lead location, including those described in Davis. PO Resp. 53–54 (citing Ex. 2033 ¶ 135). Patent Owner also argues that a person of ordinary skill would have had no reason to manipulate the axial length of Davis’s spinal column image given that it already represents the patient’s actual anatomy. *See id.* at 48 (citing Ex. 2033 ¶ 124). However, Petitioner argues that Davis teaches “scaling” the image for more accurate modeling and programming. Pet. Reply 22 (citing Pet. 73–77; Ex. 1027 ¶ 19).

We are persuaded that a person of ordinary skill would have sought to incorporate the teachings of Davis into Bradley’s system in order to more accurately model lead placement, as expressly taught by Davis, and thereby more accurately determine effective stimulation parameters and to determine these parameters “automatically,” i.e., without depending upon a patient experiencing paresthesia as the feedback mechanism for demonstrating whether the stimulation was effective. *See generally* Ex. 1027 ¶ 19; Ex. 1002 ¶¶ 126, 220; *see also 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 also argues that Bradley and Davis have fundamental differences because Bradley does not disclose using fluoroscopic images, and also that Davis’s fluoroscopic images result in a larger data file. PO Resp. 55 (citing *Adidas AG v. Nike, Inc.*, 963 F.3d 1355, 1359 (Fed. Cir.

2020); Ex. 2033 ¶¶ 138–139; Ex. 2034, 166:19–167:4, 167:18–21).

Petitioner replies that storing and displaying a fluoroscopic image was conventional, and the references teach the use of such images without expressing any concern about their size. Pet. Reply 24. Petitioner argues that the added precision enabled by incorporating Davis’s rescaling methods would outweigh the drawbacks identified by Patent Owner. Pet. Reply 24 (citing *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1165 (Fed. Cir. 2006)). We are persuaded by Petitioner in view of Dr. Mihran’s testimony that Bradley “already discloses a display screen on the CP in which lead images are positioned on a spinal image (Ex. 1004 ¶ 63, Fig. 10), and a person of ordinary skill in the art would have understood how to substitute Davis’s more-detailed spinal image and allow the user to resize by using, for example, the buttons provided in Davis’s programmer interface.” Ex. 1002 ¶ 218 (citing Ex. 1027, Figs. 6G-H). The teachings of Davis would have made clear to a person of ordinary skill both how to perform the scaling technique of Davis, and the advantages of increasing accuracy. *See* Ex. 1027 ¶¶ 86, 89, 90, 100.

We therefore determine that Petitioner has established that Davis discloses the “axial change” limitation by scaling the background image and aligning it with the graphical image of the leads.

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 computer programmer (CP) 18 can automatically generate a set of stimulation parameters, including an electrode combination and pulse width for delivering a pulsed electrical signal through the leads. *See* Pet. 77 (citing X.A.2.1[g] [Pet. 51]

(citing Ex. 1004 ¶¶ 65, 71, 79, Fig. 11; Ex. 1002 ¶¶ 160)). Petitioner argues 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. 51–52 (citing Ex. 1004 ¶¶ 66–68; Ex. 1002 ¶ 161). Patent Owner does not separately dispute Petitioner’s contention in this regard. *See* PO Resp. 25–67. Counsel for Patent Owner agreed at the hearing that the parameter need not be automatically delivered, only automatically identified. *See* Tr. 37:9–19.

Petitioner argues that Bradley discloses delivering pulses in accordance with the identified parameters. Pet. 52 (citing Ex. 1004 ¶ 38; Ex. 1002 ¶ 163). Bradley discloses that “the IPG 14 includes pulse generation circuitry that delivers electrical stimulation energy in the form of a pulsed electrical wave form (i.e., a temporal series of electrical pulses) to the electrode array 26 in accordance with a set of stimulation parameters.” Ex. 1004 ¶ 38. Petitioner appears to argue, e.g., with respect to claim 1, that in context, “a set of stimulation parameters” in paragraph 38 of Bradley refers to later disclosures in Bradley. Pet. Reply 14 (citing Pet. 51–52).

Patent Owner argues that although the paragraph uses the words “in accordance with,” that phrasing refers to the unremarkable fact that the system can deliver a signal in accordance with some parameter, not the parameter automatically identified by Bradley’s system. PO Resp. 26–27 (citing Ex. 2033 ¶ 83). Patent Owner argues that Petitioner’s passing reference to Bradley’s paragraph 38 lacks the developed analysis required to satisfy Petitioner’s burden of proof. *Id.* at 27 (citing *In re Magnum Oil Tools Int’l, Ltd.*, 829 F.3d 1364, 1380 (Fed. Cir. 2016)).

However, paragraph 65 of Bradley, also relied on by Petitioner, states:

Thus, it can be appreciated from the foregoing that the user interface of the CP 18 allows the user to enter information defining a therapeutic indication and information defining the type, number, and vertebral and mediolateral locations of the tissue stimulation leads 12. By analyzing this information, the 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 (*cited in* Pet. 51; Pet. Reply 13–14).²⁴ Based on paragraph 65 of Bradley, we agree with Petitioner that Bradley discloses an intent for the user to deliver pulses to the patient based on the automatically generated stimulation parameters, which in turn are based on the vertebral locations of the leads (regardless of whether paragraph 38 of Bradley is sufficiently specific as to the stimulation parameters at issue).

h) Summary of Claim 1

We, therefore, determine that Petitioner has established that claim 1 of the '460 patent would have been obvious over Bradley and Davis.

3. 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.

