Paper No. 1
Filed: July 10, 2019

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEVRO CORP.,
Petitioner,

v.

BOSTON SCIENTIFIC NEUROMODULATION CORP.,
Patent Owner.

Case No. IPR2019-01284
U.S. Patent No. 7,822,480

Petition for *Inter Partes* Review of U.S. Patent No. 7,822,480

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I. INTRODUCTION

Petitioner Nevro Corp. ("Nevro"/"Petitioner") requests *inter partes* review (IPR) of claims 1-4 and 6-8 ("challenged claims") of U.S. Patent No. 7,822,480 ("'480 patent"). The '480 patent describes certain methods for communicating with an implantable medical device such as a stimulator. During prosecution, assignee Boston Scientific Neuromodulation Corp. ("BSNC"/"Patent Owner") obtained allowance of the claims by relying on a claimed on-off keying (OOK) signal modulation technique for communications between the medical device and an external device. It was known to encode data into an OOK signal by *either* varying the length of the ON portions (*i.e.*, pulse width modulation) *or* by varying the length of the OFF portions (*i.e.*, pulse interval modulation), but the '480 patent claimed a modulation technique that encodes bits into *both* ON *and* OFF portions by varying the lengths of each portion (*i.e.*, pulse width and interval modulation).

BSNC did not invent this modulation technique, however, which had been known for decades. The prior art Grevious patent (Ex. 1005), which was not considered during prosecution of the '480 patent, even disclosed this precise technique for communicating with implantable stimulators several years before the earliest claimed priority date of the '480 patent. For the reasons set forth below, Grevious at least anticipates claim 1 and renders the remaining challenged claims obvious. The challenged claims are unpatentable and should be cancelled.

II. COMPLIANCE WITH IPR REQUIREMENTS

A. Certification of Standing (37 C.F.R. § 42.104(a))

Nevro certifies that the ’480 patent is available for IPR and Nevro is not barred or estopped from requesting an IPR of the challenged claims on the grounds identified below. Neither Nevro nor any of its privies has filed a civil action challenging the validity of any claim of the ’480 patent. This petition is timely filed within one year of the service of BSNC’s complaint alleging infringement of the ’480 patent. *See* Ex. 1014.

B. Mandatory Notices (37 C.F.R. § 42.8)

1. Real Party-in-Interest

Nevro Corp. is the real party-in-interest for this petition.

2. Related Proceedings

The ’480 patent is related to the following U.S. patents and applications: 7,177,698, 8,670,835, 9,079,041, and 60/392,475.

The ’480 patent is at issue in the following case: *Boston Scientific Corp. et al. v. Nevro Corp.*, Case No. 1-18-cv-00644 (D. Del.).

3. Counsel and Service Information

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Nevro consents to service via e-mail at its counsels' addresses above.

C. Fees

The Director is authorized to charge any fees due during this proceeding to Deposit Account No. 50-1597.

D. Service on Patent Owner

Pursuant to 37 C.F.R. § 42.105(a) and the Certificate of Service, the petition and exhibits have been served on the correspondence of record for the '480 patent.

III. IDENTIFICATION OF CHALLENGED CLAIMS

Claims 1-4 and 6-8 of the ’480 patent are unpatentable under 35 U.S.C. §§ 102-103 as follows:

Ground 1. Claim 1 is anticipated under 35 U.S.C. § 102(e) by U.S. Patent No. 6,443,891 to Grevious (“Grevious”) (Ex. 1005).

Ground 2. Claim 1 is obvious over Grevious in view of U.S. Patent No. 4,807,225 to Fitch (“Fitch”) (Ex. 1006).

Ground 3. Claims 2-4, 6, and 8 are obvious over Grevious, with or without Fitch.

Ground 4. Claims 6 and 7 are obvious over Grevious in view of U.S. Patent No. 4,327,441 to Bradshaw (“Bradshaw”) (Ex. 1009), with or without Fitch.

As further explained below, each prior art reference relied upon by Nevro is prior art to the ’480 patent, which claims priority to a provisional application filed on June 28, 2002.[1] Nevro’s challenges are further supported by the declaration and testimony of Mr. Ben Pless (Ex. 1003), an expert in implantable medical devices with over 25 years of experience. *See* Ex. 1003, ¶¶2-8; Ex. 1004 (CV).

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[1] For purposes of this Petition, Nevro has assumed that the ’480 patent’s priority date is June 28, 2002. *See* § IV.C below.

Nevro's patentability challenges do not advance "the same or substantially the same prior art or arguments previously … presented to the Office." *See* 35 U.S.C. § 325(d). As explained below, BSNC obtained allowance of the '480 patent by relying on the claimed characteristics of the "*first modulated signal*." *See* §IV.C below. The prior art relied on by the present petition to teach this feature—Grevious and Fitch—were not previously considered by the Examiner during prosecution of the '480 patent. The Examiner also did not have the benefit of the detailed testimony of Mr. Pless and the further evidence of record.

IV. THE '480 PATENT

A. Technical Background

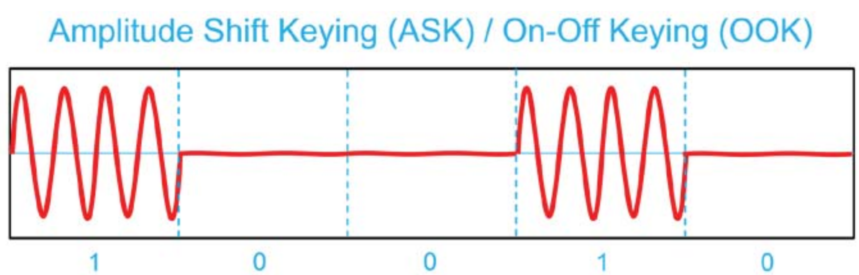
1. <u>Radio Frequency Communications</u>

Communication via radio frequency (RF) and other portions of the electromagnetic spectrum has been used for over a century. *See, e.g.*, Ex. 1019. Radio waves are generated artificially by transmitters and are received by radio receivers, such as antennas. Ex. 1020, 77. Radio carrier waves can be modulated to communicate information between these transmitters and receivers, resulting in wireless communication. *Id.*; Ex. 1021, 1752; Ex. 1003, ¶31.

2. <u>Modulation Techniques</u>

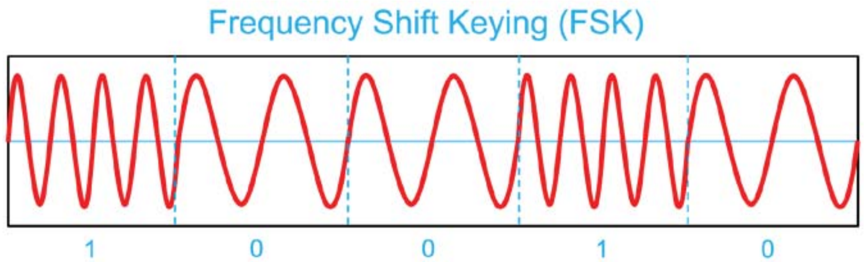
A variety of modulation techniques have been developed over the years to encode information into a carrier wave. Ex. 1021, 1752; Ex. 1003, ¶¶32-38.

Amplitude modulation (AM) involves encoding information into a carrier wave by varying the amplitude of the carrier wave. Ex. 1024, 125-26; Ex. 1021, 1752-53. One technique for encoding digital information via amplitude modulation is known as amplitude-shift keying (ASK), where binary symbols are represented by transmitting specific amplitudes of a fixed frequency radio wave. Ex. 1020, 82. The simplest form of ASK is on-off keying (OOK), where digital data is indicated via the presence (a value '1') or absence (a value '0') of a carrier wave (*Id.*):



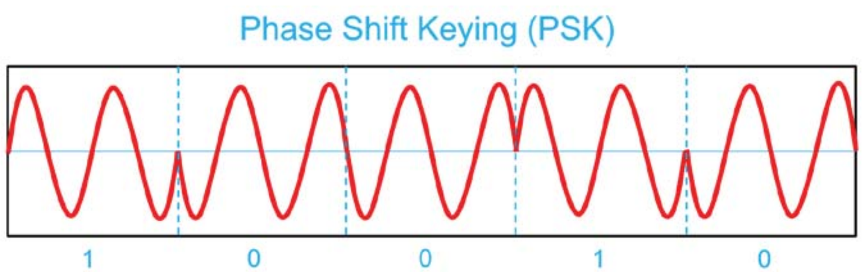
Ex. 1003, ¶33; Ex. 1020, 80-81; Ex. 1024, 125-26.

Frequency modulation (FM) involves encoding information into a carrier wave by varying the instantaneous frequency of the carrier wave. Ex. 1024, 125-26; Ex. 1020, 80-82. Encoding digital information via frequency modulation is known as frequency-shift keying (FSK), where information is conveyed by discrete frequency changes in a carrier signal. Ex. 1024, 125-26. A binary FSK scheme would involve the use of a first frequency for a value '1' and a second frequency for a value '0' (*Id.*).



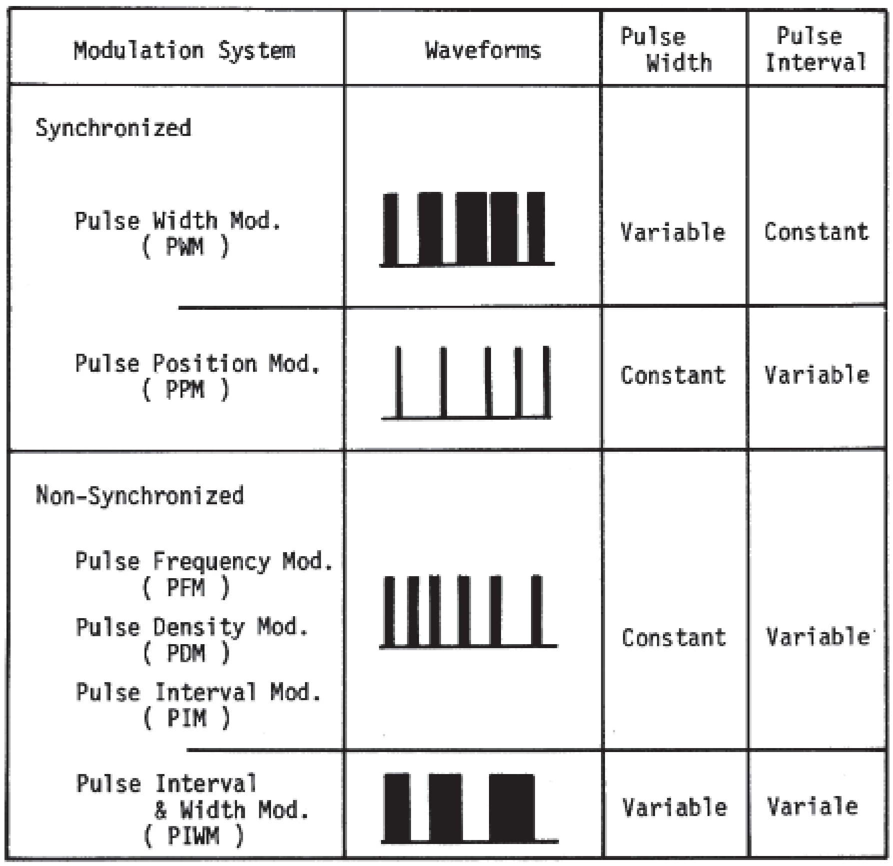
Ex. 1003, ¶34; Ex. 1020, 80-82; Ex. 1024, 125-26.

Phase modulation (PM) is a modulation technique that encodes a message signal as variations in the instantaneous phase of a carrier signal. Ex. 1024, 125-26; Ex. 1020, 80-82. Phase-shift keying (PSK) is a digital version of phase modulation that conveys data by modulating the phase of the carrier wave (Ex. 1020, 82).



Ex. 1003, ¶35; Ex. 1020, 80-81; Ex. 1024, 125-26.

Many variations of these and other techniques were known by the early 2000s. *See, e.g.*, Ex. 1021, 1756; Ex. 1018, 167; Ex. 1003, ¶¶36-38. For example, pulse width modulation (PWM) is a modulation technique that encodes information into a series of pulses sent at a regular interval by varying the width of pulses to correspond to specific values. Ex. 1018, 167. Pulse interval modulation (PIM) is a modulation technique that encodes information by varying the interval between fixed-length pulses. *Id*. It was also known to combine PWM and PIM into a single modulation scheme, *i.e.*, pulse width and interval modulation (PIWM), varying both the pulse width and the interval width to encode data into both parts of the signal. Ex. 1022; Ex. 1018, 167; *see* Ex. 1006 (Fitch), Fig. 10. These techniques were summarized in 1978 as follows, including PIWM (varying both the pulse widths and intervals):



Modulation System	Waveforms	Pulse Width	Pulse Interval
Synchronized Pulse Width Mod. (PWM)		Variable	Constant
Pulse Position Mod. (PPM)		Constant	Variable
Non-Synchronized Pulse Frequency Mod. (PFM) Pulse Density Mod. (PDM) Pulse Interval Mod. (PIM)		Constant	Variable
Pulse Interval & Width Mod. (PIWM)		Variable	Variale

Fig. 2 Examples of Pulse Analog Modulation

Ex. 1018, 167; Ex. 1003, ¶38.

3. Implantable Stimulators

Battery operated implantable stimulators capable of RF communications were well known in the art long before 2002. Ex. 1003, ¶39; Ex. 1001, 1:19-30; Ex. 1011, Abstract. Implantable stimulators were used to, for example, prevent or treat various disorders associated with prolonged inactivity, confinement, or immobilization. Ex. 1001, 1:31-47; Ex. 1007, 1:14-27; Ex. 1011, 1:7-11. It was also known to communicate with implantable stimulators using RF communications to, for example, transfer power to the stimulator, transfer data to and from the stimulator, program the stimulator, and monitor the stimulator's various functions. Ex. 1001, 1:48-57, Ex. 1007, 1:15-6:35; Ex. 1011, 1:11-55. Prior art implantable medical devices were further known to communicate using a variety of formats or modulation techniques, including OOK, FSK, PWM, PIM, and PWN+PIM. Ex. 1005, 2:65-3:4; Ex. 1007, 3:37-44, 3:61-67; Ex. 1008, 2:33-45, 3:29-33; Ex. 1011, 3:9-13.

B. Overview of the '480 Patent

The '480 patent is entitled "Systems and Methods for Communicating with an Implantable Stimulator." Ex. 1001, Face. The '480 patent describes an implantable stimulator capable of communicating with an external device using a signal modulated with on-off keying (OOK). *Id.*, Abstract, 1:61-2:4. Figure 1 illustrates an external device communicating with an implantable stimulator:

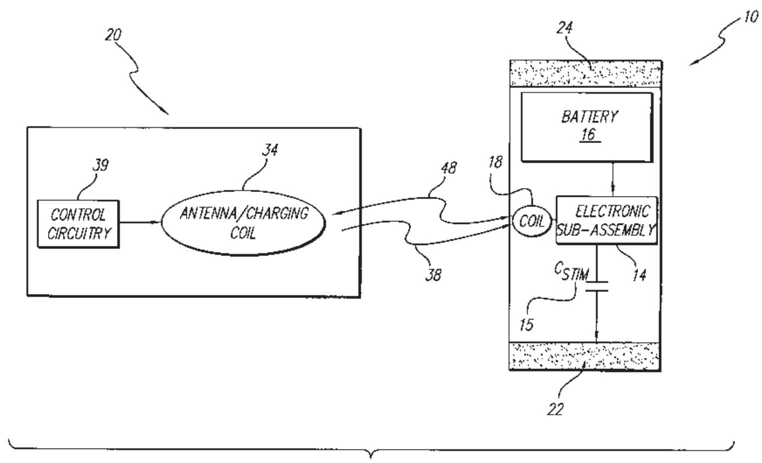


FIG. 1

Id., Fig. 1, 2:12-14, 3:25-56; Ex. 1003, ¶40.

