

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.

IPR2020-01563
Patent 10,076,665 B2

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

WEATHERLY, *Administrative Patent Judge*.

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

I. INTRODUCTION

A. BACKGROUND

Boston Scientific Corp. and Boston Scientific Neuromodulation Corp. (collectively, “Petitioner”) filed a petition (Paper 1, “Pet.”) to institute an *inter partes* review of claims 1–21 (the “challenged claims”) of U.S. Patent

No. 10,076,665 B2 (Ex. 1001, “the ’665 patent”). 35 U.S.C. § 311. Nevro Corp. (“Patent Owner”) timely filed a Preliminary Response (Paper 6). With authorization, the parties filed further pre-institution briefing related to the issue of discretionary denial of a petition under 35 U.S.C. § 314(a). Petitioner filed a reply to the Preliminary Response (Paper 11). Patent Owner filed a sur-reply (Paper 13).

On March 16, 2021, based on the record before us at the time, we instituted an *inter partes* review of all challenged claims on all grounds alleged as indicated in the table below. Paper 14 (“Institution Decision” or “Dec.”).

Claim(s) Challenged	35 U.S.C. §¹	Reference(s)/Basis
1–21	102	Bradley857 ²
1–21	103	Bradley857, Bradley384 ³ , Meadows ⁴

After we instituted this review, Patent Owner filed a Patent Owner Response in opposition to the Petition (Paper 24, “PO Resp.”) that was supported by a Declaration from Robert T. Stone, Ph.D. Ex. 2033. Petitioner filed a Reply in support of the Petition (Paper 29, “Reply”).

¹ The Leahy-Smith America Invents Act (“AIA”), Pub. L. No. 112-29, 125 Stat. 284, 296–07 (2011), took effect on September 16, 2011. The changes to 35 U.S.C. §§ 102 and 103 in the AIA do not apply to any patent application filed before March 16, 2013. Because the application for the patent at issue in this proceeding has an effective filing date (April 2, 2012, based on a provisional application (*see* Ex. 1001, code(60))) before either of these dates, we refer to the pre-AIA version of the statute.

² US 2012/0083857 A1, pub. Apr. 5, 2012 (Ex. 1004, “Bradley857”).

³ US Patent 6,993,384 B2, iss. Jan. 31, 2006 (Ex. 1005, “Bradley384”).

⁴ US Patent 6,516,227, iss. Feb. 4, 2003 (Ex. 1006, “Meadows”).

Patent Owner filed a Sur-reply responding to the Reply (Paper 37, “Sur-reply”).

We heard oral argument on December 14, 2021, a transcript of which has been entered (Paper 44, “Tr.”).

We have jurisdiction under 35 U.S.C. § 6. The evidentiary standard is a preponderance of the evidence. *See* 35 U.S.C. § 316(e) (2018); 37 C.F.R. § 42.1(d) (2019). This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73.

For the reasons expressed below, we conclude that Petitioner has demonstrated by a preponderance of evidence that claims 1–7 and 9–21 are unpatentable but has failed to do so for claim 8.

B. RELATED PROCEEDINGS

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.

Patent Owner also states that the ’665 patent “is related to the following U.S. patents and applications: 61/619,358, 8,767,331, 9,002,460, 9,604,059, and 16/128,276 (pending).” Paper 4, 1.

We note that Petitioner has filed a petition for *inter partes* review challenging U.S. Patent No. 9,002,460 (“the ’460 patent”) (IPR2020-01562) and U.S. Patent No. 9,002,461 (“the ’461 patent”) (IPR2021-00295). The ’460 patent, the ’461 patent, and the ’665 patent in the proceeding before us, each relate to spinal cord modulation to manage pain. The ’665 patent issued from an application that was a continuation of the application that matured into the ’460 patent. Ex. 1001, code (63).

C. THE '665 PATENT

The '665 patent is titled “Devices for Controlling Spinal Cord Modulation for Inhibiting Pain, and Associated Systems and Methods, Including Controllers for Automated Parameter Selection.” Ex. 1001, code (54). The disclosed devices and methods relate “to devices for controlling spinal cord modulation for inhibiting pain, and associated systems and methods, including simplified controllers.” *Id.* at 1:24–27.

As disclosed in the '665 patent, implantable neurological stimulation systems for spinal cord stimulation (SCS) generally have an implantable pulse generator and one or more leads that deliver electrical pulses to neurological tissue or muscle tissue. *Id.* at 1:34–37. Once implanted, the pulse generator applies electrical pulses to the electrodes, which in turn modify the function of the patient’s nervous system, such as by altering the patient’s responsiveness to sensory stimuli and/or altering the patient’s motor-circuit output. *Id.* at 1:46–50. In pain treatment, the pulse generator applies electrical pulses to the electrodes, which in turn can generate sensations that mask or otherwise alter the patient’s sensation of pain. *Id.* at 1:50–53.

The therapeutic effect of the disclosed devices and methods is produced by “inhibiting, suppressing, downregulating, blocking, preventing, or otherwise modulating the activity of the affected neural population.” *Id.* at 3:37–40. In some of the disclosed techniques, “therapy-induced paresthesia is not a prerequisite to achieving pain reduction, unlike standard SCS techniques.” *Id.* at 3:40–43. The disclosed technology can be embodied “in a special-purpose computer or data processor that is

specifically programmed, configured or constructed to perform one or more of the computer-executable instructions.” *Id.* at 3:53–57.

Figure 1A of the '665 patent (reproduced right) 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, 1:64–67. Overall patient system 100 can include one or more signal delivery devices 110, which may be implanted within patient

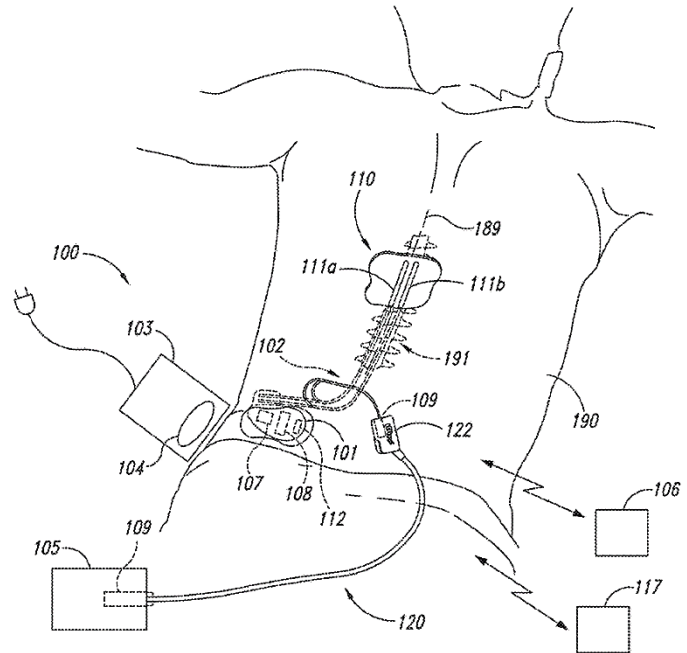


Fig. 1A

190, typically at or near patient's spinal cord midline 189, coupled to implantable pulse generator 101. *Id.* at 4:15–19. Signal delivery devices 110 carry features for delivering therapy to patient 190 after implantation. *Id.* at 4:19–21. 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 4:21–24. 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 4:24–27. Leads 111 can include one or more electrodes or electrical contacts that direct electrical signals into the patient's tissue, such as to provide for patient pain relief. *Id.* at 4:31–34.

As explained in the '665 patent, a potential mechanism of action by which the presently disclosed therapies may operate is by reducing hypersensitivity by “moving the ‘baseline’ of the neural cells in chronic pain patients toward the normal baseline and firing frequency of non-chronic pain patients. This effect can in turn reduce the sensation of pain in this patient population without affecting other neural transmissions.” Ex. 1001, 15:35–42. The '665 patent also discloses an increased ability of high frequency modulation (compared to standard SCS stimulation) to penetrate through the cerebral spinal fluid (CSF) around the spinal cord. *Id.* at 15:61–64. Another such mechanism is the expected reduction in impedance presented by the patient’s tissue to high frequencies, as compared to standard SCS frequencies. *Id.* at 15:64–67.

As shown in Figure 13F, each contact identifier can in turn include an impedance level associated with that contact. *Id.* at 30:59–66. The operator can activate impedance check button 1342 to initiate an impedance check, which updates the values indicated by contact identifiers 1331a, 1331b. *Id.* at 30:66–31:2. On the basis of the impedance values associated with each contact, the program can automatically select particular contacts having an impedance value within an appropriate, pre-established range, that are located near a target vertebral level, and/or can reject one or more contacts having an impedance value that is outside the pre-established range. *Id.* at 31:2–8.

During prosecution, Patent Owner amended the pending claims to require lead alignment based, at least in part, on “impedance values.” Ex. 1015, 195. Patent Owner argued that the cited references did not disclose using impedance values to align lead images. *Id.* at 204–205.

Following this amendment, the Examiner allowed the amended claims. *Id.* at 222–230. The Examiner did not state specifically the reasons for allowing the amended claims. *See* 37 C.F.R. § 1.104(e) (“If the examiner believes that the record of the prosecution as a whole does not make clear his or her reasons for allowing a claim or claims, the examiner may set forth such reasoning.”).

