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Paper 7
Entered: January 21, 2020

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEVRO CORP.,
Petitioner,

v.

BOSTON SCIENTIFIC NEUROMODULATION CORP.,
Patent Owner.

IPR2019-01284
Patent 7,822,480 B2

Before ROBERT A. POLLOCK, SCOTT C. MOORE, and RICHARD J. SMITH, *Administrative Patent Judges*.

POLLOCK, *Administrative Patent Judge*.

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

A. Background

Nevro Corp. ("Petitioner") filed a Petition for *inter partes* review of claims 1–4 and 6–8 of U.S. Patent No. 7,822,480 B2 ("the '480 patent," Ex. 1001). Paper 1 ("Pet."). Boston Scientific Neuromodulation Corp. ("Patent Owner") timely filed a Preliminary Response. Paper 6 ("Prelim. Resp."). Along with its Preliminary Response, Patent Owner filed a Statutory Disclaimer of claim 1 of the '480 patent. Prelim. Resp. 1–2; Ex. 2001. We review the Petition, Preliminary Response, and accompanying evidence under 35 U.S.C. § 314.

B. Real Parties in Interest

Petitioner identifies itself, Nevro Corp. as the real party-in-interest. Pet. 2. According to Patent Owner, its real parties-in-interest are Boston Scientific Neuromodulation Corp. and Boston Scientific Corp. Paper 4, 2.

C. Related Proceedings

The '480 patent is at issue in *Boston Scientific Corp. et al. v. Nevro Corp.*, 1:18-cv-00644 (D. Del.). *See* Paper 4, 3.

Patent Owner notes the '480 patent is related to U.S. Patent Nos. 9,162,071 B2 ("the '071 patent") and 7,587,241 B2 ("the '241 patent"). Paper 4, 2. The '241 patent was involved in IPR2017-01899. In IPR2017-01899, the Board issued a final written decision finding claims 1–20 unpatentable. The Board's Final Written Decision on IPR2017-01899 is currently on appeal to the Federal Circuit. *See Boston Scientific Neuromodulation Corp. v. Nevro Corp.*, No. 19-1584 (Fed. Cir.). According to Patent Owner, the '241 patent is also at issue in the district court case *Boston Scientific Corporation et al. v. Nevro Corp.*, 1:16-cv-01163 (D.

Del.). Paper 4, 2. Petitioner has separately filed an IPR petition on the '071 patent (IPR2019-01318).

D. Legal Effect of Patent Owner's Statutory Disclaimer

We address first the legal effect of Patent Owner's Statutory Disclaimer of claim 1 of the '480 patent. Ex. 2001. Patent Owner filed the Statutory Disclaimer cancelling claim 1 to "focus the issues and simplify the proceedings both here and before the district court." Prelim. Resp. 1. Patent Owner argues that "no *inter partes* review should be instituted based on claim 1 of the '480 Patent (*i.e.*, grounds 1 and 2 of the Petition) as only Petitioner's challenges to claims 2–4 and 6–8 (*i.e.*, grounds 3 and 4 of the Petition) are at issue here." *Id.* at 2, citing 37 C.F.R. § 42.107(e).

The United States Supreme Court has held that a decision to institute an *inter partes* review under 35 U.S.C. § 314 may not proceed on fewer than all claims challenged in the petition. *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1355 (2018). The Court recognized, however, that all "claims challenged 'in the petition' will not always survive to the end of the case; some may drop out thanks to the patent owner's actions." *Id*. at 1357. Here, Patent Owner has statutorily disclaimed challenged claim 1 of the '480 patent such that it is no longer regarded as a claim challenged in the Petition. *See Vectra Fitness, Inc. v. TNWK Corp.*, 162 F.3d 1379, 1383 (Fed. Cir. 1998) ("This court has interpreted the term 'considered as part of the original patent' in section 253 to mean that the patent is treated as though the disclaimed claims never existed.") (citing *Guinn v. Kopf*, 96 F.3d 1419, 1422 (Fed. Cir. 1996)). Accordingly, neither *SAS*, nor the precedent of our reviewing court, is at odds with Rule 42.107(e), which states that a patent owner, in a preliminary response, "may file a statutory disclaimer under 35

U.S.C. 253(a) . . . disclaiming one or more claims in the patent. No *inter partes* review will be instituted based on disclaimed claims." 37 C.F.R. § 42.107(e).

In light of the above, we treat claim 1 as having never been part of the '480 patent, such that Petitioner cannot seek *inter partes* review of that claim. Grounds 1 and 2, which are directed solely to claim 1, are deemed withdrawn. And because no *inter partes* review will be instituted based on a disclaimed claim, we do not institute an *inter partes* review of claim 1.

E. Summary of Institution Decision

In view of the above, we address the merits of the issues raised regarding claims 2–4 and 6–8 of the '480 patent in the Petition and Preliminary Response. For the reasons provided below, we determine Petitioner has satisfied the threshold requirement set forth in 35 U.S.C. § 314(a). Because Petitioner has demonstrated a reasonable likelihood that at least one claim of the '480 patent is unpatentable, we institute an *inter partes* review of the claims 2–4 and 6–8.

F. *Asserted Grounds of Unpatentability*

Petitioner asserts four grounds of unpatentability. Pet. 4. Because Grounds 1 and 2 are directed to claim 1, for which we do not institute *inter partes* review by rule, we only list Grounds 3 and 4, directed to claims 2–4 and 6–8.

Ground	Claims	Basis	Asserted References
3	2–4, 6, 8	103(a)[1]	Grevious[2] with or without Fitch[3]
4	6, 7	103(a)	Grevious and Bradshaw[4], with or without Fitch

In support of its patentability challenges, Petitioner relies on, *inter alia*, the Declaration of Mr. Ben Pless. Ex. 1003. The Declaration refers to several background references including Kruse,[5] Thompson,[6] Brenig,[7] Oetting,[8] Silvian,[9] Torgerson,[10] and Ohno.[11] *See* Ex. 1003 ¶¶ 127–143.

G. The '480 Patent and Relevant Background

1. Specification

The '480 patent is directed to telemetry systems and methods for communicating with an implantable stimulator. Ex. 1001, Abstract, 2:41–60. According to the '480 patent's Specification, implantable stimulators include spinal cord stimulators, cochlear implants, deep brain stimulators,

[1] The Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) ("AIA"), amended 35 U.S.C. §§ 102 and 103. Because the challenged claims of the '480 patent have an effective filing date before the effective date of the applicable AIA amendments, we refer to the pre-AIA versions of 35 U.S.C. § 103 throughout this Decision.
[2] U.S. Patent No. 6,443,891 B1, issued Sept. 3, 2002. Ex. 1005.
[3] U.S. Patent No. 4,807,225, issued Feb. 21, 1989. Ex. 1006.
[4] U.S. Patent No. 4,327,441, issued Aug. 27, 1982. Ex. 1009.
[5] U.S. Patent No. 6,201,993 B1, issued Mar. 13, 2001. Ex. 1007.
[6] U.S. Patent No. 6,577,901 B2, issued June 10, 2003. Ex. 1008.
[7] Theodore Brenig, *Data Transmission for Mobile Radio,* Vol. VT-27 IEEE TRANSACTIONS ON VEHICULAR TECHNOLOGY 77-85 (1978). Ex. 1020.
[8] John D. Oetting, *A Comparison of Modulation Techniques for Digital Radio*, IEEE 1752-1762 (1979). Ex. 1021.
[9] U.S. Patent No. 5,466,246, issued Nov. 14, 1995. Ex. 1011.
[10] U.S. Patent No. 7,167,756 B1, issued Jan. 23, 2007. Ex. 1017.
[11] U.S. Patent No. 6,045,042, issued Apr. 4, 2000. Ex. 1026.

and microstimulators "to stimulate tissue to alleviate urinary incontinence, reduce pain, or otherwise provide therapy for various disorders." *Id.* at 3:27–39.

