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Paper 14
Date: March 16, 2021

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

NEVRO CORP.,
Patent Owner.

IPR2020-01563
Patent 10,076,665 B2

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

GROSSMAN, *Administrative Patent Judge*.

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

I. INTRODUCTION

A. Background and Summary

Boston Scientific Corp. and Boston Scientific Neuromodulation Corp. (collectively, "Petitioner") filed a Petition (Paper 1, "Pet.") requesting 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"). 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 discretionary denial of a petition under 35 U.S.C. § 314(a). Petitioner filed a reply to the Preliminary Response (Paper 11, "Prelim. Reply"). Patent Owner filed a sur-reply (Paper 13, "Prelim. Sur-Reply").

We have jurisdiction under 35 U.S.C. § 314. Under § 314, an *inter partes* review may not be instituted "unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). The Board determines whether to institute a trial on behalf of the Director. 37 C.F.R. § 42.4(a). If an *inter partes* review is instituted, a final written decision under 35 U.S.C. § 318(a) must decide the patentability of all claims challenged in the petition. *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1353 (2018).

For the reasons set forth below, we determine that Petitioner has demonstrated that there is a reasonable likelihood that at least one of claims 1–21 is unpatentable. Accordingly, we institute an *inter partes* review of all challenged claims and on all grounds asserted in the Petition.

B. Real Parties in Interest

Petitioner identifies Boston Scientific Corp. and Boston Scientific Neuromodulation Corp. as real parties-in-interest. *See* Pet. 3. Patent Owner identifies Nevro Corp. as a real-party-in-interest. Paper 4, 1.

C. Related Matters

The parties note as related litigation in federal district court, *Boston Scientific Corp. et al v. Nevro Corp.*, Nos. 16-cv-1163, 18-cv-00644 (consolidated) (D. Del. 2018). *See* Pet. 3; Paper 4, 1.

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 '665 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 is a continuation of the application that matured into the '460 patent. Ex. 1001, code (63).

D. 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 and relate "to devices for controlling spinal cord modulation for inhibiting pain, and associated systems and methods, including simplified controllers." Ex. 1001, 1:24–27. This technology generally is well-known, as reflected by the 2 page listing of "References Cited." *Id.* at code (56).

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. Ex. 1001, 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 is reproduced below:

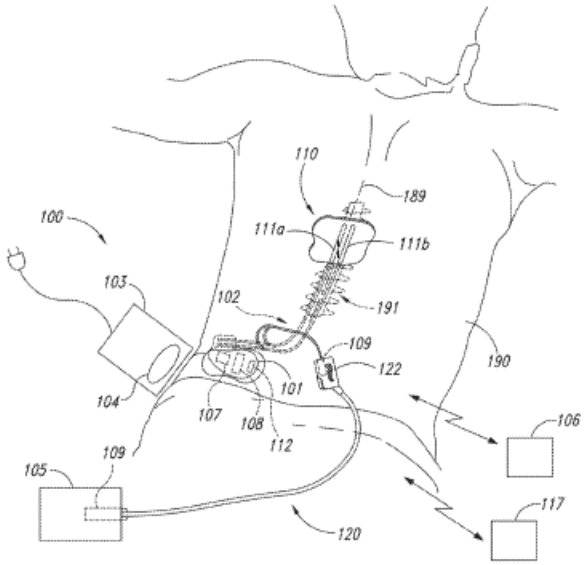

Fig. 1A

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, 1:64–67.

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 4:15–19. 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 4:15–18. *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. Ex. 1001, 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.").

E. Illustrative Claim

Claims 1, 12, and 18 are the independent claims challenged in the Petition. 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.

F. Prior Art and Asserted Grounds

Petitioner asserts that claims 1–21 would have been unpatentable on the following grounds (Pet. 29–30):

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

Petitioner also relies on the Declaration testimony of Richard T. Mihran, Ph.D. (*see* Ex. 1002).

[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").

II. ANALYSIS

A. Legal Standards

Petitioner has the burden of proof. *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016) ("In an IPR, the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable.").

"The hallmark of anticipation is prior invention." *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1369 (Fed. Cir. 2008). As explained in *Net MoneyIN,*

> unless a reference discloses within the four corners of the document not only all of the limitations claimed but also all of the limitations arranged or combined in the same way as recited in the claim, it cannot be said to prove prior invention of the thing claimed and, thus, cannot anticipate under 35 U.S.C. § 102.

Id. at 1371; *see also Verdegaal Bros. v. Union Oil Co.*, 814 F.2d 628, 631 (Fed. Cir. 1987) ("A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference."). "The identical invention must be shown in as complete detail as is contained in the . . . claim." *Richardson v. Suzuki Motor Co*., 868 F.2d 1226, 1236 (Fed. Cir. 1989).

Section 103(a) forbids issuance of a patent when "the differences between the subject matter sought to be patented 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." *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of 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) when available, evidence such as commercial success, long felt but unsolved needs, and failure of others.[5] *Graham v. John Deere Co*., 383 U.S. 1, 17–18 (1966); *see KSR*, 550 U.S. at 407 ("While the sequence of these questions might be reordered in any particular case, the [*Graham*] factors continue to define the inquiry that controls."). The Court in *Graham* explained that these factual inquiries promote "uniformity and definiteness," for "[w]hat is obvious is not a question upon which there is likely to be uniformity of thought in every given factual context." 383 U.S. at 18.

The Supreme Court made clear that we apply "an expansive and flexible approach" to the question of obviousness. *KSR*, 550 U.S. at 415. Whether a patent claiming the combination of prior art elements would have been obvious is determined by whether the improvement is more than the predictable use of prior art elements according to their established functions. *Id*. at 417. To support this conclusion, however, it is not enough to show merely that the prior art includes separate references covering each separate limitation in a challenged claim. *Unigene Labs., Inc. v. Apotex, Inc*., 655 F.3d 1352, 1360 (Fed. Cir. 2011). Rather, obviousness additionally requires that a person of ordinary skill at the time of the invention "would have selected and combined those prior art elements in the normal course of research and development to yield the claimed invention." *Id*.; *see also Orexo AB v. Actavis Elizabeth LLC*, 903 F.3d 1265, 1273 (Fed. Cir. 2018) ("The question is not whether the various references separately taught

[5] Patent Owner does not direct us to any objective evidence of non-obviousness in its Preliminary Response.

components of the ’330 Patent formulation, but whether the prior art suggested the selection and combination achieved by the ’330 inventors.”).

In determining whether there would have been a motivation to combine prior art references to arrive at the claimed invention, it is insufficient to simply conclude the combination would have been obvious without identifying any reason *why* a person of skill in the art would have made the combination. *Metalcraft of Mayville, Inc. v. The Toro Co.*, 848 F.3d 1358, 1366 (Fed. Cir. 2017).