²⁴ Patent Owner argues that Petitioner’s argument on page 13 of the Reply brief is post hoc analysis, but Patent Owner does not make a motion to strike. In any event, we determine that Petitioner’s argument is adequately based on its citation to paragraph 65 of Bradley in the Petition at 51.

Petitioner asserts that Bradley recognizes that leads can “gradually or unexpectedly move” after implantation, requiring reprogramming to redirect stimulation to the target area. *See* Pet. 77 (citing Pet. § X.A.2.1[g] [Pet. 52] (citing Ex. 1004 ¶ 11)). Petitioner argues that the same disclosures of Bradley 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. Pet. 52 (citing Pet. §§ X.A.2.1[c]-[d]; Ex. 1002 ¶ 165). Petitioner argues that 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. Pet. 53 (citing § X.A.2.1[g]; Ex. 1002 ¶ 165).

Petitioner also argues that Bradley incorporates the disclosure of Zhu. Pet. 53 (citing Ex. 1004 ¶ 61). Petitioner argues that Zhu discloses receiving an updated lead location and, in response, automatically updating a stimulation parameter such as the active electrode combination. Pet. 54 (citing Ex. 1002 ¶¶ 167–168). Petitioner asserts that Zhu’s clinician’s programmer 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.” *Id.* (citing Ex. 1024 ¶ 61). The CP can continuously monitor lead migration. *Id.* (citing Ex. 1024 ¶ 89).

Patent Owner argues that speculating about what a prior art reference could do is not sufficient to meet Petitioner’s burden to show that the reference discloses the claim limitations. PO Resp. 58 (citing *Wonderland Nurserygoods Co. v. Baby Trend, Inc.*, 727 F. App’x 1017, 1020 (Fed. Cir.

2018)). Patent Owner argues that Petitioner is apparently suggesting that Bradley's first three inputs can be repeated, but Petitioner points to no disclosure in Bradley that supports that suggestion. *Id.* (citing Ex. 2033 ¶ 147). Patent Owner also argues that Petitioner does not contend that a skilled artisan would have been motivated to repeat Bradley's steps so as to arrive at the claim limitations. *Id.*

Patent Owner argues that claim 1 makes clear that the "location of a signal delivery device" refers to the "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." PO Resp. 59 (citing Ex. 1001, 37:24–29).²⁵ Patent Owner argues, on this basis, that the "updated location of the signal delivery device" recited in claim 2 refers to an updated location of a lead relative to a vertebra, and argues that this would be the only reason to update the delivery parameter. *Id.* at 59–60 (citing Ex. 2033 ¶ 150; Ex. 1001, 33:61–34:5). Patent Owner argues that at most, Zhu discloses methods for "determining the relative positioning . . . of the percutaneous leads"—i.e., the position of one lead relative to another, but does not determine the position of a lead relative to a vertebra. PO Resp. 60–61 (citing, e.g., Ex. 1024 ¶¶ 47, 61–63; Ex. 2033 ¶¶ 151–154).

²⁵ Patent Owner argues that "For the reasons explained in Patent Owner's Response in IPR2020-01563, even if portions of Zhu are incorporated by reference in Bradley, Zhu and the other references cited in Bradley's paragraph 0061 are not incorporated in their entirety." PO Resp. 59 n.9. We regard this argument as an improper incorporation by reference that avoids the word count of the response, and therefore regard this argument as waived. *See* 37 C.F.R. § 42.24(b)(2). In any event, we decided in our Decision on Institution that Bradley at least incorporates the portions of Zhu relied on by Bradley, and in view of the evidence of record we reach the same conclusion. *See* Dec. Inst. 39–41.

Petitioner argues that Patent Owner tries to import an unclaimed limitation—“an updated location of a lead *relative to a vertebra*”—and that the claim only requires “an updated location of a lead.” *See* Pet. Reply 15 (discussing PO Resp. 59–60). We agree with Petitioner that Patent Owner is reading words into claim 2 without an adequate basis. Patent Owner relies on portions of claim 1, but these portions of claim 1 do not define “location” as a relative location, and instead claim 1 requires a step of establishing a positional relationship between the lead and the vertebra.

Petitioner argues that Zhu also monitors the position of the leads relative to the target tissue or vertebra. Pet. Reply 16 (citing Ex. 1024 ¶¶ 8, 87–89). Patent Owner argues that Zhu does not explicitly disclose updating lead position relative to a vertebra and instead only discloses a purpose of achieving correct lead placement. PO Sur-reply 23. Based on our review of Zhu, we agree with Patent Owner that Zhu’s technique of determining lead migration is to determine the distance of leads from each other and that this does not necessarily correspond to a relationship between the leads and the vertebrae (Ex. 1024 ¶¶ 47, 61–63) and that Petitioner is merely relying on a statement of purpose from paragraphs 8 and 87–89 that does not constitute a method of determining lead placement relative to a vertebra. *See* Ex. 2033 ¶ 151.

Nevertheless, Petitioner also argues that Patent Owner “concedes that Bradley[] teaches establishing a positional relationship between the lead location and the patient’s vertebra (element 1[d]), and Zhu discloses the common sense idea of updating that information when a lead shifts.” Pet. Reply 15.

We agree with Petitioner that claim 2 would have been obvious in view of Bradley because a person of ordinary skill reading Bradley would

have understood that a lead can migrate (*see, e.g.*, Ex. 1004 ¶ 11), and would therefore have sought to repeat the steps disclosed in Bradley for limitations 1[c], 1[d], and 1[g] to assess the location of a migrated lead relative to the vertebral level. *See* Ex. 1002 ¶ 165 (disclosure applies equally when a lead is updated).