The Specification discloses that "[a] typical stimulator or microstimulator is configured to transcutaneously communicate with an external device." *Id.* at 3:44–46. "Several types of implantable stimulators and external devices utilize a magnetic field to achieve transcutaneous communication via a bidirectional telemetry link." *Id.* at 2:42–44. Both implantable and external devices may include a radio frequency ("RF") coil that functions as the transmitter and receiver of the magnetic field. *Id.* at 2:45–47. The implantable stimulator may include a precise reference clock to synchronize timing of data transmission to and from the implantable stimulator and the external device for accurate communication. *Id.* at 2:47–53. The precise reference clock may be provided by a precision circuit that receives calibration data from the external device via the bidirectional telemetry link. *Id.* at 2:54–60. The Specification states, however, that "in some instances, the bidirectional telemetry link may fail due to a number of factors including, but not limited to, a loss of battery power in the stimulator, interference, and/or coil malfunction." *Id.* at 2:60–63. Failure of the telemetry link may result in the implantable stimulator not receiving calibration data from the external device. *Id.* at 2:63–67.

The '480 patent Specification discloses an implantable stimulator with a first telemetry receiver for receiving a first telemetry scheme and a second telemetry receiver for receiving a second telemetry scheme. Ex. 1001, 3:5–9. "In some embodiments, the first telemetry scheme includes frequency shift keying (FSK) modulation and the second telemetry scheme includes on-off keying (OOK) modulation. *Id.* at 3:9–12. The Specification further

describes an embodiment wherein, if the first telemetry scheme using a bidirectional telemetry link fails, a second telemetry scheme using a frequency independent telemetry link may be used to transmit the calibration data to the reference clock. *Id.* at 5:57–6:4. The calibration data may then be used to resynchronize the reference clock and reestablish transmission via the bidirectional telemetry link. *Id.* 6:5–9. According to the Specification, such resetting is possible "[b]ecause the OOK receiver compares pulse widths, the frequency of the clock signal generated by the clock generation circuit does not have to be synchronized with the frequency of the external device in order for the OOK receiver to function." *Id.* at 7:25–32 (internal numbering omitted).

Figure 1 of the '480 patent is reproduced below:

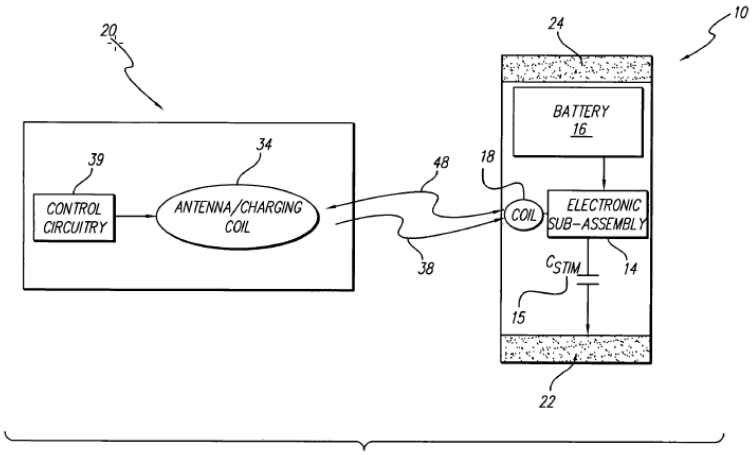

FIG. 1

Figure 1 of the '480 patent shows implantable stimulator 10 and external device 20. Ex. 1001, 3:25–26, 57–62.

The Specification states that "external device (20) may be embodied by [] external components (20) shown in FIG. 1 of the present application's parent application (U.S. patent application Ser. No. 10/607,962)," which

issued as U.S. Pat. No. 7,177,698 ("the '698 patent").[12] *Id.* at 4:6–9. Figure 1 of the '698 patent is reproduced below:

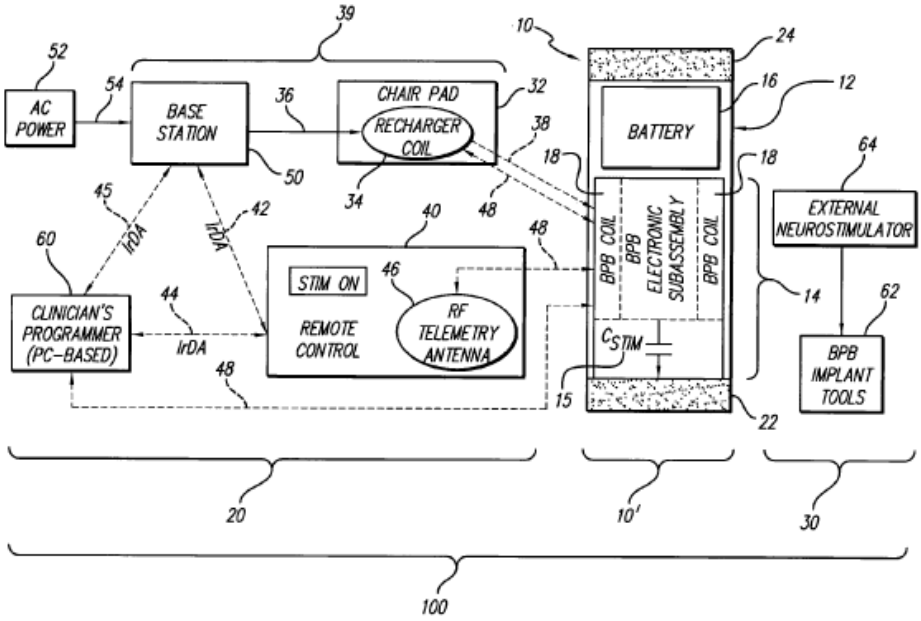

FIG. 1

Figure 1 of the '698 patent is a block diagram for a battery powered implantable microstimulator system including external device 20, implantable components 10′ and surgical components 30. *See* Ex. 1012, 4:49–51; 10:1–4.

The '480 patent's Specification states that external device 20 includes control circuitry 39 that controls the operation of coil 34 configured to emit and receive a magnetic field to communicate with implantable stimulator 10. Ex. 1001, 4:19–24. Coil 34 may communicate via bidirectional link 48 with coil 18 of implantable stimulator 10. *Id.* at 4:24–27. The Specification states that "RF signals sent across [] bidirectional telemetry link (48) may be

[12] The '480 patent is a continuation-in-part of and claims priority to "U.S. patent application Ser. No. 10/607,962, filed Jun. 27, 2003 now U.S. Pat. No. 7,177,698, and which is incorporated herein by reference in its entirety." Ex. 1001, 1:7–11.

modulated using a frequency dependent telemetry scheme, such as frequency shift keying (FSK), or by some other modulation scheme." *Id.* at 4:27–31. The Specification states that coil 34 and coil 18 "may also communicate via [] forward telemetry link (38)," which "may use an on/off keying (OOK) modulation scheme." *Id.* at 4:31–34.

