UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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NEVRO CORP.,
Petitioner

v.

BOSTON SCIENTIFIC NEUROMODULATION CORP.,
Patent Owner

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Case IPR2019-01318
Patent 9,162,071

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# PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 9,162,071

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| **1003** | Expert Declaration of Dr. Mark W. Kroll |
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| **1005** | U.S. Patent No. 6,453,198 B1 to Torgerson *et al.* (“Torgerson198”) |
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| **1015** | Hoon –Kyeu Lee *et al.*, “Bio-medical FM-FM-FSK Radiotelemtry System for Multi-signal Transmission,” *Proc. 22nd Annual EMBS International Conference*, 1553-1555 (2000) (“Lee”) |
| **1016** | Martin Hudec *et al.*, “Case report of out-of-hospital heat dissipation of an implantable cardioverter-defibrillator,” *EP Europace*, Vol. 13, Issue 6, 902–904 (June 2011) |
| **1017** | *Telecomms Integrated Circuit Handbook*, Plessy Semiconductors (April 1984) |
| **1018** | “FSK: Signals and Demodulation,” WJ Tech Notes (1980) |

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| **1019** | Rajoua Anane, *et al.*, "Optimal Modulation Scheme for Energy Efficient Wireless Sensor Networks," *10th International Conference on Wireless Communications, Networking and Mobile Computing*, (September 2014) |
| **1020** | U.S. Patent No. 8,682,447 B2 to Bradley *et al.* ("Bradley") |

# I. INTRODUCTION

Boston Scientific Neuromodulation Corporation ("BSNC") is the assignee of U.S. Patent No. 9,162,071. The '071 patent is directed to a "method for controlling an implantable medical device." EX1001, '071 patent, 20:39. Implantable medical devices ("IMDs") of the type described in the '071 patent—namely, implantable microstimulators—were well known in the art by June 2002, the earliest possible priority date of the '071 patent. EX1003, Kroll Decl., ¶¶23-30. The '071 patent itself candidly acknowledges this by describing in the Background Section no less than a dozen exemplary prior art microstimulators. EX1001, 1:25-2:61. The method for controlling the device, which centers on conserving battery power in an IMD by selectively activating and deactivating certain device telemetry in response to the monitored voltage of a power source, would have been obvious in view of the cited prior art. In fact, the Board reached the same conclusion in the *inter partes* review of related U.S. Patent 7,587,241. *See* IPR2017-01899, Paper 35, Final Written Decision (PTAB Feb. 4, 2019).

# II. GROUNDS FOR THE UNPATENTABILITY OF THE '071 PATENT

Nevro requests *inter partes* review of claims 1-10 of the '071 patent and a determination that those claims are unpatentable based on the following grounds:

| Ground | Prior Art | Basis | Claims Challenged |
|---|---|---|---|
| 1 | Torgerson198 (EX1005)<br>Torgerson756 (EX1006)<br>Torgerson883 (EX1007) | 35 U.S.C. § 103 | 1, 4-10 |
| 2 | Torgerson198 (EX1005)<br>Torgerson756 (EX1006)<br>Torgerson883 (EX1007)<br>Abrahamson (EX1008) | 35 U.S.C. § 103 | 2, 3 |

The earliest priority date of the ’071 patent, on its face, is June 28, 2002. EX1001, Related U.S. Application Data. The prior art references cited for each ground above qualify as prior art to the ’071 patent for the following reasons:

- Torgerson198 (EX1005) is U.S. Patent No. 6,453,198, which qualifies as a prior art patent under 35 U.S.C. § 102(e) because it was filed on April 28, 2000 and issued on Sep. 17, 2002.
- Torgerson756 (EX1006) is U.S. Patent No. 7,167,756, which qualifies as a prior art patent under 35 U.S.C. § 102(e) because it was filed on April 28, 2000 and issued on Jan. 23, 2007.
- Torgerson883 (EX1007) is U.S. Patent No. 6,456,883, which qualifies as a prior art patent under 35 U.S.C. § 102(e) because it was filed on April 26, 2000 and issued on Sep. 24, 2002.
- Abrahamson (EX1008) is U.S. Patent No. 6,647,298, which qualifies as a prior art patent under 35 U.S.C. § 102(e) because it was filed on June 4, 2001 and issued Nov. 11, 2003.

The three Torgerson references are related. They share the same named first inventor, Nathan Torgerson. EX1005; EX1006, EX1007. Torgerson198 and Torgerson756 were filed on the same day and incorporate each other by reference, in their entireties. EX1005, 8:53-59; EX1006, 10:22-31. Torgerson883 was filed two days earlier and is also referenced by Torgerson756. EX1006, 1:21-27.

During prosecution of the ’071 patent, the examiner issued a first-action allowance. EX1002, 9-15. The three Torgerson patents were not considered, applied, or even referenced during prosecution below, nor was the Abrahamson patent.

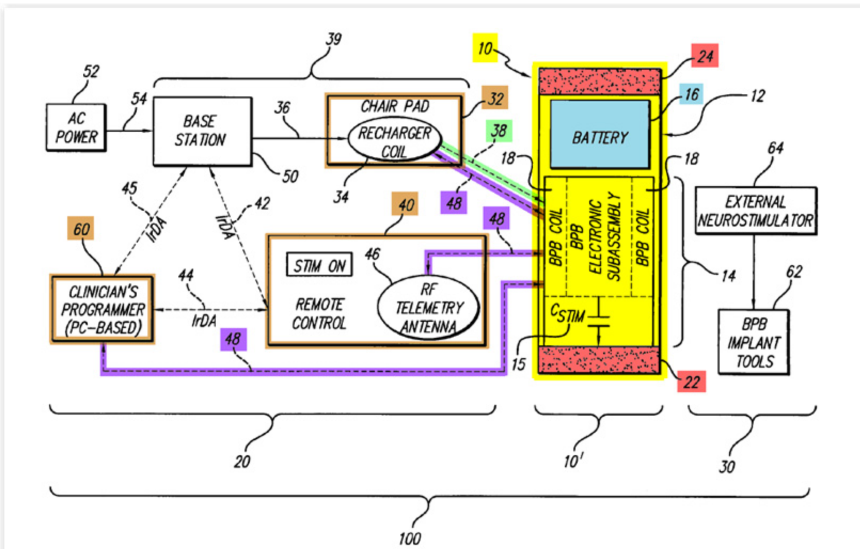
## III. OVERVIEW OF THE ’071 PATENT

The ’071 patent is directed to a method for controlling telemetry in an implantable medical device based on power source capacity. EX1001, Title. It includes one set of claims: claims 1-10. Claim 1, the only independent claim, is illustrative and is reproduced below:

> 1. A method for controlling an implantable medical device, the device having telemetry circuitry to receive both a first type of telemetry and to receive a second type of telemetry, the method comprising:
>
> listening for the first and second telemetry types;
>
> monitoring a voltage of a power source within the implantable medical device; and
>
> if the voltage falls below a first threshold, discontinuing listening for the first telemetry type while continuing listening for the second telemetry type.

### A. The claims operate on an implantable medical device having certain features.

The IMD upon which the claimed method operates is illustrated below in Figure 1 of the ’071 patent:




EX1001, Fig. 1; EX1003, ¶34.

The ’071 patent discloses a particular IMD that it refers to as a battery-powered BION® (“BPB”) device 10 (highlighted in yellow). *See, e.g.*, EX1001, 1:25-30, 5:56-67. The implantable device 10 includes a battery 16 (highlighted in blue) that serves as a power source for the electronics (shown in yellow) contained in the implantable device 10. EX1001, 5:56-61, 8:38-44, 11:32-37, 12:28-34; EX1003, ¶¶34-35.