Moreover, in determining the differences between the prior art and the claims, the question under 35 U.S.C. § 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. *Litton Indus. Prods., Inc. v. Solid State Sys. Corp*., 755 F.2d 158, 164 (Fed. Cir. 1985) (“It is elementary that the claimed invention must be considered as a whole in deciding the question of obviousness.”); *see also Stratoflex, Inc. v. Aeroquip Corp*., 713 F.2d 1530, 1537 (Fed. Cir. 1983) (“[T]he question under 35 U.S.C. § 103 is not whether the differences *themselves* would have been obvious. Consideration of differences, like each of the findings set forth in *Graham*, is but an aid in reaching the ultimate determination of whether the claimed invention *as a whole* would have been obvious.”).

As a factfinder, we also must be aware “of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning.” *KSR*, 550 U.S. at 421.

Applying these general principles, we consider the evidence and arguments of the parties.

B. Level of Ordinary Skill in the Art

The level of skill in the art is "a prism or lens" through which we view the prior art and the claimed invention. *Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001). "This reference point prevents . . . factfinders from using their own insight or, worse yet, hindsight, to gauge obviousness." *Id.*

Factors pertinent to a determination of the level of ordinary skill in the art include: (1) educational level of the inventor; (2) type of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology; and (6) educational level of workers active in the field. *Env't Designs, Ltd. v. Union Oil Co*., 713 F.2d 693, 696–697 (Fed. Cir. 1983) (citing *Orthopedic Equip. Co. v. All Orthopedic Appliances, Inc.*, 707 F.2d 1376, 1381–82 (Fed. Cir. 1983)). Not all such factors may be present in every case, and one or more of these or other factors may predominate in a particular case. *Id*. Moreover, these factors are not exhaustive but are merely a guide to determining the level of ordinary skill in the art. *Daiichi Sankyo Co. Ltd, Inc. v. Apotex, Inc.*, 501 F.3d 1254, 1256 (Fed. Cir. 2007).

In determining a level of ordinary skill, we also may look to the prior art, which may reflect an appropriate skill level. *Okajima*, 261 F.3d at 1355.

Additionally, the Supreme Court informs us that "[a] person of ordinary skill is also a person of ordinary creativity, not an automaton." *KSR*, 550 U.S. at 421.

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. *Id.* (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 for purposes of the decision on institution but reserves the right to challenge Petitioner's formulation should trial be instituted. Prelim. Resp. 11.

For purposes of this Decision, we adopt Petitioner's undisputed definition.

C. Claim Construction

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

Petitioner asserts that the claims do not require construction. Pet. 19. Patent Owner does not propose any constructions but reserves the right to propose constructions should trial be instituted. Prelim. Resp. 11.

Given the lack of dispute on this record, we need not construe the claims. *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). We note that on February 25, 2021, following a *Markman* hearing, the District Court issued a "Claim Construction Order" construing only a single phrase in the claims of the '665 patent . *See* Ex. 3001, 4 (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.

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

Patent Owner contends that the Board should deny institution under 35 U.S.C. § 314(a) because institution would be an inefficient use of Board resources. Prelim. Resp. 17. As detailed above, we authorized additional briefing from the parties on the issue of discretion under 35 U.S.C. § 314(a). We address the parties' arguments as follows.

1. Applicable Precedent

Institution of an *inter partes* review under 35 U.S.C. § 314(a) is discretionary. *See Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2140 (2016) ("[T]he agency's decision to deny a petition is a matter committed to the Patent Office's discretion."). In exercising that discretion, the Board may consider the advanced state of a related district court proceeding,

among other considerations, as a "factor that weighs in favor of denying the Petition under § 314(a)." *NHK Spring Co. v. Intri-Plex Techs., Inc.*, IPR2018-00752, Paper 8 at 20 (PTAB Sept. 12, 2018) (precedential); *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 at 5–6 (PTAB Mar. 20, 2020) (precedential) ("the *Fintiv* Order").

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

2. Procedural Background

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

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

In November 2016, Patent Owner sued Petitioner for patent infringement of six patents, including the '102 patent, in the U.S. District Court for the Northern District of California. Ex. 1012. Petitioner did not

file any petitions for *inter partes* review for Patent Owner's five other asserted patents.

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

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

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

Petitioner filed a second lawsuit in April 2018 against Patent Owner in the District of Delaware ("second Delaware lawsuit") alleging infringement of four patents, trade secret misappropriation, and tortious interference. *Boston Scientific Corp. and Boston Scientific Neuromodulation Corp. v. Nevro Corp.*, Case No. 1:16-cv-00644-GMS (D.Del., filed Apr. 27, 2018) (Ex. 2018). Nearly three months later, Petitioner filed a First Amended Complaint dropping three of the originally

asserted patents and adding eight other asserted patents. Ex. 1018. Patent Owner filed a motion to dismiss Petitioner's First Amended Complaint. Ex. 2019. In November 2019, the Court granted Patent Owner's motion to dismiss Petitioner's direct infringement claims as to eight of the nine asserted patents, indirect infringement and willful infringement claims as to all patents, and tortious interference claim. Ex. 2020, 27.

On December 9, 2019, Patent Owner answered the claims that were not dismissed and asserted counterclaims for infringement of five of its own patents, including the '665 patent. Ex. 1019. Petitioner subsequently filed a Second Amended Complaint, and Patent Owner filed its Answer and Counterclaims to Petitioner's Second Amended Complaint.

Patent Owner filed petitions for *inter partes* review of seven of Petitioner's nine originally asserted patents. *See* IPR2019-01216; IPR2019-01284; IPR2019-01313; IPR2019-01315; IPR2019-01318; IPR2019-01340; IPR2019-01341. In January 2020, the Board instituted review of all seven patents.

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

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

Petitioner has now filed the petition in this proceeding against the '665 patent as well as petitions for *inter partes* review against the '460 patent (IPR2020-01562) and the '461 patent (IPR2021-00295) (i.e.,

three of the five patents alleged to be infringed in Patent Owner's counterclaims from the second Delaware lawsuit).

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

Petitioner has submitted a stipulation that if an *inter partes* review is instituted, Petitioner will not pursue in the District Court any grounds that Petitioners raised or reasonably could have raised in the *inter partes* review. Prelim. Reply 2 (citing Ex. 1036).

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

3. Analysis

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

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

Petitioner asserts that "[t]here is ample evidence that the court will stay Nevro's counterclaims if the Board institutes review here." Pet. 9. Petitioner argues that because Petitioner's affirmative patent claims from the

2018 litigation are currently stayed, there will be another as-of-yet unscheduled trial over at least some of Petitioner's stayed claims, and therefore the court has a readily-available option to stay Patent Owner's counterclaims. Pet. 9.

Patent Owner argues that the court's prior grants of stays were under different circumstances in which an *inter partes* review had been instituted on the '280 patent, which comprised 84% of Petitioner's damages claim and after the soon-to-retire Judge Sleet expressed concerns over the availability of the next judge who would preside over the case. Prelim. Resp. 13 (citing Ex. 2022, 7:13–8:24), 14.