The '480 patent's Specification shows an exemplary implantable stimulator in Figure 2, reproduced below:

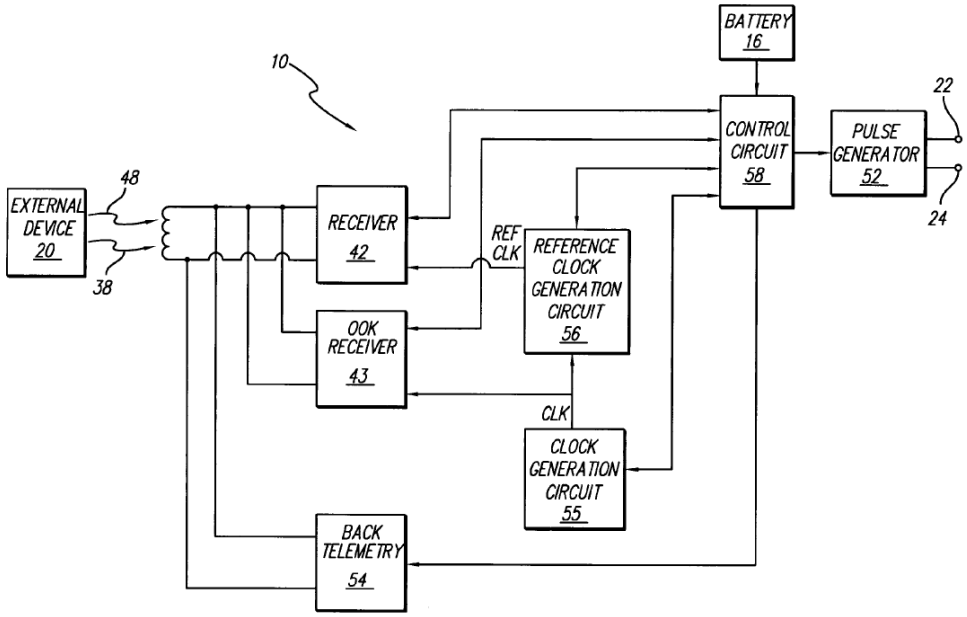

FIG. 2

Figure 2 shows a functional block diagram of implantable stimulator 10 and external device 20. Ex. 1001, 2:15–17; 4:52–5:7.

Implantable stimulator 10 includes coil 18 (not labeled) coupled to receiver 42 configured to receive a signal via bidirectional link 48. Ex. 1001, 4:52–55. External device 20 may send a carrier signal having modulated control data to receiver 42. *Id.* at 4:62–67. Receiver 42 rectifies the carrier signal to provide charging power to battery 16 and demodulates the carrier signal to extract control data. *Id.* The '480 patent's Specification also discloses embodiments wherein coil 18 is connected to OOK receiver

43 to receive OOK modulated data. *Id.* at 5:17–24. "OOK receiver (43) may be integrated into [] receiver (42)." *Id.* at 5:27–28.

The '480 patent's Specification states that "OOK telemetry link (38) allows [] external device (20) to communicate with [] stimulator (10) even when [] stimulator (10) is not actively listening for an RF signal to be transmitted via the bidirectional telemetry link (48)," e.g., when the stimulator is in hibernation or storage state. Ex. 1001, 6:30–35. "OOK telemetry link (38) also provides a communication interface . . . that may be used in emergency situations, e.g., when [] bidirectional telemetry link (48) fails or when there is an emergency power shutdown." *Id.* at 6:35–40.

The '480 patent's Specification provides an embodiment including first and second modulated signals (*see* Ex. 1001, 6:41–54), shown in Figure 3, reproduced below:

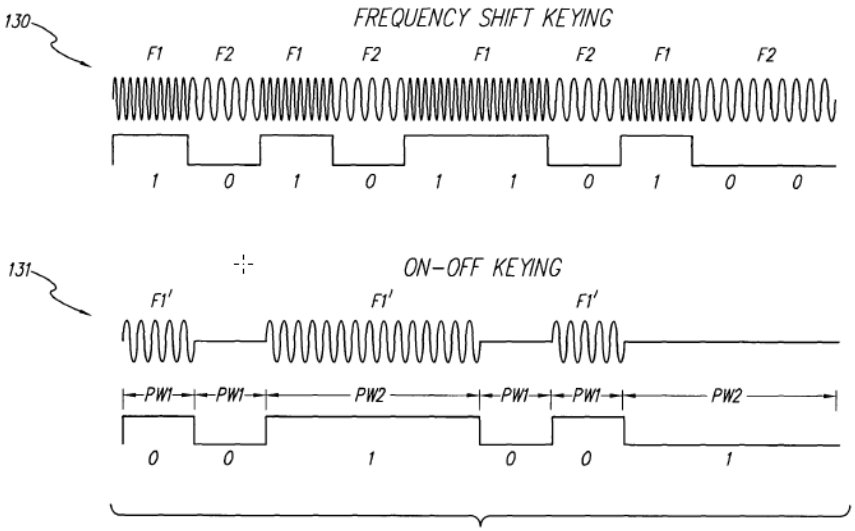

FIG. 3

Figure 3 shows "first signal (130) including control data that has been modulated using FSK and [] second signal (131) including control data that has been modulated using OOK, or [pulse wave modulation] PWM." *Id.* at 6:41–44.

The signals communicate bits of binary code by changing frequency or pulse width. Ex. 1001, 6:41–67. Second signal 131 represents OOK modulation, wherein pulse widths PW1 and PW2 designate a binary code regardless if the signal is on or off. Ex. 1001, 6:55–67. As explained by the '480 patent Specification:

> A transmitted signal having a first pulse width, PW1, regardless of whether the frequency is F1' or Zero (off), is interpreted as, e.g., a binary "0"; whereas a transmitted signal having a second pulse width, PW2, regardless of whether the frequency is F1' or zero (off), is interpreted as, e.g., a binary "1". Alternatively, a "1" may correspond to PW1 and a "0" may correspond to PW2. A change from the F1' frequency to the zero (off) frequency is used to indicate a data transition from one bit to the next bit in the data stream.

Id. "Because [] OOK receiver (43) compares pulse widths, the frequency of the clock signal . . . does not have to be synchronized with the frequency of [] external device (20) in order for [] OOK receiver (43) to function. Hence, [] OOK telemetry link (38) is considered to be 'frequency independent.'" *Id.* at 7:26–33.

2. Challenged Claims

The '480 patent includes 8 claims. Of these Petitioner challenges claims 1–4 and 6–8. As discussed above, claim 1 was disclaimed. However, because claim 2 depends from claim 1, and claims 3, 4, and 6–8 all depend from claim 2, we reproduce claims 1 and 2 below:

> 1. A system, comprising:
>
> an external device, comprising:
>
> first modulation circuitry for producing from first data a first signal modulated with on-off keying (OOK) modulation, wherein the first modulated signal comprises logic '0' bits of a first pulse width and logic '1' bits of a second pulse width different from the first pulse width, wherein

each bit further comprises either an ON state with a signal that varies with a first frequency or an OFF state, wherein a transition between adjacent bits in the first signal is marked by a change in the first modulated signal between the ON and OFF states;

a coil configured to wirelessly transmit the first modulated signal to the implantable medical device; and

an implantable medical device, comprising a first telemetry receiver in the implantable medical device for demodulating the first modulated signal to recover the first data.

2. The system of claim 1, further comprising:

second modulation circuitry in the external device for producing from second data a second signal modulated with frequency modulation, wherein the coil is further configured to wirelessly transmit the second modulated signal to the implantable medical device; [and]

a second telemetry receiver in the implantable medical device for demodulating the second modulated signal to recover the second data.

Ex. 1001, 11:1–28. Among the dependent claims before us, claim 3 recites that "the frequency modulation comprises frequency shift keying (FSK) modulation. *Id.* at 12:1–2.

3. Relevant Prosecution History

During the prosecution leading to the issuance of the '480 patent, the Examiner rejected claims 54 and 57–61 (now claims 1 and 4–8) as obvious over Lenzkes[13] (Ex. 1015) or Borkan.[14] Ex. 1002, 166–170. The Examiner

[13] U.S. Patent No. 3,727,616, issued Apr. 17, 1973.
[14] U.S. Patent No. 4,612,934, issued Sept. 23, 1986. A typographical error in the rejection lists the patent number as U.S. Pat. No. 6,612,934 (Ex. 1016). The correct number is listed in the Notice of References cited. *See* Ex. 1002, 122.

also rejected claims 55 and 56 (now claims 2 and 3) as obvious over Lenzkes or Borkan, further in view of Eisenberg[15] (Ex. 1010). *Id*. at 169.