The “BPB electronic sub-assembly” contains the claimed “telemetry circuitry” of the implantable device 10. EX1001, 12:28-30. The ’071 patent does not provide any further details about the "telemetry circuitry," except for its physical location within the BPB device 10. *See e.g.*, EX1001, Figs 4, 11A, 11B. The '071 patent thus leaves the actual design of the telemetry circuitry to the skilled artisan.

The '071 patent describes two "telemetry links"—namely, a "forward telemetry link 38" (shown in green) and "bi-directional telemetry link 48" (shown in purple). EX1001, 8:45 – 9:7. The two telemetry links are used by various external devices (shown in brown) for different purposes, such as a chair pad 32 of a recharging system, a remote control 40, and a clinician programmer 60. EX1001, 8:45-51, 8:57-63, 8:65-9:7; EX1003, ¶36. A POSA would have recognized that both telemetry links rely on near-field or inductive telemetry links. EX1003, ¶¶38-39.

Once device 10 is implanted in a patient, the electronics of the implantable device generate stimulating pulses (*i.e.*, electrical currents) that are delivered via electrodes 22 and 24 (shown in red) to the patient's tissue to provide the desired therapy. EX1001, 1:55-59, 4:3-15, 11:38-42; EX1003, ¶36.

Dependent claims 2 and 3 further limit the IMDs operable by claim 1 by identifying certain keying or modulation schemes as defining the two telemetry types—namely, frequency shift keying (FSK) for the first "type of telemetry" and on-off keying (OOK) for the "second type of telemetry." EX1001, 20:49-54. FSK and OOK, which were well known keying or modulation schemes prior to the '071 patent, are two different techniques for encoding data into a signal. EX1003, ¶183-187. As its name suggests, frequency shift keying ("FSK") encodes data into a signal by modulating (*i.e.*, altering) the frequency of the carrier signal. *Id.* In contrast, on-off keying ("OOK") denotes the simplest form of amplitude-shift keying ("ASK") modulation that represents digital data at the presence or absence of a carrier wave. Id., ¶186. Dependent claim 3 requires the telemetry circuitry to comprise at least an OOK receiver, an FSK receiver, and an FSK transmitter. EX1001, 20:52-54. This is a nonce requirement, however, because any telemetry circuitry employing the FSK and OOK modulation schemes of dependent claim 2 would necessarily have these components. EX1003, ¶196.

Dependent claim 4 requires the IMD defined by claim 1 to include a register for holding a threshold value used for performing the claimed methods of the '071 patent. EX1001, 20:55-56. Dependent claim 8 recites that the method includes receiving programming and recharging by a clinician, while dependent claim 9 limits the IMDs operable by claim 1 by requiring that the IMD's internal power source include a lithium ion battery. *Id*.

### B. Claims cover methods that enable and disable stimulation and telemetry listening features of an implantable medical device based on the device's power source voltage

The claims of the '071 patent cover a method for enabling and disabling the stimulation and telemetry features of an IMD. The steps are provided in claims 1, 5-8 and 10. Independent claim 1 entails: (1) listening for the first and second telemetry types, (2) monitoring a voltage of a power source within the implantable medical device, and (3) if the voltage falls below a first threshold, discontinuing listening for the first telemetry type while continuing listening for the second telemetry type. EX1001, 20:38-48.

Figure 6 of the '071 patent is illustrative:.

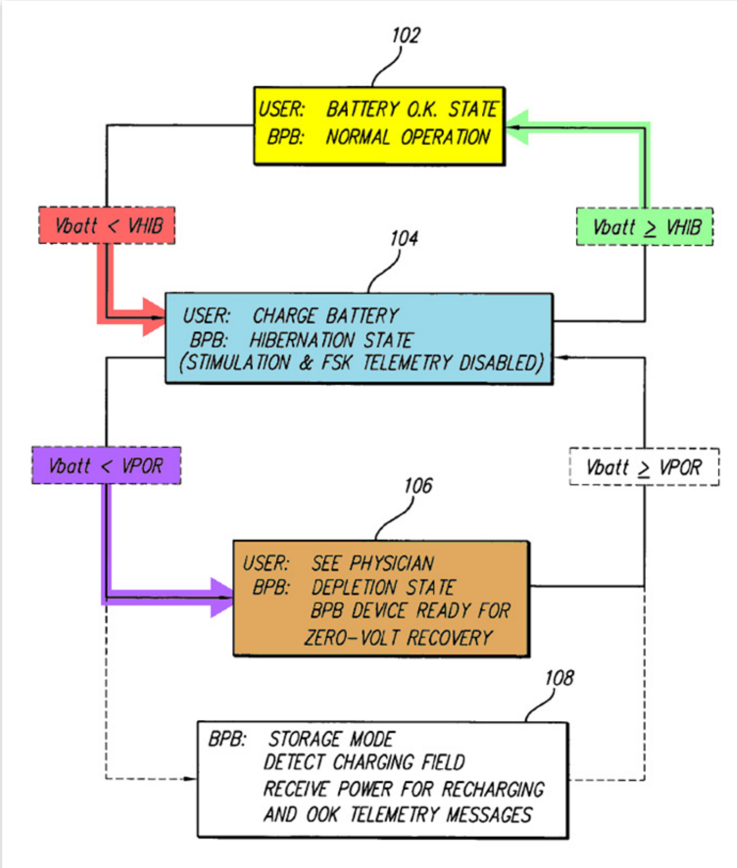



FIG. 6

EX1001, Fig. 6; EX1003, ¶51.

As shown in Figure 6 above, the '071 patent contemplates operating an IMD in one of three different states (shown in yellow, blue and brown above). EX1001, 13:19-62; EX1003, ¶52. State 102 (shown in yellow) represents the "normal operation" state, in which the IMD is operated to provide stimulation and to listen for two different telemetry types. EX1001, 13:19-39; EX1003, ¶52. State 104 (shown in blue) represents the "hibernation state," in which the IMD is operated with stimulation and listening for one of the two telemetry types (e.g., FSK) disabled. EX1001,13:19-55; EX1003, ¶52. State 106 (shown in brown) represents the "depletion state," in which stimulation and listening for one of the two telemetry types (e.g., FSK) remain discontinued until the IMD is recharged, for example, by a clinician. *Id.*

The states change based on the voltage level of the IMD's internal power source. EX1003, ¶¶53-54. Figure 6 above is illustrative. As shown highlighted in green, if the voltage of the IMD's power source Vbatt is above a first threshold VHIB, the IMD is operated in the "normal operation" state 102 (yellow) in which the IMD is able to provide stimulation and listen for two different types of telemetry. EX1001, 13:11-47; EX1003, ¶54.

As shown highlighted in red, if the IMD's power source voltage Vbatt falls below the first threshold VHIB, the IMD is operated in the "hibernation state" 104 (blue), which causes the IMD to discontinue both stimulation and listening for one of the two telemetry types. *Id*. Finally, as shown highlighted in purple, if the IMD's power source voltage Vbatt falls below the second threshold VPOR, the IMD is operated in the "depletion state" (brown) which causes both stimulation and listening for one of the two telemetry types to remain discontinued until the IMD is recharged. *Id.*

## IV. LEVEL OF ORDINARY SKILL IN THE ART

A POSA in the context of the '071 patent at the time of its earliest priority date of June 28, 2002, would have been a person who 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. EX1003, ¶15-18. A POSA of the '071 patent would have had general knowledge of implantable medical devices and various related technologies as of June 28, 2002. *Id*.