Patent Owner also argues that Petitioner ignores evidence that strongly suggests the court will not stay Patent Owner's counterclaims. Patent Owner asserts that Judge Connolly cautioned Petitioner to "think about it" when Petitioner informed the court that it planned to move for a stay of Patent Owner's counterclaims. Prelim. Resp. 16 (citing Ex. 1010, 34:19–35:2).[6] Patent Owner also argues that the case will be at a late stage because it is likely that by the time an institution decision issues, there will have been a claim construction hearing conducted, a claim construction

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

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

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

order issued, fact discovery will have closed, and the parties will be working on preparing expert reports. Prelim. Resp. 19 (citing, e.g., Ex. 1020, 20–21; *HIP, Inc. v. Hormel Foods, Corp.*, No. 18-615-CFC, 2019 WL 7667104, at *1 (D. Del. May 16, 2019) (denying motion to stay pending IPR where parties have engaged in "substantial amount of discovery" and claim construction already completed). Subsequent to the Preliminary Response, the District Court held a *Markman* hearing and issued a *Markman* Order. *See* Ex. 3001. Patent Owner argues that the timing of these *inter partes* reviews is accordingly different from the previous *inter partes* reviews that resulted in a stay.

Petitioner responds that Patent Owner has twice successfully moved for stays in the district court proceedings based on parallel *inter partes* reviews. Prelim. Reply 5. Petitioner adds that in the January 6, 2021, hearing, the court stated: "I'm also worried about spending court time trying to resolve these issues when everything could change come March if there's an institution of an IPR, and I don't want to waste time on Markmans unnecessarily." *Id.* (citing Ex. 1038, 75:8–76:13).

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

Although the District Court previously issued a stay as to certain of Petitioner's patent claims, we agree with Patent Owner that it is difficult to extrapolate to Patent Owner's counterclaims because the court's stay

decision was based in part on Judge Sleet's uncertainty at the time as to a next judge's availability. *See* Ex. 1022, 8:17–20. We decline to speculate on how the District Court would rule on a stay motion for Patent Owner's counterclaims.

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

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

A jury trial in District Court is currently scheduled for October 18, 2021. Ex. 1020, 21. Should *inter partes* review be instituted, the statutory deadline for the final written decision will be one year from the date of our Decision in March of 2022. Thus, the jury trial is scheduled to commence approximately 5 months before the statutory deadline.

Patent Owner asserts that there is no evidence that the court's trial date will not hold. Prelim. Resp. 21 (citing *Fintiv*, Paper 15, 13). Patent Owner's Preliminary Response stated that neither Petitioner nor Patent Owner have sought or been granted an extension of any date (Prelim. Resp. 21), although the court did reschedule the *Markman* hearing from January 6, 2021, to February 11, 2021 (Prelim. Reply 3 (citing Ex. 1037)).

Petitioner asserts that, during a motions hearing on January 6, 2021, the District Court and parties addressed broader case management issues, including whether Patent Owner's counterclaims (including infringement of the '665 Patent) should be tried in October 2021 or stayed. Prelim. Reply 3 (citing Ex. 1038, 80:12–81:25, 83:11–84:9). Petitioner asserts that Patent Owner has disclosed its intent to move to amend its theories in its

counterclaims, and the District Court has commented, at hearings on January 6 and 13, 2021, that allowing Patent Owner to amend its counterclaims "may affect whether or not the October trial date would include the "[460 Patent] counterclaims" and that Patent Owner "runs the risk that it loses its trial date." Prelim. Reply 3–4 (citing Ex. 1038, 83:11–84:2; Ex. 1039, 11:16–12:8).

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

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

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

Petitioner asserted in the Petition that this factor weighs in favor of institution based on the investment in the litigation, which was in early stages of fact discovery at the time of the Petition. Pet. 10–11 (citing *Sand*

Revolution II, LLC v. Continental Intermodal Grp.—Trucking LLC, IPR2019-01393, Paper No. 24 (PTAB June 16, 2020) (informative)).

Patent Owner asserts that the parties have each already served and responded to over 20 interrogatories and hundreds of document requests, and each produced over 450,000 pages of documents. Prelim. Resp. 23. Patent Owner asserts that the document production deadline passed on November 20, 2020, that the parties have already completed claim construction briefing (i.e., opening, responsive, reply, and sur-reply briefs) on 29 terms related to Patent Owner's counterclaim patents, that Patent Owner submitted the declaration of its expert in support of claim construction, and that Petitioner took the deposition of Patent Owner's expert. Prelim. Resp. 23 (citing Ex. 1020, 20; Ex. 2010). Patent Owner also asserts that each party's expert has spent multiple days reviewing the other party's source code. *Id.* Patent Owner asserts that the District Court, in consolidating the first and second Delaware lawsuits, stated that "[t]he parties and this Court have already invested substantial resources in setting schedules, conducting discovery, construing claims and engaging in motion practice for both of these cases." Prelim. Resp. 23–24 (citing Ex. 1010, 24:7–10) (emphasis omitted). Patent Owner asserts that by the time of an institution decision, the claim construction hearing will have been held, a claim construction order likely issued,[7] the parties will have completed fact discovery, made their final elections of asserted claims and asserted prior art, and be just days away from serving opening expert reports. *Id.* (citing Ex. 1020, 20–21). Patent Owner's predictions about the progress in the litigation have been accurate. *See, e.g.*, Ex. 3001. Further, according to the

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

District Court's scheduling order, the cut off for fact discovery will have been February 18, 2021, and opening expert reports will be due on March 19, 2021. *See* Ex. 1020, 21.

We determine that the District Court and the parties have invested substantial resources in the parallel proceeding through claim construction and fact discovery, and will have invested some resources in expert discovery. The parties have briefed claim construction, the Court has held a *Markman* hearing, and the Court has issued a *Markman* Order. *See* Ex. 3001. We accept Patent Owner's undisputed representation that the parties have each already served and responded to over 20 interrogatories and hundreds of document requests, and each produced over 450,000 pages of documents. *See* Prelim. Resp. 19. We have not been directed, however, to any persuasive evidence that the totality of this discovery concerns the validity or patentability of the '665 patent, which is the only issue in the proceeding before us. Further, Patent Owner has filed a motion to dismiss Petitioner's counterclaim for inequitable conduct. *See* Ex. 3002.