The external device may include control circuitry and a coil to communicate with the implantable device. Ex. 1001, 4:19- 22. The external device and implantable device may include and utilize different telemetry schemes, including an on/off keying (OOK) scheme, a frequency shift keying (FSK) scheme, or "some other modulation scheme." *Id.*, 4:24-39. Exemplary OOK and FSK schemes are illustrated with respect to Figure 3:

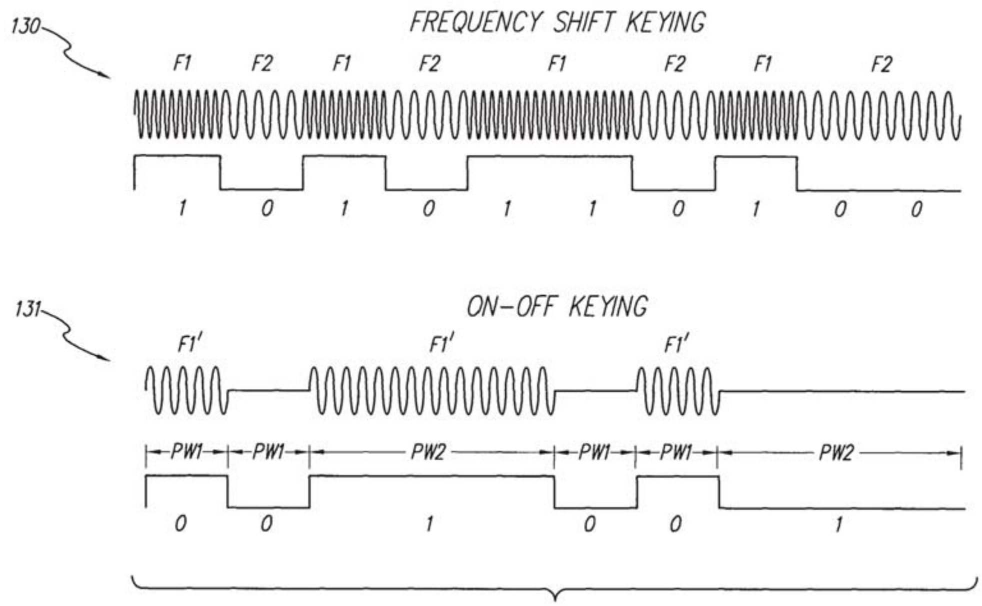


FIG. 3

Ex. 1001, Fig. 3, 2:18-23, 6:41-7:33; Ex. 1003, ¶41.

The first signal in Figure 3 is modulated using conventional FSK, where a binary "1" is represented by a first frequency (F1) and a binary "0" is represented by a second frequency (F2). Ex. 1001, 6:41-54. Claim 1 of the '480 patent is directed to the second signal in Figure 3, which is modulated using a form of OOK modulation where the signal includes either a first frequency F1 (ON) or no transmitted signal (OFF) for one of two widths, PW1 or PW2. Ex. 1001, 6:55-59.[2]

[2] Although a "pulse" conventionally refers to the portion of an OOK or PWM signal that is ON (*see, e.g.*, Ex. 1018, 167; Ex. 1022, 231), the '480 patent refers to both the ON and OFF portions of a signal as "pulses." Ex. 1001, 6:55-67, Fig. 3; Ex. 1003, ¶43.

A signal pulse (ON portion) or interval (OFF portion) having a first width (PW1), regardless of whether the signal is ON or OFF, is interpreted as a binary "0," while a signal pulse or interval having a second width (PW2) is interpreted as a binary "1." *Id.*, 6:59-65. A change from the first frequency (ON) state to the zero frequency (OFF) state indicates a transition from one bit to the next bit in the data stream. *Id.*, 6:65-67; Ex. 1003, ¶42.

C. Prosecution History and Effective Filing Date

The '480 patent was filed on January 25, 2005 as Application No. 11/043,404, a continuation-in-part of U.S. Patent No. 7,177,698 (Ex. 1012), and claiming priority to provisional application No. 60/392,475 (Ex. 1013), filed on June 28, 2002. Ex. 1001, Face. Each of the prior art references in this petition was filed or published well before June 28, 2002, so whether the '480 patent is entitled to its earliest claimed priority date of June 28, 2002, is not relevant to Nevro's patentability challenge. Nevro's analysis assumes a June 28, 2002 priority date. *See* Ex. 1003, ¶44-45.

After several rounds of restriction requirements and elections (Ex. 1002, 15-24, 100-112, 135-144, 152-162), the Examiner rejected original claims 54 and 57-61 (now claims 1 and 4-8) as anticipated or obvious over U.S. Patent No. 3,727,616 to Lenzkes (Ex. 1015) or U.S. Patent No. 6,612,934 to Foster (Ex. 1016). Ex. 1002, 166-170. The Examiner concluded that both references disclosed the use of pulse width modulation, which the Examiner determined was sufficient to satisfy the claimed OOK modulation technique. *See id.*, 168-169. The Examiner also rejected claims 55 and 56 (now claims 2 and 3) as obvious in further view of U.S. Patent No. 6,434,194 to Eisenberg (Ex. 1010). *Id.*, 169.

BSNC responded by arguing that pulse width modulation did not satisfy the claimed modulation technique. Ex. 1002, 285-292. BSNC compared Figure 3 of the ’480 patent with a hypothetical signal from Lenzkes allegedly showing a pulse width modulated signal encoding the same data (‘001001’):

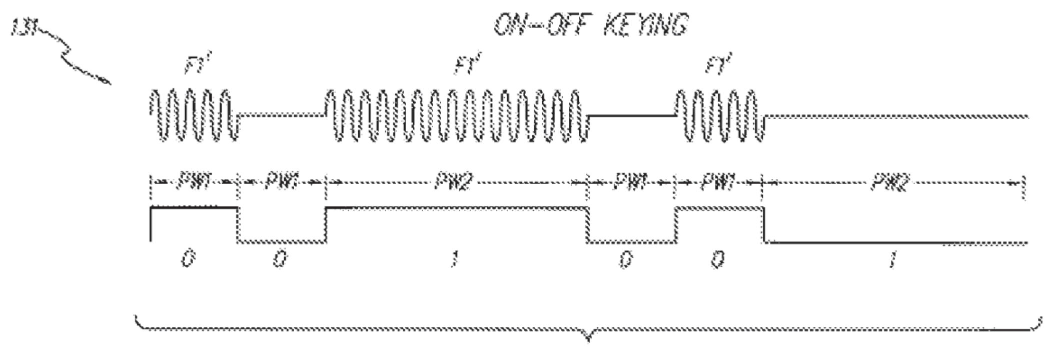
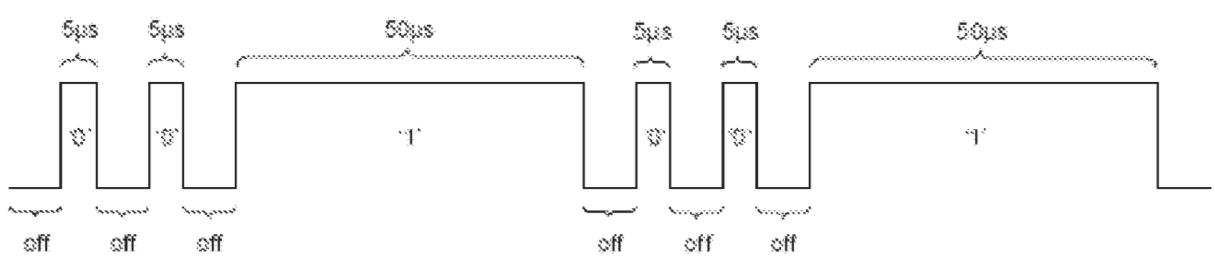


FIG. 3

Figure 3 of the ’480 Patent

Id., 289.



Applicant’s Illustration of Lenzkes’ PWM Scheme

Id., 289.

BSNC asserted that Lenzkes' pulse width modulation would not meet the claim limitation 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, 290. According to BSNC, the OFF state in pulse width modulation does "not comprise bits at all, but instead operate to differentiate the pulses from each other." *Id.* The Examiner maintained that the claims read on standard pulse width modulation, and requested that BSNC explain how the claim language distinguished such a scheme. *Id.*, 296-298. BSNC replied by pointing to language from claim 54 (now claim 1) and asserting that it was not met by either Lenzkes or Borkan:

> 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***

Id., 302 (original emphasis). The Examiner then issued a Notice of Allowance with two examiner's amendments to clarify "that the first frequency is in a bit signal rather [than] a series of bit signals." *Id.*, 309-316. The '480 patent issued on October 26, 2010. *Id.*, 361.

D. Person of Ordinary Skill in the Art

A person of ordinary skill in the art in the field of the ’480 patent in 2002 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. Ex. 1003, ¶¶50-56.

V. CLAIM CONSTRUCTION

Claims in an IPR filed after November 13, 2019, are given their “ordinary and customary meaning … 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); 83 Fed. Reg. 51,358 (Oct. 11, 2018). Nevro is unaware of any “prior claim construction determination” related to the ’480 patent (*see* 37 C.F.R. § 42.100(b)), but the ’480 patent provides several definitions regarding claim terms:

- “*Stimulator*” (All Claims): “As used herein and in the appended claims, unless otherwise specifically denoted, the terms ‘stimulator’ and ‘microstimulator’ will be used interchangeably to refer to any implantable medical device that may be implanted within a patient for therapeutic purposes.” Ex. 1001, 3:39-45.
- “*Control bit*” (Claims 6-7): “As used herein and in the appended claims, the terms ‘control data’ or ‘control bits’ will be used to refer to

> any data or bits that are transmitted from the external device (20) to the implantable stimulator (10) or from the implantable stimulator (10) to the external device (20)." *Id.*, 4:67-5:4.

Because an ordinary artisan would find the challenged claims unpatentable under any interpretation consistent with their plain and ordinary meaning in the context of the '480 patent, the Board need not expressly construe the claims. *See Vivid Techs., Inc. v. Am. Sci. & Eng.'g. Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999).

VI. THE CHALLENGED CLAIMS ARE UNPATENTABLE

A. Claim 1 Is Anticipated by Grevious (Ex. 1005)

1. Overview of Grevious

Grevious is a U.S. patent filed on September 20, 2000, and is prior art under at least 35 U.S.C. § 102(e). Ex. 1005, [22]. Grevious discloses a telemetry system for communicating with medical devices such as Implantable Neuro Stimulators (INS), which are used to send precise, electrical pulses to the spinal cord, brain, or neural tissue to provide a desired treatment therapy. *Id.*, Abstract, 1:30-52, 4:13-18. Physician programmer 20 and patient programmer 30 communicate with medical device 5 over radio frequency (RF) telemetry links 3 and 4 (*id.*, 1:53-2:5, 4:46-5:13):

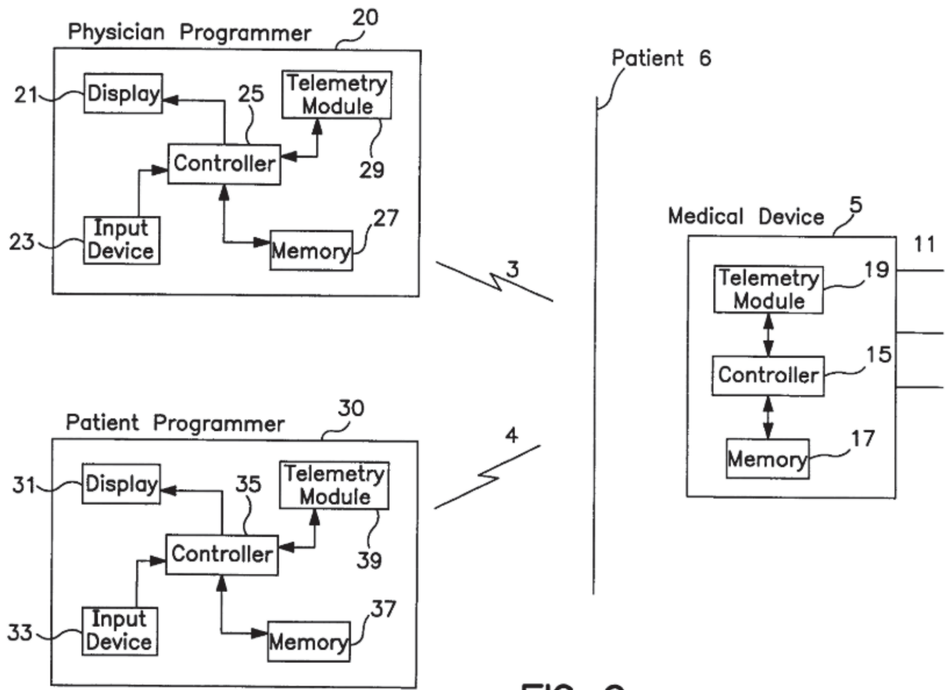


FIG. 2

Id., Fig. 2; Ex. 1003, ¶¶61-62.

The programmers and the medical device each include a telemetry module used for bi-directional communications. Ex. 1005, 5:13-24. This telemetry module comprises telemetry coil 42, receiver 44, transmitter 46, and telemetry processor 47 (*id.*, 5:25-37):

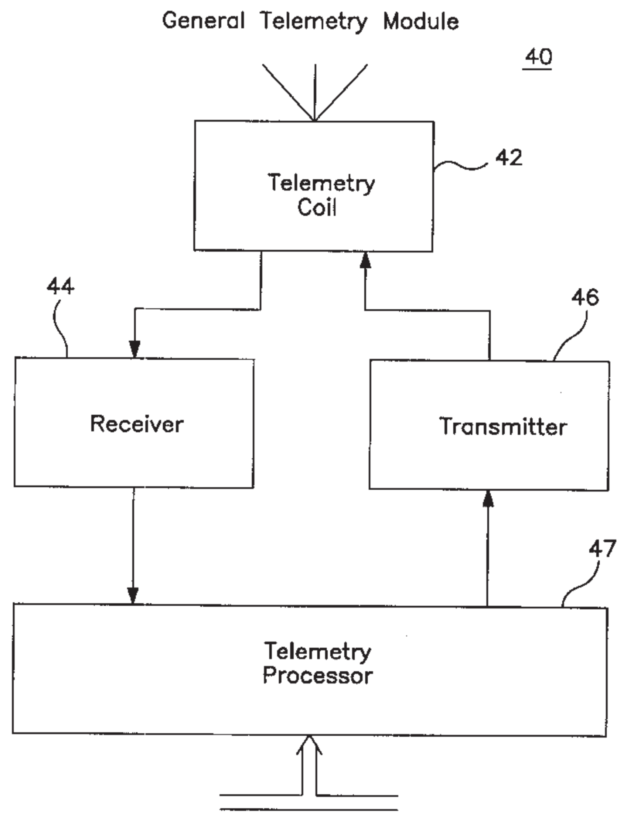


FIG. 3

Ex. 1005, Fig. 3; Ex. 1003, ¶63.