Further, the mere duplication of parts without unexpected results is not inventive. *In re Harza*, 274 F.2d 669 (CCPA 1960). Here, the claimed repetition of steps to ascertain the location of a lead and establish a positional relationship and identify treatment parameters in the event that a lead has migrated represents the mere duplication of instructions on a computer-readable medium without any argued unexpected results.

For these reasons, we determine that a person of ordinary skill would have found claim 2 obvious over Bradley and Davis.

4. *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 argues that the same disclosures of Bradley identified regarding claim 2 also disclose claim 3. Pet. 55. Petitioner argues that if the leads have migrated far enough, different electrodes will be selected to deliver the energy. *Id.* (citing Ex. 1024 ¶ 88; Ex. 1002 ¶¶ 168, 170).

Patent Owner does not argue the patentability of claim 3 separately from that of claim 2. We, therefore, determine that Petitioner has made an adequate showing for similar reasons as for claim 2.

5. *Analysis of Dependent Claims 4–10*

Claims 4–10 depend directly from claim 1. Petitioner argues that Bradley and Davis also describe the limitations introduced in each of these respective dependent claims and supports its argument with citations to specific portions of Bradley and Davis and testimony from Dr. Mihran. Pet. 78–79 (citing Pet. 56–62 (citing, e.g., Ex. 1004 ¶¶ 62, 66–71, Fig. 10; Ex. 1027 ¶¶ 93, 103–105)). Patent Owner proffers no argument that Bradley fails to describe the limitations introduced in these dependent claims. PO Resp. 25–67 (arguing only alleged failure of Bradley and Davis to describe elements of independent claims and dependent claims 2–3, 15–17, and 22–24).

Based on our review of Petitioner’s arguments and evidence relating to dependent claims 4–10, which we adopt as our own (*see In re NuVasive*, 841 F.3d at 974), and our analysis of claim 1 in Part II.G.2. above, we conclude that Petitioner has proven by a preponderance of evidence that Bradley and Davis render obvious dependent claims 4–10.

6. *Analysis of Independent Claim 11*

a) a computer-readable medium having instructions that when executed:” b) “A patient treatment system, comprising: c) “present a computer-based image of an implanted signal delivery device and a vertebra of a patient;”

Petitioner’s assertions for these limitations are similar to the corresponding limitations in independent claim 1. *See* Pet. 79. Patent Owner does not dispute these limitations separately from claim 1. *See* PO Resp. 25–67.

We determine that Bradley discloses these recitations for similar reasons as for independent claim 1. *See supra* Section II.G.2.a.–c.

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 e) “update the computer-based image of the vertebra to reflect the requested change”

Petitioner relies on similar evidence for these limitations as for the “third input” limitation of claim 1. *See* Pet. 80. Patent Owner does not dispute these limitations separately from claim 1. *See* PO Resp. 25–67.

We determine that Bradley discloses these limitations for similar reasons as for independent claim 1. *See supra* Section II.G.2.f.

We, therefore, determine that Petitioner has established that claim 11 would have been obvious over Bradley and Davis.

7. Analysis of Claim 12

Claim 12 depends from claim 11 and further recites:

[a] wherein the input is a first input and wherein the computer-readable medium further includes instructions that, when executed:

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

[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.

Ex. 1001, 38:27–36 (bracketed matter added).

a) “wherein the input is a first input and wherein the computer-readable medium further includes instructions that, when executed”

Petitioner argues that Bradley discloses a computer-readable medium having instructions that are executed to perform the functions. Pet. 80 (citing, e.g., Pet. § X.A.13.12[a] [Pet. 63] (citing Ex. 1004 ¶ 53–56; Pet.

§ X.A.2.1[b]; Ex. 1002 ¶ 188)). Patent Owner does not separately dispute that Bradley discloses these recitations. *See* PO Resp. 25–67.

We adopt Petitioner’s undisputed assertions as factual findings. *See generally In re NuVasive*, 841 F.3d at 974.

b) “receive a second input corresponding to a medical indication of the patient”

Petitioner’s assertions for this limitation is similar to the corresponding limitation in independent claim 1. *See* Pet. 79. Patent Owner does not dispute this limitation separately from claim 1. *See* PO Resp. 25–67.

We determine that Bradley discloses these recitations for similar reasons as for independent claim 1. *See supra* Section II.G.2.e.

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”

Petitioner’s assertions for this limitation is similar to the corresponding limitations in independent claim 1. *See* Pet. 80. Patent Owner does not dispute this limitation separately from claim 1. *See* PO Resp. 25–67.

We determine that Bradley discloses this limitation for similar reasons as for independent claim 1. *See supra* Section II.G.2.g.

Accordingly, we determine that Petitioner has established that claim 12 would have been obvious over Bradley and Davis.

8. *Analysis of Claim 13*

Claim 13 depends from claim 12 and further recites “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.” Ex. 1001, 38:37–40.

Petitioner argues that Bradley discloses implanted leads with multiple electrodes and that identifying the stimulation parameter includes identifying active electrodes. Pet. 80 (citing Ex. 1002 ¶ 253; Pet. § X.A.14 [Pet. 64] (citing Ex. 1004 ¶¶ 38, 44, 70–71, 76–77, Fig 3; Ex. 1002 ¶ 191; Pet. §§ X.A.2.1[c], §X.A.2.1[g], X.A.4)).