## V. CLAIM CONSTRUCTION

The claim construction standard set forth in *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) applies to this proceeding. *See* 83 Fed. Reg. 51340, 51340-51359 (Oct. 11, 2018); 37 C.F.R. 42.100. Under this standard, words in a claim are given their plain meaning, which is the meaning understood by a person of ordinary skill in the art at the time of the alleged invention, and after reading the entire patent. *Phillips*, 415 F.3d 1303, 1312-13.

Here, the patentee did not use any unusual claim terms. Nor do any of claim terms appear to be used outside their ordinary and customary meaning, as understood by a POSA and in view of the specification. The patentee did not provide a glossary, and the patentee does not appear to have acted as its own lexicographer for any term.

### A. "Telemetry"

The related IPR2017-01899 proceeding involves U.S. Patent No. 7,587,241. The '071 patent is a related patent through a string of continuation and divisional applications. *See* EX1001, Related U.S. Application Data. The ’071 patent thus shares a substantially identical specification with the ’241 patent. In the ’1899 IPR, BSNC asked the Board to construe the term “telemetry” as the “transmission of data or information.” ’1899IPR, POR, 11. The Board preliminarily adopted that construction in its Decision on Institution. ’1899IPR, DI, 8-9. In its Final Written Decision, the Board construed “telemetry” as a “transmission of data or information,” in the form of “transmission of energy (power),” with the clarification that “‘telemetry’ does not include an unmodulated ‘transmission of energy (power).’” ’1899IPR, FWD, Paper 35, 18. In this petition, Nevro applies the Board’s construction of this term.

**B. “Type of Telemetry”**

A dispute arose over the construction of the term “type of telemetry” in the ’1899IPR on the related ’241 patent. Late in the trial, during deposition, BSNC’s expert Dr. Ronald Berger took the position that the “type of telemetry” refers not to the transmission of different types of data or information, as BSNC’s construction of telemetry would suggest, but rather to different types of what he called the “modality of energy transfer.” ’1899IPR, EX1011, 123:22-124:13.

For example, Dr. Berger believes that what the ’071 patent refers to as “inductive telemetry” and “RF telemetry,” are the claimed two different “types of telemetry.” Nevro argued in its Reply that even under that too narrow construction, the prior art still renders the claims obvious. ’1899IPR, Reply, Paper 19, 14-18. BSNC then adopted Dr. Berger’s narrow construction, and argued that position for the first time in its Sur-Reply. ’1899IPR, Sur-Reply, Paper 26, 3-5. The Board should not narrowly construe the term “type of telemetry” as being limited to the “modality of energy transfer” of the telemetry because that construction reads into the claims a particular type of telemetry, even though neither the claims themselves nor the ’071 patent specification are so limited.

At the outset, the word “type” is inherently broad. It simply refers to a particular kind, class, or group. If one were to ask: “What ‘type of car’ do you drive,” one might respond a variety of ways, all valid “types”—e.g., gasoline or diesel, sedan or minivan, Audi or Kia, etc. For most objects, without being more specific, there are a similarly wide variety of “types.” The same is true for “telemetry,” as the ’071 patent specification itself makes clear. Although the claims refer to a “type of telemetry,” the ’071 patent does not define what it means as a “type of telemetry.” The specification does, however, characterize and distinguish its two telemetry links in a variety of ways. EX1003, ¶37.

For example, the ’071 patent initially describes its two “telemetry links” as a “bidirectional telemetry link 48,” *see e.g.*, EX1001, 8:51, and a “forward telemetry link 38,” *id*, 8:67 – 9:1. So one way the ’071 patent characterizes its two telemetry links is by their directionality. This is consistent with dependent claim 3, which requires the telemetry circuitry to support bi-directional FSK telemetry and, at a minimum, unidirectional OOK telemetry. EX1001, 20:53-54; *see* EX1003, ¶38.

The Patent Owner has argued that the modality of energy transfer is another way in which the ’071 patent purports to characterize its two telemetry links. EX1011, Berger, 123-125. For example, the ’071 patent states that “forward telemetry link 38 … is typically an inductive telemetry link.” EX1001, 9:1-3. So the purported modality of energy transfer is another way that the ’071 patent characterizes at least one of its telemetry links. The ’071 patent also states that “[t]he bidirectional telemetry link 48 is also known as … RF telemetry link.” EX1001, 8:65-67. But it is a little unclear whether the ’071 patent is referring to the particular frequency band of telemetry link within which the communication takes place—i.e., within a frequency band that includes the radio frequency band—or whether it more colloquially refers to non-inductive, wireless transmission of data or information via radio waves. Ex.1003, ¶38-39.

Nonetheless, a POSA reading the entire specification would understand the ’071 patent to describe only inductive telemetry communication for use between the BPB device and the external programmers, irrespective of the particular modulation scheme. EX1003, ¶¶38-39. For example, with respect to the telemetry antenna on the BPB device, the ’071 patent discloses only antenna 18, which it consistently describes as a “coil.” EX1001, 12:42-44, 13:63-14:5, 17:32-56; FIG.

21. Both telemetry links 38 and 48 are coupled to coil 18. EX1001, FIG. 1. Indeed, in FIG. 21, coil 18 is coupled to a telemetry module having both the FSK and OOK modulation schemes. EX1001, FIG. 21. Finally, a POSA would have recognized that the disclosed frequency for FSK telemetry—127 KHz, +/-8KHz, EX1001, 10:33-36—is indicative of near-field or inductive coupling. EX1003, ¶39. So it is likely that when the ’071 patent refers to an “RF telemetry link” (e.g., EX1001, 8:65-67) it is referring to communication falling anywhere within the RF spectrum, and not the modality of energy transfer.

As another example of the “type of telemetry,” the ’071 patent characterizes its two telemetry links by the keying or modulation scheme that they use. EX1003, ¶40. For example, the ’071 patent states that “[t]he bidirectional telemetry link 48 is also known as the FSK (Frequency Shift Key) telemetry link,” EX1001, 8:65-66, and that the forward telemetry link 38 “may use OOK-PWM (On/Off Keying-Pulse Width Modulation),” EX1001, 9:1-2. This is also consistent with dependent claim 2, where “the first telemetry type comprises Frequency Shift Keying (FSK), and wherein the second telemetry type comprises On/Off Keying (OOK).” EX1001, 20:49-51; EX1003, ¶40. It also appears consistent with dependent claim 3, which further limits the telemetry circuitry to circuitry related to these keying schemes. EX1001, 20:52-54; *see* EX1003, ¶40.

As yet another example, the ’071 patent distinguishes its two telemetry links by the functionality of the communication systems that they link together—that is, by the type of data or information they convey. EX1003, ¶41. For example, the ’071 patent specification states that “BPB device 10 receives commands and data from the remote control 40, clinician’s programmer 60, and/or charging system 39 via FSK (frequency shift keying) telemetry link 48.” EX1001, 9:64-67. And it states that “[t]he OOK (On-Off Keying) telemetry link 38 … allows commands and data to be sent by the charging system 39 to BPB device 10,” and “allows the charging system 39 to communicate with the BPB device 10 even when the BPB device 10 is not actively listening for a telemetry signal....” EX1001, 10:10-18; *see* EX1003, ¶41. This, too, is consistent with the dependent claims which suggest that the “second type of telemetry” is associated with battery charging operations. EX1001, 20:60-67.