Grevious implements a telemetry system on these devices that automatically selects a modulation protocol configuration to establish a reliable symmetric telemetry link between the devices. Ex. 1005, Abstract, 2:51-57. Numerous modulation formats are supported, including (1) a pulse or burst width modulation (PWM) format, (2) a pulse or burst width modulation (PWM) plus pulse interval modulation format (PIM), and (3) a modified phase shift keying (MPSK) modulation format. *Id.*, 2:58-3:13. Grevious refers to the pulse width modulation (PWM) plus pulse interval modulation format (PIM) as "Format B." *Id.*, 12:1-3, 15:23-52. Format B involves encoding bits into both the ON and OFF portions of the signal by varying the lengths of each portion, with a pulse or interval width having a length T_{zero} being interpreted as a '0' and a length of T_{one} being interpreted as a '1':

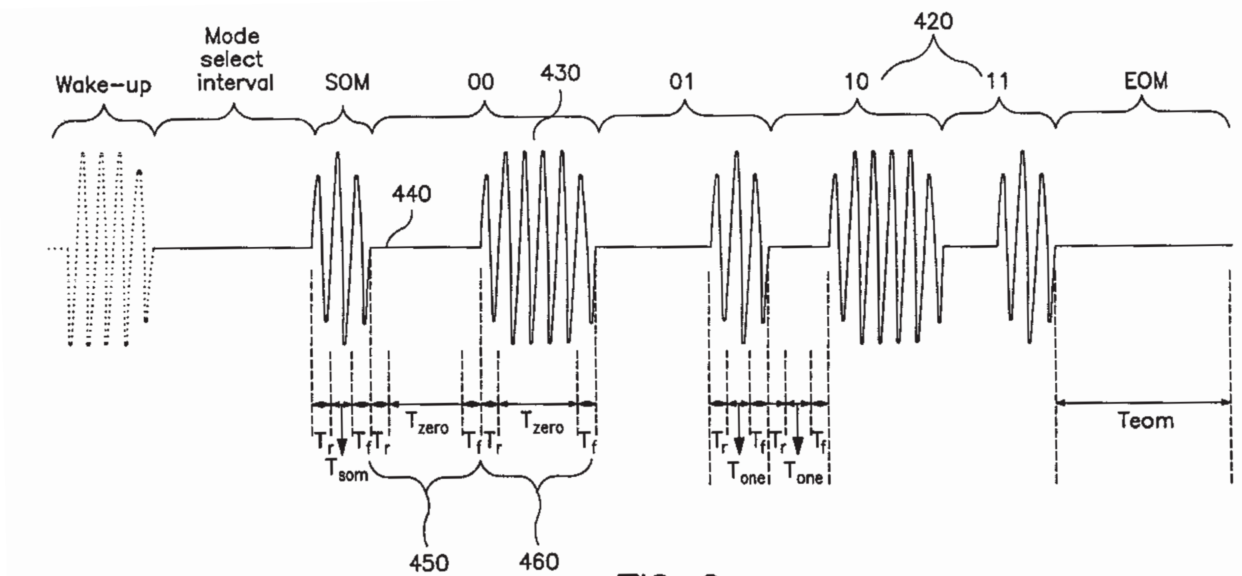


FIG. 9

Ex. 1005, Fig. 9; Ex. 1003, ¶64.

2. Independent Claim 1

i. "A system, comprising:"

To the extent the preamble is limiting, Grevious discloses it. Ex. 1003, ¶¶65-67. Figure 2 of Grevious shows a schematic block diagram of a typical implanted medical device and associated components in communication with two programmer devices via telemetry (collectively the "*system*") (Ex. 1005, 3:38-41, 4:46-50):

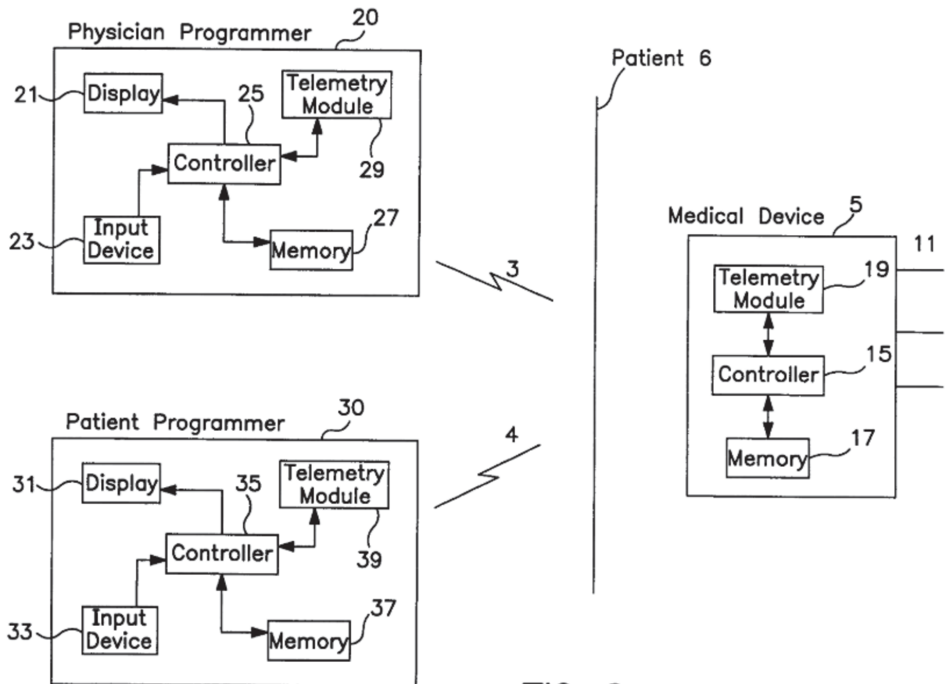


FIG. 2

Ex. 1005, Fig. 2; Ex. 1003, ¶66.

ii. "an external device, comprising …"

Grevious discloses this feature. Ex. 1003, ¶¶68-70. Physician and patient programmers 20 and 30 are each "*external devices*" within Grevious' system that communicate with implanted medical device 5 via telemetry 3 and 4, respectively. Ex. 1005, 4:65-67, Fig. 2; Ex. 1003, ¶69. Grevious characterizes the programmers as "external devices" relative to the implanted medical device, explaining that medical device 5 includes "a telemetry module 19 for two-way communication with ***external devices such as physician or patient programmers 20 and 30***." Ex. 1005, 5:5-13 (emphasis added).

iii. "first modulation circuitry for producing from first data a first [modulated] signal …"

Grevious discloses these features. Ex. 1003, ¶¶71-77. Grievous discloses that physician and patient programmers 20 and 30 comprise telemetry modules 29 and 39, which allow them to communicate with medical device 5. Ex. 1005, 4:65-5:13. Figure 3 illustrates a block diagram of a typical telemetry module 40 that can be used in programmers 20 and 30 or medical device 5, and that enables the external devices to communicate bi-directionally with the medical device via telemetry 3 and 4 (*Id.*, 5:13-18):

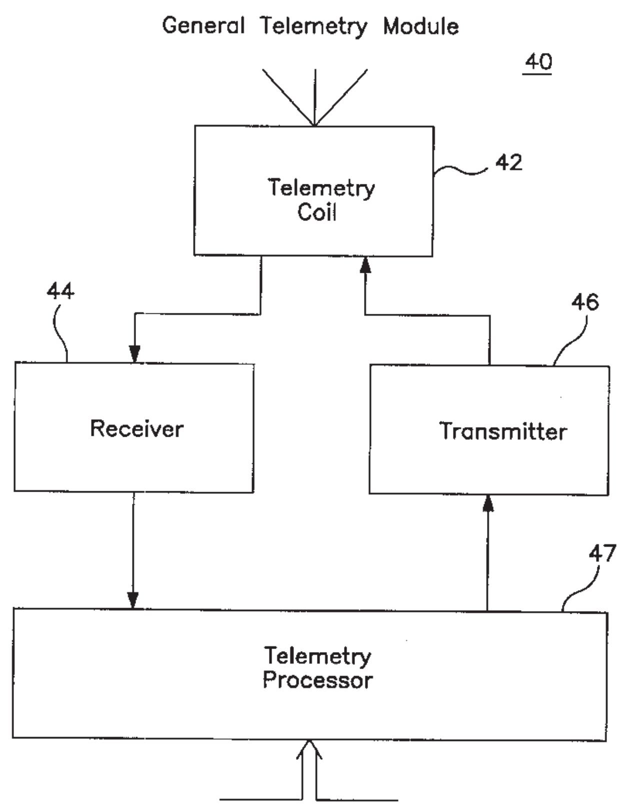


FIG. 3

Id., Fig. 3. Telemetry module 40 comprises a telemetry coil 42, a receiver 44, a transmitter 46, and a telemetry processor 47. *Id.*, 5:18-21.

Telemetry transmitter 46 and telemetry processor 47, as configured with Format B as discussed below, satisfy the claimed "*first modulation circuitry*." Ex. 1003, ¶¶72-74. Programmers 20 and 30 may transmit commands to the medical device, such as commands to adjust stored therapy programs and therapy settings (*e.g.*, "*first data*"). Ex. 1005, 5:51-67. Telemetry processor 47 provides logic necessary to encode that data for transmission, which is then provided to the transmitter 46 to "generate[] a Radio Frequency (RF) modulated signal from [the] digital signal generated from the telemetry processor 47." *Id.*, 5:30-35, 5:42-47. Grevious further explains the operation of these components with respect to an exemplary transmission from medical device 5 to programmer 20 or 30, as shown in Figure 4B (*id.*, 6:1-3, 5:13-21):

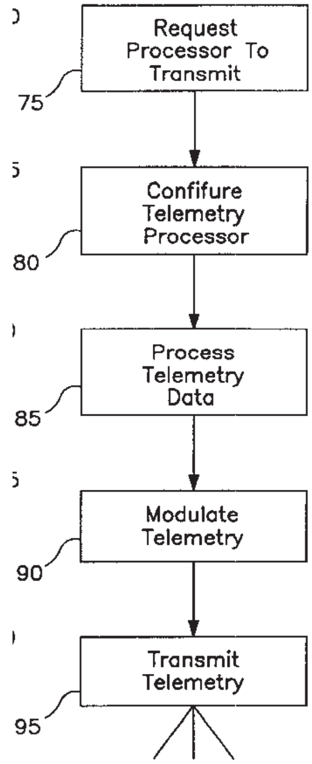


FIG. 4B

Id., Fig. 4B; Ex. 1003, ¶74.

In step one (75) of Figure 4B, a controller sends a request/command to the telemetry processor 47 to transmit data. Ex. 1005, 6:3-6. In step two (80), the telemetry processor 47 is configured with the appropriate telemetry protocol to communicate, including the type of modulation and the speed for transmission. *Id.*, 6:6-10. In step three (85), the telemetry processor 47 processes the binary data into time based digital pulses. *Id.*, 6:10-12. In step four (90), the transmitter 46 modulates the digital signal into an RF signal. *Id.*, 6:12-13. In step five (95), the transmitter 46 transmits the telemetry signal via the telemetry coil 42. *Id.*, 6:13-17.

The same steps discussed with respect to Figure 4B would apply when an external programmer device transmits information to the implanted medical device. Ex. 1003, ¶76. Figures 4A-B "show[] a generic operation flowchart of the typical telemetry module shown in Fig. 3," (Ex. 1005, 3:45-50), and "Fig. 3 shows a block diagram of a typical telemetry module 40 that can be used in programmers 20 and 30 ***or*** medical device 5 shown in Fig. 2." *Id.*, 5:13-24. Programmers and medical device communicate "bi-directionally with each other" via telemetry uses the same inductive coupled physical transmission method to uplink and downlink." *Id.*, 5:16-18, 6:19-22.

a. "*modulated with on-off keying (OOK) modulation*"

Grevious discloses these features. Ex. 1003, ¶¶78-86. Grevious discloses that its telemetry system supports "a family of related symmetrical modulation protocol configurations." Ex. 1005, 6:22-30. Each of these configurations includes a format used to configure the telemetry processor to generate time based digital pulses, which are then used by the transmitter to modulate a carrier wave before it is sent to the coil. *Id.*, 6:3-17. A first of these modulation formats is Format A, or "pulse or burst width modulation." *Id.*, 6:30-31. Another of these modulation formats is Format B, or "pulse or burst width modulation (PWM) plus pulse interval modulation (PIM)." *Id.*, 6:32-33. The '480 patent explains that "[o]n/off keying (OOK) modulation … is also known as pulse width modulation

(PWM).” Ex. 1001, 4:36-37, 6:41-44 (“… modulated using OOK, or PWM.”). Grevious’s use of Format B satisfies each and every requirement of the claimed “*first modulated signal*.” Ex. 1003, ¶¶82-98. Because Grevious teaches Format B (PWM+PIM) partially in relation to Format A (PWM), both are explained below.

Both Formats A and B use alternating ON and OFF intervals (referred to as “burst” or “not burst” by Grevious) to encode digital data, *i.e.*, on-off keying. Ex. 1005, 15:5-43, Figs. 8-9; Ex. 1003, ¶82. Format A, *i.e.*, pulse width modulation, is described with respect to Figure 8. Ex. 1005, 3:60-63, 15:5-22. Format A transmits data via variable width bursts of 175 kHz transmitted at a constant rate. *Id.*, 15:10-13. A burst width of T_{zero} represents a ‘0’ bit (400), whereas a burst width of T_{one} represents a ‘1’ bit (410), as illustrated in Figure 8 (*id.*, 15:12-14):

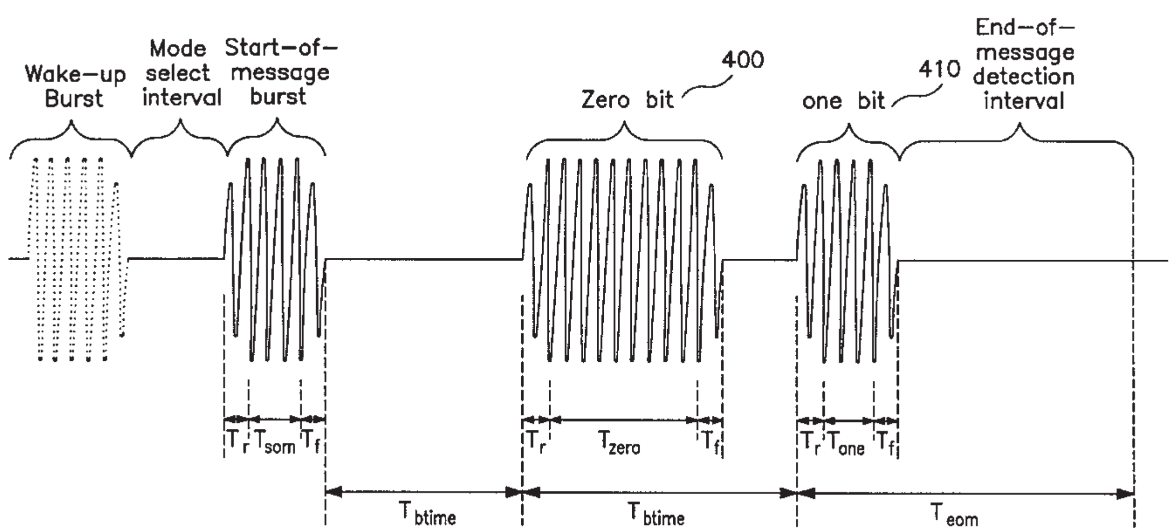


FIG. 8

Id., Fig. 8. These bursts are transmitted at a regular rate T_{btime} to produce a constant bit rate per second. *Id.*, 15:14-16.