Patent Owner does not dispute this limitation, and we adopt Petitioner’s assertions as factual findings. *See generally In re NuVasive*, 841 F.3d at 974.

We, therefore, determine that Petitioner has established that claim 13 would have been obvious over Bradley and Davis.

9. Analysis of Claim 14

Claim 14 depends from 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.

Petitioner argues that Bradley discloses that the computer-readable medium has instructions that, when executed, deliver a pulsed electrical signal to the patient. Pet. 80 (citing Ex. 1002 ¶ 254; Pet. § X.A.15 [Pet. 65] (citing § X.A.2.1[g]; Ex. 1004 ¶ 38; Ex. 1002 ¶192)).

Patent Owner does not dispute this limitation, and we adopt Petitioner’s assertions as factual findings. *See generally In re NuVasive*, 841 F.3d at 974.

We, therefore, determine that Petitioner has established that claim 14 would have been obvious over Bradley and Davis.

10. Analysis of Independent Claim 18 and Dependent Claims 19–21

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. Dependent claims 19–21 contain similar recitations to those of claims 12–14.

Petitioner’s contentions for claims 18–21 are similar to those for claims 12–14. *See* Pet. 80–81. Patent Owner does not present arguments its response addressing the specific merits of Petitioner’s contention, separately from Patent Owner’s arguments as to claims 11 and 12. *See* PO Resp. 25–67. We determine that Petitioner has established that claims 18–21 would have been obvious over Bradley and Davis for the same reasons as for claims 11–14.

H. Obviousness of Claims 2 and 3 over Bradley, Davis, and Zhu

Petitioner’s assertions for the ground of obviousness of claims 2 and 3 over Bradley, Davis, and Zhu are similar to its assertions for the ground of obviousness of claims 2 and 3 over Bradley and Davis. *See* Pet. 81–83. Petitioner has asserted, and we find above, that Bradley incorporates the relevant portions of Zhu. *See supra* Section II.G.3. We also find above that Bradley discloses the relevant limitations even without Zhu. *See id.* In this ground, Petitioner additionally provides reasons why a person of ordinary skill in the art would have sought to combine the teachings of Bradley and Zhu.

Patent Owner does not dispute these limitations separately from the ground of obviousness of claims 2 and 3 over Bradley and Davis. *See* PO Resp. 57–62.

We determine that Petitioner has shown that claims 2 and 3 would have been obvious over Bradley, Davis, and Zhu for similar reasons as for the ground of obviousness of claims 2 and 3 over Bradley and Davis. *See supra* Section II.G.3–4.

I. Obviousness of Claims 15–17 and 22–24 over Bradley, Davis, and Alataris

Petitioner contends that claim 15–17 and 22–24 would have been obvious over Bradley, Davis, and Alataris. Pet. 83–85. Patent Owner disagrees. PO Resp. 62–67.

1. Alataris

Alataris is titled “Devices for Controlling High Frequency Spinal Cord Modulation for Inhibiting Pain, and Associated Systems and Methods, Including Simplified 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. Patent Owner argues that Bradley, by contrast, is directed to conventional stimulation at lower frequencies where the purpose and

solution of Bradley is to induce paresthesia to mask the patient's pain. PO Resp. 63 (citing Ex. 1004 ¶¶ 8, 10; Ex. 2033 ¶ 159; Ex. 2034, 83:19–84:20).

2. Analysis of Claims 15–17

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.

Claim 16 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 50 kHz.” Ex. 1001, 38:47–49.

Claim 17 depends from claim 14 and further recites “wherein the pulsed electrical signal has a frequency in a frequency range of from about 3 kHz to about 20 kHz.” Ex. 1001, 38:50–52.

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. 85 (citing Pet. § X.C.2. [Pet. 71] (citing Ex. 1005 ¶ 48; Ex. 1002 ¶ 214)). We determine that Alataris discloses the frequency ranges of about 1.5 kHz to 100 kHz, about 1.5 kHz to about 50 kHz, and about 3 kHz to about 20 kHz, which are the ranges recited in claims 15–17. Ex. 1005 ¶ 48.

Petitioner argues that a person of ordinary skill would have modified the device of Bradley/Davis to provide “high frequency” stimulation for patients who, according to Alataris, do not benefit from stimulation at frequencies below 1.5 kHz but who may benefit from stimulation above 1.5 kHz. *See* Pet. 84 (citing, e.g., Ex. 1005 ¶¶ 4, 22–23, 37; Ex. 1002 ¶¶ 271–273).

Patent Owner argues that a skilled artisan would not have been motivated to combine Alataris with Bradley’s paresthesia-based system. PO Resp. 62. Patent Owner presents several arguments against the modification of Bradley with Alataris, which we address as follows.

Patent Owner argues that Alataris and Bradley have diametrically opposed objectives because Alataris is directed to paresthesia-free stimulation achieved at frequencies that are “significantly higher than the frequencies associated with standard SCS.” *Id.* (citing Ex. 1005 ¶ 37; Ex. 2033 ¶ 158). Patent Owner argues that the purpose of Alataris is to deliver effective therapy “without creating unwanted sensory ... side effects” such as paresthesia. *Id.* (citing Ex. 1005, Abstract, ¶¶ 22–23, 45, 50, 91, 106; Ex. 2033 ¶ 158) (emphasis omitted).