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

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

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

Petitioner initially asserts that it has stipulated that if the Board institutes review, Petitioner will not pursue district court invalidity

challenges on the same grounds raised in this proceeding. Pet. 11 (citing Ex. 1011). Petitioner argues that this narrow stipulation lessens concerns of duplicative efforts and conflicting decisions. *Id.* (citing *Sand Revolution*, IPR2019-01393, Paper No. 24, at 11–12; *Apple v. Seven Networks*, IPR2020-00266, Paper 12, at 15). Petitioner asserts that any further AIA challenges to the '665 patent are now barred under 35 U.S.C. 315. *Id.*

Patent Owner responds that Petitioner's narrow stipulation was unlike the broader stipulation in *Sotera* for grounds that could reasonably have been raised. Prelim. Resp. 25 n.8 (citing *Sotera Wireless, Inc. v. Masimo Corp.*, IPR2020-01019, Paper 12, 18-19 (PTAB Dec. 1, 2020) (precedential)). Patent Owner also argues that Petitioner's challenges here largely overlap with Petitioner's invalidity contentions in District Court. Prelim. Resp. 26 ("Petitioner's election of asserted prior art in the litigation includes the prior art on which the Petition grounds rely (i.e., Bradley857, Bradley384, and Meadows) in other combinations for the '665 patent").

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

Patent Owner responds that Petitioner's invalidity grounds in the litigation, which overlap with the challenges raised here, include nine obviousness grounds based on a combination of a prior art system (e.g., Boston Scientific's Precision™ Plus SCS System) and the same prior art references used here. Prelim. Sur-reply 2–3.

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

Sotera, Paper 12, at 18–19 ("Petitioner's stipulation here mitigates any concerns of duplicative efforts between the district court and the Board, as well as concerns of potentially conflicting decisions.").

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

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

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

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

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

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

g) Holistic Analysis of Fintiv Order Factors

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

E. Patent Owner's Arguments Regarding 35 U.S.C. § 325(d)

Patent Owner also argues that the Board should exercise discretion, and deny institution under 35 U.S.C. § 325(d) because the "same or substantially the same prior art or arguments previously were presented to the Office" during prosecution. Prelim. Resp. 30. Patent Owner argues that "Bradley857 is cumulative of the Woods reference over which the examiner allowed the claims", and that "Meadows and Bradley857" were both considered during prosecution before allowing the claims. *Id.* Patent Owner also argues that "Bradley857 is cumulative of a half-dozen other Bradley references that were also considered by the examiner. The Bradley family cumulatively disclose the same basic system described in Bradley857." *Id.* at 31.

Additionally, Patent Owner argues that "Petitioner relies on Meadows and Bradley384 to teach the impedance elements in the claims, but

completely ignores that both Meadows and Bradley384 were expressly considered by the examiner during prosecution." Prelim. Resp. 31. Bradley384 was cited on an IDS during prosecution of the '665 patent and is listed on the patent's face. *Id.* at 33 (citing Ex. 1015, 170, 227). Patent Owner also asserts Meadows and a continuation of Meadows, "Meadows323" (*see* Ex. 2003) were considered during examination of one of the '665 patent's parent applications (the 539 Application). *Id.* at 34–35. (citing Ex. 2001).

Patent Owner also asserts that, during examination of the '665 patent *and its parent applications*, "at least six different Bradley references were considered." *Id.* at 36–37. Patent Owner concedes, however, that these various Bradley references "are not identical to Bradley857." *Id.* at 37. It is Patent Owner's position, however, that "the Bradley family discloses the same elements that Petitioner relies on here." *Id.*

35 U.S.C. § 325(d), which provides: "[T]he Director may take into account whether, and reject the petition or request because, the same or substantially the same prior art or arguments previously were presented to the Office." 35 U.S.C. § 325(d). Thus, 35 U.S.C. § 325(d) identifies two separate issues for the Director to consider in exercising discretion to deny institution of review: "whether the petition presents to the Office the same or substantially the same art previously presented to the Office, or whether the petition presents to the Office the same or substantially the same arguments previously presented to the Office." *Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6, 7 (PTAB Feb. 13, 2020) (precedential).

The *Becton, Dickinson*[8] factors provide guidance into how to apply the framework under 35 U.S.C. § 325(d) in determining when a ground of unpatentability presents "substantially the same prior art or arguments" previously presented to the Office. The factors set forth in *Becton, Dickinson* should be read broadly to apply to any situation in which a petition relies on the same or substantially the same art or arguments previously presented to the Office during a proceeding pertaining to the challenged patent. *Advanced Bionics*, Paper 6 at 10.

Becton, Dickinson identifies the following non-exclusive factors: (a) the similarities and material differences between the asserted art and the prior art involved during examination; (b) the cumulative nature of the asserted art and the prior art evaluated during examination; (c) the extent to which the asserted art was evaluated during examination, including whether the prior art was the basis for rejection; (d) the extent of the overlap between the arguments made during examination and the manner in which petitioner relies on the prior art; (e) whether petitioner has pointed out sufficiently how the examiner erred in its evaluation of the asserted prior art; and (f) the extent to which additional evidence and facts presented in the petition warrant reconsideration of the prior art or arguments. *See Becton, Dickson*, Paper 8 at 17–18 (§ III.C.5, first paragraph).

Although *Becton, Dickinson* factors (a) and (b) pertain to art evaluated "during examination," these factors more broadly provide guidance as to whether the art presented in the petition is the "same or substantially the same" as the prior art previously presented to the Office during *any*

[8] *Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 (Dec. 15, 2017) (precedential as to § III.C.5, first paragraph).

proceeding, including prior AIA proceedings. *Advanced Bionics*, Paper 6 at 10.

Here, Patent Owner makes general and conclusory assertions that the same or similar art and arguments were presented in various patents or applications that were in the family of the challenged patent without more specific analyses. As is evident from the two pages of "References Cited" in the '665 patent (*see* Ex. 1001, code (56)), implantable neurological stimulation systems for spinal cord stimulation is a highly developed technology, and nearly every one of the numerous patents cited includes the same or similar basic components of an implantable pulse generator and leads that deliver electrical pulses to neurological tissue or muscle tissue. Ex. 1001, 1:34–48. The '665 patent recognizes that it is not only the physical components that are described and claimed, but many of the disclosed and claimed embodiments take the form of computer-executable instructions, including routines executed by a programmable computer. *Id.* at 3:48–50, 38:10–46.

Based on the evidence and arguments presented by Patent Owner for *Becton, Dickinson* factors (a), (b), and (d), we determine for purposes of this Decision that the same or substantially the same art or arguments presented in the proceeding before us were *not* presented previously to the Office, and, thus, we do not exercise discretion under § 325(d) to deny the Petition. For example, we have not been directed to persuasive evidence that argument as to the scope of Bradley857, and whether Bradley857 incorporated-by-reference Bradley 384 and Meadows, was presented previously to the Office. This is a key issue in the case before us. *See* Section II.F.1.b *infra.*

We now turn to the merits of Petitioner's two Grounds of asserted unpatentability.

F. Ground 1
Whether Bradley857 anticipates Claims 1–21

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 verterbral level and/or mediolateral location relative to the spine) and optionally the type and number of the tissue

stimulation leads and the positional information of the tissue stimulation leads to each other. *See id.* ¶ 15. The external control device further comprises circuitry for analyzing the information and generating a stimulation parameter set and output circuitry (e.g., telemetry circuitry) for transmitting the set to the tissue stimulation device. *Id.* ¶ 16.