Format B extends Format A (PWM) to additionally include "pulse interval modulation (PIM)." Ex. 1003, ¶83; Ex. 1005, 15:23-30 ("pulse or burst width modulation (PWM) ***plus*** pulse interval modulation (PIM)" (emphasis added)). Grevious explains that, like Format A, data transmissions using Format B are based on variable width bursts of 175 kHz transmitted at a constant rate. Ex. 1005, 15:23-37. Instead of transmitting bursts at regular rate T_{btime}, however, Format B further "modulates the interval ***between*** bursts to effectively double the amount of data transmitted per unit of time." *Id.*, 15:23-37 (emphasis added); *cf id.*, 15:10-16. Figure 9 illustrates the resulting PWM+PIM modulated signal (*id.*, 15:23-26):

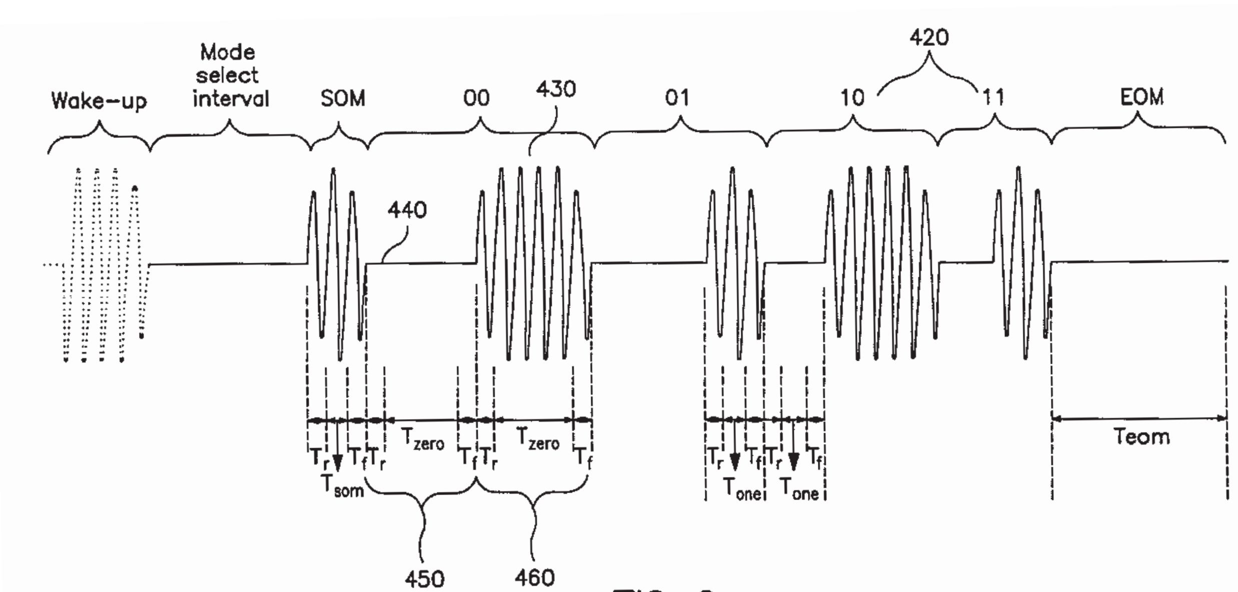


FIG. 9

Ex. 1005, Fig. 9. Each data bit is represented by burst 430 (ON) or a "not burst" 440 (OFF). *Id.*, 15:38-43.

Grevious explains that data bits are transmitted in pairs, or "dibits" 420. Ex. 1003, ¶83; Ex. 1005, 15:38-43. Preferably, each pair of bits starts with a not burst 440 (OFF) state followed by a burst 430 (ON) state. *Id.*, 15:44-49, Fig. 9. Alternatively, the order can be reversed. *Id.*, 15:49-52.

The bit timing for either type of bit (zero or one) is the same for the "ON" and "OFF" burst states. Ex. 1003, ¶84. For example, a time interval of T_{zero} represents a zero bit for either of burst state 430 (ON) or not burst 440 (OFF). Ex. 1005, 15:38-43. The time interval of the not burst (OFF) state "is simply the length of time measured from the end of the previous burst to the start of the next," and can have the value T_{zero} (a zero bit) or T_{one} (a one bit). *Id.*, 15:38-49. The time interval of a burst (ON) state "is measured from the start to the end of a burst," and can likewise have the value T_{zero} (a zero bit) or T_{one} (a one bit). *Id.*, 15:12-14, 15:38-49.

This disclosure is consistent with other prior art that discloses pulse width and interval modulation (PWIM). Ex. 1003, ¶85; *see, e.g.*, Ex. 1018, 167 (explaining that such a scheme encodes "information on both pulse interval and width," effectively doubling the amount of information compared to PIM or PWM individually); Ex. 1022, 232 (explaining that such a scheme "employs a waveform in which both marks and spaces represent the sampled data")); Ex. 1006 (Fitch), Fig. 10.

b. "*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*"

Grevious discloses these features. Ex. 1003, ¶¶87-90.[3] As explained above (§ VI.A.ii.3.a), for example, Grevious discloses that Format B uses alternating burst (ON) and not burst (OFF) pulses of varying widths to encode data bits. Ex. 1005, 15:12-14, 15:23-33, 15:38-49. The length of both burst (ON) or not burst (OFF) data bit pulses is either the value T_{zero} (a zero bit) or T_{one} (a one bit). *Id.*, 15:12-14, 15:38-49, Fig. 9. As Mr. Pless explains, "each 'zero' data bit in Figure 9 corresponds to a pulse width of T_{zero} (red) and each 'one' data bit corresponds to a pulse width of T_{one} (blue), which has a different width than T_{zero} (red)":

[3] As explained above (§ IV.B n.2), the '480 patent refers to both the ON and OFF portions of an OOK signal as "pulses." Ex. 1001, 6:55-67, Fig. 3; Ex. 1003, ¶43.

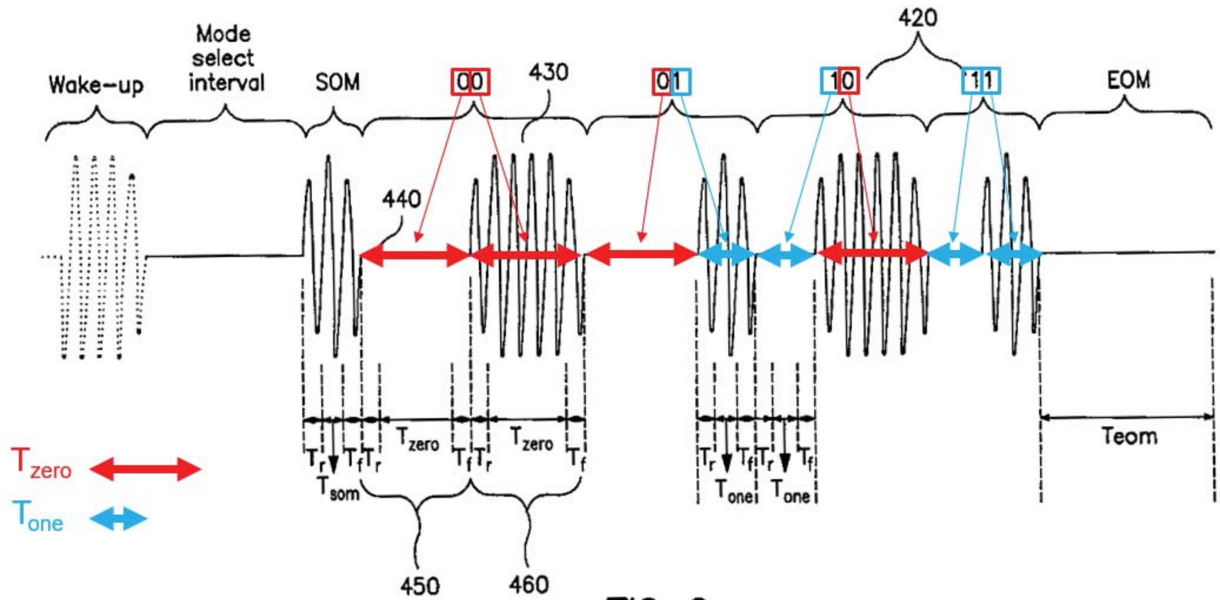


FIG. 9

Ex. 1003, ¶88; Ex. 1005, Fig. 9 (annotated).

This disclosure precisely corresponds to Figure 3 in the ’480 patent, where each ‘zero’ data bit corresponds to a pulse width of PW1 (blue) and each ‘one’ data bit corresponds to a pulse width of PW2 (red), which has a different width than PW1 (blue):

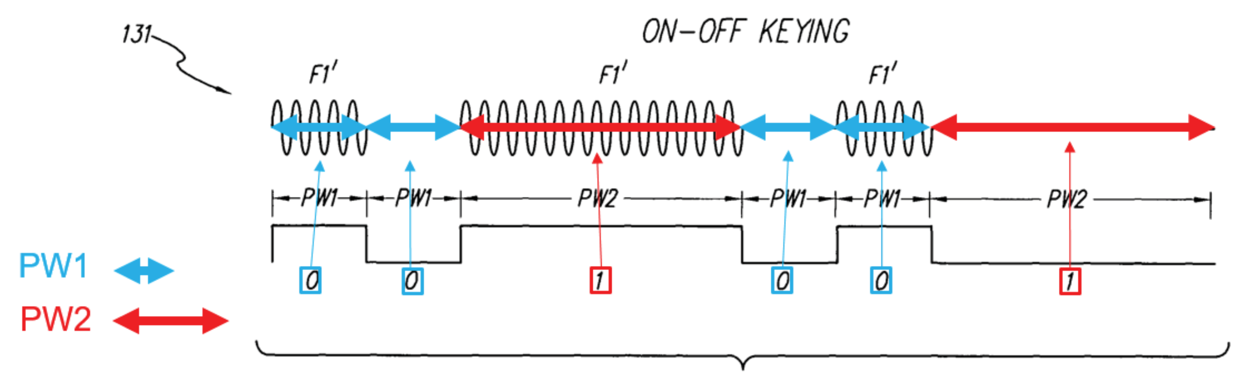


FIG. 3

Ex. 1001, Fig. 3 (annotated), 6:55-7:9; Ex. 1003, ¶89.

c. "*wherein each bit further comprises either an ON state with a signal that varies with a first frequency or an OFF state*"

Grevious discloses these features. Ex. 1003, ¶¶91-94. As explained above (§ VI.A.ii.3.a), for example, Grevious discloses that Format B uses alternating burst (ON) and not burst (OFF) pulses to encode data bits. Ex. 1005, 15:12-14, 15:23-33, 15:38-49. Data bits encoded as burst (ON) pulses comprise 175 kHz ("*a signal that varies with a first frequency*"), while data bits encoded as not burst (OFF) pulses comprise the interval between these burst pulses (an "*OFF state*"). *Id.*, 15:10-13, 15:29-33, Fig. 9. As illustrated in Figures 8 and 9, Grevious' 175kHz signal is an oscillating waveform that "*varies*" between high and low voltages at a set frequency. Ex. 1003, ¶92. As Mr. Pless explains, "each data bit comprises either a burst (ON) (blue) or not burst (OFF) (red) state":

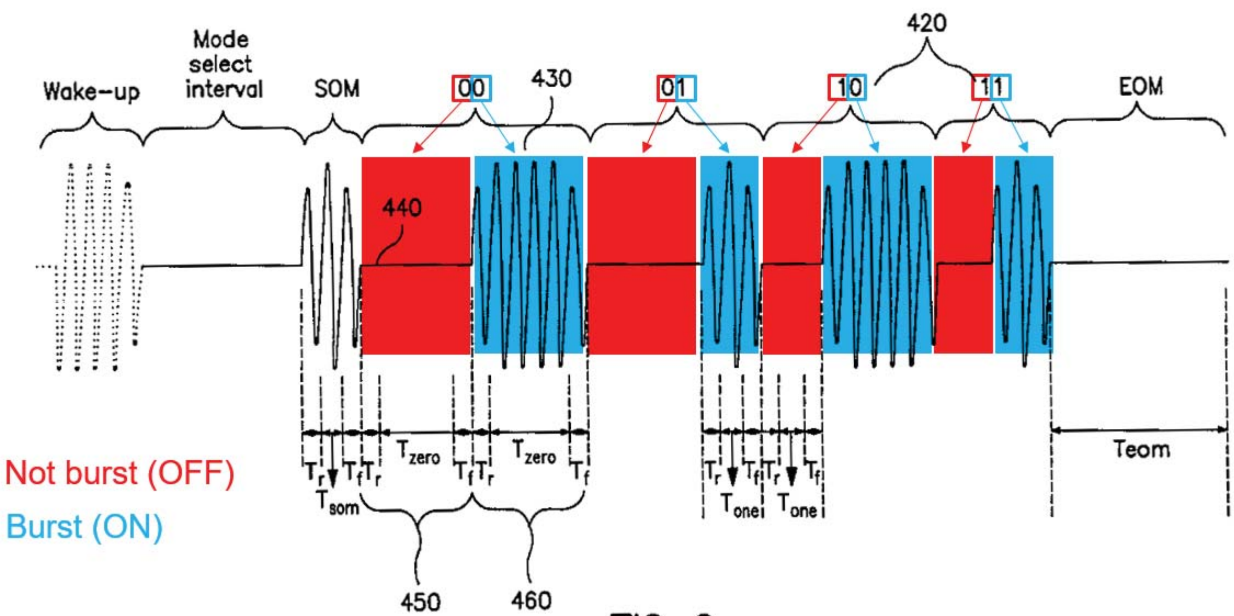


FIG. 9

Ex. 1003, ¶92; Ex. 1005, Fig. 9 (annotated) .

This disclosure again precisely corresponds to Figure 3 in the ’480 patent, where each data bit comprises either an ON (blue) or OFF (red) state:

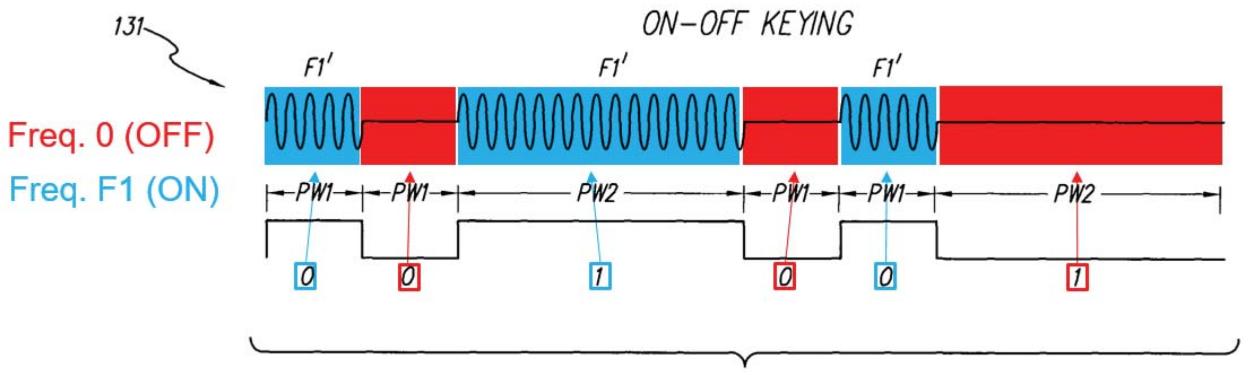


FIG. 3

Ex. 1001, Fig. 3 (annotated), 6:55-7:9; Ex. 1003, ¶93.

d. “*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*;”

Grevious discloses these features. Ex. 1003, ¶¶95-98. As explained above (§ VI.A.ii.3.a), for example, Grevious explains that Format B modulates both the burst (ON) interval and also the not burst (OFF) interval to “effectively double the amount of data transmitted per unit of time” when compared to Format A (PWM). Ex. 1005, 15:5-16, 15:23-33; Ex. 1003, ¶82-85. The time interval of the not burst (OFF) state is “the length of time measured from the end of the previous burst to the start of the next,” meaning 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. Ex. 1005, 15:38-49, Fig. 9. Likewise, the time interval of a burst (ON) state "is measured from the start to the end of a burst," meaning that both the transitions between the data bits represented by the not burst (OFF) pulses preceding and following the data bit represented by the burst (ON) pulse are marked by a change between the OFF and ON state in the signal. *Id.*, 15:12-14, 15:38-49; Ex. 1003, ¶96.