D. ILLUSTRATIVE CLAIMS

Claims 1, 12, and 18 are the independent claims among those challenged. Claim 1, reproduced below, is illustrative of the subject matter:

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

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

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

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

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

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

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

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

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

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

Ex. 1001, 38:10–46 (with certain line breaks and bracketed labels employed by Petitioner to ease discussion).

Independent claim 12, like claim 1, also claims a patient treatment system. The system in claim 1 includes a “non-transitory computer-readable medium having instructions” that perform specific functions. *Id.*

at 38:11–12. Independent claim 12 is substantially similar but states specifically that it is “a programmer in wireless communication with the implantable signal generator” that has a “computer-readable medium with instructions that, when executed” perform specific functions similar to those included in claim 1. *Id.* at 39:40–43.

Independent claim 18 claims a method of operating a patient operating system. Each of the independent claims require contacts with “impedance values within a pre-established range” used to align the computer-based images of the “signal delivery” devices. *E.g., id.* at 38:32–38, 39:55–61, 40:42–50.

II. 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.

III. ANALYSIS

A. CLAIM INTERPRETATION: “ALIGN” AND “ALIGNING”

We interpret claims in the same manner used in a civil action under 35 U.S.C. § 282(b) “including construing the 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). When applying that standard, we interpret the claim language as it would be understood by one of ordinary skill in the art in light of the specification. *Wasica Finance GmbH v. Continental Automotive Sys., Inc.*, 853 F.3d 1272, 1279–80 (Fed. Cir. 2017). Thus, we give claim terms their ordinary and customary meaning as understood by an ordinarily skilled artisan. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc). Only terms that are in controversy need to be construed, and then only to the extent necessary to resolve the controversy. *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017).

During the trial, the parties disputed whether to “align” images leads as used in clauses 1[i] and 12[k] and “aligning” images of leads as used in clause 18[e] requires “repositioning” previously displayed images of the leads or may encompass merely “positioning” the displayed images relative to each other. Patent Owner refers to clauses 1[i], 12[k], and 18[e] as reciting an “impedance alignment feature,” PO Resp. 19, and we do as well when it aids our discussion below. Patent Owner implies that aligning

images means repositioning them by arguing that neither Bradley⁸⁵⁷ nor Bradley³⁸⁴ describes such “repositioning” of images. *Id.* at 19–28. Patent Owner expressly argues its interpretation of “align” in its Sur-reply. Sur-reply 2–7. Petitioner contends that “aligning” an image of a lead to an image of another lead more broadly encompasses positioning or repositioning one image relative to another. Reply 3–5. We agree with Petitioner.

1. The Plain Language

Clause 1[i] of claim 1 recites “based at least in part on impedance values of one or more of the second plurality of contacts, *align a computer-based image of the second signal delivery device [lead] relative to a computer-based image of the first signal delivery device [lead].*” Ex. 1001, 38:34–38 (emphasis added). Clause 12[k] recites substantially the same limitation as follows: “based at least in part on impedance values of one or more of the second plurality of contacts, *align a computer-based image of the second lead relative to a computer-based image of the first lead.*” *Id.* at 39:58–61 (emphasis added). Clause 18[e] recites substantially the same limitation as follows: “based at least in part on impedance values of one or more of the second plurality of contacts, *aligning a computer-based image of the second signal delivery device [lead] relative to a computer-based image of the first signal delivery device [lead].*” *Id.* at 40:46–50 (emphasis added).

At the outset, we find that the plain language of clauses 1[i], 12[k], and 18[e], in isolation, requires only that the displayed image of one lead is aligned with the displayed image of the other lead without requiring any “repositioning” of previously displayed images. However, Patent Owner

argues that other language recited in each independent claim requires first “establishing” the positions of the first and second leads, which necessarily means that “aligning” the images of the first and second leads refers to repositioning them on the display. Sur-reply 2–3. However, Patent Owner’s argument fails to recognize the distinction between establishing the physical “position” of the leads relative to a physical frame of reference and aligning computer-based images of those leads. For example, clauses 18[b] and 18[c] of independent claim 18 recite: “[b] establishing a first positional relationship between a location of a first signal delivery device and an anatomical feature of a patient” and “[c] establishing a second positional relationship between a location of a second signal delivery device and at least one of the location of the first signal delivery device or the anatomical feature of the patient.” Ex. 1001, 40:34–41. None of clauses 18[b] or 18[c] or the substantively identical clauses 1[d], 1[f], 12[h], 12[i]⁵ from the other independent claims mentions displaying an image of either lead on a computer screen. Rather, these clauses encompass establishing the spatial position of each of the first and second physical leads relative to a physical frame of reference (e.g., an anatomical feature of a patient or another lead). These limitations may be met without displaying leads on a computer screen at all. Accordingly, we reject Patent Owner’s argument that the claims first require positioning images of the leads on a display before aligning those images on the display. Rather, we find that a plain reading of “align” or

⁵ See Ex. 1001, 38:17–19 (1[d]), 38:24–27 (1[f]), 39:48–52 (12[h]–12[i]).

“aligning” images of the first and second leads refers to arranging the images of the first and second leads on a screen relative to each other.⁶

2. The Specification

The Specification does not support a different interpretation of “align” as used on clauses 1[d], 1[f], 12[h], 12[i], 18[b], and 18[c]. Patent Owner argues that the Specification describes the “only embodiment” of the impedance alignment feature in connection with Figure 13F, reproduced below. Sur-reply 4–6 (citing Ex. 1001, 31:9–16, 31:28–36, Fig. 13F).

⁶ We note that on February 25, 2021, following a *Markman* hearing, the District Court issued a “Claim Construction Order” construing for independent claims 1, 12, and 18, the phrase “based at least in part on impedance values of one or more of the second plurality of contacts, align[ing] a computer-based image of the second signal delivery device relative to a computer-based image of the first signal delivery device”). The Court determined that this phrased should be construed according to its “[p]lain and ordinary meaning.” Ex. 3001, 4 (first alteration in original).

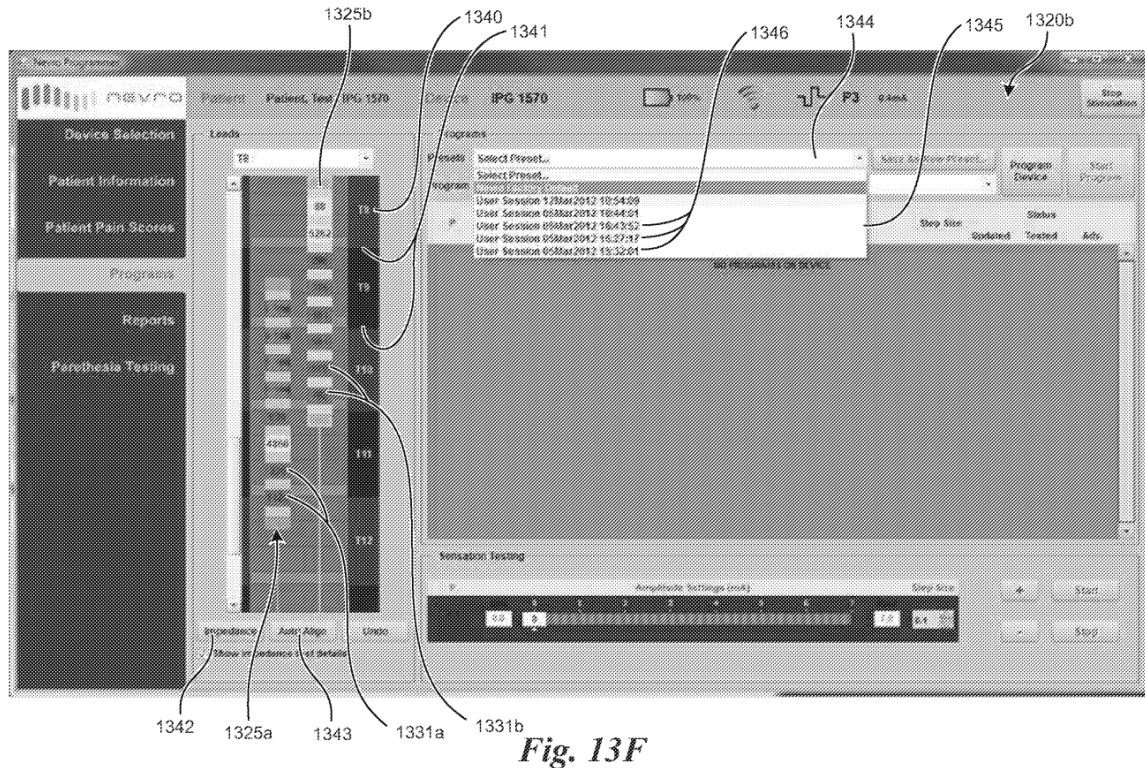


Fig. 13F

FIG. 13F is a partially schematic illustration of a display 1320b configured in accordance with another embodiment of the present disclosure. Ex. 1001, 30:59–61.

Patent Owner explains that the Specification describes permitting the user to “automatically *adjust the location of the other lead identifier* relative to the first by activating an ‘auto align button’ 1343.” Sur-reply 4 (quoting Ex. 1001, 31:28–36). Patent Owner argues that the “reference to ‘*adjust[ing]* the location’ of the second lead relative to the first clarifies that the positional relationship between the two leads has *already* been established and displayed, and that ‘aligning’ the leads repositions them.” *Id.* at 5. We disagree with Patent Owner’s characterization of the quoted portion of the Specification.