The Examiner found the prior art disclosed implantable devices that receive communications using pulse width modulation. Ex. 1002, p. 168–169. The Examiner indicated that Lenzkes taught an implantable device having a second receiver. *Id.* at 168. And with respect to Borkan, the Examiner determined that "[a] back up receiver is envisioned for when the first one breaks down. A clock and a bit counter are part of the circuitry." *Id.* at 169. As to claim 55 (now claim 2), the Examiner determined that it would have been obvious "[t]o have provided second circuitry for transmitting and receive [pulse wave modulation] PWM or FSK modulation for the benefits taught by [Eisenberg]." *Id.*

In response, Patent Owner argued that neither Lenzkes nor Borkan taught that a "transition between adjacent bits in the first signal is marked by a change in the first modulated signal between the ON and OFF states." Ex. 1002, p. 303–305. In light of this argument, the Examiner entered an Examiner's Amendment in the Notice of Allowance as follows:

> In claim 1
> At line 6, after ", wherein";
> "the first modulated" has been deleted
> - - each bit - - has been inserted
> At line 7, before "an OFF state",
> "signal further comprises an ON state of a first frequency and" has been deleted
> - - further comprises either an ON state with a signal that varies with a first frequency or - - has been inserted.

[15] U.S. Patent No. 6,434,194 B1, issued Aug. 13, 2002. Ex. 1010.

Id. at 314. According to the Examiner, "[t]he amendment clarifies that the first frequency is in a bit signal rather that a series of bit signals." *Id.* at 315.

II. ANALYSIS

A. Legal Standards

"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 of persuasion never shifts to Patent Owner. *See Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015) (discussing the burden of proof in *inter partes* review).

A claim is unpatentable under 35 U.S.C. § 103(a) if 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 that 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) objective evidence of nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

In analyzing the obviousness of a combination of prior art elements, it can be important to identify a reason that would have prompted one of skill in the art "to combine . . . known elements in the fashion claimed by the

patent at issue." *KSR*, 550 U.S. at 418. A precise teaching directed to the specific subject matter of a challenged claim is not necessary to establish obviousness. *Id.* Rather, "any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed." *Id.* at 420. Accordingly, a party that petitions the Board for a determination of unpatentability based on obviousness must show that "a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so." *In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1381 (Fed. Cir. 2016) (internal quotations and citations omitted).

B. Level of Ordinary Skill in the Art

In determining the level of skill in the art, we consider the type of problems encountered in the art, the prior art solutions to those problems, the rapidity with which innovations are made, the sophistication of the technology, and the educational level of active workers in the field. *Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc.*, 807 F.2d 955, 962 (Fed. Cir. 1986); *Orthopedic Equip. Co. v. U. S.*, 702 F.2d 1005, 1011 (Fed. Cir. 1983).

Petitioner contends that a person of ordinary skill in the art as of the relevant date "would have had (1) at least a bachelor's degree in electrical engineering, biomedical engineering, or equivalent coursework, and (2) at least one year of experience researching or developing implantable medical devices." Pet. 15 (citing Ex. 1003 ¶¶ 50–56). Patent Owner does not presently dispute Petitioner's proposed definition of the reasonably skilled

artisan. Prelim. Resp. 6. And as Petitioner's proposed definition is not inconsistent with the cited prior art, we adopt it for the purposes of this Decision. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (explaining that specific findings regarding ordinary skill level are not required "where the prior art itself reflects an appropriate level and a need for testimony is not shown" (quoting *Litton Indus. Prods., Inc. v. Solid State Sys. Corp.*, 755 F.2d 158, 163–64 (Fed. Cir. 1985))).

C. Claim Construction

We interpret a claim "using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. 282(b)." 37 C.F.R. § 42.100(b) (2019). Under this standard, we construe 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." *Id.* Furthermore, at this stage in the proceeding, we need only construe the claims to the extent necessary to determine whether to institute *inter partes* review. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) ("[W]e need only construe terms 'that are in controversy, and only to the extent necessary to resolve the controversy.'" (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999))).

Petitioner refers us to the express definitions of "stimulator" and "control bit" at columns 3–5 of the '480 patent's Specification and contends that no further construction is necessary. Pet. 15–16; *see also* Ex. 1001, 3:39–45; 4:67–5:4. On the present record, Patent Owner does not dispute Petitioner's proposed claim construction. Prelim. Resp. 6 ("For the purposes of this Preliminary Response, Patent Owner has used Petitioner's proposed

definition of the terms of "stimulator" and "control bit."). At this stage of the proceeding, we apply the express definitions of those terms as set forth in the Specification.

D. Obviousness in view of Grevious and Fitch (Ground 3)

As Ground 3, Petitioner challenges claims 2–4, 6, and 8 as obvious in view of Grevious with or without Fitch. Pet. 46–62. Petitioner's challenge of claim 2 refers to the challenge of claim 1 (Ground 1), from which claim 2 depends. *See id.* at 46. Petitioner's challenge includes a detailed mapping of the teachings of these references to each element of claim 2. *Id.* at 46–56. We begin our analysis with an overview of the references asserted under Ground 3.

1. Overview of Grevious (Ex. 1005)

Grevious is directed to an implantable medical system with "a standardized telemetry system that automatically selects a modulation protocol configuration to establish a reliable symmetric telemetry link between medical devices and programmers." Ex. 1005, Abstract, 2:51–55. The standardized system will automatically select any one of the following modulation formats depending on the type of hardware in the corresponding implanted medical device and external programmer: "(1) a pulse or burst width modulation (PWM) format; a pulse or burst width modulation (PWM) plus pulse interval modulation format; (3) a modified phase shift keying (MPSK) modulation format; (4) pulse position modulation (PPM); or (5) pulse interval modulation (PIM)." *Id.* at 2:58–3:4; *see also id.* at 10:47–52 ("In one preferred embodiment [illustrated in Figure 6], there are nine different modulation protocol configurations 210 that can provide a communications interface for a broad range of products."). The system can

therefore "be used in a wide array of medical devices and programmers for patient treatment." *Id.* at 2:29–34. Grievous also supports "on the fly" switching between modulation protocols to ensure that a communications link is not lost. *Id.* at 11:4–19. "This switching of modulation protocol configuration can be done repeatedly to automatically select a different modulation format than the current communications link modulation format. The telemetry system automatically selects the best modulation format, and then switches 'on the fly', to transmit and receive information and data in the most efficient and timely manner possible." *Id.* at 11:19–26.

Grevious further discloses typical system components for a telemetry systems implemented in a medical device, such as an Implantable Neuro Stimulator ("INS"), in Figure 2, reproduced below:

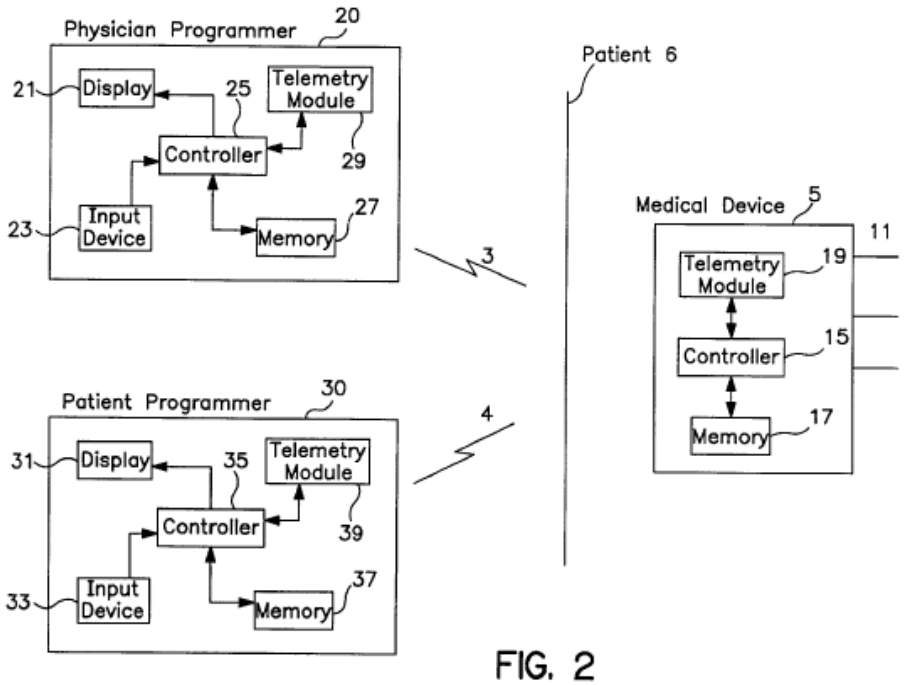

FIG. 2

Figure 2 shows a system including medical device 5, physician programmer 20 and patient programmer 30. Ex. 1005, 4:46–51.