This construction is also consistent with BSNC’s originally proposed construction of “telemetry” as simply the “transmission of information or data,” because different *types* of telemetry would thus refer to the transmission of different *types* of information or data—e.g., a “first type of telemetry” would be the communication between the clinician programmer and BPB device 10, and a “second type of telemetry” would be the communication between an external charging component and BPB device 10, with each communicating different types of data or information. *See* EX1003, ¶42.

* * *

In sum, the ’071 patent does not define what it means by “type of telemetry.” And as shown above, it characterizes and distinguishes its two telemetry links in at least four different ways—by (1) directionality, (2) modality of energy transfer (although the ’071 patent teaches only inductive transfer between the BPB and external devices), (3) keying or modulation scheme, and (4) functionality. None of these “types of telemetry” are inconsistent with the broadly claimed method, which requires no specific “type of telemetry” at all. EX1003, ¶¶37-43.

It would thus be a legal error for the Board to limit the “type of telemetry” to any specific structure or category of telemetry link. To do so would violate the fundamental claim construction cannon of not importing specific embodiments of the invention into the claims. *See Acceleration Bay, LLC v. Activision Blizzard Inc.*, 908 F.3d 765, 770 (Fed. Cir. 2018) (“We see no legal error in the Board’s refusal to import detailed structural information into the term ‘participant.’ … Neither the claims nor the specifications define or expressly describe the term in this manner….”); *see also*, *Blackbird Tech LLC v. ELB Elecs., Inc.*, 895 F.3d 1374, 1377 (Fed. Cir. 2018) (“The language in the specifications falls far short of the language we have found sufficient to limit claims to configurations described in the specification.")

In view of the above arguments, the Board should construe the "type of telemetry" in a way that encompasses each of the at least four different ways in which the '071 patent itself distinguishes its two "telemetry links," and consistent with BSNC's own broad construction of "telemetry." EX1003, ¶43.

# VI. GROUND 1: CLAIMS 1 AND 4-10 OF THE '071 PATENT ARE UNPATENTABLE UNDER 35 U.S.C. § 103 OVER TORGERSON198 AND TORGERSON756 IN VIEW OF TORGERSON883.

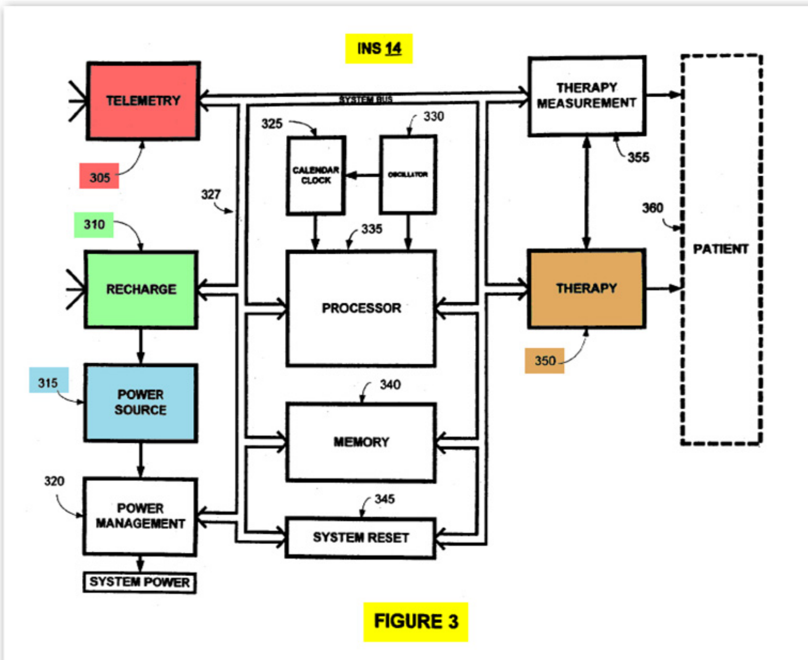
A POSA would have found claims 1 and 4–10 of the '071 patent to have been obvious in light of the disclosures of Torgerson198 (EX1005), Torgerson756 (EX1006) and Torgerson883 (EX1007). Section VI.A. below explains that the three related Torgerson patents disclose an implantable medical device that is operable by the claimed methods of the '071 patent. Section VI.B below explains that the Torgerson patents also disclose the claimed methods of the '071 patent. In Section VI.C., a detailed mapping of the Torgerson patents to the claims 1 and 4-10 of the '071 patent is provided.

## A. Torgerson198 and Torgerson756 in view of Torgerson883 disclose an IMD that is operable by claims 1 and 4-10 of the '071 patent

Torgerson198/756, in view of Torgerson883, disclose the claimed structural features of an IMD that can implement the claimed method.

### 1. Torgerson198 and Torgerson756 disclose most of the features of the claimed IMD.

In describing INS 14, Torgerson198 and Torgerson756 use the same Figures 1-4 in their specifications. A block diagram of INS 14 is provided in their Figure 3, which is reproduced below:




EX1005, EX1006, Fig. 3.

Like the IMDs defined by the claims of the ’071 patent, INS 14 of Torgerson198/756 includes an internal power source 315. It provides stimulation therapy via therapy module 350, and it communicates via telemetry with external devices in at least two separate ways—via telemetry module 305 and also via recharge module 310. EX1005, 6:12-20; EX1006, 6:10-19; EX1003, ¶¶59-61.

**(a) Telemetry module 305 employs circuitry for at least first type of telemetry.**

INS 14 includes a telemetry unit 305 (highlighted in red in Fig. 3 above), which provides bi-directional communications with an external device such as a physician programmer 30 or a patient programmer 35. EX1003, ¶¶61-64; EX1005, 6:12-20; EX1006, 5:60-67, 6:10-18, 6:50-52. Such devices are used to communicate with INS 14, for example, to program or make adjustments to the stimulation therapy that is provided by INS 14. EX1003, ¶62; EX1005, 2:13-19, 5:15-24, 5:63-6:6; EX1006, 5:60-67.

Torgerson756 describes those programmers as having "an antenna *or* coil locator that indicates when the telemetry head is aligned closely enough with the implanted INS 14 for adequate telemetry and charge coupling." EX1006, 8:48-51 (emphasis added), 5:67 – 6:3; EX1003, ¶63. Torgerson756 also teaches that, in recharge module 310 for example, "[t]he recharge coil can be the same coil as the telemetry antenna if multiplexed or the recharge coil can be separate from the telemetry antenna." EX1006, 7:49-52. So in at least one embodiment, telemetry module 305 can communicate with an external patient or physician programmers via its "telemetry antenna." EX1006, 6:50-54, 8:47-57; EX1003, ¶64. Use of a "telemetry antenna," in lieu of the separately described "recharge coil," indicates that one modality of energy transfer is via radio-wave telemetry (e.g., for wireless, non-inductive RF telemetry). EX1003, ¶64. In another embodiment, Torgerson756 describes a programmer where "[t]he recharge coil can be the same coil as the telemetry antenna" for communicating with telemetry module 305 in INS 14. EX1006, 7:49-52. Use of the recharge coil for communication indicates that a second modality of energy transfer could be via inductive telemetry. EX1003, ¶63.