The Specification describes automatically adjusting the location of the “lead identifier” for the second lead not adjusting the “positional relationship” between the first and second leads themselves. Ex. 1001,

31:28–36. The context for this quoted portion of the Specification is the ’665 patent’s description of how a user “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.” *Id.* at 31:9–11 (emphasis added). This passage reflects that display 1320b is designed to allow a user to adjust displayed images so that the images “match or closely correspond to the actual relative locations of the leads in the patient’s body.” *Id.* The physical positions of the leads in the patient’s body are separately established in clauses 1[d], 1[f], 12[h], 12[i], 18[b], and 18[c], which do not recite that an image of the leads or the patient’s body is displayed. *See id.* at 38:17–19 (1[d]), 38:24–27 (1[f]), 39:48–52 (12[h]–12[i]), 40:34–41 (18[b], 18[c]). We discern no description in the Specification of using display 1320b as a mechanism for altering the previously established physical positions of the leads in the patient’s body. *Id.* at 30:59–31:51. We discern no reason, based on the Specification, to modify our reading of the plain language of clauses 1[i], 12[k], and 18[e].

3. Conclusion

Accordingly, we conclude that “align” or “aligning” as used in clauses 1[i], 12[k], and 18[e] refers to arranging computer-based images of the first and second leads relative to each other.

B. THE PARTIES’ POST-INSTITUTION ARGUMENTS

In our Institution Decision, we concluded that the argument and evidence adduced by Petitioner demonstrated a reasonable likelihood that claims 1–21 were unpatentable as anticipated and obvious based on the challenges identified in the table in Part I.A above. Dec. 49–50. We must now determine whether Petitioner has established by a preponderance of the

evidence that the specified claims are unpatentable over the cited prior art. 35 U.S.C. § 316(e). We previously instructed Patent Owner that “any arguments for patentability not raised in the [Patent Owner Response] may be deemed waived.” Paper 15, 6; *see also In re NuVasive, Inc.*, 842 F.3d 1376, 1381 (Fed. Cir. 2016) (holding that patent owner’s failure to proffer argument at trial as instructed in scheduling order constitutes waiver). Additionally, the Board’s Trial Practice Guide states that the Patent Owner Response “should identify all the involved claims that are believed to be patentable and state the basis for that belief.” Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,766 (Aug. 14, 2012).

C. LEGAL STANDARDS

Petitioner challenges the patentability of claims 1–21 on the grounds that the claims are either anticipated or obvious. To prevail in its challenges to the patentability of the claims, Petitioner must establish unpatentability by a preponderance of the evidence. 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d). “In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable.” *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016) (citing 35 U.S.C. § 312(a)(3) (requiring *inter partes* review petitions to identify “with particularity . . . the evidence that supports the grounds for the challenge to each claim”)). This burden never shifts to Patent Owner. *See Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015) (citing *Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1326–27 (Fed. Cir. 2008)) (discussing the burden of proof in *inter partes* review).

The Supreme Court in *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), reaffirmed the framework for determining obviousness as set forth in *Graham v. John Deere Co.*, 383 U.S. 1 (1966). The *KSR* Court summarized the four factual inquiries set forth in *Graham* that we apply in determining whether a claim is unpatentable as obvious under 35 U.S.C. § 103(a) as follows: (1) determining the scope and content of the prior art, (2) ascertaining the differences between the prior art and the claims at issue, (3) resolving the level of ordinary skill in the pertinent art, and (4) when in evidence, considering objective evidence indicating obviousness or nonobviousness. *KSR*, 550 U.S. at 406 (citing *Graham*, 383 U.S. at 17–18).

Petitioner must explain how the proposed combinations of prior art would have rendered the challenged claims unpatentable. An obviousness analysis “need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” *KSR*, 550 U.S. at 418; *accord In re Translogic Tech., Inc.*, 504 F.3d 1249, 1259 (Fed. Cir. 2007). However, Petitioner cannot satisfy its burden of proving obviousness by employing “mere conclusory statements,” but “must instead articulate specific reasoning, based on evidence of record” to support an obviousness determination. *In re Magnum Oil Tools Int’l, Ltd.*, 829 F.3d 1364, 1380–81 (Fed. Cir. 2016). Petitioner also must articulate a reason why a person of ordinary skill in the art would have combined the prior art references. *NuVasive*, 842 F.3d at 1382.

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

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

D. LEVEL OF ORDINARY SKILL

We review the grounds of unpatentability in view of the understanding of a person of ordinary skill in the art at the time of the invention. *Graham*, 383 U.S. at 17. Petitioner asserts that a person of ordinary skill in the art at the relevant times would have had a degree in engineering, biomedical engineering, or a related discipline, along with relevant experience researching or developing neural stimulation systems or other implantable medical devices (i.e., at least 2–3 years of additional experience for a person with a Ph.D., 3–5 years for a person with a Master’s, or greater than 5 years for a person with a Bachelor’s degree). Pet. 20 (citing Ex. 1002 ¶ 21). Dr. Mihran states the factors he considered in reaching his opinion, in addition to his “own personal experience in the SCS industry.” 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. Pet. 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. 17.

For purposes of this Decision, we adopt Petitioner’s undisputed definition. We also find that Petitioner’s proposed definition is consistent

with the level of skill demonstrated in the cited prior art references. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001).

E. CLAIMS 1–21: ANTICIPATION BY BRADLEY857

1. *Bradley857*

a. Overview

Bradley857 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.

Bradley857 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. Bradley857 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.

Bradley857 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, Bradley857 discloses that the external control device further comprises memory storing a database, which may further contain a plurality of pulse width 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 Bradley857 is reproduced below:

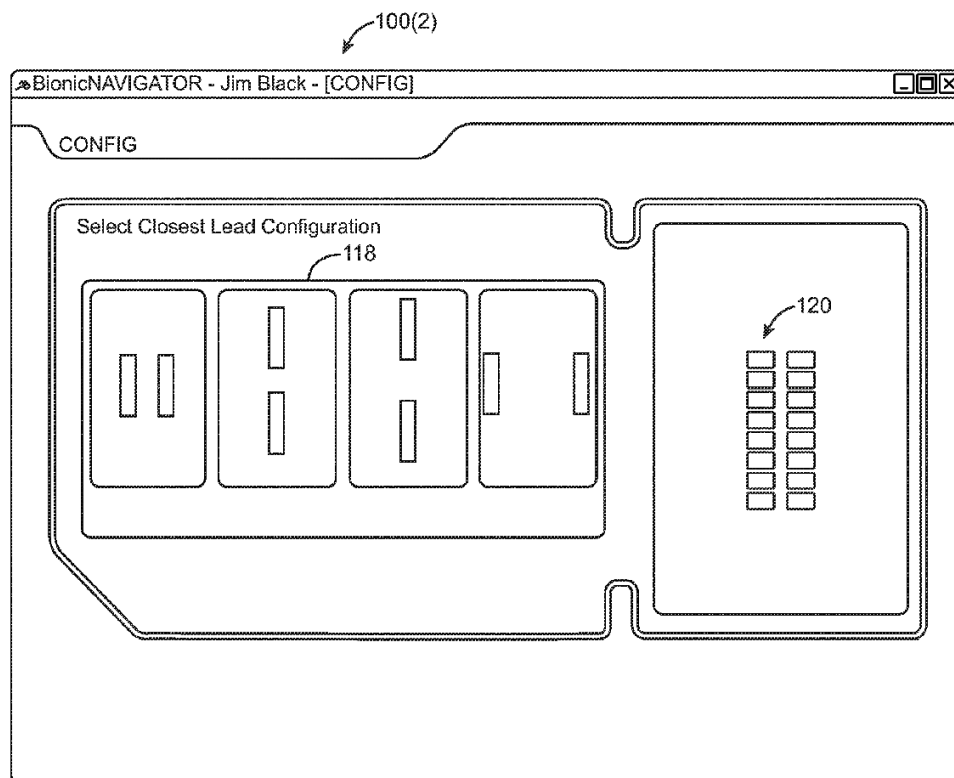


FIG. 8

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

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

Figure 9 of Bradley857 is reproduced below:

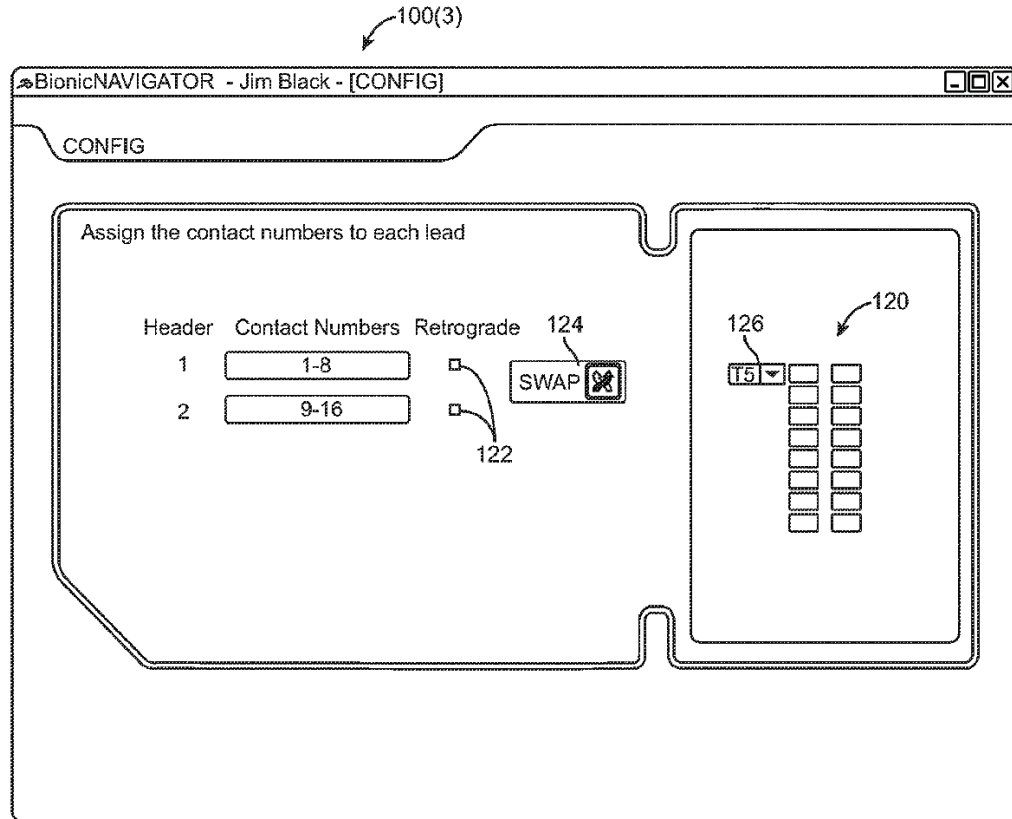


FIG. 9

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

b. Incorporation of Bradley384 and Meadows by Reference

Incorporation by reference provides “a method for integrating material from various documents into a host document[] ... by citing such material in a manner that makes clear that the material is effectively part of the host document as if it were explicitly contained therein.” *Paice LLC v. Ford Motor Co.*, 881 F.3d 894, 906–07 (Fed. Cir. 2018) (citing *Advanced Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272, 1282 (Fed. Cir. 2000)). “To incorporate material by reference, the host document must identify with

detailed particularity what specific material it incorporates and clearly indicate where that material is found in the various documents.” *Id.* Incorporation language must be read in context and holistically. *Paice*, 881 F.3d at 910 (Fed. Cir. 2018).

Bradley857 states: “Further details discussing the detailed structure and function of IPGs⁷ are described more fully in [Meadows] and [Bradley384], which *are* expressly incorporated herein by reference.” Ex. 1004 ¶ 47 (emphasis added).

Petitioner states that Bradley857 “expressly incorporates the disclosures of both Bradley384 and Meadows.” Pet. 31 (citing Ex. 1004 ¶¶ 47, 61; Ex. 1002 ¶¶ 81–82, 100, 138).

Patent Owner argues that this passage, “[o]n its face,” Bradley857 fails to incorporate Bradley384 or Meadows in their entirety but rather incorporates only “details discussing the detailed structure and function of IPGs.” PO Resp. 45. Patent Owner also argues that Bradley857’s “incorporation language” is “nearly identical to the language at issue in *Zenon Environmental, Inc. v. US Filter Corporation*, 506 F.3d 1370 (Fed. Cir. (2007),”⁸ which reads:

The vertical skein is not the subject matter of this invention and any prior art vertical skein may be used. Further *details relating to the construction and deployment of a most preferred skein* are

⁷ An IPG is an “implantable pulse generator.” See Ex. 1004 ¶ 4.

⁸ Patent Owner also cites *Cook Biotech Inc. v. Acell, Inc.*, 460 F.3d 1365 (Fed. Cir. 2006) and *Callaway Golf Co. v. Acushnet Co.*, 576 F.3d 1331, 1345 (Fed. Cir. 2009) as support for its argument. PO Resp. 46–47. However, Patent Owner does not present any persuasive analysis of how those decisions support its argument, and our review of these decisions reveals no persuasive support for Patent Owner’s position.

found in the parent U.S. Pat. No. 5,639,373, and in Ser. No. 08/690,045, the relevant disclosures of each of which are included by reference thereto as if fully set forth herein.

Id. at 46 (quoting *Zenon*, 506 F.3d at 1379 with emphasis). Patent Owner argues that *Zenon* requires that we conclude that Bradley857 incorporates only “details discussing the detailed structure and function of IPGs.” *Id.* at 47; Sur-reply 20–21. We find Patent Owner’s arguments to be unpersuasive.

The Federal Circuit reached its conclusion in *Zenon* because the clause at issue expressly limited the scope of material that was incorporated by stating that “the *relevant disclosures* of each of [the pair of references] are included by reference.” *Zenon*, 506 F.3d at 1379 (emphasis added). By contrast, Bradley857’s incorporation statement at ¶ 47 contains no such limit on its scope.

Rather, we find Bradley857’s ¶ 47 to be more akin to the incorporation statement in *Paice*, which reads:

This application discloses a number of improvements over and enhancements to the hybrid vehicles disclosed in the inventor’s U.S. Pat. No. 5,343,970 (the “’970 patent”) [Severinsky], which is incorporated herein by this reference.

Paice, 881 F.3d at 907. The Federal Circuit held that this statement incorporated Severinsky in its entirety because: “[t]his passage is broad and unambiguous. It states that Severinsky ‘*is*,’ without qualification, incorporated into the ’817 application ‘by *this* reference’—i.e., the reference contained in the sentence.” *Id.*

Here, Bradley857 includes a grammatically similar incorporation statement that reads: “Further details discussing the detailed structure and function of IPGs are described more fully in [Meadows] and [Bradley384],

which *are* expressly incorporated herein by reference.” Ex. 1004 ¶ 47 (emphasis added). The incorporation statement in Bradley857 contains the operative relative clause, “which are incorporated herein by reference.” This statement is grammatically parallel to the clause at issue in Paice, “which is incorporated herein by this reference.” *Paice*, 881 F.3d at 907. We conventionally read Bradley857’s incorporation clause as modifying the immediately preceding pair of references, Meadows and Bradley. In *Paice*, the Federal Circuit read a grammatically identical relative clause beginning with “which is,” as referring to the immediately preceding reference, Severinsky. We therefore consider *Paice* to be more instructive for our interpretation of Bradley857’s incorporation statement.

For all these reasons, we conclude that Bradley857 incorporates by reference the entirety of each of Meadows and Bradley384.

2. Independent Claims 1, 12, and 18

a. Undisputed Subject Matter

The parties do not dispute that Bradley857 describes much of the subject matter recited in the independent claims. Petitioner contends that Bradley857 expressly describes the limitations of independent claim 1 recited in clauses 1[a]–1[g]. Pet. 32–36, 38–40 (citing Ex. 1004 ¶¶ 2, 10, 14, 15, 38, 41, 43, 51, 52, 55, 57, 59, 61–63, 65, 70, 71, Figs. 1–3, 8–10). In support of its showing for clause 1[e], Petitioner also cites Bradley384 as describing methods of using measured values of impedance to determine the relative spacing of leads and to align the images of the two leads to reflect that spacing. *Id.* at 37 (citing Ex. 1005, 6:57–67, 6:43–7:51; Ex. 1002 ¶¶ 127–128 and cross-referencing showing for clause 1[i] at Pet. 43–44 (citing Ex. 1005, 6:43–7:51, Ex. 1002 ¶ 149)). Petitioner contends that

Bradley⁸⁵⁷ expressly describes limitations of independent claim 12 recited in clauses 12[a]–12[i], 12[l]. *Id.* at 56–60 (cross-referencing its showing for clauses 1[a]–1[g] and also citing Ex. 1004 ¶¶ 37, 38, 40, 41, 43–45, 55, 59, 61–63, 67, Figs. 2, 3). Petitioner contends that Bradley⁸⁵⁷ expressly describes limitations of independent claim 18 recited in clauses 18[a]–18[c]. *Id.* at 63–64 (citing cross-referencing showing for clauses 1[c]–1[f] and also citing Ex. 1004 ¶¶ 36, 38, 44, 62, 63, 65, 65, 70, 71, 79, Figs. 3, 9).

Petitioner also cites testimony from Dr. Mihran to support its contentions regarding clauses 1[a]–1[g], 12[a]–12[i], 12[l], and 18[a]–18[c]. *Id.* at 32–40 (citing Ex. 1002 ¶¶ 107–125, 127–130, 132–137), *id.* at 56–60 (citing Ex. 1002 ¶¶ 181–188, 192, 193), *id.* at 63–64 (citing Ex. 1002 ¶¶ 201–205).

Patent Owner does not contest Petitioner’s showing that Bradley⁸⁵⁷ describes the subject matter recited in clauses 1[a]–1[g], 12[a]–12[i], 12[l], and 18[a]–18[c]. *See* PO Resp. 18–37 (contesting only Petitioner’s showing regarding whether the prior art described the subject matter of clauses 1[h]–1[j], 12[j], 12[k], 12[m], 18[d], 18[e]). Accordingly, based on Petitioner’s reasoning, which we adopt as our own, and the evidence proffered by Petitioner, we find that Petitioner has demonstrated by a preponderance of evidence that Bradley⁸⁵⁷ describes the subject matter recited in clauses 1[a]–1[g], 12[a]–12[i], 12[l], and 18[a]–18[c].

b. Disputed Subject Matter

The table below includes the language from independent claims 1, 12, and 18 with substantively similar language arranged side-by-side along with the bracketed labels used by Petitioner to ease our discussion and analysis. We italicize the clauses in the claims for which the parties dispute whether that element is described by Bradley⁸⁵⁷ with subject matter incorporated

from Bradley384 and Meadows or by the combined teachings of
Bradley857, Bradley384, and Meadows.