In one embodiment, Bradley857 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 Bradley857 is reproduced below:

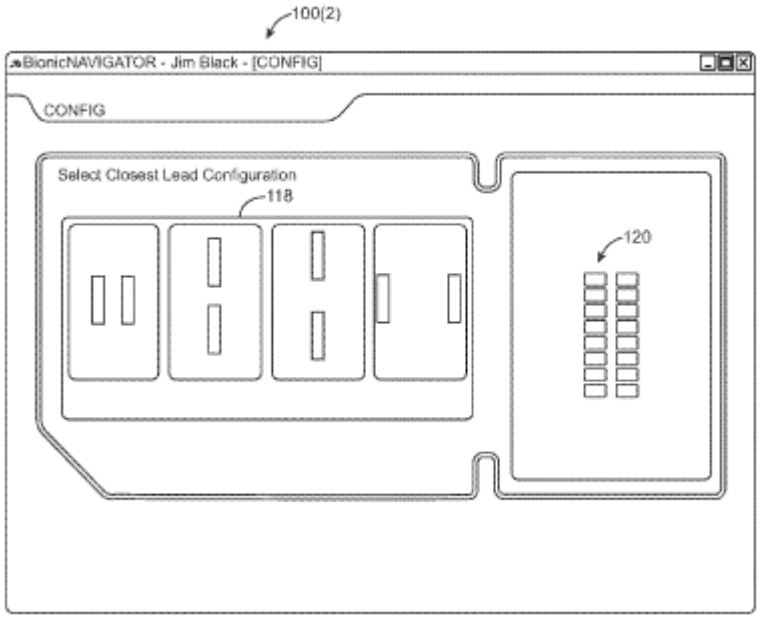

FIG. 8

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:

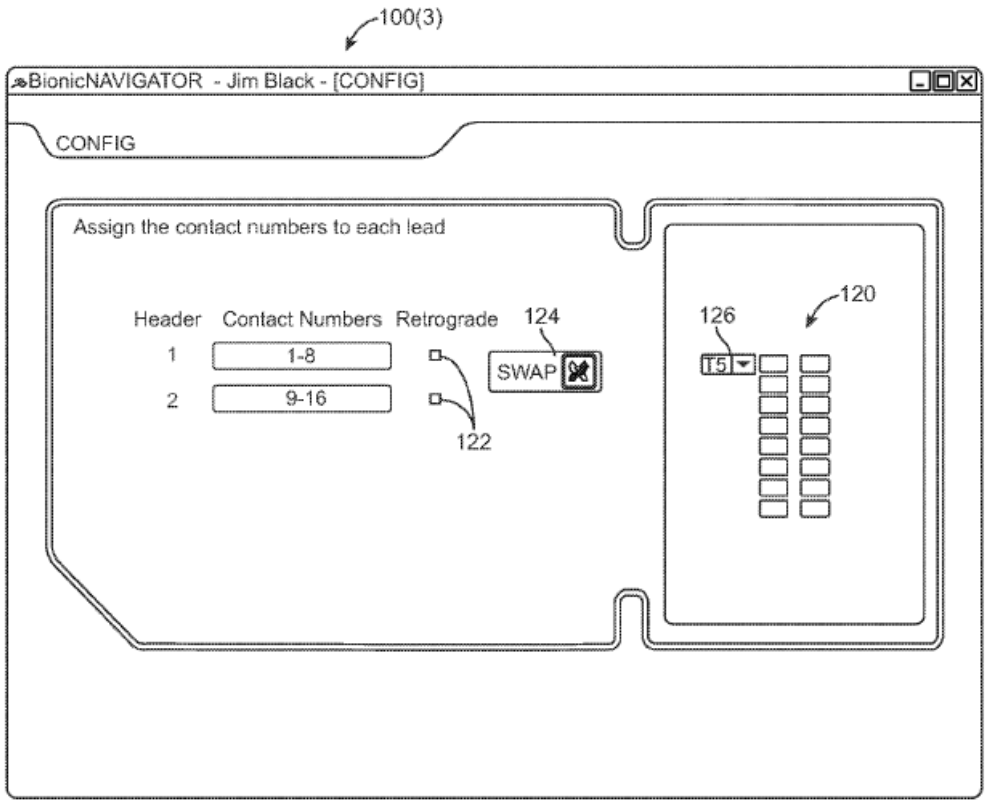

FIG. 9

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-by-Reference

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

In paragraph 47, Bradley857 states: "Further details discussing the detailed structure and function of IPGs[9] are described more fully in U.S. Pat. Nos. 6,516,227 [Meadows, Ex. 1006] and 6,993,384 [Bradley384, Ex. 1005], which *are* expressly incorporated herein by reference." Ex. 1001 ¶ 47 (emphasis added).

In paragraph 61, Bradley857 states:

> Alternatively, rather than inputting the lateral spacing between the leads 12 using the lead configuration screen 100(2), the positions of the tissue stimulation leads 12 relative to each other can be determined based on the measured electrical parameters in a conventional manner, such as, e.g., any one or more of the manner disclosed in U.S. Pat. No. 6,993,384 . . . which [is] expressly incorporated herein by reference.

Ex. 1001 ¶ 61.

It is Petitioner's position that the entirety of the disclosures of Bradley384 and Meadows are incorporated into the disclosure of Bradley857 and thus all three disclosures are "properly considered together in an anticipation analysis." Pet. 31.

Patent Owner takes a different view of the evidence. Patent Owner asserts that "Bradley857 does not incorporate the entirety of both Meadows

[9] An IPG is an "implantable pulse generator." *See* Ex. 1004 ¶ 4.

and Bradley384 by reference." Prelim. Resp. 47. Patent Owner asserts that "Bradley857 incorporates specific portions of each reference, none of which contain the impedance features that Petitioner relies on those references to disclose." *Id.*

Patent Owner asserts that, based on paragraph 47 from Bradley857, Bradley857 incorporates only "***the detailed structure and function of IPGs***" from Meadows and Bradley384. Prelim. Resp. 48 (emphasis in original). Patent Owner argues that Bradley857 does not incorporate any other material from Meadows. *Id.*

Patent Owner also asserts that based on paragraph 61 from Bradley857, Bradley857 incorporates only Bradley384's disclosure of "***the positions of the tissue stimulation leads 12 relative to each other can be determined based on the measured electrical parameters***." Prelim. Resp. 48–49 (emphasis in original). Patent Owner argues that Bradley857 does not incorporate any other material from Bradley384. *Id.* at 49. Patent Owner concludes that "[b]ecause these two passages in Bradley857 identify specific material from the cited references to be incorporated, the passages incorporate only the specifically identified material." *Id.* (citing *Callaway Golf Co. v. Acushnet Co.*, 576 F.3d 1331, 1346 (Fed. Cir. 2009)).

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).