Additional prior art confirms that it was well known at the time of invention that IMD's could communicate with external devices using a variety of energy transfer modalities. *See* EX1010, Mann, ¶42 . Mann's Figure 1 is exemplary:

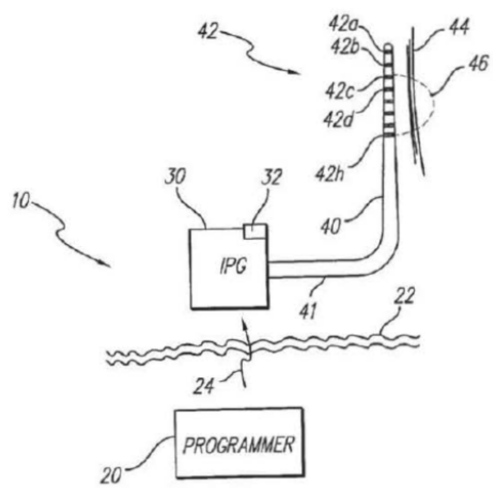



FIG. 1

In describing the "communications link" 24, Mann discloses that "[e]xemplary transcutaneous links 24 may be realized, e.g., through inductive coupling, RF transmission, magnetic coupling, optical coupling, and the like." EX1010, ¶42. Mann thus confirms that prior-art programmers could communicate with implantable devices—e.g., Mann's implantable pulse generator—using a variety of modalities of energy transfer. EX1003, ¶65; *see also* EX2020, 3:61-67

("Representative links that may be used to couple the programmer 60 with the IPG 40 include a radio frequency (RF) link, an inductive link, an optical link, or a magnetic link.").

*     *     *

In sum, telemetry unit 305 communicates bi-directionally with external physician or patient programmers to receive therapy adjustments and send feedback to the programmer. It does so using at least radio-wave coupling, but could also do so via inductive coupling. EX1003, ¶60-65. Telemetry unit 305 thus has circuitry that listens for at least a "first type of telemetry," whether the "type" of telemetry refers to directionality, the type of data or information transmitted, or the type of modality of energy transfer. *Id.*

**(b) Telemetry module 310 employs circuitry for a second type of telemetry, different from that used in telemetry module 305.**

INS 14 also includes a recharge module 310 (highlighted in green in Fig. 3 above). Recharge module 310 communicates with an external charger such as physician programmer 30 or patient programmer 35. EX1003, ¶66; EX1005, 6:12-20; EX1006, 7:41-45, 8:40-61, 9:35-53. Such external devices are also used to recharge the internal power source 315 of INS 14. EX1003, ¶66; EX1006, 8:40-61, 9:23-53. In one embodiment, recharge module 310 communicates to an external charger "via telemetry unit 305." EX1006, 9:46-47.

But recharge module 310 must also be able to communicate with an external component independently from telemetry unit 305 as well, since in the Power Off state, telemetry module 305 is shut down. EX1005, 9:Table B; EX1003, ¶¶66-67. And indeed it does. As Torgerson756 discloses, recharge module 310 includes a recharge regulation control unit 525 that can—separately from the telemetry unit 305—communicate with such external chargers by implementing a different communications technique. EX1006, 9:35-53; EX1003, ¶67. Torgerson756's Figure 5 is illustrative:

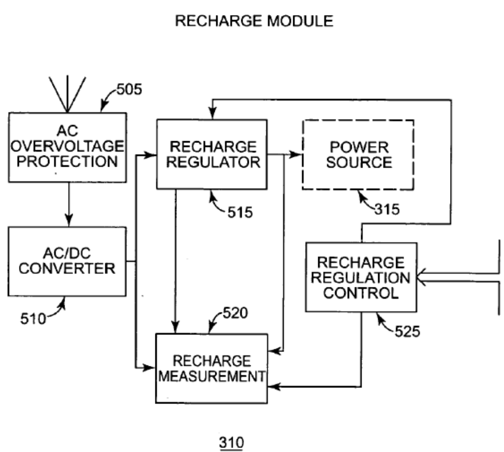



**Fig. 5**

Torgerson756 gives a precise example of how recharge module 310 would operate in this alternate embodiment. Specifically, it discloses that "the recharge regulation control unit 525 communicates with the external component *by modulating the load on the recharge coil*." EX1006, 9:49-53 (emphasis added). Further, "[t]his change in the load can then be sensed in the circuitry driving the source coil of the external component*." Id*. Modulating a load on a coil is the hallmark of an inductive modality of energy transfer. EX1003, ¶67-68. Recharge module 310 thus employs circuitry that uses a second type of telemetry, different and independent from that used in telemetry unit 305, through its recharge coil using an inductive telemetry link, for use in recharge operations. *See id*.

Recharge module 310 thus employs a "second type of telemetry," different from the first type of telemetry, irrespective of whether the "type" of telemetry refers to directionality, the type of data or information transmitted, or the type of modality of energy transfer.

#### (c) Patent Owner BSNC agrees that Torgerson756 discloses using a second type of telemetry in recharge module 310.

In the related '1899IPR on the '241 parent patent, Petitioner's expert Dr. Berger was forced to concede that Torgerson756 relies on two telemetry types when this second embodiment of recharge module 310 is employed:

> Q. Okay. Is it still your position that Torgerson '756 does not disclose a second type of telemetry in that example?
>
> ….
>
> THE WITNESS: No. But, it is possible that that makes use of a different form of telemetry outbound to the external device.
>
> Q. So, [Torgerson '756] does use a second type of telemetry for battery charging operations. Torgerson '756 discloses at least two

> types of telemetry to communicate with the external module. Is that correct?
>
> ….
>
> THE WITNESS: I think in that embodiment, it is possible that the Torgerson ’756 may use two types of telemetry to, for the internal device to communicate outward to the external device.

EX1011, 139:25 – 140:20.

Torgerson756’s recharge module 310 (via recharge regulation control unit 525) thus, in at least one embodiment, uses a second type of telemetry for recharging operations that is different than the first type of telemetry that telemetry unit 305 uses for programming operations. EX1003, ¶¶66-68.

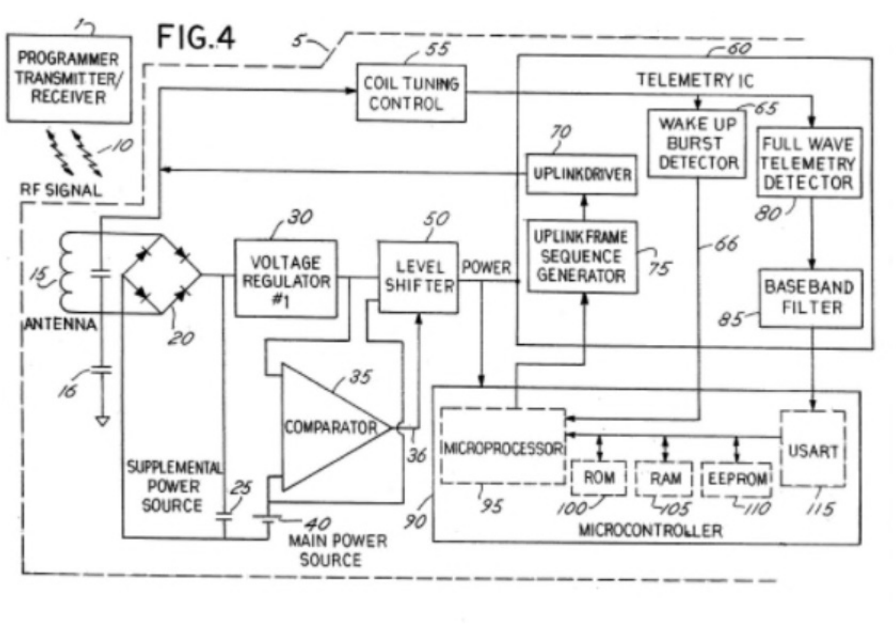
#### 2. Torgerson883 renders obvious the one feature not explicitly disclosed by Torgerson198 and Torgerson756

Although Torgerson756 explicitly discloses that telemetry unit 305 performs bi-directional communication, EX1006, 6:50-52, it does not explicitly disclose that recharge module 310 (via recharge regulation control unit 525) performs bi-directional communication so as to receive (or listen for) communication from an external device. EX1003, ¶69. Torgerson756 does, however, suggest that when power source 315 “is almost depleted of energy” the “external component may deliver an initial large burst of energy to ‘wake up’ the power source 315 and the recharge module 310.” EX1006, 8:62-67. If that “wake up” burst communicates, for instance, a command to the implanted device, then the implanted device would also be listening for a second type of telemetry. Torgerson883 confirms that position. EX1003, ¶¶69-70.