As Mr. Pless explains with respect to the encoded data '00011011,' "each transition between data bits in Figure 9 corresponds with a transition in the signal between a burst/ON (blue) and a not burst/OFF (red) state":

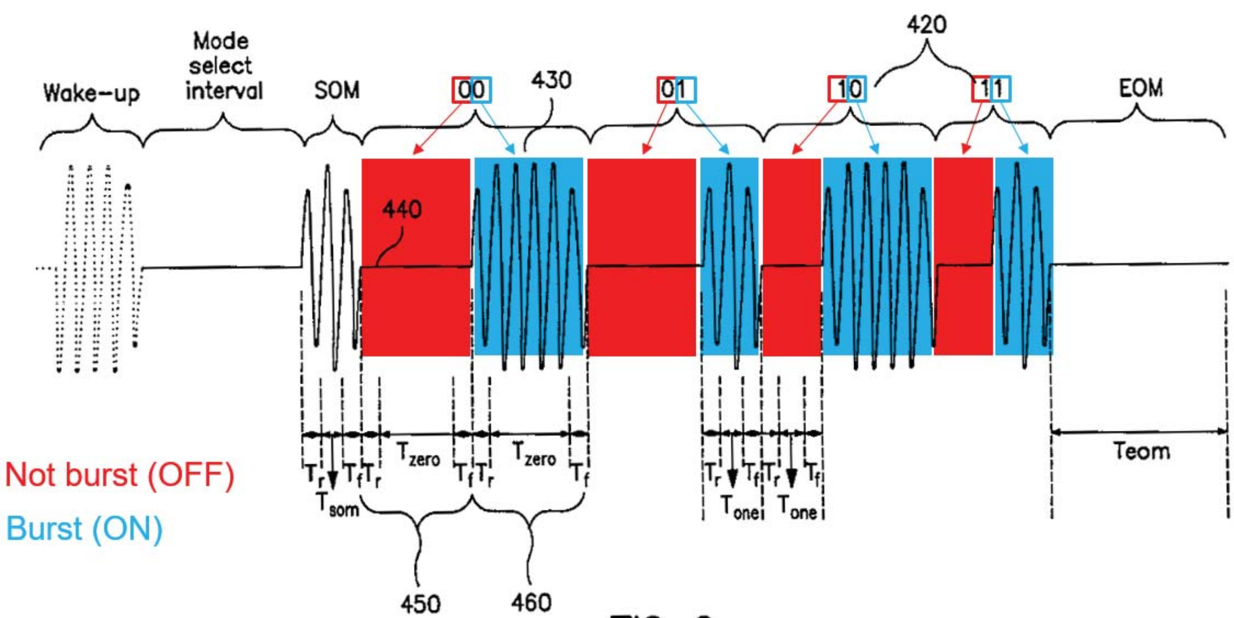


FIG. 9

Ex. 1003, ¶96; Ex. 1005, Fig. 9 (annotated).

This disclosure again precisely corresponds to the encoded data '001001' in Figure 3 in the '480 patent, where each transition between data bits corresponds with a transition in the signal between an ON (blue) and an OFF state:

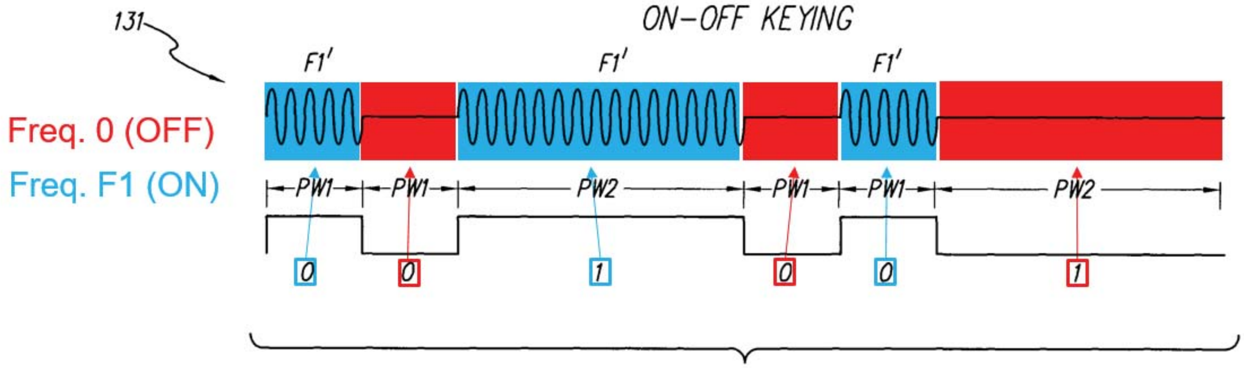


FIG. 3

Ex. 1001, Fig. 3 (annotated), 6:55-7:9; Ex. 1003, ¶97.

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

Grevious discloses these features. Ex. 1003, ¶¶99-102. As explained above (§ VI.A.ii.3), for example, Grievous discloses that physician and patient programmers 20 and 30 comprise telemetry modules 29 and 39, which allow them to communicate with implanted medical device 5. Ex. 1005, 4:65-5:13. Figure 3 illustrates a block diagram of a typical telemetry module 40—which can be used in programmers 20 and 30 or medical device 5—that includes telemetry coil 42 ("*a coil*") and enables those devices to communicate bi-directionally with each other via telemetry 3 and 4 (*id.*, 5:13-18):

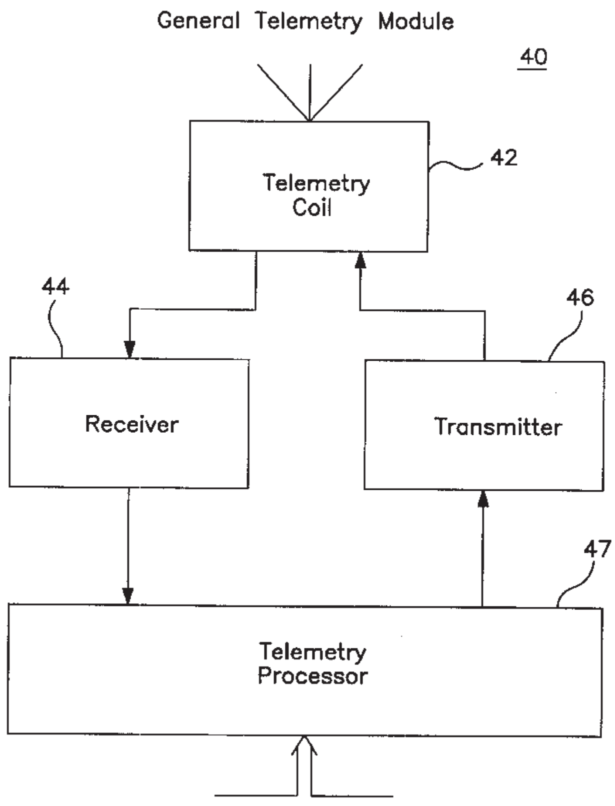


FIG. 3

Ex. 1005, Fig. 3.

Grevious discloses using the external programmer's telemetry coil 42 to "*wirelessly transmit the first modulated signal to the implantable medical device*." Ex. 1003, ¶¶100-101. As explained above (§VI.A.ii.3), the telemetry processor 47 is first configured with the appropriate telemetry protocol to communicate, including the type of modulation (*e.g.*, Format B), and then processes binary data into time based digital pulses. Ex. 1005, 6:6-12. The transmitter 46 modulates the digital signal into an RF signal and transmits the telemetry signal via the telemetry coil 42. *Id.*, 6:12-17; *id.*, 5:13-24, 6:19-22 ("The telemetry system of the present invention … uses the same inductive coupled physical transmission method to uplink and downlink.”).

v. *“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.”*

Grevious discloses these features. Ex. 1003, ¶¶103-107. Grievous discloses that one example of medical device 5 is “an Implantable Neuro Stimulator (INS) 5,” which is preferably a modified implantable pulse generator used to send precise, electrical pulses to the spinal cord, brain, or neural tissue to provide the desired treatment therapy (“*an implantable medical device*”). Ex. 1005, 3:34-37, 4:13-45; *see id.*, 1:30-52. Implantable medical device 5 is illustrated in Figure 1 (*id.*, 3:34-37):

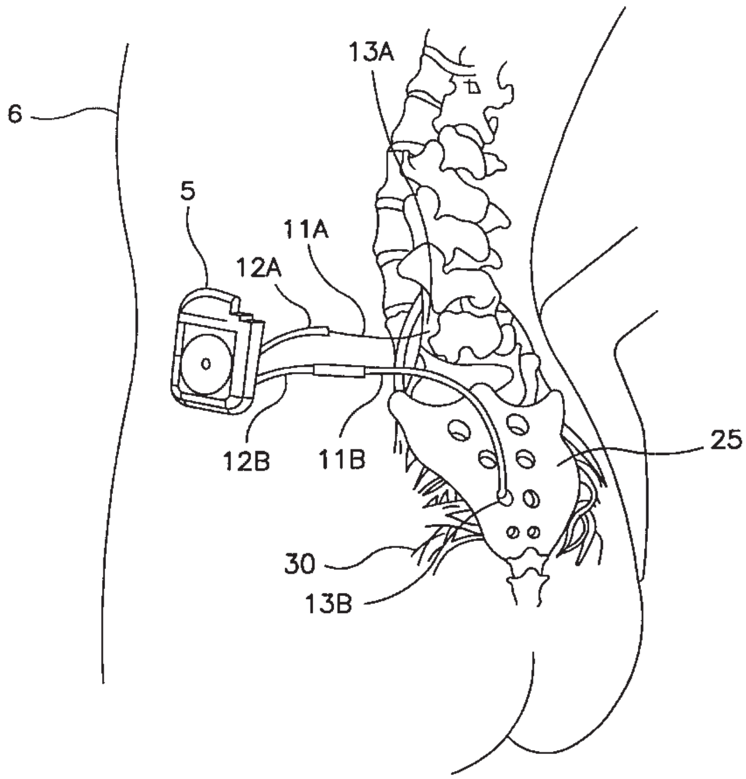


FIG. 1

Ex. 1005, Fig. 1.

Grevious discloses that the implantable medical device comprises "*a first telemetry receiver*." Ex. 1003, ¶¶103-104. For example, Figure 3 illustrates a block diagram of a typical telemetry module 40 comprising telemetry receiver 44 and telemetry processor 47, which can be used in implantable medical device 5 to communicate bi-directionally with programmers 20 and 30 via telemetry (Ex. 1005, 5:13-21):

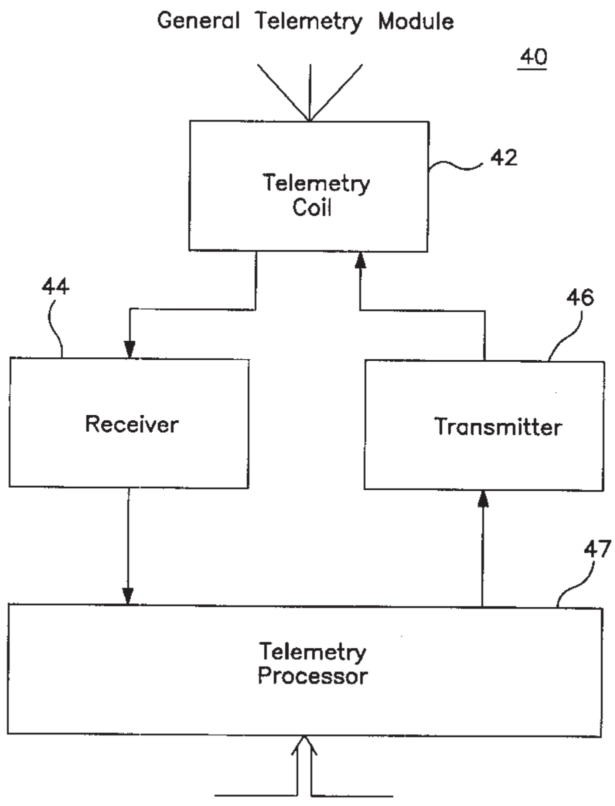


FIG. 3

Ex. 1005, Fig. 3.

Telemetry receiver 44 and telemetry processor 47, as configured with Format B as discussed above, satisfy the claimed "*first telemetry receiver*." The first telemetry receiver and telemetry processor 47, when configured with the Format B modulation format, "*demodulat[e] the first modulated signal to recover the first data*." Ex. 1003, ¶105. For example, Grevious explains, with respect to Figure 4A, that a typical telemetry operation involves "*[d]emodulat[ing] telemetry signal*" when a medical device 5 receives a signal (Ex. 1005, 3:45-46, 5:51-52):

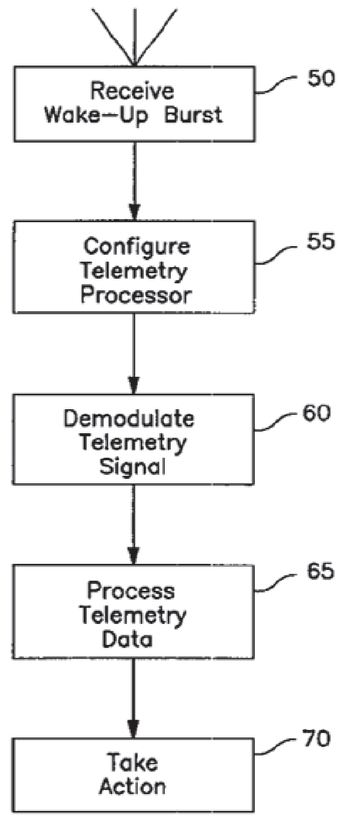


FIG. 4A

Ex. 1005, Fig. 4B (cropped); Ex. 1003, ¶105.

In step one (50), the incoming RF telemetry signal 3 (from programmer 20) or 4 (from programmer 30) is received by the telemetry coil 42 shown in Figure 3. Ex. 1003, ¶106; Ex. 1005, 5:14-21, 5:51-57. In step two (55), the telemetry processor 47 is configured to receive a predetermined telemetry protocol that includes the type of telemetry modulation (*e.g.*, Format B) of the incoming telemetry signal. *Id.*, 5:57-60. In step three (60), the telemetry receiver 44 demodulates the time base signal into digital pulses. *Id.*, 5:60-62. In step four

(65), the telemetry processor 47 converts/processes the digital pulses into binary data that is stored into memory. *Id.*, 5:62-64. Finally, in step five (70), the medical device controller 15 will take whatever action is directed by the received telemetry signals such as adjusting stored therapy programs and therapy settings. *Id.*, 5:64-67.

B. Claim 1 Is Obvious over Grevious (Ex. 1005) in view of Fitch (Ex. 1006)

1. Independent Claim 1

To the extent one might argue that Grevious does not expressly disclose the requirements of the claimed "*first modulated signal*" as recited in claim 1, such a signal modulation technique would have been obvious to incorporate into Grevious. Ex. 1003, ¶¶108-120.

U.S. Patent No. 4,807,225 (Ex. 1006) to Fitch ("Fitch")[4] discloses various techniques to improve radio frequency (RF) communications in a telephone line carrier system. Ex. 1006, Abstract. One such technique is a modulation format called the "Pulse Width Encoded – Non Return to Zero (PWE-NRz)" modulation format. *Id.*, 6:19-38. Binary digital data is 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

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[4] Fitch is a U.S. Patent that was published on February 21, 1989, and is prior art under at least 35 U.S.C. § 102(b). Ex. 1006, [45].

2 ms. *Id.* This digital data is then on-off keyed into a carrier signal. *Id.* Figure 10 discloses an exemplary binary digital signal ("10110001") that is encoded with this scheme:

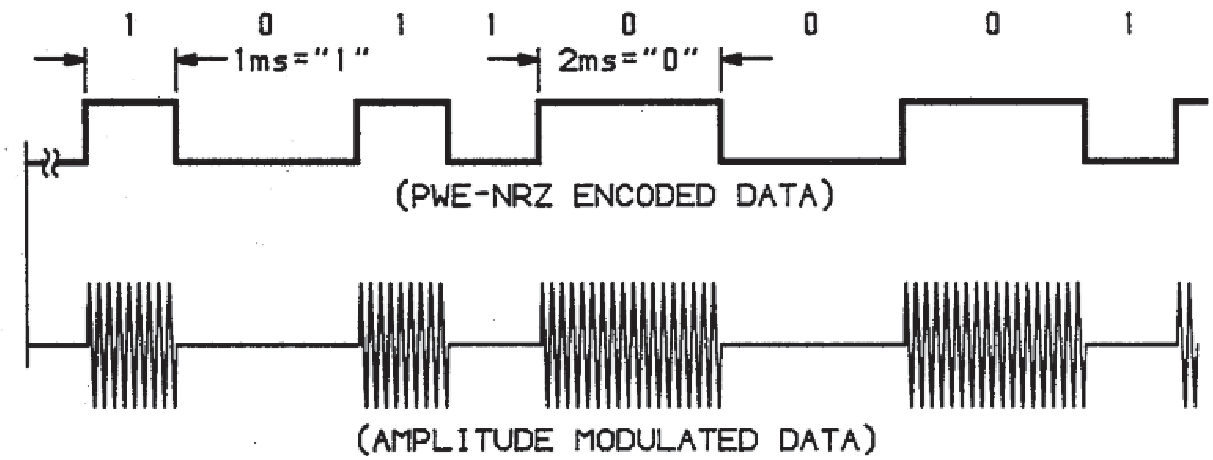

FIG. 10

Id., Fig. 10, 3:5-7; Ex. 1003, ¶¶109-110.