Grevious discloses that physician programmer 20 and patient programmer 30 "can use the telemetry system of the present invention for

either bi-directional or uni-directional communication with [] medical device 5." Ex. 1005, 4:50–54. More specifically, "[i]nformation, commands and instructions can then be communicated back and forth between the devices via telemetry 3 and 4 when in a bi-directional system. In a uni-directional system, [] physician programmer 20 or patient programmer 30 communicate with [] medical device 5." *Id.* at 4:54–59. The telemetry module of each component may include a telemetry coil, a receiver, a transmitter, and a telemetry process, as illustrated in Figure 3, reproduced below:

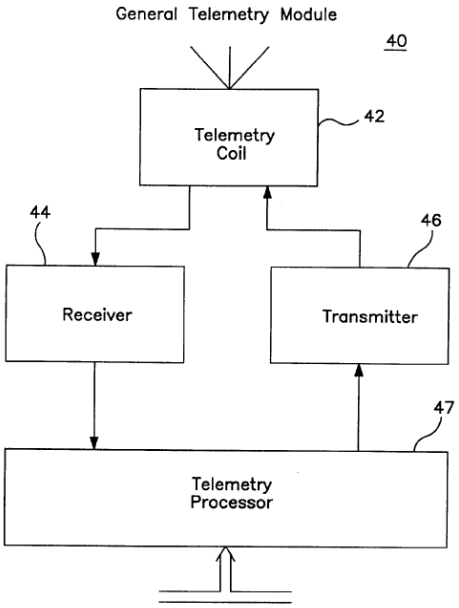

FIG. 3

Figure 3 shows a block diagram of a "typical telemetry module 40" that "enables the medical device 5 and programmers 20 and 30 to communicate bi-directionally with each other via telemetry 3 and 4." *Id.* at 5:13–18 (referencing Figure 2, shown above). "[T]elementary module 40 comprises a telemetry coil 42, a receiver 44, a transmitter 46, and a telemetry processor 47." *Id.* at 5:18–21.

According to Grevious, communication between the programmers and implantable device may occur using at least five modulation formats,

including preferred modulation formats: Formats A, B, and C. Ex. 1005, 6:19–40; 11:51–67; 12:35–39. Format B "uses pulse or burst width modulation (PWM) plus pulse interval modulation (PIM)." *Id*. at 12:1–3. Figure 9, reproduced below, shows greater detail of Format B modulation:

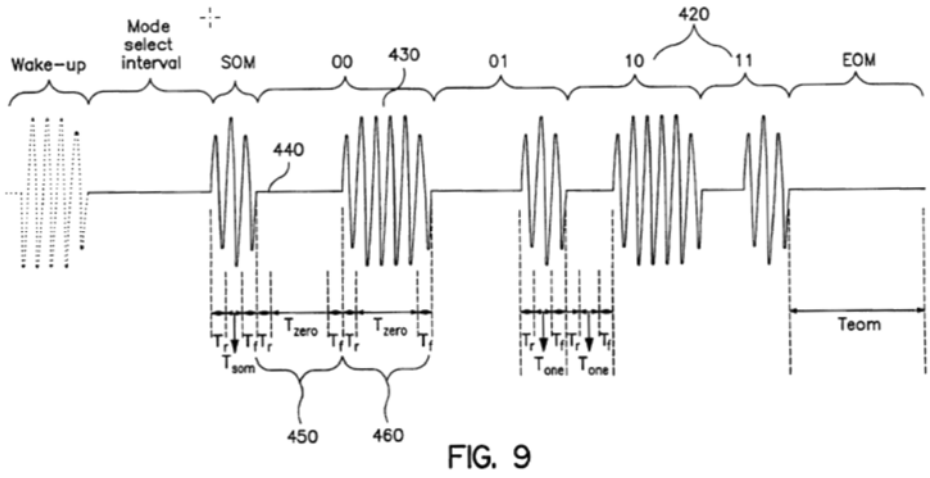

FIG. 9

Figure 9 shows data bits transmitted in pairs 420, wherein each bit is represented by burst 430 or not burst 440. Ex. 1005, 15:38–43.

Grevious further describes:

> In a preferred embodiment of Format B, [] first bit 450 of each dibit begins with a "not burst" 440. The size of the not burst is simply the length of time measured from the end of the previous burst to the start of the next (T_{zero} or T_{one}). The second bit 460 of the dibit is a burst. This period is measured from the start to the end of a burst. Those skilled in the art will readily recognize that the "not burst"-burst sequence of the first and second bits can be easily varied, for example into burst-"not-burst" sequence.

Ex. 1005, 15:44–52.

2. Overview of Fitch

Fitch describes a telephone line carrier system having a data communication channel designed to be an inexpensive technique for reliable communications. Ex. 1006, Abstract, 6:5–6. Fitch describes a data

transmitter responsive to a binary digital signal "encoded into a series of pulses having alternating polarity in which a '1' has a duration of 1 ms and a '0' has a duration of 2 ms. . . . This signaling scheme is known as the Pulse Width Encoded – Non Return to Zero (PWE-NRz) format." *Id.* 6:19–28. Fitch describes "on/off carrier keying" as shown in Figure 10, reproduced below:

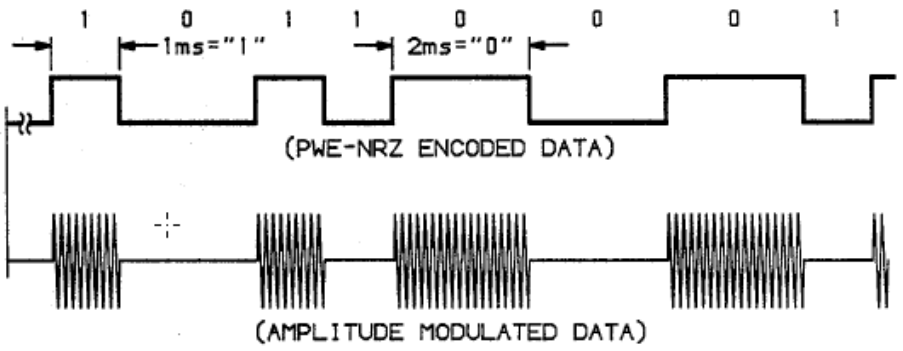

FIG. 10

Figure 10 "illustrates various waveforms associated with data transmission using a pulse width encoded - non return to zero format and on/off carrier keying." Ex. 1006, 3:5–7.

3. Analysis of Claim 2

Petitioner argues claim 2 is obvious over Grevious, with or without Fitch. We address the elements of claim 2, incorporating the elements of disclaimed claim 1, from which claim 2 depends.

a) "A system comprising:"

Petition asserts that Grevious discloses a schematic block diagram of a system in Figure 2. Pet. 19.