Torgerson883 (EX1007), a related patent, discloses one such known bi-directional communication technique used by a charging circuit of an IMD. EX1003, ¶¶71-72; EX1007, 5:17-57. In particular, Torgerson883 describes how a "wake up burst" of energy from an external charging component can deliver both power *and* telemetry to an IMD operating in a depleted state, such as Torgerson198's Power Off mode. *See* EX1003, ¶¶69-70.

Specifically, Torgerson883 discloses a charging circuit 20 of an IMD that is able to receive telemetry signals from an external device and charge a supplemental power source 25 when its main internal power source has been depleted. EX1003, ¶71; EX1007, 5:17-57, 7:24-48, 8:10-20, 12:53-65. By charging the supplemental power source 25, which may be a small capacitor, the charging circuit 20 allows the IMD to have sufficient power to perform bi-directional communications with the external device even when its main power source has been depleted. EX1003, ¶72; EX1007, 5:17-57, 7:24-48, 8:10-20, 12:53-65. Torgerson883 discloses that by doing so, the IMD is advantageously able to always perform bi-directional communications with external devices to enable medical personnel to interrogate the IMD and obtain crucial information from the device at all times. EX1003, ¶71-72; EX1007, 2:24-39, 10:57-67.

Torgerson883's Figure 4 is illustrative:




Central to Torgerson883's operation is its "wake up burst." Torgerson883 describes in detail what Torgerson756 alludes to when it discloses that when its power source 315 is almost depleted of energy, "the external component may deliver an initial large burst of energy to 'wake up' the power source 315 and the recharge module 310." EX1006, 8:62-67; EX1003, ¶¶73-74.

Torgerson883's "wake up burst" is a dual purpose signal. It delivers both energy to charge a supplemental power source, and it functions as telemetry in the form of a command to, at a minimum, "wake up" the INS. With respect to delivering energy, Torgerson883 discloses that when the main power source 40 is depleted, "RF programmer 1 transmits a wake up burst RF signal 10" and "[e]lectromagnetic energy is delivered as a result of the transmission of RF signals 10." EX1007, 7:51-55; EX1003, ¶75.

Torgerson883's wake up burst also functions as telemetry in the form of a command to which the INS responds. Torgerson883 teaches that "[t]he wake-up burst, or RF signal 10, will then be detected by the wake-up burst detector 65, which will send an interrupt to the controller 95." EX1007, 8:48-50, 6:37-41. The controller 95 then "enters a high or active state due to the RF transmissions 10 from the RF programmer 1" causing the controller 95 to assemble and send device and status information relating to the implanted medical device 5." EX1007, 8:51-9:1, 9:1-6; EX1003, ¶76.

In the related '1899IPR, BSNC's expert Dr. Berger confirmed that Torgerson883 provides bi-directional telemetry communication—he testified that when Torgerson883's wake up burst is received, it commands the microprocessor to wake up and communicate back to the external charging component:

> Q. Doesn't Torgerson '883 receive telemetry from the external charging component in the form of the wake up burst?
>
> ….
>
> THE WITNESS: It receives telemetry and that telemetry includes wake up burst.
>
> BY MR. WRIGHT: Q. Right. And what does that wake up burst do?
>
> A. I believe it wakes up the microprocessor.

Q. Right. And it commands it, am I correct in understanding that it basically commands the microprocessor to, thereafter, transmit device information, for instance, back out to the external charging component?

….

THE WITNESS: I think the micro, it wakes up the microprocessor to do many things, including the ability to communicate via telemetry.

BY MR. WRIGHT: Q. To the external charging component, right?

….

THE WITNESS: To the external device which is both a transmitter receiver and a charging unit.

EX1011, 142:8–143:12.

It would have been obvious for a POSA to incorporate the teachings of Torgerson883 into the recharge module 310 of INS 14. EX1003, ¶¶71, 77-79. Recharge module 310 of INS 14 would be enabled to perform bi-directional communications with an external charger even when its main internal power source 315 becomes depleted, by listening for the "wake up burst." *Id.* Such bi-directional communications would enable an external charger to interrogate INS 14 and obtain crucial information that INS 14 includes a depleted power source that can be recharged wirelessly even when the patient's condition does not allow the patient to provide that information directly to medical personnel. *Id.*; EX1007, 2:24-39, 10:57-67.

A POSA also would have had a reasonable expectation that the teachings of Torgerson883 would be compatible with the INS 14 of Torgerson198 and Torgerson756. EX1003, ¶78. For example, Torgerson756 discloses that recharge module 310 of INS 14 should operate similarly to the recharging circuit 20 of Torgerson883. EX1006, 8:62-9:2; EX1003, ¶78. Torgerson756 discloses that when INS 14's power source 315 is almost depleted, its recharge module 310 should take on an initial burst of energy from an external device to obtain enough power to wake up and perform its functions—e.g., as a wake-up burst. EX1006, 8:62-9:2; EX1003, ¶78. Accordingly a POSA would have understood that recharge module 310 of INS 14 would have been modifiable to include a supplemental power source as taught by Torgerson883. EX1003, ¶79.

In sum, the INS 14 of Torgerson198 and Torgerson756 as modified by the above teachings of Torgerson883 disclose an IMD that includes (1) a power source 315, (2) a telemetry unit 305 that performs a first type of telemetry, (e.g., radio-wave telemetry) in bi-directional communications with an external device, which programs the stimulation therapy provided by INS 14, and (3) a recharge module 310 that performs a second type of telemetry (e.g., inductive telemetry) in bi-directional communications with an external charger, which wirelessly recharges the internal power source 315 of INS 14. The circuitry of the INS 14 of Torgerson198 and Torgerson756 as modified by the above teachings of Torgerson883 thus receives both a first and second type of telemetry, irrespective of whether the "type" of telemetry refers to directionality, the type of data or information transmitted, or the type of modality of energy transfer. EX1003, ¶¶80-81.

### B. Torgerson198 discloses the claimed methods of the '071 patent.

The claims of the '071 patent are all directed to methods that control the operation of an IMD by enabling and disabling the stimulation and telemetry features of the IMD based on the voltage level of its internal power source. Torgerson198 discloses these methods.

More specifically, Torgerson198 discloses a method in which INS 14 is operated in one of three different states, with each state having a different set of components (and therefore features) enabled, depending on whether the voltage level of its power source 315 is above, below, or between two threshold values. *Id*. It would have also been obvious to modify Torgerson198 to operate in only two states depending on whether the voltage level of its power source 315 is above or below a single threshold value, which also renders the claims obvious. Before providing a detailed claim-by-claim mapping, we provide an overview below of how Torgerson198 discloses the claimed methods.