Claim 1	Claim 12	Claim 18
1[a]. A patient treatment system, comprising:	12[a]. A patient treatment system, comprising:	18[a]. A method of operating a patient treatment system, the method comprising:
	[b] an implantable signal generator;	
	[c] a first elongated signal delivery lead coupled to the implantable signal generator and positioned proximate to a patient's spinal cord, the first lead including a first plurality of contacts; ⁹	
	[d] a second elongated signal delivery lead coupled to the implantable signal generator and positioned proximate to the patient's spinal cord, the second lead including a second plurality of contacts; ¹⁰ and	

⁹ The first lead including a first plurality of contacts is analogous to clause 1[c] below.

¹⁰ The second lead including a second plurality of contacts is analogous to aspects of clause 1[c] below.

Claim 1	Claim 12	Claim 18
[b] a non-transitory computer-readable medium having instructions that, when executed:	[e] a programmer in wireless communication with the implantable signal generator, the programmer having a computer-readable medium with instructions that, when executed:	
[c] receive a first input corresponding to a location of a first signal delivery device implanted in a patient, the first signal delivery device including a first plurality of contacts;	[f] receive a first input indicating a location of the first lead;	
	[g] receive a second input indicating a location of the second lead; ¹¹	
[d] establish a first positional relationship between the location of the first signal delivery device and an anatomical feature of the patient;	[h] establish a first positional relationship between the first lead and a vertebra of the patient;	[b] establishing a first positional relationship between a location of a first signal delivery device and an anatomical feature of a patient, the first signal delivery device including a first plurality of contacts;

¹¹ See aspects of clause 1[e] below for analogous language appearing in claim 1.

Claim 1	Claim 12	Claim 18
[e] receive a second input corresponding to a location of a second signal delivery device implanted in the patient, ¹² the second signal delivery device including a second plurality of contacts; ¹³		
[f] establish a second positional relationship between the location of the second signal delivery device and at least one of the location of the first signal delivery device or the anatomical feature of the patient;	[i] establish a second positional relationship between the second lead and at least one of the first lead or the vertebra of the patient;	[c] establishing a second positional relationship between a location of a second signal delivery device and at least one of the location of the first signal delivery device or the anatomical feature of the patient;

¹² See aspects of clause 12[g] above for analogous language appearing in claim 12.

¹³ The second lead including a second plurality of contacts is analogous to aspects of clause 12[d] above.

Claim 1	Claim 12	Claim 18
[g] identify one or more contacts of the first plurality of contacts for delivering therapy to the patient, wherein the identified one or more contacts are (a) located at a target vertebral level of the patient, and [h] (b) have impedance values within a pre-established range;	[j] identify one or more contacts of the first plurality of contacts for delivering a pulsed electrical signal to the patient, wherein <i>the identified one or more contacts have impedance values within a pre-established range;</i>	[d] identifying one or more contacts for delivering therapy to the patient, wherein <i>the identified one or more contacts have impedance values within a pre-established range;</i> and
[i] <i>based at least in part on impedance values of one or more of the second plurality of contacts, align a computer-based image of the second signal delivery device relative to a computer-based image of the first signal delivery device;</i> and	[k] <i>based at least in part on impedance values of one or more of the second plurality of contacts, align a computer-based image of the second lead relative to a computer-based image of the first lead;</i>	[e] <i>based at least in part on impedance values of one or more of the second plurality of contacts, aligning a computer-based image of the second signal delivery device relative to a computer-based image of the first signal delivery device.</i>
	[l] access an established database of patient information, wherein the database includes a predetermined correlation including the first and second positional relationships for other patients; and	

Claim 1	Claim 12	Claim 18
<i>[j] automatically identify a signal delivery parameter value for a pulsed electrical signal that is to be delivered to the patient via at least one of the first signal delivery device or the second signal delivery device, wherein the signal delivery parameter value has a predetermined correlation with at least one of the first positional relationship or the second positional relationship.</i>	<i>[m] based at least in part on the predetermined correlation, automatically identify a value of a signal delivery parameter for a pulsed electrical signal to be delivered to the patient's spinal cord via at least one of the first or second pluralities of contacts.</i>	

As indicated by the italicized portions of the claims in the table above, the parties' dispute whether the prior art describes the subject matter recited in clauses 1[h], 1[i], and 1[j] in claim 1 and the substantively similar clauses recited in independent claims 12 and 18. Clauses 1[h], 1[i], and 1[j] are substantively similar to clauses 12[j], 12[k], and 12[m] respectively. *Compare* Ex. 1001, 38:32–46, *with id.* at 39:53–61, 39:66–40:3. Clauses 1[h] and 1[i] are substantively similar to clauses 18[d] and 18[e] respectively. *Compare id.* at 38:32–46, *with id.* at 40:42–50. PO Resp. 18–37. Thus, we focus our analysis below of the scope and content of the prior art as it compares to the claims on these clauses of independent claims 1, 12, and 18.

i. Clauses 1[h], 12[j], and 18[d]:
The Pre-Established Range Feature

Clause 1[h] of claim 1 the claimed system includes instructions that, when executed will “identify one or more contacts of the first plurality of contacts for delivering therapy to the patient, wherein the identified one or more contacts . . . have impedance values within a pre-established range.” Ex. 1001, 38:28–33. Clause 12[j] recites substantially the same limitation as follows: “identify one or more contacts of the first plurality of contacts for delivering a pulsed electrical signal to the patient, wherein the identified one or more contacts have impedance values within a pre-established range.” *Id.* at 39:53–57. Clause 18[d] recites substantially the same limitation as follows: “identifying one or more contacts for delivering therapy to the patient, wherein the identified one or more contacts have impedance values within a pre-established range.” *Id.* at 40:42–44. Patent Owner refers to this group of clauses as reciting a “pre-established range” feature, PO Resp. 29, and we do as well in our discussion below.

Petitioner asserts that Meadows, incorporated into Bradley⁸⁵⁷, discloses that “an important feature included within the IPG 100 is its ability to measure electrode impedance.” Pet. 40 (citing Ex. 1006, 20:5–8; Ex. 1002 ¶¶ 138–140). According to Petitioner, Meadows provides a pre-established range— “[f]or a spinal cord implantation, the electrode impedance will typically range between about 400 ohms and 1000 ohms.” *Id.* (citing Ex. 1006, 20:18–20). Hardware recognition occurs once the clinician programmer is connected to the system and “the system identifies the stimulator, the patient programmer, and electrode availability (through electrode impedance measurements).” *Id.* (citing Ex. 1006, 32:35–39). As stated in Meadows, impedance values that are too high suggest an open or

broken electrode; impedance values that are too low suggest a short circuit. Ex. 1006, 46:55–64. Petitioner concludes from this that “Meadows [and thus Bradley857, which incorporates Meadows] teaches that the electrodes for delivering therapy that are located at the target vertebral level must have impedance values within a pre-established range to be available for programming.” Pet. 41 (citing Ex. 1002 ¶ 142).

First, Patent Owner contends that Bradley857 wholly fails to describe the pre-established range feature because Bradley857 never mentions using impedance measurements to identify contacts for delivering therapy to a patient or for any other reason. PO Resp. 30–31. However, as we have noted above, Petitioner relies on the incorporated disclosure from Meadows rather than express statements in Bradley857 as describing the pre-established range feature. Pet. 39–41 (citing e.g., Ex. 1006, 20:5–8, 20:18–20, 32:35–39, 34:55–59, 38:32–54, 40:16–18, 46:55–65, 47:7–49:47; Ex. 1002 ¶¶ 138–142). Accordingly, we find Patent Owner’s first contention unpersuasive because it fails to address Petitioner’s reliance on disclosure within Meadows incorporated into Bradley857.

Second, Patent Owner contends that Meadows “does not disclose *identifying an electrode for therapy* based on whether its impedance is within a predetermine range” but rather merely “relies on impedance measurements only to generally determine ‘electrode availability.’” PO Resp. 31. Although Patent Owner acknowledges that Meadows describes a system that provides “the ability to stimulate simultaneously on all available electrodes,” Patent Owner contends that Meadows fails to identify contacts for “delivering therapy where the contacts have an impedance value within a predetermined range.” *Id.* at 30–31.

Petitioner responds that Bradley857's system allows a user to identify which electrodes are selected for delivering therapy. Reply 10. Petitioner also responds that Bradley857's reference to Meadows incorporates Meadows method for determining whether an electrode is "available" to the user for delivering therapy by first confirming that impedance of the electrode is within a pre-established range. *Id.* For example, Meadows indicates that the "number of implanted and available electrodes is typically automatically determined by impedance measurements during hardware interrogation," Ex. 1006, 34:57–59, and that impedance of an electrode "is a general measure of the fitness of the system to perform its required function," *id.* at 46:61–64. Dr. Stone, Patent Owner's expert, agrees that Meadows's system does not deliver therapy to an electrode if the measured impedance for that electrode is too high or too low, that is, outside a pre-established range. Ex. 1040, 82:8–87:8.