Patent Owner does not respond to this assertion.

b) "an external device comprising"

Petitioner asserts that Grevious discloses physician and patient programmers 20 and 30 that are each external devices that communicate with implanted medical device 5. Pet. 20.

Patent Owner does not respond to this assertion.

c) "first modulation circuitry for producing from first data a first signal"

Petitioner asserts that Grevious discloses telemetry transmitter 46 and telemetry processor 47 that satisfy the claimed "first modulation circuitry." Pet. 21–24.

Patent Owner does not respond to this assertion.

(1) "modulated with on-off keying (OOK) modulation"

Petitioner asserts that Grevious discloses a telemetry system that supports multiple modulation formats, including pulse width modulation, also known as on/off keying (OOK) modulation. Pet. 24–28.

Patent Owner does not respond to this assertion.

(2) "wherein the first modulated signal comprises logic '0' bits of a first pulse width and logic '1' bits of a second pulse width different from the first pulse width"

Petitioner asserts that Grevious discloses a first modulated signal, Format B, which uses alternating burst (ON) and not burst (OFF) pulses of varying widths to encode bits. Pet. 28–29. Mr. Pless states that each '0' data bit in Grevious' Figure 9 corresponds to a pulse width of T_{zero} and each '1' data bit corresponds to a pulse width of T_{one}, which has a different width than T_{zero}. *Id.* (citing Ex. 1003 ¶ 88).

Patent Owner does not respond to Petitioner's assertions.

(3) "wherein each bit further comprises either an ON state with a signal that varies with a first frequency or an OFF state"

Petitioner asserts that Grevious discloses modulation Format B using alternating burst (ON) and not burst (OFF) pulses to encode data bits. Pet. 30–31. Mr. Pless states that each data bit comprises either a burst (ON) or not burst (OFF) state. *Id.* (citing Ex. 1003 ¶ 92).

Patent Owner does not respond to Petitioner's assertions.

(4) "wherein a transition between adjacent bits in the first signal is marked by a change in the first modulated signal between the ON and OFF states;"

Petitioner asserts that Grevious discloses that "both the transitions between the data bits represented by the burst (ON) pulses preceding and following the data bit represented by the not burst (OFF) pulse are marked by a change between the ON and OFF state in the signal." Pet. 31–32. Mr. Pless states that the following annotated Figures correspond with a transition in the signal between a burst/ON (blue) and a not burst/OFF (red) state:

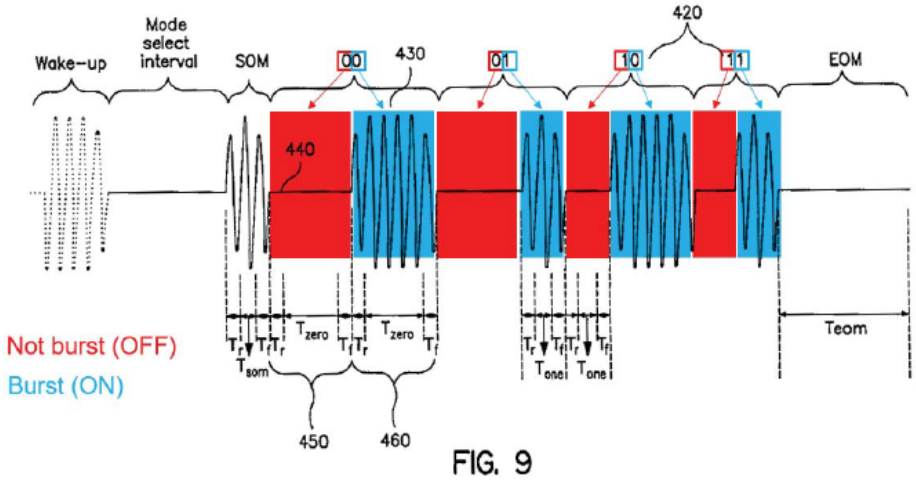

FIG. 9

Grevious Figure 9 is annotated by Petitioner's expert to show burst/ON pulses in blue and not burst/OFF pulses in off which correspond to binary code 00011011. *Id.* (citing Ex. 1003 ¶ 96).

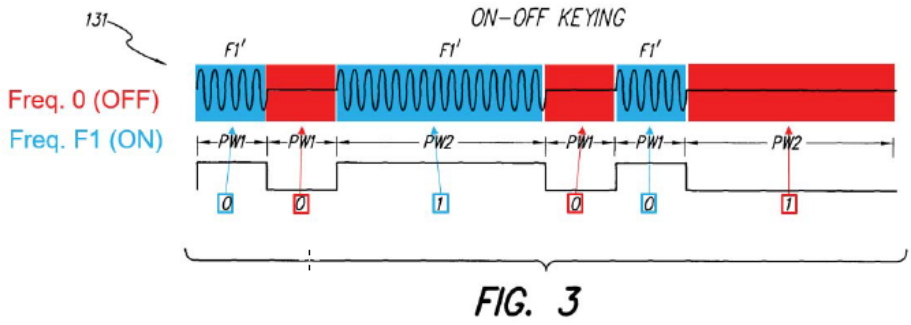

FIG. 3

The '480 patent's Figure 3 is annotated by Petitioner's expert to show ON pulses in blue and OFF pulses in red which correspond to binary code 001001. *Id.* (citing Ex. 1003 ¶ 97).

Alternatively, Petitioner asserts that Fitch discloses on/off keying modulation, having logic bits '0' and '1' with different pulse widths, wherein a transition between adjacent bits is marked by a change in the signal between ON and OFF states. *See* Pet. 39–43. Petitioner argues that Grevious and Fitch are analogous art to the '480 patent, and it would have been obvious to combine the references as an "application of a known technique to a piece of prior art ready for [] improvement." Pet. 44 (citing *KSR*, 550 U.S. at 417.

Patent Owner does not respond to Petitioner's assertions.

> *d) "a coil configured to wirelessly transmit the first modulated signal to the implantable medical device; and"*

Petitioner asserts that Grevious discloses telemetry module 40 that includes telemetry coil 42 that enables bidirectional communication. Pet. 33–35.

Patent Owner does not respond to this assertion.

> *e) "an implantable medical device, comprising a first telemetry receiver in the implantable medical device for demodulating the first modulated signal to recover the first data."*

Petitioner asserts that Grevious discloses implantable medical device 5 including a telemetry module that includes telemetry processor 47 and telemetry receiver 44. Pet. 35–39. Petitioner relies on Grevious to show that telemetry processor receives a predetermined protocol including a type of telemetry modulation (e.g., Format B) that is demodulated by telemetry receiver 44 from a time base[d] signal into data pulses. *Id.* at 38.

Patent Owner does not respond to Petitioner's assertions.

> *f) "The system of claim 1, further comprising: second modulation circuitry in the external device for producing from second data a second signal modulated with frequency modulation"*

Petitioner asserts that Grevious discloses a system that supports at least five modulation formats. Pet. 46–47. Petitioner argues Grevious' "[t]elemetry transmitter 46 and telemetry processor 47, as configured with FSK . . . satisfy the claimed '*second modulation circuitry*." *Id.* at 47. Petitioner argues "[t]elemetry processor 47 is first configured with the appropriate telemetry protocol to communicate, including one of these at least five modulation protocols, and then processes binary data ('*second data*') into time based digital pulses. *Id.*, 6:6-12. Transmitter 46 then modulates the digital signal into an RF signal ('*second [modulated] signal*')." *Id.* (citing Ex. 1003 ¶ 124). In addition:

> The '480 patent discloses a single "control circuitry (39)" that controls the operation of coil 34 to transmit data using either FSK or the OOK modulation schemes disclosed by the '480 patent. Ex. 1001, 4:19-39. The claimed "*first modulation circuitry*" and "*second modulation circuitry*" therefore must

> encompass a single control circuitry capable of a "*first modulation*" and a "*second modulation*."