Patent Owner also argues that modifying Bradley’s system to deliver Alataris’s high-frequency signals would eliminate Bradley’s paresthesia-inducing effect and thus would eliminate the very therapy that Bradley is designed to deliver. *Id.* at 63 (citing Ex. 2033 ¶ 160). Patent Owner argues that such a modification changes the entire nature of Bradley’s system, and is plainly driven by hindsight bias. *Id.* Patent Owner cites cases for the proposition that an obviousness analysis must examine whether a modification would change the principles under which the primary reference operates, or render the prior art inoperable for its intended purpose, or is otherwise hindsight bias. *Id.* at 63–64 (citing *Adidas AG v. Nike, Inc.*, 963 F.3d 1355, 1359 (Fed. Cir. 2020); *Plas-Pak Indus., Inc. v. Sulzer Mixpac AG*, 600 F. App’x 755, 758 (Fed. Cir. 2015); *Metalcraft of Mayville, Inc. v. The Toro Co.*, 848 F.3d 1358, 1367 (Fed. Cir. 2017)); PO Resp. 24.

Petitioner replies that Bradley is not limited to paresthesia-based systems, and neither the ’460 patent nor Alataris is limited to paresthesia-

free systems. *See* Pet. Reply 25 (citing Pet. 83–85; Pet. Reply § V [17] (citing Pet. Reply § III.A.2.b; Ex. 1001, 3:32–34, 11:2–16, 29:12–15; Ex. 1005 ¶¶ 23, 50, 91, 106)).

Discussion

In our view, the use of high frequency electrical pulses itself, as taught by Alataris, does not change the overall mode of operation of Bradley because both references disclose instilling pulses of electrical current to the patient’s area of pain. Alataris simply makes use of the discovery that higher frequencies do not produce paresthesia while still treating the pain in certain patients. *See* Ex. 1005 ¶ 45.

On the one hand, we disagree with Petitioner’s assertion that Bradley is not limited to paresthesia-based systems. Bradley discloses, in the background section, that “in order to achieve an effective result from SCS, the lead or leads must be placed in a location, such that the electrical stimulation will cause paresthesia.” Ex. 1004 ¶ 10. Bradley also states that the “paresthesia induced by the stimulation and perceived by the patient should be located in approximately the same place in the patient’s body as the pain that is the target of treatment.” *Id.* Although Petitioner argues that Dr. Mihran stated that Bradley could be used to deliver therapy without paresthesia (Pet. Reply 10 (citing Ex. 2034, 84:21–85:5)), Petitioner does not point us to a disclosure in Bradley delivers such therapy.

Also, we note that Alataris explains that it is was commonly understood that with standard SCS therapies, the therapies relied on paresthesia (i.e., masking) to produce pain relief. Ex. 1005 ¶ 45. Bradley makes use of a conventional SCS device (*see* Ex. 1002 ¶¶ 80, 82, 87). Thus, there is some support for Patent Owner’s contentions that Bradley was directed to treatment of pain by causing paresthesia.

On the other hand, it is not entirely clear that paresthesia itself would have been understood to be the solution to the problem of pain in Bradley at the time of the invention. Dr. Mihran and Dr. Stone both explain that paresthesia is a tingling sensation. Ex. 1002 ¶ 53; Ex. 2003 ¶ 31. Alataris teaches, based on experiments with its system, that its system produces no paresthesia while alleviating pain and removing sensation in certain patients. Ex. 1005 ¶ 45.²⁶ Therefore, the prior art as a whole taught that a user could alleviate pain and block sensation by applying electrical impulses without also producing paresthesia, i.e., by instilling pulses with higher frequencies as taught by Alataris.

Even if we agree with Patent Owner that Bradley solved pain by causing paresthesia, in our view that would speak to Bradley's effect on the human body. The principle on which Bradley's device operates would still be applying electrical impulses to the human body to alleviate pain, which is not changed by Alataris. *See, e.g.*, Ex. 1002 ¶ 271 ("Bradley857 and Davis are directed to programming SCS systems to treat a patient's pain. Alataris316 also is directed to programming SCS to treat a patient's pain, and discloses analogous SCS systems in the same field of endeavor. First, all three systems use the same types of hardware components (including an IPG, implanted leads, and an external programmer).") (citing Ex. 1004 ¶¶ 2–3, 14–15, 14–18, 37, Fig. 1; Ex. 1027 ¶¶ 2–7, 37, 42–44, Fig. 2; Ex. 1005 ¶¶ 2, 22–24, 29, Fig. 1A).

²⁶ Alataris discusses various potential mechanisms of action for its invention and discloses that pain signals transmitted by the small, slow A δ and C fibers may be inhibited without affecting signal transmission along the larger, faster A β fibers. Ex. 1005 ¶ 67. Alataris explains that the A δ and C were believed to be nociceptive and related to pain. *See id.* ¶¶ 63–64.

Patent Owner further argues that Bradley cannot easily be modified to transmit Alataris's high-frequency signals. PO Resp. 64. Patent Owner asserts that Petitioner's own Precision Plus SCS system operated within a frequency range of 2 Hz to 1.2 kHz (citing Ex. 1023); that Petitioner's higher frequency systems were not released until after the priority dates of the '460 patent, Bradley, and Alataris (citing Ex. 2045); and that Dr. Mihran acknowledged that typical SCS systems such as Bradley's were constrained to operate at frequencies below 1.2 kHz (citing Ex. 2034, 252:10–20). *Id.*; PO Sur-reply 25. Patent Owner cites *Vicor Corp. v. SynQor, Inc.*, 869 F.3d 1309, 1320 (Fed. Cir. 2017) for as a case where it was recognized that a skilled artisan would not have been motivated to combine prior art references given “operating frequency incompatibilities between the references’ circuits.” PO Resp. 64.