Patent Owner responds on sur-reply that when Bradley857 identifies electrodes for therapy it "does so based *solely* on the proximity to a target—not impedance." Sur-reply 13. Patent Owner's argument is unavailing. Patent Owner ignores that Bradley857 incorporates Meadows's method for identifying which electrodes are available into Bradley857's ability to identify an electrode for therapy. Ex. 1004 ¶ 47. Bradley857's system cannot identify an "unavailable" electrode for delivering therapy.

Patent Owner also responds that Meadows fails to describe measuring "impedance values within a pre-determined range" because it merely describes "typical or exemplary impedance values." Sur-reply 13. Patent Owner's argument is unavailing. When Meadows states that "the electrode impedance will typically range between about 400 ohms and 1000 ohms,"

Meadows also refers to the discussion of Figures 11A and 11B for details of the “impedance measuring feature.” Ex. 1006, 20:18–22. In that discussion, Meadows explains that it verifies that impedance measurements outside the typical range indicate that “the device may be unable to perform its intended function.” *Id.* at 46:55–64.

For all these reasons, we find that Petitioner has proven by a preponderance of evidence that Bradley857 and Meadows as incorporated into Bradley857 describes the subject matter of clauses 1[h], 12[j], and 18[d] (the pre-established range feature).

ii. Clauses 1[i], 12[k], and 18[e]:
The Impedance Alignment Feature

Clause 1[i] of claim 1 recites “based at least in part on impedance values of one or more of the second plurality of contacts, align a computer-based image of the second signal delivery device relative to a computer-based image of the first signal delivery device.” Ex. 1001, 38:34–38. Clause 12[k] recites substantially the same limitation as follows: “based at least in part on impedance values of one or more of the second plurality of contacts, align a computer-based image of the second lead relative to a computer-based image of the first lead.” *Id.* at 39:58–61. Clause 18[e] recites substantially the same limitation as follows: “based at least in part on impedance values of one or more of the second plurality of contacts, aligning a computer-based image of the second signal delivery device relative to a computer-based image of the first signal delivery device.” *Id.* at 40:46–50.

Petitioner contends that Bradley857 describes an interface in which the user can graphically depict images of the two leads (first and second plurality of contacts) as those leads relative to a patient’s spine. Pet. 42

(citing Ex. 1004 ¶ 63, Fig. 10 (screen 100(4))). Petitioner contends that Bradley857 teaches that the relative positions of implanted leads can be determined based on “measured electrical parameters.” *Id.* at 41 (citing Ex. 1004 ¶ 61). Petitioner asserts that Bradley857 specifically points to and incorporates Bradley384 for details of the manner in which “measured electrical parameters” are used to position the images of the two leads relative to each other and the spine. *Id.* (citing Ex. 1004 ¶ 61; Ex. 1002 ¶¶ 81–82). Petitioner further contends that “Bradley384, in turn, teaches the use of impedance, a ‘measured electrical parameter’ to align images of leads.” *Id.* at 41–42 (citing Ex. 1005, 6:43–7:60, 10:56–61, Figs. 8–10; Ex. 1002 ¶ 144). For example, Bradley384 states: “The monopolar impedances are used to ‘correct’ the bipolar impedances for the first factor of bulk impedance, the strongly-weighted impedance near the electrode. The corrected bipolar impedances are then used to develop an impedance ‘map’ between the electrodes. This map reveals the relative orientation of the leads.” Ex. 1005, 7:17–22; *see also id.* Figs. 4–6. Bradley384 continues: “[t]his information may then be loaded into a programmer, which can then provide a graphic display of the assumed relative lead positions.” *Id.* at 7:43–46. Bradley384 further describes that the displayed images can be compared to help the physician track the lead orientation. *Id.* at 7:46–51.

Patent Owner first argues that Bradley857 alone fails to describe explicitly using impedance to align images of the leads. PO Resp. 20. We find Patent Owner’s argument unavailing because Petitioner relies upon Bradley857’s incorporation of Bradley384 as describing this aspect of the impedance alignment feature. Pet. 41–44; Reply 16. Rather than expressly identifying “impedance” as the parameter used to align images of the leads,

Bradley857 states that “positions of the [leads] relative to each other can be determined based on the measured electrical parameters.” Ex. 1004 ¶ 61. Bradley857 expressly incorporates Bradley384 as describing details of how the alignment based on “measured electrical parameters,” *id.*, which Bradley384 identifies as “impedance,” Ex. 1005, 10:56–61. *See also* Ex. 1040, 69:14–19 (Dr. Stone testifying that the “relative position of leads with respect to each other can be determined using impedance parameters” by Bradley857).

Patent Owner concedes that Bradley384 describes using impedance information to “provide a graphic display of the assumed lead positions” and to track lead movement by comparing that displayed position with prior graphical displays of the leads. PO Resp. 21. However, Patent Owner argues that Bradley384 fails to describe the impedance alignment feature because tracking lead movement does not necessarily involve repositioning images into alignment. *Id.* Patent Owner also contends that the only way in which Bradley857 or Bradley384 describe repositioning images of leads is Bradley857’s drag-and-drop feature shown in its Figure 10, which does not involve using impedance to align the images. *Id.* at 20.

We have interpreted clauses 1[i], 12[k], and 18[e] such that they are not limited to “repositioning” images of the leads relative to each other but also encompass arranging images of the leads in the first instance. *See* Part III.A *supra*. Bradley857 incorporating Bradley384 indisputably describes using impedance to align images of two leads relative to each other and to track changes in the relative positions of those images. Ex. 1004 ¶¶ 59, 61–63, Figs. 8–10; Ex. 1005, 6:43–7:60, 10:56–61, Fig. 5.

For all these reasons, we find that Petitioner has proven by a preponderance of evidence that Bradley857 and Bradley384 as incorporated into Bradley857 describes the subject matter of clauses 1[i], 12[k], and 18[e] (the impedance alignment feature).

iii. Clauses 1[j] and 12[m]:
The Automatic Signal Delivery Feature

Clause 1[j] of claim 1 recites that the claimed system includes instructions that, when executed will:

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

Ex. 1001, 38:39–46. Clause 12[m] recites a broader version of the same limitation as follows: “based at least in part on the predetermined correlation, automatically identify a value of a signal delivery parameter for a pulsed electrical signal to be delivered to the patient’s spinal cord via at least one of the first or second pluralities of contacts.” *Id.* at 39:66–40:3. Patent Owner refers to this group of clauses as reciting an “automatic signal delivery feature,”¹⁴ PO Resp. 35, and we do as well in our discussion below.

Petitioner asserts Bradley857 discloses that once a clinician enters a patient’s indication and lead location information, the system automatically accesses a stored database and identifies signal delivery parameter values,

¹⁴ Patent Owner’s Response identifies independent claim 18 among those that recites the automatic signal delivery feature. PO Resp. 35. However, at the hearing, Patent Owner confirmed that independent claim 18 does not recite this feature and, therefore, Patent Owner does not argue to preserve the patentability of independent claim 18 on this basis. Tr. 64:4–8.

such as pulse width values and cathode-anode patterns for use in the patient. Pet. 44–45 (citing Ex. 1004 ¶¶ 18, 21, 65–68, 71; Ex. 1002 ¶ 151). For example, Bradley857 states: “IPG 14 includes a battery and pulse generation circuitry that delivers the electrical stimulation energy in the form of a pulsed electrical waveform to the electrode array 26 in accordance with a set of Stimulation parameters programmed into the IPG 14.” Ex. 1004 ¶ 45. Bradley857 explains that: “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).” *Id.* ¶ 65. Those stimulation parameters may be selected from a database.

Petitioner contends that:

For example, that database can include empirical data from other patients, including information about lead and electrode position—the claimed first or second positional relationships (e.g., two cathodes separated by 5mm along the midline of the spinal cord and an anode laterally separated by 10mm)—and signal delivery parameter values (pulse width values and cathode-anode pattern used). *Id.* ¶67; Ex. 1002 ¶152. The processor matches a patient’s indication to a reference indication (and corresponding stimulation location). Ex. 1004 ¶69 (providing example selecting parameters in ¶67, mentioned above).

Pet. 45. Based on Bradley857, incorporating the disclosure from Bradley384, Petitioner concludes that Bradley857 discloses a predetermined correlation between lead position and signal delivery parameter values, and taking corrective action to move the field based on that correlation. *Id.* at 47 (citing Ex. 1002 ¶¶ 151–155).

Patent Owner argues that Petitioner fails to identify where Bradley857 describes actually delivering a signal to the patient that reflects the

stimulation parameters that its CP 18 automatically generated as a “starting point” as allegedly required by the claims. PO Resp. 35–36; *see also* Sur-reply 13–14. Patent Owner’s argument is unavailing for two reasons.

First, neither clauses 1[j] and 12[m] nor any other portion of claims 1 and 12 require that the “pulsed delivery signal” is actually delivered to the patient. Clause 1[j] recites that the system “automatically identify a signal delivery parameter value for a pulsed electrical signal that is *to be delivered* to the patient via at least one of the first signal delivery device or the second signal delivery device.” Ex. 1001, 38:39–41. Similarly, clause 12[m] recites that the system “automatically identify a value of a signal delivery parameter for a pulsed electrical signal *to be delivered* to the patient’s spinal cord via at least one of the first or second pluralities of contacts.” *Id.* at 39:67–40:3 (emphasis added). Thus, claims 1 and 12 merely require that the system identify a value for a signal that can later be delivered to a patient via one or more leads.