During the IPR trial on the related ’241 patent, the Patent Owner did not challenge Petitioner’s mapping to the challenged claims of either the three-state operation, or obvious two-state operation of Torgerson’s disclosed methods.

#### 1. Torgerson198 disclose a three state method of enabling and disabling the stimulation and telemetry features of an implantable medical device.

Torgerson198 discloses a method of operating INS 14 in one of three different states: normal operation, low power, and power off. EX1003, ¶85; EX1005, 9:14-19. For each operating state, Torgerson198 discloses that a different set of components within INS 14 is enabled as shown in its Table B (reproduced below with annotations added). EX1003, ¶85; EX1005, 9:31-60. As discussed above, those components include telemetry unit 305 (which receives a first type of telemetry), recharge module 310 (which receives a second type of telemetry), and therapy module 350 (which provides stimulation). EX1003, ¶85; EX1005, 9:31-60.

TABLE B

| State of Operation | Components On | Components Off | |
|---|---|---|---|
| Normal Operation | All | None | |
| Low Power | Power Management 320<br>Recharge 310<br>Telemetry 305<br>Oscillator 330<br>Calendar Clock 325<br>Volatile Memory<br>High Freq Protection Circuit<br>High Energy Protection Circuit<br>System Shutdown/ POR 345 | Therapy 350<br>Measurement 355<br>Permanent Memory<br>Non-volatile Memory<br>EEPROM<br>Memory Management<br>System Bus 327<br>Processor 335 | T1 |
| Power Off | Recharge 310<br>High Freq. Protection Circuit<br>High Energy Protection Circuit | Therapy 350<br>Measurement 355<br>Permanent Memory<br>Non-volatile Memory<br>EEPROM<br>Memory Management<br>System Bus 327<br>Processor 335<br>Power Management 320<br>Telemetry 305<br>Oscillator 330<br>Calendar Clock 325<br>Volatile Memory<br>System Shutdown/POR 345 | T2 |

EX1005, 9:34-60; EX1003, ¶86.

As shown in Table B above, when INS 14 operates in the "normal operation" state, all of its components are enabled. EX1003, ¶86; EX1005, 9:31-60. When INS 14 operates in the "power off" state, therapy module 350 (*i.e.*, stimulation therapy) and telemetry unit 305 (*i.e.*, reception of/listening for the first telemetry type) are disabled while recharge module 310 (*i.e.*, reception of/listening for the second telemetry type) remains enabled. EX1003, ¶86; EX1005, 9:31-60. In the intermediate "low power" state, therapy module 350 is disabled while both telemetry unit 305 and recharge module 310 are enabled. EX1003, ¶86; EX1005, 9:31-60.

Torgerson198 further discloses that INS 14 transitions between the three operating states based on the voltage of its power source 315. EX1003, ¶87; EX1005, 8:3-19, 8:47-49, 9:14-30, 9:60-10:18. For example, if the voltage level of power source 315 indicates that it is nearly fully charged, INS 14 is operated in the "normal operation" state. EX1005, 8:3-11, 9:31-60. If the voltage of power source 315 thereafter falls below a transition point T1, INS 14 is operated in the "low power" state. EX1005, 8:3-19. If the voltage of power source 315 thereafter falls further below a second transition point T2, INS 14 is operated in the "power off" state. EX1005, 8:47-49, 9:14-30; *see* EX1003, ¶87.

If the power source 315 is recharged and its voltage level increases above transition point T2, INS 14 is transitioned to operate in the "low power" state again. EX1005, 9:14-30, 9:60-10:11. If the power source 315 is further recharged and its voltage increases above transition point T1, INS 14 is transitioned to operate in the "normal operation" state again. EX1005, 10:12-17. Thus the "transition points T1 and T2 provide boundaries for the three states of operation: (1) normal operation state; (2) low power state; and (3) power off state" of INS 14. EX1005, 9:14-19; EX1003, ¶88.

#### (a) Independent claim 1

Torgerson198's method of operating INS 14 in one of three different states discloses the method of the independent claim 1 of the '071 patent. EX1003, ¶89.

The independent claims of the ’071 patent cover methods that control the operation of an IMD by listening for two types of telemetry if the voltage level of its internal power source falls below a first threshold, discontinuing listening for the first telemetry type while continuing listening for the second telemetry type. *Id.* Torgerson198’s method of operating INS 14 in three operating states discloses the independent claims of the ’071 patent when either the transition point T1 or T2 is considered the claimed “first threshold.” *Id.*

More specifically, if the voltage level of power source 315 of INS 14 is at a level that is above transitional points T1 and T2 because, for example, the power source is nearly fully charged, INS 14 will be operating in the “normal operation” state. EX1003, ¶90. In the “normal operation state,” all of the components of INS 14 including therapy module 350 (*i.e.*, stimulation therapy), telemetry unit 305 (*i.e.*, reception of the first telemetry type), and recharge module 310 (*i.e.*, reception of the second telemetry type) are enabled. *Id.*; EX1005, 9:30-60. Accordingly regardless of whether the claimed “first threshold” is the transition point T1 or T2, Torgerson198 discloses that if the power source 315 is nearly fully charged to have a voltage above the claimed “first threshold,” stimulation and listening for two different types of telemetry will be enabled. EX1003, ¶90.

Furthermore if the voltage level of power source 315 of INS 14 is at a level that is below transitional points T1 and T2 because, for example, the power source is nearly depleted, INS 14 will be operating in the “power off” state. EX1003, ¶91. In the “power off” state, therapy module 350 (*i.e.*, stimulation therapy) and telemetry unit 305 (*i.e.*, reception of the first telemetry type) are disabled while recharge module 310 (*i.e.*, reception of the second telemetry type) remains enabled. *Id.* Thus regardless of whether the claimed “first threshold” is the transition point T1 or T2, Torgerson198 discloses that if the power source 315 becomes nearly depleted to have a voltage that falls below the claimed “first threshold,” listening for one of the two types of telemetry will be disabled (e.g., telemetry unit 305), while recharge module 310 continues listening for the second type of telemetry (e.g., a wake up burst), as required by the independent claim of the ’071 patent. *Id.*

Accordingly Torgerson198’s method of operating INS 14 in three operating states discloses, at least, independent claim1 of the ’071 patent when either of the transition points T1 or T2 is considered the claimed “first threshold.”

**(b) Dependent claims 5 and 10**

Torgerson198’s method of operating INS 14 in three different states also discloses the methods of the dependent claims 5 and 10 when the transition point T2 is considered the claimed “first threshold.” EX1003, ¶93. As discussed in Section III.B above, dependent claims 5–8 and 10 each specify another step of the method of the independent claim. That additional step requires taking some action based on a first or second voltage threshold.