Patent Owner argues that Bradley cannot deliver paresthesia-free therapy and that it makes no difference that Alataris can deliver both low and high frequency therapies. PO Sur-reply 25. Patent Owner argues that Dr. Mihran acknowledged that modifications would have to be made to Bradley's hardware (citing Ex. 2012 ¶ 212) and, citing Dr. Stone, states that to deliver high-frequency stimulation, the system would require higher speed components (e.g., digital-to-analog converters, processors, and power supplies (Ex. 2033 ¶ 163). PO Resp. 64–65. Patent Owner also argues that further modifications would be required to mitigate deleterious effects of direct current that may develop as a result of employing high frequencies. *Id.* Patent Owner also argues that modifying Bradley's system to deliver high-frequency stimulation would either require a larger battery, which may be difficult to implant, or would “require[] increased daily/weekly recharge sessions” of Bradley's IPG, which is inefficient from an operational

standpoint and inconvenient from a patient's perspective. PO Resp. 65–66 (citing, e.g., Ex. 2046, 8; Ex. 2036, 236). Patent Owner argues that these modifications would not be trivial, and that it is Petitioner's burden to show how these modifications would be made. PO Resp. 65–66; PO Sur-reply 26 (citing *Trivascular, Inc. v. Samuels*, 812 F.3d 1056, 1066 (Fed. Cir. 2016); *In re Magnum Oil Tools International, Ltd.*, 829 F.3d 1364, 1375 (Fed. Cir. 2016)).

Nevertheless, Petitioner acknowledges that some modifications to Bradley might be made and points out that this was the position of Dr. Mihran, i.e., in his declaration filed with the Petition. *See* Pet. Reply 19.²⁷ Petitioner asserts that Dr. Mihran states that higher frequencies would require “no, or minimal, hardware modifications—they could be implemented simply by programming stimulation at specific frequencies.” *Id.* (citing Ex. 1002 ¶ 212). Petitioner argues that Patent Owner does not provide support for its argument that these modifications would be significant. *Id.* Petitioner also disputes that a larger battery would necessarily be required, and points to a statement in Alataris that some energy savings would be possible with a higher frequency treatment. *Id.* (citing Ex. 1005 ¶¶ 28, 67). Petitioner further argues that even if a larger battery would be required, this would be a trade-off that does not preclude

²⁷ The parties are primarily disputing the extent to which *hardware* modifications would have had to have been made to Bradley. We note that with respect to software modifications, Petitioner asserts that the only modifications that would have had to have been made to Bradley would be programming stimulation at a different frequency. Pet. 71 (citing Ex. 1002 ¶ 212; Ex. 1004 ¶ 50).

obviousness. *See id.* (citing *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1165 (Fed. Cir. 2006)).

Patent Owner’s arguments implicate two related issues, i.e.,
(i) whether a person of ordinary skill would still have been motivated to modify Bradley in view of Alataris, even with the required modifications and (ii) whether Petitioner has shown that the modifications would have been within the level of skill in the art.

i. motivation to combine

Dr. Stone avers that, in order to deliver higher frequencies, Bradley’s system would need to be outfitted with higher speed components, including digital-to-analog converters, processors, and power supplies to handle increased energy requirements, by selecting appropriate conductive components among other possible modifications to prevent scar formation, and by having a larger battery. Ex. 2033 ¶¶ 163–165. Dr. Stone avers that these changes are “not trivial.” Dr. Mihran provides examples of hardware modifications such as changing the filter characteristics or otherwise modifying circuitry to support higher pulse rate, and is of the opinion that they would have been “minimal” and “routine.” Ex. 1002 ¶ 212. Although we credit Dr. Stone’s testimony that the modifications would not have been trivial, we also take into account the testimony of Dr. Mihran that Bradley, Davis, and Alataris all use substantially the same hardware components (Ex. 1002 ¶ 271), and we conclude that the proposed modification of Bradley in view of Alataris would not rise to the level of a rearrangement or redesign that would have eroded the motivation of a person of ordinary skill. *Cf. In re Ratti*, 270 F.2d 810, 813 (CCPA 1959) (modification would require a substantial reconstruction and redesign of its elements as well as a change in the basic principles under which its construction was designed to operate).

Rather, we conclude that a person of ordinary skill in the art reading the benefits of Alataris, i.e., that it was possible to block a patient's pain and sensation without causing paresthesia (Ex. 1005 ¶ 45), would have been motivated to modify certain hardware components of Bradley's device, such as changing the filter and modifying the circuitry in a non-trivial but routine way (*see* Ex. 1002 ¶ 212; Ex. 2033 ¶ 163), to provide higher frequencies.²⁸

ii. reasonable expectation of success

As to Patent Owner's argument that Petitioner's higher frequency systems were not released until after the priority dates of the '460 patent, Bradley, and Alataris (PO Resp. 64), we observe that Patent Owner does not dispute that the Alataris reference is prior art and does not appear to argue that the Alataris reference is non-enabling.²⁹ Patent Owner's argument appears to be that some modification of Bradley's device would be required to program it to provide higher frequencies, as taught by Alataris. Petitioner

²⁸ Alataris indicates that scarring would have been a known risk of high frequency treatment in certain patients. Ex. 1005 ¶ 91. However, the known trade-off between lack of paresthesia and risk of scarring would not have rendered high frequency treatment non-obvious, *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1165 (Fed. Cir. 2006), and Alataris discloses that practitioners could adapt by selecting different electrodes. *See* Ex. 1005 ¶ 91 (discussed *infra*).