"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." *Advanced Display*, 212 F.3d at 1282. Whether and to what extent material has been incorporated by reference is a question of law. *Harari v. Lee*, 656 F.3d 1331, 1334 (Fed. Cir. 2011). "[T]he standard of one reasonably skilled in the art should be used to determine whether the host document describes the material to be incorporated by reference with sufficient particularity." *Paice*, 881 F.3d at 906–07 (citing *Advanced Display*, 212 F.3d at 1283).

In *Paice*, the issue was whether the following sentences incorporated the referenced patent in its entirety:

> 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. Where differences are not mentioned, it is to be understood that the specifics of the vehicle design shown in the '970 patent are applicable to the vehicles shown herein as well.

Paice, 881 F.3d 907. The first sentence refers to "improvements and enhancements" and concludes with a clause stating the cited document "is incorporated herein by this reference." The Federal Circuit held the cited document was incorporated in its entirety because:

> [t]he first sentence of this 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. The sentence identifies with detailed

> particularity the specific material subject to incorporation (Severinsky, and not just particular portions thereof) and where that material can be found (U.S. Patent No. 5,343,970). Such language is plainly sufficient to incorporate Severinsky in its entirety.

Paice, 881 F.3d 907. The Federal Circuit also held that the second sentence merely states that Severinsky's features are understood to also apply to the vehicles described as the invention in the '817 application, except where the '817 application's specification "mention[s]" otherwise. *Id.* In other words, the '817 application refers to differences from Severinsky only to the extent necessary to describe differences between the inventions of Severinsky and the '817 application. *Id.*

In *Harari*, there were two statements of incorporation. The first stated:

> Optimized erase implementations have been disclosed in two copending U.S. patent applications. They are copending U.S. patent applications, Serial No. 204,175, filed June 8, 1988, by Dr. Eliyahou Harari and one entitled "Multistate EEprom Read and Write Circuits and Techniques," filed on the same day as the present application, by Sanjay Mehrotra and Dr. Eliyahou Harari. *The disclosures of the two applications are hereby incorporate[d] by reference*. The Flash EEprom cells are erased by applying a pulse of erasing voltage followed by a read to verify if the cells are erased to the "erased" state. If not, further pulsing and verifying are repeated....

Harari, 656 F.3d at 1335. The second "incorporation was more limiting and stated: "Relevant portions of the disclosures are hereby incorporated by reference." *Id.*

The Federal Circuit held that the first incorporation passage incorporates the entire disclosures of the two applications rather than just the portions describing optimized erase implementations. *Id.* The Court noted

particularly the difference between the incorporation language that referred to "the disclosures," and the incorporation language used later in the same specification to "relevant portions of the disclosures." *Id.*

In *Callaway Golf*, the relevant passage of incorporation describing the materials that may be used in the cover layers of golf ball was:

> The inner, intermediate, or first layer or ply 14 and the outer cover, second layer or ply 16 or either of the layers may be cellular when formed of a foamed natural or synthetic polymeric material. Polymeric materials are preferably such as ionomer resins which are foamable. *Reference is made to the application Ser. No. 155,658, of Robert P. Molitor issued into U.S. Pat. No. 4,274,637 which describes a number of foamable compositions of a character which may be employed for one or both layers 14 and 16 for the golf ball of this invention.*

Callaway Golf Co. v. Acushnet Co., 576 F.3d 1331, 1345 (Fed. Cir. 2009) (emphases added). The Federal Circuit noted that it had previously held that language nearly identical to that used in *Callaway Golf* ("[r]eference is made to") "can be sufficient to indicate to one of skill in the art that the referenced material is fully incorporated in the host document." *Id.* at 1346. The Court concluded that the incorporation language was sufficient to incorporate by reference the potential cover layer materials described in Molitor '637, including polyurethane and ionomer resin blends. *Id.* at 1347.

Applying the analyses from these cases, we determine that the incorporation clause in paragraph 47 of Bradley857 is similar to the clauses in *Paice* and *Harari* and thus incorporates Meadows and Bradley384 in their entirety. The sentence states "Further details discussing the detailed structure and function of IPGs are described more fully in *U.S. Pat. Nos. 6,516,227 and 6,993,384, which are expressly incorporated herein by reference*." Ex. 1004 ¶ 47 (emphasis added). For purposes of this Decision,

we determine that this sentence incorporates without qualification the entirety of the Meadows and Bradley384 patents. The sentence in Bradley857 includes a clause, "which are expressly incorporated herein by reference," which is nearly identical to the clause in the first sentence in *Paice*. Like the clause in *Paice*, the clause in Bradley857 identifies with detailed particularity the specific material subject to incorporation (Meadows and Bradley384, and not just particular portions of these patents) and where that material can be found (U.S. Patent Nos. 6,516,227 and 6,993,384). As held in *Paice*, such language is plainly sufficient to incorporate Meadows and Bradley384 in their entirety.

Similarly, in *Harari*, the incorporation language was part of a paragraph discussing "[o]ptimized erase implementations." Nonetheless, the language was held to incorporate in its entirety the cited document.

Here, we determine the language is specific to stating that Meadows and Bradley384 are "are expressly incorporated [into Bradley857] by reference," and also that details of IPGs can be found in these references. As in *Harari*, there is no indication that the incorporation clause was limited in any way to specific subject matter of the paragraph in which it appeared.

This same analysis applies to the incorporation clause in paragraph 61 of Bradley857.

Having determined the scope of the references, we now turn to whether the challenged claims are anticipated.

2. Claim 1

Petitioner provides a clause-by-clause analysis of independent claim 1 asserting where each element or limitation is disclosed in Bradley857. Pet. 32–66.

On the merits of the references, the principal dispute centers on clauses 1[h], 1[i], and 1[j] in claim 1 and similar clauses in independent claims 12 and 18.[10] Patent Owner asserts that "[b]ecause no references disclose elements 1[h], 1[i], or 1[j], the combination of those references," whether through incorporation by reference or individually under an "obviousness" challenge, cannot render any of the challenged claims unpatentable, and Petitioner's arguments fail. Prelim. Resp. 67. Thus, we focus on these clauses.

a) Clause 1[h]

Clause 1[h] requires impedance values within a pre-established range. Pet. 40. It is in the context of identifying one or more 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 (b) have impedance values within a pre-established range. Ex. 1001, 38:28–33.

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

[10] These paragraph designations were added to the claims by Petitioner to simplify the analysis of the claims. Patent Owner also refers to these paragraph designations. To avoid confusions and promote consistency, we too will refer to these same designations.

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, 46:55–65. 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).

Patent Owner asserts that Bradley857 and Meadows do not disclose identifying contacts having impedance values within a pre-established range. Prelim. Resp. 51 (*see* Section Heading VI.B). The entirety of Patent Owner's argument is that the "impedance" disclosure of Meadows has not been incorporated into Bradley857, and thus Bradley857 does *not* anticipate claim 1. As explained above, we have determined that, for purposes of this Decision, Bradley857 incorporates the entirety of Meadows. Accordingly, Patent Owner's argument is not persuasive at this stage of the proceeding.