Fitch's PWE-NRz scheme satisfies the requirements of the claimed "*first modulated signal*." Ex. 1003, ¶¶111-115. First, Fitch's PWE-NRz scheme modulates a data signal "*with on-off keying (OOK) modulation*." *Id.*, ¶111. Fitch explains that the disclosed scheme uses "on/off carrier keying," which is further demonstrated in Figure 10. Ex. 1006, 6:34-38, Fig. 10.

A signal modulated with Fitch's PWE-NRz scheme "*comprises logic '0' bits of a first pulse width and logic '1' bits of a second pulse width different from the first pulse width*." Ex. 1003, ¶112. Binary digital data is 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. Ex. 1006, 6:20-24. This is illustrated in Figure 10:

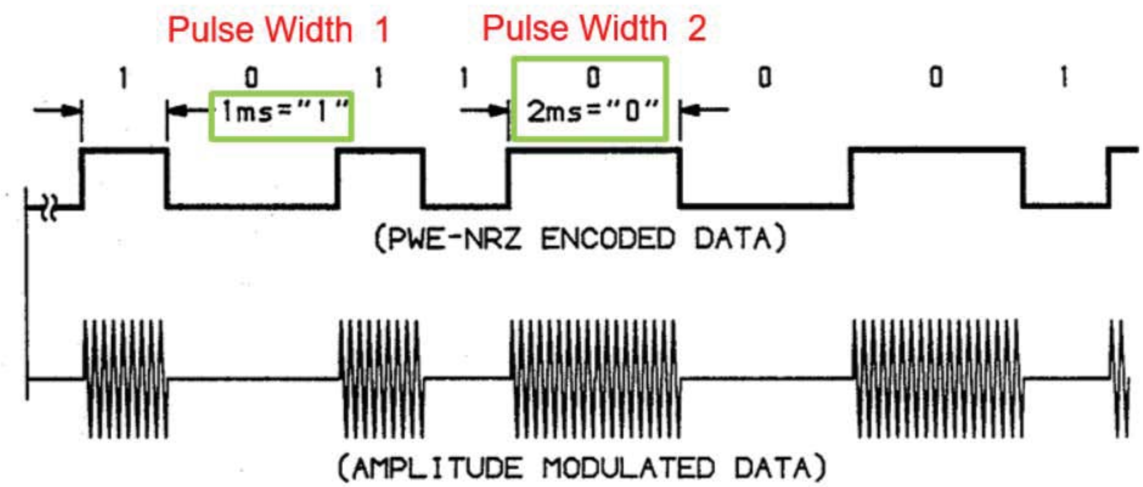

FIG. 10

Ex. 1006, Fig. 10 (annotated); Ex. 1003, ¶112.

Each bit in a signal modulated with Fitch's PWE-NRz scheme "*comprises either an ON state with a signal that varies with a first frequency or an OFF state*." Ex. 1003, ¶113. Fitch's scheme uses a data transmitter "responsive to a binary digital signal for turning a 455 kHz carrier off and on." Ex. 1006, 6:19-20. Fitch explains that the "data receiver converts the presence and absence of 455 kHz carrier into discrete levels and thereafter performs appropriate decoding to recover the binary digital signal." *Id.*, 6:28-31. This is illustrated in Figure 10, which includes both ON and OFF states in the signal. *Id.*, Fig. 10; Ex. 1003, ¶¶112-113.

A "*transition between adjacent bits*" a signal modulated with Fitch's PWE-NRz scheme "*is marked by a change in the first modulated signal between the ON and OFF states*." Ex. 1003, ¶114. Fitch's scheme encodes a binary digital signal "into a series of pulses having alternating polarity." Ex. 1006, 6:20-24. Figure 10 illustrates the encoding of the sequence "10110001" (*id.*, 6:31-34), and each alternating ON and OFF portion comprises a data bit from that sequence:

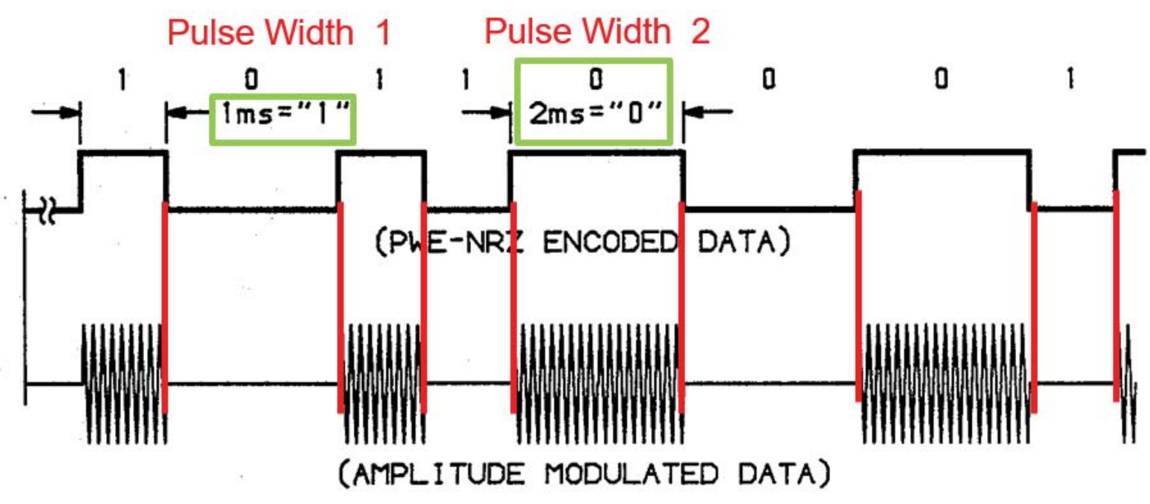

FIG. 10

Id., Fig. 10 (annotated); Ex. 1003, ¶114.

Fitch's modulation scheme is the same as the on-off keying scheme described by the '480 patent with respect to Figure 3:

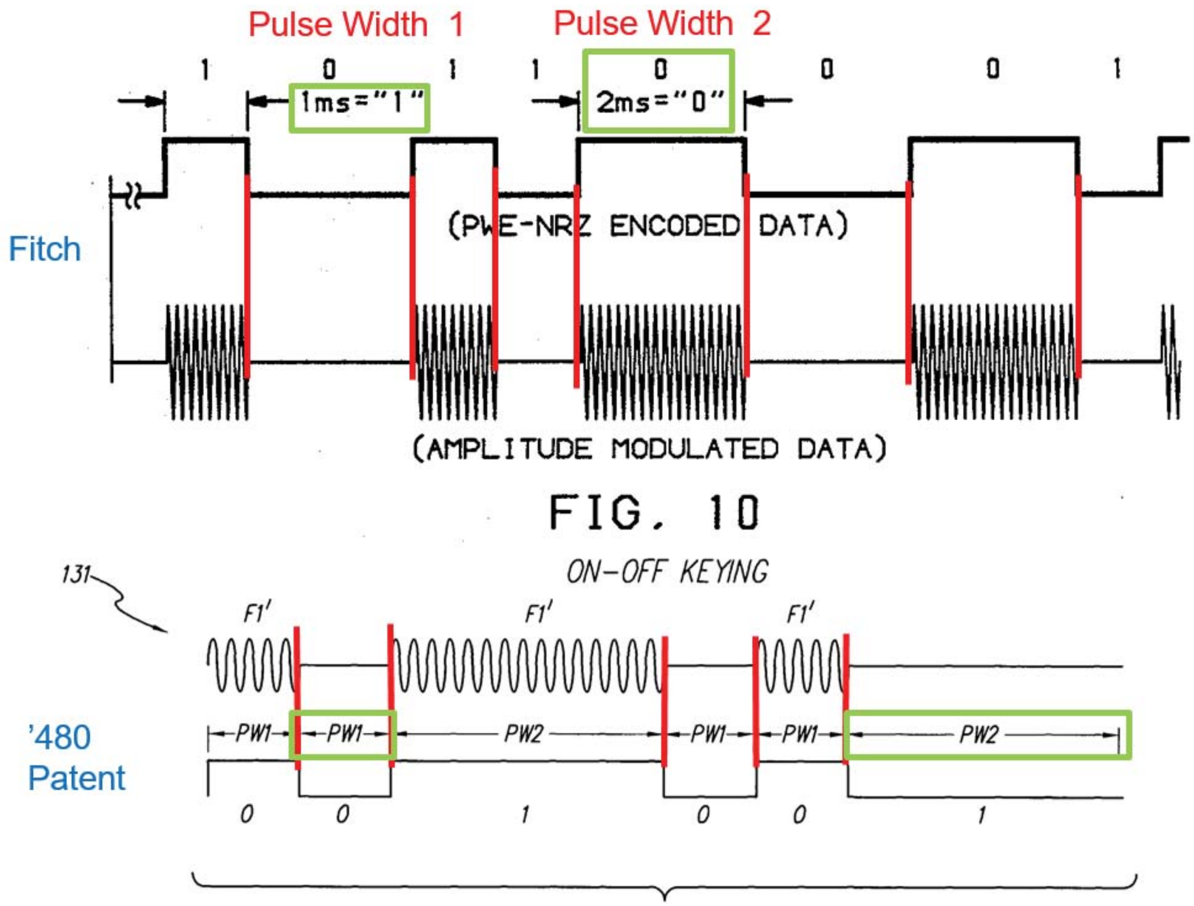

FIG. 3

Ex. 1006, Fig. 10 (annotated); Ex. 1001, Fig. 3 (annotated); Ex. 1003, ¶115.

Grevious and Fitch are analogous art to the ’480 patent. Ex. 1003, ¶116. Grevious is from the same field of endeavor as the claimed invention: communicating with an implantable medical device. *See, e.g.*, Ex. 1001, 1:48-57, 1:61-2:4, 3:1-2, 3:25-47; Ex. 1005, 1:5-8, 2:51-57. Each reference is also reasonably pertinent to the problem faced by the ’480 patent’s inventors: ensuring accurate communications. *See, e.g.*, Ex. 1001, 1:48-57, 2:42-67; Ex. 1005, 1:5-8, 2:51-57, Ex. 1006, 6:5-7 (“The Data Communication channel is designed to be an inexpensive technique for reliable communications in a potentially [noisy] environment”). Fitch is also reasonably pertinent to the problem mentioned in the ’480 Patent that, “in some instances, the bidirectional telemetry link may fail due to a number of factors including … interference.” Ex. 1001, 2:60-63; Ex. 1006, 6:5-8; Ex. 1003, ¶116.

It would have been obvious to a person having ordinary skill in the art in 2002 to incorporate Fitch’s PWE-NRz scheme as an additional modulation format supported by Grevious’s telemetry modules in programmers 20 and 30 and medical device 5. Ex. 1003, ¶¶117-119. Modifying Grevious to additionally support PWE-NRz would have been an “application of a known technique to a piece of prior art ready for the improvement.” *KSR Intern. Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007). Grevious already supports numerous modulation formats and explains that “[o]ther modulation formats are also possible” (Ex. 1005, 12:35-39), and it would have involved only routine skill to modify Grevious to additionally support Fitch’s PWE-NRz modulation format. Ex. 1003, ¶117. As Mr. Pless explains, “RF modulation techniques used for one field of use, such as telephony, have obvious applications in other fields of use, such as medical devices, because the basic principles of RF communications are the same.” *Id.* Adding PWE-NRz support to Grevious thus 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. *See KSR*, 550 U.S. at 417.

Grevious provides abundant motivation to incorporate additional modulation formats. Ex. 1003, ¶118. For example, Grevious states that its 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). An ordinary artisan would have been motivated to support an even "wide[r] array of medical devices," such as those that support or could desire to support PWE-NRz. Ex. 1003, ¶118.

A skilled artisan would have also been motivated to incorporate PWE-NRz because Fitch explains that it is designed to be "an inexpensive technique for reliable communications in a potentially [noisy] environment." Ex. 1006, 6:5-7; Ex. 1003, ¶119. 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; Ex. 1003, ¶119. An ordinary artisan would have been motivated to support additional modulation formats such as PWE-NRz to ensure flexibility during the automatic configuration process and to avoid lost connections in high-interference situations. *Id.* Therefore, for all these reasons, it would have been obvious to modify

Grevious to additionally support Fitch's PWE-NRz format, which independently satisfies the requirements of the claimed "*first modulated signal*."

C. Claims 2-4, 6 and 8 Are Obvious Over Grevious (Ex. 1005) With or Without Fitch (Ex. 1006)

1. Claim 2

i. *"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"*

Grevious anticipates or renders obvious in view of Fitch the "*system of claim 1*," as explained above. *See* § VI.A-B above. Grevious renders the further features of claim 2 obvious. Ex. 1003, ¶¶121-146. As explained above (*see* § VI.A.ii.3), Grevious discloses that physician and patient programmers 20 and 30 comprise telemetry modules 29 and 39, which allow them to communicate with medical device 5. Ex. 1005, 4:65-5:13. These modules are explained with respect to typical telemetry module 40, which comprises a telemetry coil 42, a receiver 44, a transmitter 46, and a telemetry processor 47. *Id.*, 5:13-21, Fig. 3. These components and their operation are common to both medical device 5 and programmers 20 and 30. *Id.*, 5:13-24, 6:19-22; Ex. 1003, ¶122.

Grevious discloses "*second modulation circuitry in the external device for producing from second data a second signal modulated with [a different modulation technique]*" than Format B (the claimed "*on-off keying (OOK)* *modulation*" technique). Ex. 1003, ¶¶123-125. Grevious discloses that its telemetry system supports "a family of related symmetrical modulation protocol configurations" including "at least five modulation formats": (1) "pulse or burst width modulation (Format A)," (2) "pulse or burst width modulation (PWM) plus pulse interval modulation (PIM) (Format B)," (3) "a modified phase shift keying (MPSK) modulation scheme (Format C)," (4) "pulse position modulation (PPM)," and (5) "pulse interval modulation (PIM)." Ex. 1005, 6:22-37.

Telemetry transmitter 46 and telemetry processor 47, as configured with FSK as discussed below, satisfy the claimed "*second modulation circuitry*." Telemetry 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.*, 6:12-13; Ex. 1003, ¶124.

This mapping of "*first modulation circuitry*" and "*second modulation circuitry*" to Grevious is confirmed by the '480 patent. 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*." Ex. 1003, ¶125.

Although 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). Frequency modulation, where information is conveyed in an RF signal by varying the frequency of that signal, is a well-known and commonly used modulation format that was in wide use by 2002. Ex. 1003, ¶¶126-128. As explained above (§ IV.A.ii), one form of frequency modulation is known as frequency-shift keying (FSK), where information is conveyed by discrete frequency changes in a carrier signal. Ex. 1024, 125-26. A binary FSK scheme would involve the use of a first frequency for a value '1' and a second frequency for a value '0.' *Id.*; Ex. 1020, 80-82; Ex. 1003, ¶126.