²⁹ Petitioner also asserts that Patent Owner does not dispute that Alataris teaches using higher frequencies in the same level of detail as the '460 patent. Pet. Reply 18 (citing Pet. 70–71; Ex. 1005 ¶ 50; Ex. 1040, 167:14–171:2). We regard this as additional evidence that Patent Owner regarded the use of high frequencies as within the level of skill in the art. *See Trustees of Columbia University in City of New York v. Illumina, Inc.*, 620 F. App'x. 916, 931 (However, as already explained, if novel and nonobvious chemistry was needed to practice the claimed inventions, Dr. Ju would have been obligated to disclose this chemistry in the patent.).

argues that Alataris provides detailed instruction of how to provide stimulation at these frequencies. Pet. 84–85 (citing Ex. 1005 ¶¶ 36–37, 48, 82–111; Ex. 1002 ¶ 274; Pet. § X.C.1.).

Taking the evidence as a whole, although some hardware modifications would have been necessary to program Bradley’s system to deliver high frequency therapy (as averred by Dr. Stone and Dr. Mihran), we determine that it would have been within the level of skill in the art to do so, i.e., in view of Alataris. *See* Ex. 1005 ¶¶ 36–37, 48, 82–111. For example, Alataris discloses that the contacts can be formed from conductive silicone, e.g., silicone impregnated with a suitable loading of conductive material, such as platinum, iridium, or another noble metal (*id.* ¶ 89) and notes that scarring may occur in some patients, which may cause the physician to select different contacts (*id.* ¶ 91). Alataris discloses that a feedback feature may be of particular value to a patient receiving non-paresthesia inducing therapy because the patient may not immediately sense such therapy otherwise. *Id.* ¶ 93. Alataris also discloses that unipolar modulation may be provided, as opposed to the more typical bipolar modulation associated with standard SCS treatments. *Id.* ¶ 90. Alataris also discloses that either a non-rechargeable battery or a rechargeable battery may be used. *Id.* ¶ 28.

Alataris also states that:

Although the higher frequencies associated with the presently disclosed techniques may initially appear to require more power than conventional SCS techniques, the signal amplitude may be reduced when compared to conventional SCS values (due to improved signal penetration) and/or the duty cycle may be reduced (due to persistence effects described later). Accordingly, the presently disclosed techniques can result in a net power savings when compared with standard SCS techniques.

Id. ¶ 67. These teachings from Alataris would have provided guideposts to a person of ordinary skill and indicate that it would have been possible with available technology, such as available batteries. *See id.* ¶¶ 27, 67.

We, therefore, determine that Petitioner has established that claims 15–17 would have been obvious over Bradley, Davis, and Alataris.

3. *Analysis of Claims 22–24*

Claims 22–24 depend from claim 21, and contain further recitations that are identical to the further recitations of claims 15–17. We determine that claims 22–24 would have been obvious over Bradley, Davis, and Alataris, for the same reasons as for claims 15–17.

III. PATENT OWNER’S MOTION TO AMEND

Patent Owner filed a contingent motion to amend claims. Paper 25. Patent Owner affirmatively withdrew its motion, Paper 36, after we issued Preliminary Guidance on the motion, Paper 32. Accordingly, Patent Owner’s motion to amend is moot, and we do not reach any issue presented in that motion.

IV. CONCLUSION³⁰

For the foregoing reasons, we conclude that Petitioner has established by a preponderance of the evidence that claims 1–24 of the ’460 patent are unpatentable.

³⁰ Should Patent Owner wish to pursue amendment of the challenged claims in a reissue or reexamination proceeding subsequent to the issuance of this decision, we draw Patent Owner’s attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding*. *See* 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent

Claims	35 U.S.C. §	References/Basis	Claims Shown Unpatentable	Claims Not Shown Unpatentable
1–14, 18–21	103	Bradley, Polefko		1–14, 18–21
2, 3	103	Bradley, Polefko, Zhu		2, 3
15–17, 22–24	103	Bradley, Polefko, Alataris		15–17, 22–24
1–14, 18–21	103	Bradley, Davis	1–14, 18–21	
2, 3	103	Bradley, Davis, Zhu	2, 3	
15–17, 22–24	103	Bradley, Davis, Alataris	15–17, 22–24	
Overall Outcome			1–24	

V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that Petitioner has proved by a preponderance of the evidence that claims 1–24 of the '460 patent are unpatentable; and

FURTHER ORDERED that, because this is a Final Written Decision, parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. *See* 37 C.F.R. §§ 42.8(a)(3), (b)(2).

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*.

Opinion for the Board filed by *Administrative Patent Judge* WEATHERLY

Opinion Dissenting-in-part filed by *Administrative Patent Judge*
WORTH

WORTH, *Administrative Patent Judge, Dissenting-in-part*

If it is impossible to apply the prior art to one or more claims, the proper course is for the panel to proceed to a final written decision on the other claims and exclude the claims with an impossibility problem from the final written decision. *See Intel Corp. v. Qualcomm Inc.*, 21 F.4th 801, 812–813 (Fed. Cir. 2021). For the reasons that follow, I would determine that it is impossible to apply the art, i.e., obviousness over Bradley in combination with and at least one of Polefko and Davis, with respect to certain of Petitioner’s contentions

as to independent claim 1. Therefore, I would exclude independent claim 1 and its dependent claims from a determination of patentability in the final written decision.