Alternatively, Petitioner argues that even if Bradley857 were to incorporate the entirety of Meadows, neither reference discloses this claim element. Prelim. Resp. 54. According to Patent Owner, Petitioner fails to address the claim limitation as a whole, which specifies "identify[ing]… contacts… for delivering therapy… [that] have impedance values within a pre-established range." *Id.* Patent Owner acknowledges that Meadows discloses measuring impedance values of electrodes. *Id.* (citing Ex. 1006, 47:7–49:47). It is Patent Owner's position that "simply measuring impedance values is insufficient to meet this claim element." *Id.*

Petitioner relies on Bradley857 for the disclosure of clause 1[g], to which clause 1[h] is closely related. As Petitioner points out, the processor

in Bradley857 is configured for accessing the database and comparing a patient's indication with reference indications in the database to determine the stimulation target. Pet. 40 (citing Ex. 1004 ¶ 69). The processor then selects electrodes "adjacent the desired stimulation target" based on the positional information of the lead. *Id*. (citing Ex. 1004 ¶¶ 70, 71, 73, 74) (disclosing electrodes, or contacts, responding to various electrical signal parameters, such as pulse width); Ex. 1002 ¶¶ 136–137). Bradley857 teaches that the relative positions of implanted leads can be determined based on "measured electrical parameters." Ex. 1004 ¶ 61. Meadows, incorporated into Bradley857 adds an impedance option to the electrical signal parameters.

b) Clause 1[i]

Clause 1[i] requires that 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. *See* Ex. 1001, 38:34–38.

As stated above, Bradley857 teaches that the relative positions of implanted leads can be determined based on "measured electrical parameters." Ex. 1004 ¶ 61. Petitioner asserts that with respect to using such "measured electrical parameters," Bradley857 specifically points to and incorporates Bradley384. Pet. 41 (citing Ex. 1004 ¶ 61; Ex. 1002 ¶¶81–82). Petitioner reasons that "Bradley384, in turn, teaches the use of impedance, a 'measured electrical parameter' to align images of leads. *Id.* (citing Ex. 1005, 6:43–7:60; Ex. 1002 ¶ 144).

Patent Owner asserts that Bradley857 does not disclose limitation 1[i] because Bradley384 is not incorporated in its entirety into Bradley857. Prelim. Resp. 56. As explained above, we have determined that, for

purposes of this Decision, Bradley857 incorporates the entirety of Meadows. Accordingly, Patent Owner's argument is unpersuasive.

Patent Owner also focuses on the disclosure in Bradley857 (Prelim. Resp. 58–61) and concludes asserts that "irrespective of what Bradley384 discloses, Bradley857 does not disclose that the leads on screen 100(4) can be aligned using any measured electrical parameters—only by a user manually dragging-and-dropping leads." Prelim. Resp. 61. We disagree. Based on our determination that Bradley857 incorporates the entirety of Bradley384, our analysis of the disclosure of Bradley857 is not *irrespective* of what Bradley384 discloses; our analysis of the disclosure of Bradley857 is *inclusive* of what Bradley384 discloses. Thus, contrary to Patent Owner's argument (*see* Prelim. Resp. 57) Bradley857 *does* incorporate Bradley384's discussion of how lead position can be displayed on a screen.

Patent Owner argues that "[n]either Bradley857 nor Bradley384 disclose a system that 'aligns' images of two signal delivery devices based at least in part on impedance values." Prelim. Resp. 58. Patent Owner's arguments, however, disregard Bradley384.

Bradley384 discloses a cross-check technique for verifying the position of the electrodes of the implanted leads using inter-electrode impedance. Ex. 1005, 1:43–45, Fig. 4, Fig. 6. As further disclosed in Bradley384, an SCS system where either inter-electrode impedance or field potential is used "to determine the relative orientation of one electrode on an implanted lead to other electrodes on the implanted lead or adjacent implanted leads in the spinal column." *Id.* at 3:10–15. The inter-electrode impedance technique is performed by measuring impedance vectors. *Id.* at 6:45–46. A vector is defined as an impedance value measured between two electrodes in the body. *Id.* at 6:46–48.

Bradley384 also discloses that the value of the impedance vector is due primarily to (1) the electrode-electrolyte interface, and (2) the bulk impedance between the electrodes. *Id.* at 6:48–51. Bradley384 relies upon the bulk impedance between the electrodes. *Id.* at 6:53–56. The bulk impedance portion of the impedance vector may be further broken up into two contributing factors: (a) the impedance of the tissue adjacent to the electrodes, and (b) the impedance of the tissue between the electrodes. *Id*. at 6:57–60. The second factor (factor b) is used by the inter-electrode impedance technique embodiment disclosed in Bradley384 to determine the relative spacing between electrodes and to determine the relative orientation of the leads. *Id.* at 7:2–5.

Bradley384 also explains the relevant impedance information may then be loaded into a programmer, "which can then provide a graphic display of the assumed relative lead positions. Such data and/or display might then be compared with previously measured or entered and stored graphics, indicating earlier orientations." *Id*. at 7:42–47. According to Bradley384, this "comparison can thus help the physician/clinician to track the lead orientation to determine appropriate programming, reprogramming, or need for surgical revision." *Id.* at 7:47–50. Bradley384 also states that the disclosed invention "may be used to automatically setup the appropriate navigation tables for steering multiple lead systems." *Id.* at 7:52–54.

Bradley384 uses impedance or electric field measurements to determine relative lead positions, which impedance or electric field measurements may be "used as an automated or assistive method for setting up a programmer for navigation, other programming, or diagnostic evaluations in spinal cord (or other neural) stimulation. *Id*. at 10:56–61.

Impedance or electric field maps may be used to chronically "track relative lead positions in a programmer linked to a database." *Id.* at 10:62–65.

We determine for purposes of this Decision, that Bradley857's disclosure to use impedance data, a graphic display, and programming to "track lead orientation," or to "steer" multiple lead systems provides the same ability to align leads based on measured data, such as impedance data, as recited in the challenged claims.

Concerning "aligning," the '665 patent discloses

> the practitioner can request that the program automatically adjust the location of the other lead identifier relative to the first by activating an 'auto align button' 1343. 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.*

Ex. 1001, 31:30–36 (emphasis added). Based on our analysis above of Bradley384, Bradley384 discloses the same process wherein a program aligns leads based on impedance data.

Thus, Bradley857, which incorporates Bradley384 in its entirety, discloses the limitation in clause 1[i].

c) *Clause 1[j]*

Clause 1[j] states:

> 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.

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, 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). The electrical pulse can then be delivered to the patient by two or more activated electrodes, which can be on different leads, and the IPG can control the current at each individual electrode. *Id.* (citing Ex. 1004 ¶¶ 46, 47; Ex. 1002 ¶ 152). 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. Pet. 57 (citing Ex. 1002 ¶¶ 151–155). Following an analysis of Bradley857, Dr. Mihran's Declaration testimony is that "Bradley857 discloses several ways" to meet the elements and limitations required by clause 1[j] in claim 1. Ex. 1002 ¶¶ 151–155.