FSK was routinely used as a modulation format for telemetry communications between implantable medical devices and external devices. Ex. 1003, ¶¶127-128. For example, U.S. Patent No. 6,201,993 (Ex. 1007) (issued March 13, 2001; prior art under 35 U.S.C. § 102(b)) to Kruse et al. ("Kruse") discloses an implantable medical device communicating with external device programmers in a telemetry session. Ex. 1007, Abstract, 8:42-9:19. Kruse explains that it was known to modulate RF carrier signals using a variety of modulation schemes, including "FM and AM, phase shift keying (PSK), ***frequency shift keying (FSK)***, biphasic frequency shift keying (BPSK) amplitude shift keying (ASK), pulse position modulation (PPM), pulse interval modulation (PIM), among numerous others." *Id.*, 3:37-44 (emphasis added). These modulation schemes, including FSK, are used for telemetry transmissions between the external programmer and implantable medical device. *Id.*, 7:56-61, 20:28-33; Ex. 1003, ¶127.

As another example, U.S. Patent No. 6,577,901 (Ex. 1008) (filed Jun. 22, 2001; prior art under 35 U.S.C. § 102(e)) to Thompson ("Thompson") also discloses an implantable medical device communicating with external devices. Ex. 1008, Abstract, 3:45-4:12. Thompson explains that:

> RF coupled systems are extensively employed communications systems in modern [implantable medical devices (IMDS)]. In such systems, information is transferred from a transmitting coil to a receiving coil by way of a radio-frequency carrier signal. The carrier signal is modulated with the data that is transmitted through the use of an appropriate modulation scheme, such as phase shift keying (PSK), ***frequency shift keying (FSK)***, or pulse position modulation (PPM), among others."

Id., 2:33-40 (emphasis added). These systems have been "used primarily to achieve communications between an [implanted medical device (IMD)] and an external programmer." *Id.*, 1:13-17, 2:40-42; Ex. 1003, ¶128.

Grevious and prior art reference that disclose the use of FSK such as Kruse and Thompson are analogous art to the ’480 patent. Ex. 1003, ¶¶129. Each reference is from the same field of endeavor as the claimed invention: communicating with an implantable medical device. *See, e.g.*, Ex. 1001, 1:48-57, 1:61-2:4, 3:1-2, 3:25-47; Ex. 1005, 1:5-8, 2:51-57, Ex. 1007, 1:7-12, 6:45-64; Ex. 1008, 1:13-17, 3:45-4:12. Each reference is also reasonably pertinent to the problem faced by the ’480 patent’s inventors: ensuring accurate communications. *See, e.g.*, Ex. 1001, 1:48-57, 2:42-67; Ex. 1005, 1:5-8, 2:51-57, Ex. 1007, 1:7-12, 6:45-64; Ex. 1008, 1:13-17, 3:45-4:12.

It would have been obvious to a person having ordinary skill in the art in 2002 to modify Grevious (*see* § VI.A) or further modify Grevious as combined with Fitch (*see* § VI.B) to incorporate frequency shift-keying (FSK) as an additional modulation format supported by Grevious’s telemetry modules in programmers 20 and 30 and medical device 5. Ex. 1003, ¶¶130-132. Modifying Grevious to additionally support FSK would have been an “application of a known technique to a piece of prior art ready for the improvement.” *KSR*, 550 U.S. at 417. Grevious already supports numerous modulation formats and explains that “[o]ther modulation formats are also possible,” Ex. 1005, 12:35-39, and it would have involved only routine skill to modify Grevious to additionally support the FSK modulation format, which was also well-known in the art. Ex. 1003, ¶130.

Adding FSK support to Grevious 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. *See KSR*, 550 U.S. at 417.

Grevious provides abundant motivation to incorporate additional well-known modulation formats such as FSK. Ex. 1003, ¶131. For example, Grevious states that its 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). An ordinary artisan would have been motivated to support an even "wide[r] array of medical devices," such as those that only support FSK. Ex. 1003, ¶131. This is particularly true where Kruse and Thompson disclose medical devices that support FSK. Ex. 1007, Abstract, 3:37-44, 8:42-9:19, 7:56-61, 20:28-33; Ex. 1008, Abstract, 1:13-17, 2:33-40, 3:45-4:12. Grevious, Kruse, and Thompson are each patents filed by Medtronic, Inc., so 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. Ex. 1003, ¶131.

A skilled artisan would have also 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. Therefore, for all these reasons, it would have been obvious to modify Grevious (with or without Fitch) to additionally support frequency shift-keying (FSK), a form of "*frequency modulation*," as an additional modulation format supported by the telemetry modules in programmers 20 and 30 and medical device 5.

ii. "wherein the coil is further configured to wirelessly transmit the second modulated signal to the implantable medical device"

Grevious discloses these features. Ex. 1003, ¶¶134-136. As explained above (§ VI.A.ii.4), for example, Grievous discloses that typical telemetry module 40, used in programmers 20 and 30, includes telemetry coil 42 (the "*coil*") and enables those devices to wirelessly communicate bi-directionally with implanted medical device 5 via telemetry 3 and 4. Ex. 1005, 5:13-18, Fig. 3. After 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.*, 6:12-17; *id.*, 5:13-24, 6:19-22.

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

Grevious discloses these features. Ex. 1003, ¶¶137-139. As explained above (§ VI.A.ii.5), for example, Grevious that typical telemetry module 40 can be used in implantable medical device 5 to communicate bi-directionally with programmers 20 and 30 via telemetry, and includes receiver 44 and telemetry processor 47. Ex. 1005, 5:13-21, Fig. 3. An incoming RF telemetry signal received by the medical device is first received by the telemetry coil 42, which causes the medical device's telemetry processor 47 to be configured with the type of telemetry modulation (*e.g.*, FSK) of the incoming telemetry signal. *Id.*, 5:51-60. Telemetry receiver 44 then demodulates the time base signal into digital pulses and telemetry processor 47 converts/processes the digital pulses into binary data that is stored into memory for use by the medical device. *Id.*, 5:60-64. Telemetry receiver 44 and telemetry processor 47, as configured with FSK as discussed above, satisfy the claimed "*second telemetry receiver*." Ex. 1003, ¶138.

This mapping of "*first telemetry receiver*" and "*second telemetry receiver*" to Grevious is confirmed by the '480 patent. The '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***." Ex. 1001, 4:55-61 (emphasis added). The '480 patent further explains that "OOK receiver (43) may be integrated into the receiver (42)." *Id.*, 5:27-28. Therefore, the portion and specific configuration of Grevious' receiver 44 and processor 47 that receives and demodulates Format B satisfies the "*first telemetry receiver*," and the portion and specific configuration of Grevious' receiver 44 and processor 47 that, as combined, receives and demodulates FSK satisfies the "*second telemetry receiver*." Ex. 1003, ¶139.

Alternatively, 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. Ex. 1003, ¶¶140-146. It was known by 2002 to implement different receivers and modulation techniques in different hardware or software elements. *Id.*, ¶¶141-143. For example, U.S. Patent No. 5,466,246 to Silvian (Ex. 1011)[5] discloses a telemetry technique communication between a programmer and implantable medical devices such as pacemakers. Ex. 1011, Abstract. Silvian's medical device supports numerous

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[5] Silvian is a U.S. Patent that was published on November 14, 1995, and is prior art under at least 35 U.S.C. § 102(b). Ex. 1011, [45].

modulation techniques when receiving information from the medical devices, including AM, FM, and PSK. *Id.*, 3:5-18, 5:39-47. Silvian implements those techniques via separate hardware or software modules, such as AM demodulator 81, FM demodulator 83, and PSK demodulator 85. *Id.*, 5:14-22, 5:39-47, Fig. 3. Each of these demodulators is a "circuit configured to receive and process an RF signal," so can be considered a "*receiver*." Ex. 1003, ¶141; Ex. 1001, 4:55-61. U.S. Patent No. 7,167,756 to Torgerson et al. (Ex. 1017) discloses an implantable medical device with two wireless receivers: telemetry module 305 and a recharge module 310. Ex. 1017, Abstract, Fig. 3. The recharge module receives an energy transfer signal that is used to charge the device and "can be the same coil as the telemetry antenna if multiplexed or the recharge coil can be separate from the telemetry antenna." *Id.*, 7:26-52; Ex. 1003, ¶142. U.S. Patent No. 6,045,042 to Ohno (Ex. 1026) discloses the use multiple parallel receivers in a wireless system, each with different configurations and specially adapted to a specific set of thresholds. . Ex. 1026, Abstract, Fig. 1, 2:55-3:3. It was therefore known to implement two different wireless communication schemes via separate receivers. Ex. 1003, ¶143.

It would have been obvious to further modify Grevious to implement the different modulation formats as separate hardware or software functionality. Ex. 1003, ¶144. Modifying Grevious as such would have been an "application of a known technique to a piece of prior art ready for the improvement." *KSR*, 550 U.S. at 417. It would have involved only routine skill to implement Grevious' modulation formats as separate hardware or software functionality. Ex. 1003, ¶144. As Mr. Pless explains, "[c]hoosing between reconfigurable hardware and software elements and separate hardware and software elements is a common design tradeoff; for example, implementing demodulation functionality via common hardware and software provides configurability, while implementing demodulation functionality via separate hardware and software can provide power efficiencies." *Id.* Modifying 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. *See KSR*, 550 U.S. at 417.

Therefore, for all these reasons, it would have been obvious to further modify Grevious to implement its different modulation formats as separate hardware or software modules. Each of these modules would be hardware or software "configured to receive and process an RF signal," so can be considered a "*receiver*." Ex. 1003, ¶145; Ex. 1001, 4:55-61.

2. Claim 3.

i. "The system of claim 2, wherein the frequency modulation comprises frequency shift keying (FSK) modulation."

Grevious as combined above discloses these features. Ex. 1003, ¶¶147-149. As explained above with respect to claim 2 (§ VI.C.i), it would have been obvious to a person having ordinary skill in the art in 2002 to modify (*see* §VI.A) or further modify (*see* § VI.B) Grevious to incorporate "*frequency shift-keying (FSK)*" as an additional modulation format supported by Grevious's telemetry modules in programmers 20 and 30 and medical device 5. Ex. 1003, ¶148.

3. Claim 4.

i. "The system of claim 2, wherein the implantable medical device further comprises a reference clock generation circuit for generating a reference clock signal used by the second telemetry receiver."

Grevious as combined renders obvious the "*system of claim 2*," as explained above. *See* § IV.C.i. Specifically, it would have been obvious to a person having ordinary skill in the art in 2002 to modify (*see* § VI.A) or further modify (*see* §VI.B) Grevious to incorporate frequency shift-keying (FSK) as an additional modulation format supported by Grevious's telemetry modules in programmers 20 and 30 and medical device 5. Ex. 1003, ¶¶126-132. As combined, however, Grevious' use of FSK does not expressly disclose "*a reference clock generation* *circuit for generating a reference clock signal used by the second telemetry receiver*."

It was well-known by 2002 to use a reference clock generation circuit to characterize modulated data, however. Ex. 1003, ¶151. For example, U.S. Patent No. 5,466,246 to Silvian (prior art under § 102(b)) discloses an implantable medical device that supports multiple modulation formats, including FSK. Ex. 1011, 1:58-2:34. The medical device includes a phase-locked loop for synchronizing a phase signal with the phase of a demodulated signal. *Id.*, 2:17-23, 5:39-47, 5:55-67. The resulting clock signal is then used to control when the modulated data signal, such as an FSK modulated data signal, is sampled to recover the signal data. *Id.* As another example, U.S. Patent No. 6,587,531 to De Mey et al. (Ex. 1027) teaches that it was known to generate clock from received digital signals (Ex. 1027, 1:15-22) and discloses a clock recovery circuit that generates a clock from received FSK data, which is then used to sample the received data and determine the symbol value. *Id.*, 3:21-33. It was therefore known to use reference clock generation circuitry to characterize modulated data, including FSK modulated data. Ex. 1003, ¶151.

It would have been obvious to a person having ordinary skill in the art in 2002 to modify Grevious as combined above (*see* § VI.C) to incorporate a reference clock generation circuit to characterize the state of an FSK signal. Ex.

1003, ¶¶152. Grevious suggests the desirability of incorporating such functionality into the medical device: it states that "in a preferred embodiment," the modulation formats are "synchronous transmission formats" where "the data and receiver clock information are transmitted together." Ex. 1005, 12:40-43. By including a reference clock generation circuit that is based on the FSK-modulated signal as described above, the FSK-modulated signal would transmit both data and receiver clock information. Ex. 1003, ¶152. This would also provide the benefit of avoiding the need for a separate local oscillator, reducing the complexity and power consumption of the device (Ex. 1025, 429) and would address the effects of temperature and age. Ex. 1003, ¶152; Ex. 1023, 1:22-34, 7:21-24.

Modifying Grevious to incorporate such a circuit would also have been an "application of a known technique to a piece of prior art ready for the improvement." *KSR*, 550 U.S. at 417. It would have involved only routine skill to modify Grevious to characterize FSK signals relative to a generated reference clock. Ex. 1003, ¶153. Incorporating a reference clock generation circuit into Grevious' telemetry modules for use when receiving FSK signals 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. *See KSR*, 550 U.S. at 417. Therefore, for all these reasons, it would have been obvious to further modify Grevious to incorporate a reference clock generation circuit to characterize the frequency of a received FSK signal.

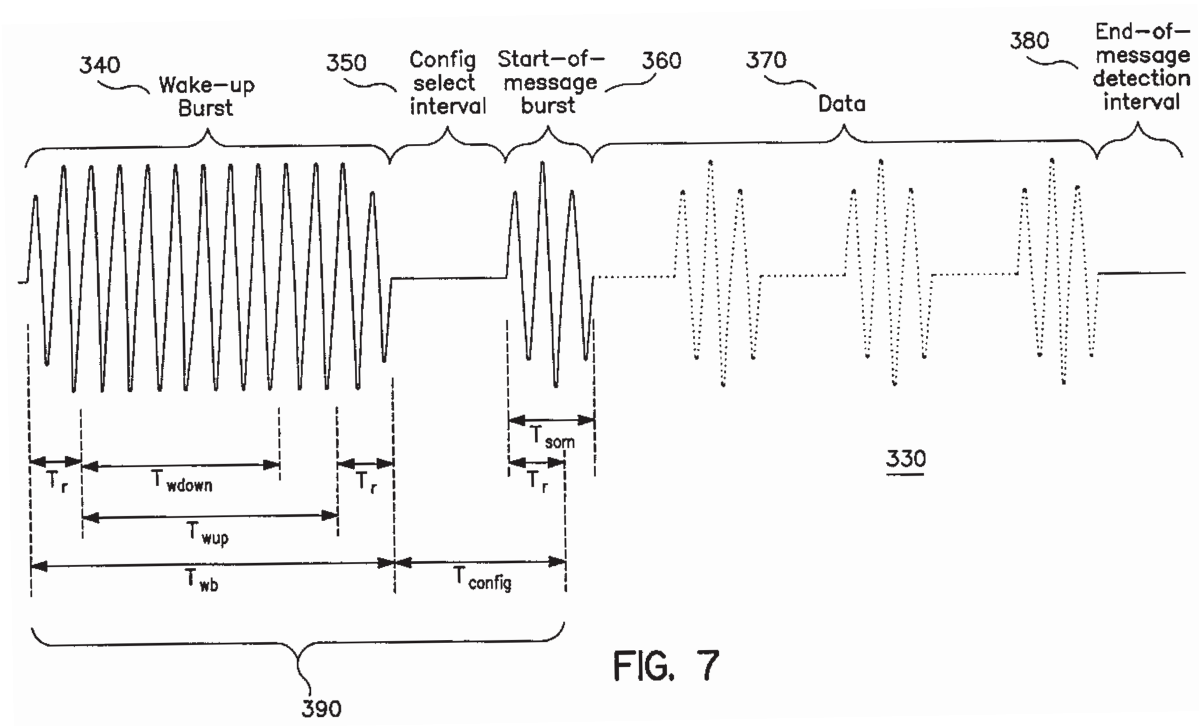
4. Claim 6.

i. *"The system of claim 2, wherein the first data comprises a start bit and a number of control bits, the start bit being transmitted before the control bits."*

Grevious discloses these features. Ex. 1003, ¶¶155-158. The '480 patent explains that "*control bits*" refer to any "bits that are transmitted" between the external device and the implantable stimulator. Ex. 1001, 4:67-5:4.