Independent claim 1 recites:

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 [the “positional relationship” clause];

receive a second input corresponding to *a medical indication* of the patient [the “medical indication” clause];

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* [the “third input” clause]; 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 [the “based . . . in part” clause].

Ex. 1001, 37:21–39 (all emphases added).

It is true that the apparent antecedent basis of “the positional relationship” in the “based . . . in part” clause is “a positional relationship between the implanted signal delivery device [the lead] and an anatomical feature [vertebra].” However, in the intervening “third input” clause, there is a “requested change” in the “axial length of a computer-based image of the vertebra.” This “requested change” in axial length may result in a

change in the positional relationship between the lead and the vertebra. For example, the '460 patent discloses that:

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. . . . If the patient's vertebral levels do not have the axial dimensions illustrated at the display 1320b, the practitioner can alter these dimensions. 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. In addition to or in lieu of the foregoing, the practitioner can scale all the vertebral levels simultaneously with a single control. The practitioner can move the lead identifier 1325a, 1325b and/or manipulate the boundaries 1341 between vertebrae based on viewing an image of the implanted lead(s) via an X-ray or other imaging protocol.

See Ex. 1001, 30:26–43.

The parties are in agreement that scaling both the background image and the representation of the leads (e.g., zooming) would change the axial length of a computer-based image of a vertebra without changing the positional relationship (the relative relationship) between the leads and the vertebra. However, the above-quoted portion of the '460 patent discloses dragging vertebral boundaries as an example of a way to change the axial dimensions (the axial length) and also to change the positional relationship between the representation of the leads and the vertebral level.

The above-quoted portion of the '460 patent also appears to disclose scaling the image of the vertebrae as a further example of a way to change the axial dimensions (the axial length) and also to change the positional relationship between the representation of the leads and the vertebral level. *See Ex. 1001, 30:26–43.* This would occur where the background image of

the vertebrae is scaled separately from the representation of the leads. For example, discussing the prior art of Davis (Ex. 1027 ¶ 92), Dr. Mihran avers that the user can change the dimensions of the vertebrae relative to the dimensions of the leads by “scal[ing]” the anatomical image “separately” from the lead images. Ex. 1002 ¶ 109.

Thus, there are two situations where changing the axial length of the image may result in a change in the positional relationship between the lead and the vertebra, as these objects are represented by the computer.³¹

Further, the only passage in the Specification that refers to a “computer-based image” appears to disclose “chang[ing] an axial length of a computer-based image of a vertebra” as an example of changing the positional relationship (the relative relationship) between the leads and at least one vertebra. *See* Ex. 1001, 35:62–65 (“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.”) (emphasis added).

Further, some of Petitioner’s contentions relate to scaling a background image of vertebrae relative to a representation of the leads. *See*, e.g., Pet. 40–41, 73, 76. In my view, if a user performs this type of scaling, this would change both the axial length of the vertebra and the positional relationship.³²

³¹ This discussion does not mean that there would be an actual change in the size of the vertebrae or the leads.

³² I note that independent claim 11 has an updating step that claim 1 lacks, i.e., “update the computer-based image of the vertebra to reflect the requested change.” One might argue that the absence of this limitation in claim 1 means that there is no change made to the axial length nor to the positional relationship based on the third input of a “requested change.” It is

Therefore, it would be impossible to apply the art to independent claim 1 because the reader would not then know which positional relationship to use later in the claim, e.g., in the “based . . . in part” clause, i.e., the positional relationship which is established in the “positional relationship” clause, or the positional relationship which is the product of the “third input” clause.

Also, in my view, the recited “change in axial length of a computer-based image of the vertebra” in the “third input” clause occurs after the positional relationship is first established in the “positional relationship” clause. In my view, the fact that the claim recites a “change” necessarily means that the one follows the other.

Thus, the positional relationship may change in the “third input” clause. There is therefore an ambiguity in whether the “positional relationship” used to identify treatment parameters in the “based . . . in part”

not necessarily the case that there would be such a claim differentiation between two independent claims. *See, e.g., Curtiss-Wright Flow Control Corp. v. Velan, Inc.*, 438 F.3d 1374, 1380 (Fed. Cir. 2006) (collecting cases) (“Different claims with different words can, of course, define different subject matter within the ambit of the invention. On the other hand, claim drafters can also use different terms to define the exact same subject matter.”). Although Patent Owner argues that the updating may occur thereafter, e.g., in claim 2 (*see* PO Sur-reply 23 n.2; PO Supp. Br. 2–3), the system of claim 1 already identifies treatment parameters for the patient in the “based . . . in part” clause of claim 1, and the updating in claim 2 relates to a fourth input which relates to a different situation where the lead has migrated or been moved. Assuming that all critical features have been claimed for operation of the system, “the positional relationship” would refer to the changed positional relationship so that the identified treatment parameters for the patient (generated in the “based . . . in part” clause) are based on the most accurate data on the positional relationship.

clause is the original positional relationship or the changed positional relationship (resulting from the third input).

With this understanding, it would not be possible to evaluate all of Petitioner's contentions as to independent claim 1. Even if it were possible to evaluate the scenario where both the background image of the vertebrae and the representation of the leads are scaled (in which case there would be no change in the positional relationship from the "positional relationship" clause in the "third input" clause), it would not be possible to evaluate the scenario where only the background image of the vertebrae is scaled (because there would be a change in the positional relationship in that scenario and it would be unclear what the antecedent basis of "the positional relationship" is).

I would therefore refrain from reaching a decision on the patentability of claim 1 and its dependent claims 2–10.

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