Id. at 47–48 (citing Ex. 1003 ¶ 125).

Petitioner further argues that "[a]lthough Grevious does not expressly disclose '*frequency modulation*' as a modulation format (*see* Ex. 1005, 6:22–37), it does expressly contemplate the use of "[o]ther modulation formats" in addition to the five exemplary formats (*id*., 12:35–39)." Pet. 48. Mr. Pless states that "FSK was routinely used as a modulation format for telemetry communications between implantable medical devices and external devices." Ex. 1003 ¶¶ 127–128 (citing Kruse and Thompson). Petitioner argues "[i]t would have been obvious to a person having ordinary skill in the art in 2002 to modify Grevious . . . to incorporate frequency shift-keying (FSK) as an additional modulation format supported by Grevious' telemetry modules in programmers 20 and 30 and medical device 5. Pet. 50 (citing Ex. 1003 ¶¶ 130–132).

Patent Owner responds that claim 2 expressly requires a "***first*** modulation circuitry" and a "***second*** modulation circuitry" "—*i.e.*, two different circuits, where the first modulation circuit produces on-off keying (OOK) modulation (*i.e.*, an amplitude modulated signal) and the second modulation circuit produces a frequency modulated signal (*e.g.*, FSK)." Prelim. Resp. 17. Patent Owner argues that the first and second modulation circuits cannot be the same circuit, "since they must produce two, distinct types of modulation signals. *Id.* 17–18. Patent Owner argues that Petitioner's argument that the first and second modulation circuity must encompass a single control circuitry capable of two different modulations hinges solely on Figure 1 of the '480 patent and ignores the '698 patent

disclosure of an exemplary external device having separate FSK and OOK transmitters. *See* Prelim. Resp. 18–20. Patent Owner further argues that Figure 1 of the '480 patent "clearly shows that external device 20 provides a first OOK modulation telemetry (380) ***and*** a second frequency modulation telemetry (48). . . . a single modulation control circuity cannot deliver both of these types of telemetry." *Id.* at 20.

Patent Owner further responds that "Grevious discloses neither a 'second modulation circuitry' nor any circuitry that produces a frequency modulation signal." Prelim. Resp. 21. Patent Owner argues that Grevious discloses "a family of related symmetrical modulation protocol configurations," all of which use amplitude modulation. *Id.* at 22 (emphasis omitted). *Id.* Therefore, Patent Owner argues, Grevious' "telemetry module is configured . . . to transmit ***only amplitude modulated signals*** at a single frequency and different data rates." *Id.* at 23. Patent Owner argues that Grevious discloses exemplary hardware implementation that is limited to a single frequency and thus "frequency modulation is not possible with Grevious's telemetry system." *Id.* at 24–25.

Patent Owner additionally responds that "Grevious provides no motivation for adding complex frequency modulation circuitry to an amplitude modulation circuit so as to enable frequency modulation." Prelim. Resp. 25. Patent Owner argues that "Petitioner fails to provide any motivation for combining two different, and incompatible, modulation schemes in the telemetry system of Grevious." *Id.* at 26. Patent Owner argues that adding frequency modulation circuity to Grevious would defeat the object of "a telemetry system that is 'simple in design, reliability and implementation' and is 'easy to implement at the device level.'" *Id.* at 27 (citing Ex. 1005, 2:29–31, 45–48).

As to the additional references cited by Mr. Pless to support the reason to modify Grevious' external device with second modulation circuitry, Patent Owner argues that Kruse and Thompson merely refer to FSK in a "long list of modulation schemes . . . that includes the amplitude modulations schemes already included in Grevious." Prelim. Resp. 27. Patent Owner argues that nothing in Kruse and Thompson "suggest that a POSITA would add the FSK modulation scheme to a device already configured to use an amplitude modulation scheme." *Id.* at 28. Patent Owner argues that Brenig and Oetting include contradictory statements to those put forth by Petitioner to support modifying Grevious. *See id.* at 28–30.

We address Patent Owner's arguments below in connection with element "h".

> *g) "wherein the coil is further configured to wirelessly transmit the second modulated signal to the implantable medical device"*

Petitioner asserts that Grevious discloses typical telemetry module 40 used in programmers 20 and 30, including telemetry coil 42 for wirelessly communicating with implanted medical device 5. Pet. 52. Petitioner argues "[a]fter transmitter 46 of programmers 20 or 30 modulates the digital signal into an RF signal ('*second modulated signal*'), the modulated telemetry signal is transmitted via the telemetry coil 42 to implanted medical device 5." *Id.* at 52–53.

Patent Owner does not respond to Petitioner's assertions.

> *h) "a second telemetry receiver in the implantable medical device for demodulating the second modulated signal to recover the second data."*

Petitioner asserts that Grevious discloses that "telemetry receiver 44 and telemetry processor 47, as configured with FSK as discussed above, satisfy the claimed '*second telemetry receiver*.'" Pet. 53 (citing Ex. 1003 ¶ 138). Petitioner notes that "[t]he '480 patent explains that a receiver 'may be any circuit configured to receive and process an RF signal,' such as, for example, 'a microprocessor, [DSP], [ASIC], processor with firmware, [FPGA], or any other combination of hardware and/or software'" and that "OOK receiver (43) may be integrated into the receiver (42)." *Id.* at 54 (citing Ex. 1005 4:55–61; 5:27–28). Petitioner argues that Grevious' receiver 44 and processor 47 configured to receive and demodulate "Format B satisfies the '*first telemetry receiver*'" and Grevious' receiver 44 and processor 47 configured to receive and demodulate "FSK satisfies the '*second telemetry receiver*.'" *Id.* (citing Ex. 1003 ¶ 139).

Petitioner argues in the alternative, if "*first telemetry receiver*" and "*second telemetry receiver*" are "mutually exclusive and non-overlapping, such a distinction would have been obvious." Pet. 54 (citing Ex. 1003 ¶¶ 140–146). Mr. Pless states that "[i]t was known by 2002 to implement different receivers and modulation techniques in different hardware or software elements." Ex. 1003 ¶¶ 140–143 (citing Silvian, Torgerson, and Ohno). Petitioner argues "[i]t would have been obvious to further modify Grevious to implement the different modulation formats as separate hardware or software functionality." Pet. 55 (citing Ex. 1003 ¶ 144). Petitioner argues that "[m]odifying Grevious to implement its different modulation formats as separate hardware or software modules simply

'arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement,' and would have been obvious." *Id.* at 56 (citing *KSR*, 550 U.S. at 417).

Patent Owner responds that claim 2 requires "two different telemetry receivers, where the first telemetry receiver demodulates the OOK signal (*i.e.*, an amplitude modulated signal) and the second telemetry receiver demodulates a frequency modulated signal (*e.g.*, FSK)." Prelim. Resp. 33. Patent Owner argues "[a]lthough the OOK receiver may be 'integrated,' *i.e.*, use some of the same elements, the circuitry does not and cannot 'overlap' as Petitioner claims. Thus, the OOK receiver is separate from the FSK receiver." *Id.* at 34.

Patent Owner further responds that "Grevious does not disclose a first telemetry receiver to demodulate an amplitude modulated telemetry (*i.e.*, OOK) ***and*** a second telemetry receiver to demodulate a frequency modulated telemetry (*i.e.*, FSK)." Prelim. Resp. 34. Patent Owner argues "Petitioner makes no attempt to explain why or how a POSITA would implement the claimed 'second telemetry receiver' in the implant of Grevious to receive a frequency modulated signal." *Id.* at 35.