Grevious explains that, in Format B, data bits are transmitted in pairs, or "dibits" 420. Ex. 1005, 15:38-43. Preferably, each pair of bits starts with a not burst 440 (OFF) state followed by a burst 430 (ON) state. *Id.*, 15:44-49, Fig. 9. There is therefore an initial bit ("*a start bit*"), *i.e.*, the first bit in a given message, followed by one or more additional data bits in that message. Ex. 1003, ¶156. These data bits are sent from a controller to the implantable medical device and trigger certain actions, such as adjusting stored therapy programs and therapy settings ("*control bits*"). Ex. 1005, 5:64-67; Ex. 1003, ¶156.

Alternatively, Grevious discloses the use of a Start-of-Message bit ("*a start bit*"), which is followed by the data bits in the transmission ("*a number of control bits*"). Ex. 1003, ¶157; Ex. 1005, 12:59-13:9, 14:36-46; *see id.*, 13:23-26 ("Start-of-Message (SOM) 360 bit"). The Start-of-Message bit "functions as the start of the data bit timing," can also "be used to convey data," and is transmitted before the data bits. *Id.*, 14:40-46. This is illustrated in Figure 7:



Ex. 1005, Fig. 7.

5. <u>Claim 8.</u>

i. "The system of claim 2, wherein the implantable medical device comprises an implantable stimulator."

Grevious discloses these features. Ex. 1003, ¶¶159-161. Grievous discloses that one example of medical device 5 is "an Implantable Neuro Stimulator (INS) 5" ("*an implantable stimulator*") which is preferably a modified implantable pulse generator used to send precise, electrical pulses to the spinal cord, brain, or neural tissue to provide the desired treatment therapy. Ex. 1005, 3:34-37, 4:13-45, Fig. 1; *see id.*, 1:30-52. The '480 patent explains that "stimulator" is used interchangeably to refer to "any implantable medical device that may be implanted within a patient for therapeutic purposes." Ex. 1001, 3:39-44.

D. Claims 6 and 7 Are Obvious Over Grevious (Ex. 1005) in View of Bradshaw (Ex. 1009), With or Without Fitch (Ex. 1006)

1. Claim 6.

i. "The system of claim 2, wherein the first data comprises a start bit and a number of control bits, the start bit being transmitted before the control bits."

To the extent one could argue that Grevious as combined above (with or without Fitch) does not disclose a "*the first data comprises start bit and a number of control bits, the start bit being transmitted before the control bits*," it would have been obvious to incorporate such functionality. Ex. 1003, ¶¶162-169.

U.S. Patent No. 4,327,441 (Ex. 1009) to Bradshaw ("Bradshaw")[6] discloses a method for synchronizing and calibrating a receiver to a pulse width modulation transmitter. Ex. 1009, Abstract. Bradshaw explains that pulse width modulation communication systems "generally require frequent manual readjustment in order to compensate for temperature and age induced drift." *Id.*, 1:22-29. As explained by Mr. Pless, clocks can be affected by temperature and age, and it was known to have to adjust for those effects. Ex. 1003, ¶163; Ex. 1023, 1:22-34, 7:21-24.

[6] Bradshaw is a U.S. Patent that was published on April 27, 1982, and is prior art under at least 35 U.S.C. § 102(b). Ex. 1009, [45].

To address this issue, Bradshaw discloses transmitting a synchronizing pulse 1, a reference pulse 2 ("*a start bit*"), and then a number of control function pulses 3 through N ("*a number of control bits*"). Ex. 1009, 2:25-37. This reference pulse can be used to characterize a value for the control function pulses. *Id.*, 1:43-60, 2:6-53, 4:30-50, 7:26-45. Bradshaw's preferred embodiment utilizes multiple timing pulses (A, B, and C) to permit multiple bits to be encoded into a single width, but Bradshaw discloses a binary embodiment where the reference signal is compared against the control bits in a binary fashion. *E.g.*, *id.*, 1:43-60, 2:6-53, 7:26-45; Ex. 1003, ¶164. In such an embodiment, if a control function pulse is shorter than the reference pulse, it is interpreted as a logical high signal, *i.e.*, a '1.' Ex. 1009, 4:37-47. If a control function pulse is longer than the reference pulse, it is interpreted as a logical low signal, *i.e.*, a '0.' *Id.*; Ex. 1003, ¶165. An exemplary control signal frame is illustrated in Figure 1a, with a reference pulse ("*start bit*") followed by multiple control function pulses ("*control bits*") (Ex. 1009, 2:25-37):

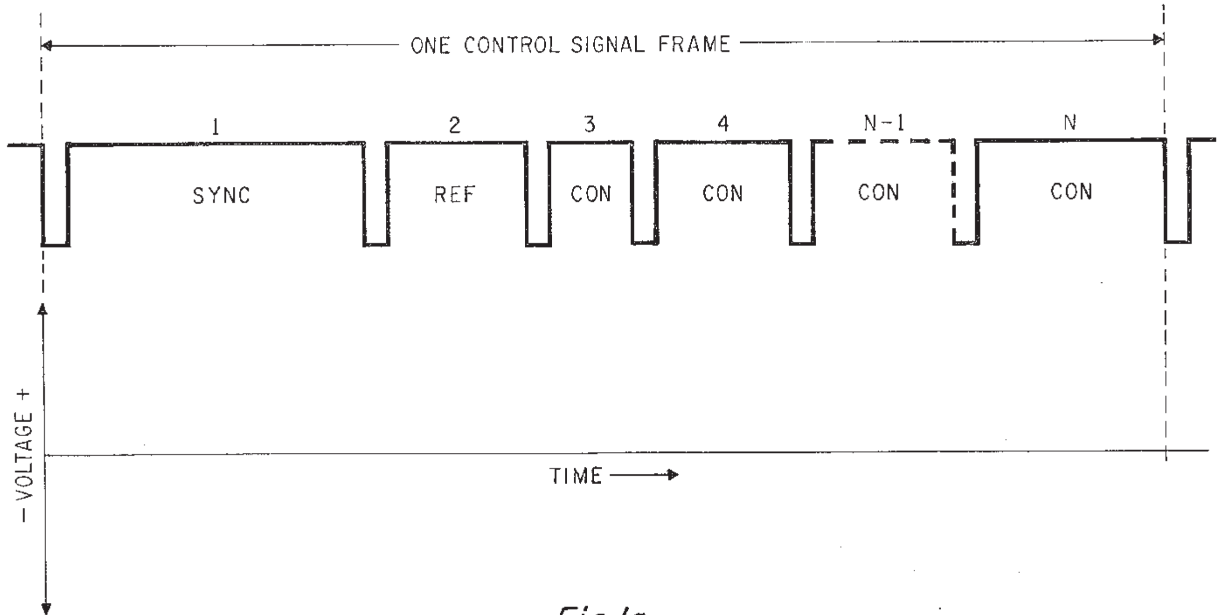


Fig. 1a

Ex. 1009, Fig. 1a.

Grevious is analogous art to the '480 patent as explained above. *See* § VI.C.i; Ex. 1003, ¶166. Bradshaw is analogous art to the '480 patent at least because it is reasonably pertinent to the problem faced by the '480 patent's inventors: ensuring accurate communications. *See, e.g.*, Ex. 1001, 1:48-57, 2:42-67; Ex. 1009, 1:9-12, 1:32-42. Bradshaw further addresses improving pulse width modulated communication systems (Ex. 1009, 1:9-12), the precise type of communication system disclosed by the '480 patent (Ex. 1001, 4:36-37, 6:41-44).

It would have been obvious to a person having ordinary skill in the art in 2002 to modify Grevious as combined above (*see* § VI.C, and with or without Fitch) to incorporate Bradshaw's reference technique to characterize the length of Grevious' message data bits relative to the length of a reference bit, such as the

Start-of-Message bit. Ex. 1003, ¶¶167-168. Modifying Grevious to incorporate Bradshaw's technique would have been an "application of a known technique to a piece of prior art ready for the improvement." *KSR*, 550 U.S. at 417. Grevious already discloses the use of a Start-of-Message bit ("*a start bit*") which "functions as the start of the data bit timing" and can also be modulated "to convey data," Ex. 1005, 12:59-13:9, 13:23-26, 14:36-46, Fig. 7, and it would have involved only routine skill to modify Grevious to characterize message data bits based on their length relative to the Start-of-Message bit, a technique known in the art. Ex. 1003, ¶167. Modulating this Start-of-Message bit to dynamically characterize subsequent data bits pursuant to Bradshaw's teachings 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. *See KSR*, 550 U.S. at 417.

Bradshaw also provides abundant motivation to incorporate its technique into other systems. Ex. 1003, ¶168. Bradshaw explains that the reference bit technique is "simple and straightforward in its operation," and allows for the rapid calibration of the receiver to the transmitter to minimize any error. Ex. 1009, 1:35-42. Adopting a reference bit technique allows for pulse width modulation communication systems to avoid "frequent manual readjustment in order to compensate for temperature and age induced drift." *Id.*, 1:22-29. A skilled artisan would have been particularly motivated to incorporate this technique in the context of Grevious, which discloses an implantable medical device that may be difficult or impossible to manually readjust. Ex. 1003, ¶168; Ex. 1005, 4:13-25. Therefore, for all these reasons, it would have been obvious to further modify Grevious to incorporate Bradshaw's reference technique to characterize the length of Grevious' message data bits relative to the length of a reference bit, such as the Start-of-Message bit (as modified a "*start bit*"). Ex. 1003, ¶168.

2. <u>Claim 7.</u>

i. "The system of claim 6, wherein the first telemetry receiver comprises: a bit threshold counter configured to measure a pulse width of the start bit to generate a bit width threshold;"

Grevious as combined above in further view of Bradshaw discloses these features. Ex. 1003, ¶¶170-172; *see* § VI.D.i. As explained with respect to claim 6, it would have been obvious to modify Grevious to incorporate Bradshaw's reference bit technique to characterize the length of Grevious' message data bits relative to the length of a reference bit, such as the Start-of-Message bit. Ex. 1003, ¶170.

Bradshaw's technique utilizes timer 18 ("*a bit threshold counter*") to measure the width of the reference bit ("*start bit*") to generate a timing pulse ("*bit width threshold*"). Ex. 1009, 1:43-60, 2:6-53, 7:26-45, Fig. 1. In response to the start of each control pulse, timer 18 provides a timing pulse. *Id.* Timing pulse is calibrated to the width of the reference pulse. Ex. 1009, 3:25-39. This is consistent with the '480 patent's disclosure, which explains that a "counter" "may be any type of counter circuitry known in the art," such as "flip-flop circuitry." Ex. 1001, 7:44-46; Ex. 1003, ¶171.

ii. "a pulse width counter configured to measure a pulse width of the bits; and"

Grevious as combined above in further view of Bradshaw discloses these features. Ex. 1003, ¶¶173-175; *see* § VI.D.i. Bradshaw's technique utilizes function controller 24 to measure the width of each control function pulse relative to the width of the reference pulse. Ex. 1009, 3:25-39, 4:30-50. Bradshaw explains that function controller 24 may be implemented in part via a conventional D-type flip-flop ("*a pulse width counter*"). *Id.* The '480 patent explains that the claimed "counter" may be "flip-flop circuitry." Ex. 1001, 7:44-46.

iii. "a comparator configured to compare the measured pulse widths with the bit width threshold to determine whether a bit comprises a logic '0' or a logic '1'."

Grevious as combined above in further view of Bradshaw discloses these features. Ex. 1003, ¶¶176-178; *see* § VI.D.i. Bradshaw's technique utilizes function controller 24 ("*a comparator*") to compare the width of each control function pulse to timing pulse A. Ex. 1009, 3:25-39, 4:30-50. If a control function pulse is shorter than the reference pulse, it is interpreted as a logical high signal, *i.e.*, a '1.' *Id.*, 4:37-47. If a control function pulse is longer than the reference pulse, it is interpreted as a logical low signal, *i.e.*, a '0.' *Id.*; Ex. 1003, ¶177. As explained above, it would have been obvious to modify Grevious to incorporate this reference bit technique to characterize the length of Grevious' message data bits relative to the length of a reference bit, such as the Start-of-Message bit. Ex. 1003, ¶¶167-168, 177.

E. No Secondary Considerations Exist

Nevro is unaware of any assertion by BSNC that secondary indicia of non-obviousness exist having a nexus to any invention of the '480 patent. Nevro reserves its right to respond to any subsequent assertion of secondary indicia of non-obviousness advanced by BSNC.

VII. CONCLUSION

For the foregoing reasons, the challenged claims are unpatentable.

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EXHIBIT LIST

No.	Exhibit Description
1001	U.S. Patent No. 7,822,480
1002	File History of U.S. Patent No. 7,822,480
1003	Declaration of Ben Pless
1004	Curriculum Vitae of Ben Pless
1005	U.S. Patent No. 6,443,891 to Grevious
1006	U.S. Patent No. 4,807,225 to Fitch
1007	U.S. Patent No. 6,201,993 to Kruse et al.
1008	U.S. Patent No. 6,577,901 to Thompson
1009	U.S. Patent No. 4,327,441 to Bradshaw
1010	U.S. Patent No. 6,434,194 to Eisenberg et al.
1011	U.S. Patent No. 5,466,246 to Silvian
1012	U.S. Patent No. 7,177,698 to Klosterman et al.
1013	U.S. Provisional App. No. 60/392,475
1014	Summons in a Civil Action, *Boston Scientific Corp. et al. v. Nevro Corp.*, Civ. No. 18-644-GMS (D. Del. July 19, 2018)
1015	U.S. Patent No. 3,727,616 to Lenzkes
1016	U.S. Patent No. 6,612,934 to Foster
1017	U.S. Patent No. 7,167,756 to Torgerson et al.
1018	Mitsutake Sato et al., *Pulse Interval and Width Modulation for Video Transmission*, IEEE Transactions on Cable Television, Vol. CATV-3, No. 4, 165-173 (Oct. 1978)
1019	Principles of Radiotelegraphy, 1st ed. (1919) (excerpts)
1020	Theodore Brenig, *Data Transmission for Mobile Radio*, IEEE Transactions on Vehicular Technology, Vol. VT-27, No. 3, 77-85 (Aug. 1978)
1021	John D. Oetting, *A Comparison of Modulation Techniques for Digital Radio*, IEEE, 1752-1762 (1979)

No.	Exhibit Description
1022	Z. Ghassemlooy et al., *Digital Pulse Interval and Width Modulation*, Microwave & Optical Tech. Ltrs, 11/4, 228-231 (1996)
1023	U.S. Patent No. 4,594,565 to Barreras
1024	Andrew S. Tanenbaum, *Computer Networks*, 4th ed. (2003) (excerpts)
1025	Christopher Hitzelberger et al., *A Microcontroller Embedded ASIC for an Implantable Electro-Neutral Stimulator*, IEEE (2001)
1026	U.S. Patent No. 6,045,042 to Ohno
1027	U.S. Patent No. 6,587,531 to De Mey et al.

CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with the type-volume limitations of 37 C.F.R. § 42.24, because it contains 11,348 words (as determined by the Microsoft Word word-processing system used to prepare the brief), excluding the parts of the brief exempted by 37 C.F.R. § 42.24.

Dated: July 10, 2019

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Pursuant to 37 C.F.R. § 42.6(e), I hereby certify that on this 10th day of July, 2019, I caused to be served a true and correct copy of the foregoing and any accompanying exhibits by Federal Express on the following counsel:

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