Second, even if the claims were to require actually delivering a signal to the patient that is configured according to the “signal delivery parameters” generated by Bradley857’s CP 18, Petitioner identifies where Bradley857 describes doing so. Reply 18 (citing Ex. 1004 ¶¶ 38, 79). Petitioner also identifies where Bradley857 describes delivering the claimed signal to the patient in connection with its showing of claim 20, which expressly requires doing so. Pet. 65 (citing Ex. 1004 ¶¶ 45, 67, 79, Fig. 2). Moreover, Dr. Stone, Patent Owner’s expert, testifies that Bradley857 describes delivering the “starting point” signal to a patient that reflects automatically generated signal delivery parameters. Ex. 1040, 87:9–94:19.

For all these reasons, we find that Petitioner has proven by a preponderance of evidence that Bradley857 describes the subject matter of clauses 1[j] and 12[m] (the automatic signal delivery feature).

c. Summary

For all the reasons expressed above, we find that Petitioner has proven by a preponderance of evidence that Bradley857 anticipates independent claims 1, 12, and 18.

3. *Dependent Claims*

a. Claim 8

Claim 8 depends from claim 6, which depends from claim 1. Claim 6 further recites:

wherein the computer-based image of the first signal delivery device and the computer-based image of the second signal delivery device are displayed on a display, and wherein *the display further includes* vertebral level identifiers corresponding to the anatomical feature of the patient, and *lead identifiers corresponding to the first signal delivery device and second signal delivery device*.

Ex. 1001, 38:65–39:5 (emphasis added). Claim 8 further recites: “wherein each lead identifier includes a contact lead identifier, and wherein automatically identifying a signal delivery parameter value is based at least in part on *impedance indicated at the contact lead identifier*.” *Id.* at 39:11–14 (emphasis added).

Patent Owner argues that Petitioner fails to demonstrate that any of Bradley857, Bradley384, or Meadows describes “impedance indicated at the contact lead identifier” as recited in claim 8. PO Resp. 37–41. Patent Owner contends that “indicate” means to “convey[] information to the practitioner, for example, by visually depicting on the computer-based image

within the GUI or otherwise supplying some indication.” *Id.* at 37. Patent Owner also contends that “indicating” can occur by providing an audible signal. *Id.* at 39 (citing Ex. 1001, 29:49–53 (describing a “power *indicator*” that may be “an LED or other visual *indicator*, audio *indicator*, or other type of *indicator*,” and its advantages)). Patent Owner contends that the Specification consistently uses “indicate” in connection with visually displayed information. *Id.* at 38–40 (citing Ex. 1001, 10:10–13, 24:65–67, 25:30–34, 25:49–53, 26:10–17, 26:23–26, 29:56–29:6, 29:14–19, 29:40–57, 31:48–54, 32:3–19).

Petitioner unpersuasively responds that “[i]mpedance indicated at the contact lead identifier’ just means the impedance level *associated with* the identifier.” Reply 22 (emphasis added). In support of its interpretation, Petitioner relies upon the following text from the Specification: “Each contact identifier can in turn include an impedance level associated with that contact.” Ex. 1001, 30:65–66. However, the next sentence of the Specification undermines Petitioner’s argument by stating: “The practitioner can activate an impedance check button 1342 to initiate an impedance check, which *updates the values indicated by the contact identifiers 1331a, 1331b.*” *Id.* at 30:66–31:2. The Specification explicitly states that the contact identifiers indicate “values” that are updated when the practitioner performs an impedance check, which we find to describe visually indicating impedance values to the practitioner on display 1320b shown in Figure 13F.

Claim 8 recites that the “contact lead identifier” is included within the “lead identifier” recited in claim 6. *Id.* at 39:11–14. Claim 6 recites that the “display further includes . . . lead identifiers.” *Id.* at 39:1–3. Claim 8

requires that “each lead identifier includes a contact lead identifier” and that “impedance [is] indicated at the contact lead identifier.” *Id.* at 39:11–14.

Based on our review of the plain language of claims 6 and 8 and the relevant Specification, we agree with Patent Owner that “impedance indicated at the contact lead identifier” as used in claim 8 requires some form of visual indication relating to impedance “at the contact lead identifier,” which is displayed in association with a computer-based image of the first and second signal delivery devices. Patent Owner persuasively argues that Petitioner wholly fails to identify any disclosure in Bradley857, Bradley384, or Meadows that describes the “impedance indicated at the contact lead identifier” of claim 8.

For these reasons, we find that Petitioner has failed to prove by a preponderance of evidence that Bradley857 including subject matter incorporated from Bradley384 and Meadows anticipates claim 8.

b. Claim 10

Claim 10 depends from claim 1 and further recites: “wherein the instructions, when executed, prevent one or more of the first plurality of contacts from being used to deliver therapy to the patient, wherein the prevented one or more contacts have impedance values outside the pre-established range.” Ex. 1001, 39:19–23.

Petitioner contends that Bradley857 along with disclosure incorporated from Meadows describes the additional limitations recited in claim 10 because Meadows explains that when electrodes are “unavailable” due to be having impedance values that are too high or too low, those electrodes cannot be programmed. Pet. 55 (cross-referencing showing for clause 1[h] (the pre-established range feature and also citing Ex. 1006,

40:14–18, Ex. 1002 ¶ 177). Petitioner thus concludes that because the system deems electrodes that exhibit out-of-range impedance values to be “unavailable” for programming, the system prevents those electrodes from delivering therapy to the patient. *Id.*

Patent Owner argues that Meadows merely describes measuring impedance, but neither Bradley⁸⁵⁷ nor Meadows describes “*preventing contacts from delivering therapy.*” PO Resp. 43. Patent Owner also cross-references its argument relating to the pre-established range feature. *Id.* at 43–44.

Patent Owner’s argument is unavailing. We find that making an electrode unavailable for programming results in preventing that electrode from delivering therapy as Petitioner contends. For this reason and the reasons expressed in Part III.E.2.b.i *supra*, we find that Petitioner proves by a preponderance of evidence that Bradley⁸⁵⁷ with material incorporated from Meadows anticipates claim 10.

c. Claim 19

Claim 19 depends from claim 18 and recites the automatic signal delivery feature in substantially identical terms to those recited in clause 1[j] as follows:

automatically identifying a value for a signal delivery parameter for a pulsed electrical signal to be delivered to the patient via at least one of the first or second pluralities of contacts, wherein the signal delivery parameter value has a predetermined correlation between a medical indication of the patient and at least one of the first positional relationship or the second positional relationship.

Ex. 1001, 40:51–59.

Patent Owner lists claim 19 as among those that recite the automatic signal delivery feature, but Patent Owner expressly addresses this feature

only in the context of the language recited in claim 1. PO Resp. 35–37. Patent Owner does not identify any substantive differences in the ways in which claims 1 and 19 recite the automatic signal delivery feature. *Id.* Patent Owner proffers no other argument opposing Petitioner’s showing that Bradley857 anticipates claim 19. *See generally id.*

For the same reasons expressed in Part III.E.2 *supra* in connection with claim 1, we determine that Petitioner has proven by a preponderance of evidence that Bradley857 anticipates claim 19.

d. Claim 20

Claim 20 depends from claim 19 and further recites: “further comprising delivering the pulsed electrical signal having the signal delivery parameter value to the patient’s spinal cord.” Ex. 1001, 40:60–62. Petitioner identifies where Bradley857 describes delivering a signal reflecting automatically identified delivery parameters to the patient. Pet. 65 (citing Ex. 1004 ¶¶ 45, 67, 79, Fig. 2).

Although Patent Owner does not expressly list claim 20 among those that remain patentable because Petitioner fails to identify how Bradley857 describes the automatic signal delivery feature, we understand Patent Owner to have made such an argument. However, Patent Owner proffers no other argument opposing Petitioner’s showing that Bradley857 anticipates claim 20. *See generally* PO Resp.

For the reasons expressed in Part III.E.2 *supra* and those identified immediately above from the Petition, we determine that Petitioner has proven by a preponderance of evidence that Bradley857 anticipates claim 20.

e. Claims 2–7, 9, 11, 13–17, and 21

Claims 2–7, 9, and 11 depend ultimately from independent claim 1, claims 13–17 depend ultimately from independent claim 12, and claim 21 depends from independent claim 18. Ex. 1001, 38:47–39:10 (claims 2–7), 39:15–18 (claim 9), 39:24–29 (claim 11), 40:4–31 (claims 13–17), 40:63–41:2 (claim 21). Petitioner contends that Bradley857, with material incorporated from Bradley384 and Meadows, anticipates dependent claims 2–7, 9, 11, 13–17, and 21. Pet. 47–53 (claims 2–7), 55–56 (claims 9, 11), 61–63 (claims 13–17), 66 (claim 21). Petitioner specifically identifies material from Bradley857, Bradley384, and Meadows and testimony from Dr. Mihran in support of its contentions. *Id.*

Patent Owner proffers no other argument opposing Petitioner’s showing that Bradley857 with material incorporated from Bradley384 or Meadows or both anticipates claims 2–7, 9, 11, 13–17, and 21. *See generally* PO Resp. (advancing arguments for subject matter recited in independent claims 1, 12, and 18 and for additional subject matter recited in dependent claims 8, 10, 19, and 20).