Patent Owner asserts that Petitioner combines disclosures from two different embodiments in Bradley857. Prelim. Resp. 64–65. According to Patent Owner,

> Bradley857 explains that '[i]n one embodiment, the memory 84 stores a database containing a plurality of reference therapeutic indications,' Ex. 1004, [0066], but that '[i]n another embodiment, the processor 82 is configured for using a heuristic set of rules to generate the set of stimulation parameters, Ex. 1004, [0072]. In this context, the phrase 'another' indicates an alternative or different ways to generate 'signal delivery parameter.' Petitioner never explains how these two embodiments could be used in a single system.

Prelim. Resp. 65–66. We have not been directed to persuasive evidence to support Patent Owner's argument that the word "another" indicates alternative or different ways to generate "signal delivery parameter." It

merely is generating the same signal delivery parameter using different rules. There is no persuasive evidence that the disclosed system is different from the claimed system.

Based on the analysis above, for purposes of this Decision, we determine that Bradley857 discloses the elements and limitations in clause 1[j].

d) Conclusion for Claim 1

Based on the analysis above, we determine, for purposes of this Decision, that there is a reasonable likelihood Petitioner will prevail in establishing that Bradley857, incorporating by reference the entirety of Bradley384 and Meadows, discloses within the four corners of the document not only all the limitations of claim 1, but also all the limitations arranged or combined in the same way as recited in the claim. Accordingly, it is reasonably likely Petitioner will prevail in establishing that claim 1 is anticipated by Bradley857.

3. Independent Claims 12 and 18

Independent claims 12 and 18 are substantially similar to independent claim 1. As Patent Owner states correctly, "[t]he Petition's analysis of claims 12 and 18 consists mainly of citing to analysis for claim 1. Therefore, the above [Patent Owner] arguments likewise apply to claim[s] 12 and 18." Prelim. Resp. 66.

Petitioner's arguments for claims 12 and 18 refer extensively to the analysis for claim 1. *E.g., see* Pet. 57, 65. Based on our analysis of the references and evidence in the context of claim 1, on the record before us, and for purposes of this Decision, we accept Petitioner's analysis for claims 12 and 18 and we reach the same conclusions for claims 12 and 18 as

we did for claim 1, which is that it is reasonably likely Petitioner will prevail in establishing that claims 12 and 18 are anticipated by Bradley857.

4. Dependent Claims

Petitioner provides a clause-by-clause analysis of each dependent claim. Patent Owner states that, for all the dependent claims, "because Petitioner's arguments as to Claim 1 (and the other independent claims) fail, they also fail with respect to the dependent claims." Prelim. Resp. 66.

Based on our analysis of the references and evidence in the context of the dependent claims, on the record before us, and for purposes of this Decision, we accept Petitioner's analysis for the dependent claims and we reach the same conclusions for the dependent claims as we did for claim 1, which is that it is reasonably likely Petitioner will prevail in establishing that the dependent are anticipated by Bradley857.

G. Ground 2
Whether Claims 1–21 Would Have Been Obvious
Based on Bradley857, Bradley384, and Meadows

This asserted ground consists of the same references as considered in Ground 1, but considers them individually, as if Bradley384 and Meadows were not incorporated into Bradley857. Pet. 67.

Novelty under 35 U.S.C. § 102 and nonobviousness under 35 U.S.C. § 103 are separate conditions of patentability. *Cohesive Techs., Inc. v. Waters Corp.*, 543 F.3d 1351, 1363 (Fed. Cir. 2008). The tests for anticipation and obviousness are different. *Id.* at 1364. The elements of proof for anticipation and obviousness are different. *Duro-Last, Inc. v. Custom Seal, Inc*., 321 F.3d 1098, 1107–08 (Fed. Cir. 2003). Thus, "it does not follow that every technically anticipated invention would also have been obvious." *Cohesive Techs.*, 543 F.3d at 1364; *see also Ericsson Inc. &*

Telefonaktiebolaget LM Ericsson v. Intellectual Ventures, IPR2014-01471, slip op. at 14 (PTAB Mar. 18, 2015) (Paper 10) ("Although Petitioner may assert that all the elements . . . are found in the prior art, we note that not every anticipated claim [would have been] obvious."). Federal Circuit precedent has rejected reliance on the "legal homily" that "anticipation is the epitome of obviousness." *Cohesive Techs.*, 543 F.3d at 1364, n.2.

We have discussed above the disclosures of the references and determined that there is a reasonable likelihood that all the elements and limitations are disclosed in at least one of the three references. Petitioner provides articulated reasoning with some rational under-pinning establishing the motivation or reason why a person or ordinary skill would have made the proposed combination of the references. Pet. 67–73.

Patent Owner argues that Petitioner provides no rationale for incorporating specific features of Meadows or Bradley384 into Bradley857. Prelim. Resp. 68. Patent Owner, however, does not address or refute the analysis and rationale set forth in the Petition (*see* Pet. 67–73).

Based on our analysis of the references and evidence in the context of Ground 2, on the record before us, and for purposes of this Decision, we accept Petitioner's analysis for the motivation to combine references as proposed in Ground 2. Accordingly, we determine it is reasonably likely Petitioner will prevail in establishing that claims 1–21 would have been obvious based on Bradley857, Bradley384, and Meadows.

III. CONCLUSION

Taking into consideration the arguments in the Petition, the Preliminary Response, the Preliminary Reply, the Preliminary Sur-reply, and the evidence of record, we institute an *inter partes* review on Grounds 1 and 2 for claims 1–21.

Our review of the Petition under 35 U.S.C. § 314 is not to determine whether an individual asserted fact is indisputable or whether a preponderance of the evidence supports Petitioner. Our review is to determine whether the totality of the information presented in the Petition and Preliminary Response shows that there is a reasonable likelihood that Petitioner would prevail with respect to at least one of the claims challenged in the Petition. "The 'reasonable likelihood' standard is a somewhat flexible standard that allows the Board room to exercise judgment." Consolidated Trial Practice Guide, 53 (Nov. 2019) (available at https://www.uspto.gov/sites/default/files/documents/tpgnov.pdf).

This is a decision to institute an *inter partes* review under 35 U.S.C. § 314. Our determinations at this stage of the proceeding are preliminary, and based on the evidentiary record developed thus far. This is not a final decision as to the patentability of claims for which *inter partes* review is instituted. Our final decision will be based on the record as fully developed during trial, including all arguments and evidence in the Patent Owner's Response, Petitioner's Reply, Patent Owner's Sur-reply, or submitted otherwise during trial, as permitted by our rules.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that the Petition is granted and an *inter partes* review is instituted for all challenged claims and on all asserted grounds.

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