As to the additional references cited by Mr. Pless to support modifying Grevious' implantable device with a second telemetry receiver, Patent Owner argues that none of the references "discloses an ***implantable device*** with receivers to demodulate amplitude modulation ***and*** frequency modulation." Prelim. Resp. 36. Patent Owner argues "Silvian envisions a programmer to receive communications from multiple different implantable devices that have different modulation schemes, not an implantable device that receives different modulation schemes from an external device." *Id.*

Patent Owner argues Torgerson discloses a telemetry module and a recharge module, not two telemetry receivers. *Id.* at 37. Patent Owner argues that although Ohno discusses more than one receiver, "they all receive the same telemetry modulation signal and merely have [a] different threshold value" and are not "two different wireless communications scheme via separate receivers." *Id.* at 37–38.

We do not agree with Patent Owner that Petitioner's argument requires a single modulation control circuitry to deliver both types of telemetry, as Patent Owner asserts. To the contrary, Petitioner contends "to the extent one could argue that "*first telemetry receiver*" and the "*second telemetry receiver*" must be mutually exclusive and non-overlapping, such a distinction would have been obvious." Pet. 54 (citing Ex. 1003 ¶¶ 140–146); *see, e.g.,* Ex. 1003 ¶ 140 ("It was known by 2002 to implement different receivers and modulation techniques in different hardware or software elements."). Moreover, Patent Owner provides no support on the present record for the assertion that "a single modulation control circuity cannot deliver both [OOK and frequency modulation] telemetry." *See* Prelim. Resp. 20. We note, however, that Eisenberg, cited by the Examiner for the benefits of "provid[ing] second circuitry for transmitting and receiving PWM or FSK modulation," discloses a "Combined OOK-FSK/PPM Modulation and Communication Protocol Scheme Providing Low Cost, Low Power Consumption Short Range Radio Link," and appears to disclose transmitter/receiver circuitry for combined OOK–FSK communication. *See* Ex. 1002, 3; Ex. 1010, Title, Abstract.

We are also not persuaded by Patent Owner's argument that one of ordinary skill in the art would not modify Grevious to employ a frequency modulation mode such as FSK because Grevious only discloses amplitude

modulated signals. *See* Prelim. Resp. 23. In particular, we note Petitioner's arguments, supported by the testimony of Mr. Pless, that (1) the FSK modulation format was well-known in the art (Pet. 50 (citing Ex. 1003 ¶ 130)); (2) Grevious's express 'objectives include "provid[ing] a telemetry protocol system to support … the use of telemetry in a wide array of medical devices' (Ex. 1005, 2:35-40) and to 'support a wide range of medical devices' (*id.*, 2:45-48)" (*id.* at 51); and, thus, (3) one of ordinary skill in the art "would have been motivated to support an even 'wide[r] array of medical devices,' such as those that only support FSK" (*id.* (citing Ex. 1003 ¶ 131); *see also id.* (because "Kruse and Thompson disclose medical devices that support FSK" and "Grevious, Kruse, and Thompson are each patents filed by Medtronic, Inc., . . . an ordinary artisan would have been motivated to modify Grevious to support the modulation formats used or expected to be used by other Medtronic medical devices") (citing Ex. 1003 ¶ 131)).

Finally, Patent Owner has raised the salient issue of whether one of ordinary skill in the art as of the time the patent was filed would have been motivated to modify Grevious to include multiple modulation circuitry and telemetry receivers as required by the challenged claims. Based on the current record, however, Petitioner has described sufficient motivation to modify Grevious to incorporate a second modulation circuitry and telemetry receiver for frequency modulation communication. We note, in particular, Petitioner's argument that one of ordinary skill in the art would have:

> been motivated to incorporate frequency modulation (FM) techniques such as FSK because they are less susceptible to interference than amplitude modulation (AM) techniques such as on-off keying (OOK). Ex. 1003, ¶132; Ex. 1020, 82; Ex. 1021, 1755. Grevious includes "automatic selection" functionality throughout the telemetry session, which avoids a "lost" communications link by switching "on the fly" to a better

> protocol for a given situation. Ex. 1005, 10:65-11:26. An ordinary artisan would have been motivated to support additional modulation formats such as FSK to ensure flexibility during the automatic configuration process and to avoid lost connections in high-interference situations. Ex. 1003, ¶132.

Pet. 51–52.[16]

In view of the above, the information presented in the Petition establishes a reasonable likelihood that the Petitioner would prevail in showing that claims 2–4 and 6, and 8 are unpatentable under 35 U.S.C. § 103(a) in view of Grevious with or without Fitch. Although Patent Owner's arguments may raise disputed factual issues, particularly with respect to motivation to modify Grevious to include multiple modulation circuitry and telemetry receivers, the parties will have the opportunity to further develop these facts during trial, and the Board will evaluate the fully-developed record at the close of the evidence.

4. Analysis of claims 3, 4, 6, and 8

We have also reviewed Petitioner's contentions with respect to dependent claims 3, 4, 6, and 8, and determine that the Petition provides the requisite showing, at this stage of the proceeding, that Grevious, with or without Fitch, discloses the subject matter of these claims. *See* Pet. 57–62.

[16] While we acknowledge Patent Owner's arguments regarding the teachings of Silvian, Torgerson, and Ohno (*see* Prelim. Resp. 36–38), these references, at a minimum, indicate that it was known to incorporate more than one telemetry receiver or modulation scheme in a medical communication system, which supports Petitioner's position. *See* Ex. 1002 ¶¶ 141–143; *see also* Ex. 1010, Abstract (disclosing "[a] communication system [that] provides robust, short range radio communications between battery operated devices by using ON-OFF-KEYED (OOK) modulation and either frequency shift keyed (FSK) modulation or pulse position/width modulation (PPM/PWM), in combination with a prescribed communications protocol").

Patent Owner relies on the arguments against claim 2, and, at this stage, does not offer any arguments addressing Petitioner's substantive showing as to claims 3, 4, 6, and 8. Prelim. Resp. 39. We determine, based on the current record, that the Petition shows a reasonable likelihood that Petitioner would prevail with respect to the contention that claims 3, 4, 6, and 8 would also have been obvious based on Grevious, with or without Fitch, as set forth with respect to Ground 3.

E. Obviousness in view of Grevious and Bradshaw, with or without Fitch (Ground 4)

As Ground 4, Petitioner challenges claims 6 and 7 as obvious over Grevious in view of Bradshaw, with or without Fitch. Pet. 62–68. Patent Owner relies on the arguments against claim 2 with respect to Grievous, and, at this stage, does not offer any additional arguments addressing Petitioner's substantive showing as to Ground 4. Based on the current record, the Petition shows a reasonable likelihood that Petitioner would prevail with respect to the contention that claims 6 and 7 would have been obvious based on Grevious and Bradshaw, with or without Fitch, as set forth with respect to Ground 4.

III. CONCLUSION

On the present record, we find Petitioner has made a sufficiently persuasive showing that the cited references would have taught or suggested each element of claims 2–4 and 6–8, and set forth a sufficient rationale for why a person of ordinary skill would have been motivated to combine these teachings and suggestions to arrive at the invention recited in claims 2–4 and 6–8. Petitioner has established a reasonable likelihood of prevailing in demonstrating that claims 2–4, 6, and 8 would have been obvious over

Grevious, with or without Fitch, and that claims 6 and 7 would have been obvious over Grevious and Bradshaw, with or without Fitch.

We do not institute review as to claim 1 because it has been disclaimed by Patent Owner.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED, pursuant to 35 U.S.C. § 314(a), that an *inter partes* review of claims 2–4 and 6–8 of the '480 patent is instituted with respect to all grounds set forth in the Petition, specifically, Grounds 3 and 4, Grounds 1 and 2 having been deemed withdrawn as directed to a disclaimed claim; and

FURTHER ORDERED, pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4(b), that the *inter partes* review of the '480 patent shall commence on the entry date of this Order, and notice is hereby given of the institution of a trial.

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