We have reviewed Petitioner’s arguments that Bradley857 with material incorporated from Bradley384 and Meadows anticipates claims 2–7, 9, 11, 13–17, and 21, and we have reviewed the evidence that Petitioner identifies in support of those arguments. We find Petitioner’s arguments as supported by the evidence that it identifies to be persuasive. Accordingly, and for the reasons identified in Part III.E.2 *supra* in connection with independent claims 1, 12, and 18, we find that Petitioner has proven by a preponderance of evidence that Bradley857 with material

incorporated from Bradley384 and Meadows anticipates claims 2–7, 9, 11, 13–17, and 21.

4. Whether Petitioner Impermissibly Relies on “Disparate” Embodiments from Bradley857 in Arguing Anticipation

Patent Owner argues that Petitioner’s anticipation argument is legally flawed because “Petitioner relies on no less than five separate embodiments, spread across Bradley857, Meadows, and Bradley384.” PO Resp. 50–52. More specifically, Patent Owner contends that material described by Bradley857 in connection with screens 100(2), 100(3), and 100(4) depicted in Figures 8–10 respectively represents three separate embodiments of Bradley857’s tissue stimulation system and that material from Bradley384 and Meadows represents two separate embodiments of systems described in those references. *Id.* at 51. Patent Owner’s argument relates to Petitioner’s showing for the impedance alignment feature and the pre-established range feature. *Id.*

We find Patent Owner’s argument to be unavailing because we agree with Petitioner that an ordinarily skilled artisan would read each portion of Bradley384 and Meadows that is incorporated into Bradley857 as part of Bradley857. *See* Parts III.E.2.b.i–ii (regarding Petitioner’s showing for the impedance alignment feature and the pre-established range feature), III.E.1.b (regarding Petitioner’s showing for incorporation by reference of Meadows and Bradley384 into Bradley857); Reply 8. We also find that Bradley857’s screens 100(2), 100(3), and 100(4) do not reflect “disparate embodiments” but rather different forms of an integrated user interface for CP 18 (the clinician’s programmer) in Bradley857’s “exemplary SCS system 10.” Ex. 1004 ¶¶ 32–34, 59–63, Figs. 8–10. Additionally, Bradley857 expressly indicates the manner in which material is integrated from Bradley384 and

Meadows into the system described in Bradley857. *Id.* ¶¶ 47, 61. For these reasons, we find that Petitioner has proven that an ordinarily skilled artisan would understand the incorporated portions of Bradley384 and Meadows to provide further details regarding Bradley857’s SCS system 10.

5. Summary

For all the reasons expressed above, we find that Petitioner has proven by a preponderance of evidence that Bradley857 with material incorporated from Bradley384 and Meadows anticipates claims 1–7 and 9–21, but has failed to do so for claim 8.

F. CLAIMS 1–21: OBVIOUSNESS IN VIEW OF BRADLEY857 IN VIEW OF BRADLEY384 AND MEADOWS

Petitioner argues that, if we were to find that Bradley384 and Meadows were not sufficiently incorporated by reference into Bradley857, an ordinarily skilled artisan would have found that the subject matter of claims 1–21 would have been obvious and thus unpatentable in view of the combined teachings of Bradley857, Bradley384, and Meadows. Pet. 67–73. Petitioner broadly contends that “[e]ach of these references recognizes the same problems and expressly points to the other references for a solution. These references themselves motivate a POSA¹⁵ to combine them.” *Id.* at 67. Petitioner contends that Bradley857 explains the importance of controlling stimulation energy, positioning electrodes correctly, being able to reprogram electrodes to account for lead migration, and using “electrical parameters” to define relative lead orientation. *Id.* at 68–69 (citing Ex. 1004 ¶¶ 5, 10, 11, 59–63).

¹⁵ The parties use “POSA” to refer to a person of ordinary skill in the art.

Petitioner specifically addresses the motive to combine Meadows’s methods for determining electrode availability into Bradley857 “to ensure that the electrodes intended to deliver stimulation energy are suitable, and therefore, available, to deliver energy.” *Id.* at 69–70 (citing Ex. 1006, 32:35–39, 34:55–59, 38:32–43, 40:14–18, 46:55–64, 47:7–49:48). Because “Bradley857 includes the same components that Meadows uses to measure impedance values (IPG, electrodes, processor) and points to the foundational Meadows’s IPG as a starting point,” Petitioner contends that an ordinarily skilled artisan would have been motivated to combine their teachings and would have reasonably expected success in doing so. *Id.* at 70 (citing Ex. 1004 ¶¶ 37, 47, Fig. 1; Ex. 1006, 5:25–6:3, 6:37–63, 32:35–39, 34:55–59, 47:7–49:48; Ex. 1002 ¶¶ 218–219).

Petitioner also specifically addresses the motive to combine Bradley384’s methods of using impedance to align images of leads into Bradley857’s system. *Id.* at 70–71 (citing Ex. 1004 ¶¶ 10–11, 61–63 (describing using measured “electrical parameters” to determine lead orientation and expressly incorporating Bradley384 to do so); Ex. 1005, 1:17–18, 1:24–25, 1:56–60, 2:3–22 (noting benefits of automatically aligning leads using impedance); Ex. 1002 ¶¶ 220–222). Petitioner relies upon the same express suggestions to combine teachings from Bradley384 into Bradley857 as demonstrating that an ordinarily skilled artisan would have expected success in combining the references’ respective teachings. *Id.* at 71 (citing Ex. 1004 ¶ 61; Ex. 1005, 3:16–6:10, 6:43–7:43; Ex. 1002 ¶ 223).

In response to Petitioner’s detailed showing of express motivation within the references themselves to combine their respective teachings,

Patent Owner argues: “it is not enough that Bradley⁸⁵⁷ merely mentions Bradley³⁸⁴ and Meadows to allow a skilled artisan to modify their disclosures in view of one another—there must still be some motivation provided to make the combinations or modifications.” PO Resp. 54. Patent Owner argues that Petitioner merely demonstrates what an ordinarily skilled artisan “could have” done rather than what she “would have” been motivated to do. *Id.* at 53. To support this argument, Patent Owner quotes the Petition while excluding critical context as follows: “A POSA . . . could have combined the elements by known methods to yield a predictable result.” *Id.* (quoting Pet. 68). Patent Owner’s exclusion of context reveals the weakness in its argument. The entire sentence from which this passage is taken reads: “A POSA would have been motivated to, and could have combined the elements by known methods to yield a predictable result.” Pet. 68. Petitioner’s other statements of “motivation” to combine teachings follow the same pattern of addressing what an ordinarily skilled artisan would have been motivated to do rather than simply what an ordinarily skilled artisan “could have” done. *Id.* at 69–73. Patent Owner’s argument is unavailing.

For the reasons expressed in Part III.E *supra*, we have determined that Bradley⁸⁵⁷, Bradley³⁸⁴, and Meadows collectively describe the subject matter of claims 1–7 and 9–21. Based on our review of the evidence summarized above that Petitioner adduces relating to the express motivations within the references to combine their respective teachings, Petitioner persuades us that an ordinarily skilled artisan would have been motivated to combine the teachings of Bradley⁸⁵⁷, Bradley³⁸⁴, and Meadows in a manner to reach the subject matter of claims 1–7 and 9–21.

We have also found that Bradley857, Bradley384, or Meadows fail to describe the limitations introduced in dependent claim 8. *See* Part III.E.3.a *supra*. Petitioner does not separately argue that those limitations are otherwise suggested by the combined teachings of Bradley857, Bradley384, and Meadows. *See* Pet. 67–73. Accordingly, we find that Petitioner fails to prove that claim 8 would have been unpatentable as obvious.

For all these reasons, we conclude that Petitioner has proven by a preponderance of evidence that the combined teachings of Bradley857, Bradley384, and Meadows render claims 1–7 and 9–21 unpatentable as obvious but has failed to do so for claim 8.

IV. CONCLUSION¹⁶

In summary,

Claim(s)	35 U.S.C. §	Reference(s)	Claim(s) Shown Unpatentable	Claim(s) Not Shown Unpatentable
1–21	102	Bradley857	1–7, 9–21	8
1–21	103	Bradley857, Bradley384, Meadows	1–7, 9–21	8
Overall Outcome			1–7, 9–21	8

¹⁶ 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 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).

V. ORDER

For the reasons given, it is:

ORDERED that Petitioner has proven by a preponderance of evidence that claims 1–7 and 9–21 of U.S. Patent 10,076,665 B2 are *unpatentable* as anticipated under 35 U.S.C. § 102 by Bradley857;

FURTHER ORDERED that Petitioner has proven by a preponderance of evidence that claims 1–7 and 9–21 of U.S. Patent 10,076,665 B2 are *unpatentable* as obvious under 35 U.S.C. § 103 in view of the combined teachings of Bradley857, Bradley384, and Meadows;

FURTHER ORDERED that Petitioner has not proven by a preponderance of evidence that claim 8 of U.S. Patent 10,076,665 B2 is unpatentable; and

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

IPR2020-01563
Patent 10,076,665 B2

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