For claim 5, the step is resuming listening for the first telemetry type after it has been discontinued if the voltage of the power source later exceeds the claimed "first threshold." *Id.*, ¶94. Similarly, claim 10 recites that the implantable medical device is configured to provide electrical stimulation to a patient, and the method comprises enabling stimulation while listening for the first telemetry type, and disabling stimulation if the voltage falls below the first threshold. As discussed above, if the voltage of INS 14's power supply 315 falls below transition point T2, INS 14 will transition to the "power off" state in which therapy module 350 (*i.e.*, stimulation therapy) and telemetry unit 305 (*i.e.*, reception of the first telemetry type) are disabled. *Id.*, ¶94; EX1005, 9:30-60. Thereafter, if INS 14's power supply is recharged to become fully charged, INS 14 will transition from the "power off" state to the "low power" state, and then finally to the "normal operation" state. *Id.* In transitioning from the "power off" state to the "normal operation" state, therapy module 350 (*i.e.*, stimulation therapy) and telemetry unit 305 (*i.e.*, reception of the first telemetry type) will both be re-enabled. EX1003, ¶95. Thus Torgerson198's method of operating INS 14 in three operating states discloses the dependent claims 5 and 10 of the '071 patent when the transition point T2 is considered the claimed "first threshold." *Id.*

**(c) Dependent claims 6 and 7**

Torgerson198's method of operating INS 14 in three different states additionally discloses the methods of the dependent claims 6 and. EX1003, *Id.*, ¶96. As discussed in Section III.B above, dependent claims 6 and 7 specify an additional step of the method of the independent claim. *Id.*. That step in claim 6 requires detecting a charging field and continuing to listen for the second telemetry type if the voltage falls below a second threshold lower than the first threshold. For claim 7, if the voltage falls below a second threshold lower than the first threshold, the method includes disabling circuitry in the implantable medical device except circuitry required for recharging the battery.

Torgerson198's method of operating INS 14 in three operating states discloses dependent claims 6 and 7 when transition point T1 is considered the claimed "first threshold," and transition point T2 is considered the claimed "second threshold." *Id.*, ¶97. As discussed above, if the voltage of INS 14's power supply 315 falls below transition point T2 (which is lower than transition point T1), INS 14 will operate in the "power off" state in which therapy module 350 (*i.e.*, stimulation therapy) and telemetry unit 305 (*i.e.*, reception of the first telemetry type) are disabled. *Id.*; EX1005, 9:30-60. Thereafter, if INS 14's power supply is recharged, via continuing to listen for the second telemetry type and detecting a charging field so as to cause INS 14 to transition back to the "normal operation" state again, its therapy module 350 (*i.e.*, stimulation therapy) and telemetry unit 305 (*i.e.*, reception of the first telemetry type) will both be re-enabled. EX1005, 9:30-60; EX1003, ¶98. And in the "power off" state, all circuitry is disabled in the implantable medical device except circuitry required for recharging the battery (e.g., recharge module 310, and the high frequency and high energy protection circuits). EX1005, 9:30-60; EX1003, ¶¶98-99.

Thus Torgerson198's method of operating INS 14 in three operating states discloses detecting a charging field and continuing to listen for the second telemetry type, and disabling circuitry in the implantable medical device except circuitry required for recharging the battery until INS 14 is recharged (as required by dependent claims 6 and 7, respectively) when T1 is considered the claimed "first threshold" and T2 is considered the claimed "second threshold." EX1003, ¶100-101.

**(d) Remaining dependent claims**

Other dependent claims 4, 8, and 9 only narrow the types of IMDs operated on by the method of the independent claim, and that programming and recharging is received by a clinician (claim 8). As discussed above in Section III.A, those IMDs are disclosed by the INS 14 of Torgerson198 and Torgerson756 in view of Torgerson883.

*    *    *

Thus the three-state method of operating INS 14 as taught by the combination of Torgerson198, Torgerson756, and Torgerson883 disclose claims 1, and 4-10 of the ’071 patent. EX1003, ¶89-101.

#### 2. Torgerson198 also makes obvious a two state method of enabling and disabling the stimulation and telemetry features of an implantable medical device.

As Torgerson198 states, a POSA would have “appreciate[d] that other power-up and power-down techniques may be implemented” based on Torgerson198’s teachings of operating an INS 14 in three states. EX1005, 11:4-6. For example, a POSA would have found it obvious to modify Torgerson198’s method of operating INS 14 in three states (normal operation, low power, and power off) using two threshold values to operate in only two states—normal operation and power off—using a single threshold value. EX1003, ¶102. Petitioner Nevro explains this obvious variation to Torgerson198 in the event that the claims are interpreted to require the telemetry and stimulation features be enabled or discontinued whenever the voltage is above or below the claimed “first threshold.”

Specifically, a POSA would have recognized that Torgerson198’s “low power” state can be omitted because it serves only as a transitional state between the “normal operation” and “power off” states. EX1003, ¶103. A POSA would have been motivated to modify INS 14 to operate in only two states to simplify the operation and implementation of INS 14, thereby minimizing potential engineering, manufacturing, or programming defects in INS 14. *Id.* Additionally a POSA would have recognized that simplifying Torgerson198's method would not have dramatically impacted the functionality, safety or effectiveness of INS 14. *Id.*

Torgerson198's obvious method of operating INS 14 in only two states is shown in a modified Table B below, with the intermediate "low power" state omitted.

Modified Two State TABLE B

| State of Operation | Components On | Components Off |
|---|---|---|
| Normal Operation | All | None |
| Power Off | Recharge 310<br>High Freq. Protection Circuit<br>High Energy Protection Circuit | Therapy 350<br>Measurement 355<br>Permanent Memory<br>Non-volatile Memory<br>EEPROM<br>Memory Management<br>System Bus 327<br>Processor 335<br>Power Management 320<br>Telemetry 305<br>Oscillator 330<br>Calendar Clock 325<br>Volatile Memory<br>System Shutdown/POR 345 |

ST

EX1005, 9:34-60.

With only two states, a POSA would have recognized that only a single transition point, referred to as ST in the annotated figure above, would be needed for transitioning the operating state of INS 14 between the "normal operation" and "power off" states. EX1003, ¶105. Like the three-state method of Torgerson198, a

POSA would have recognized that the two-state method would (1) monitor the voltage of power source 315 of INS 14, (2) transition INS 14 to operate in the "normal operation" state if the voltage of the power source 315 becomes above ST and (3) transition INS 14 to operate in the "power off" state if the voltage falls below ST. *Id.*

A POSA would have appropriately selected a voltage value for ST that would have allowed for all of the components of INS 14 to be enabled in the "normal operation" state. *Id.*, ¶106. For example, for a certain type of 4V battery disclosed by Torgerson198 as being a suitable power source for an INS, a POSA would have selected a voltage value that is above 2.75 volts for ST. *Id.*; EX1005, 2:47-58. Doing so would have enabled INS 14 to provide stimulation in the "normal operation" state without damaging the battery. EX1003, ¶105; EX1005, 2:47-58.

#### (a) Independent claim 1

This obvious two-state method of operating INS 14 also discloses the method of the independent claim 1, of the '071 patent when the transition point ST is considered the claimed "first threshold." EX1003, ¶107-108. For example, whenever the voltage of power source 315 is above transition point ST, INS 14 is operated in the "normal operation" state in which all of its components including therapy module 350 (*i.e.*, stimulation therapy), telemetry unit 305 (*i.e.*, reception of the first telemetry type), and recharge module 310 (*i.e.*, reception of the second telemetry type) are enabled. *Id.*, ¶108; EX1005, 9:30-60. And whenever the voltage of power source 315 is below ST, INS 14 is operated in the "power off" state in which therapy module 350 (*i.e.*, stimulation therapy) and telemetry unit 305 (*i.e.*, reception of the first telemetry type) are disabled while recharge module 310 (*i.e.*, reception of the second telemetry type) remains enabled. EX1005, 9:30-60. Accordingly the two-state method of operating INS 14 discloses the independent claims of the '071 patent when ST is considered the claimed "first threshold."

**(b) Dependent claims 5 and 10**

The obvious two-state method of operating INS 14 also discloses dependent claims 5 and 10 when the transition point ST is considered the claimed "first threshold." EX1003, ¶¶109-110. Dependent claims 5 and 10 add an additional step to the method of the independent claim. For claim 5, the step is resuming listening for the first telemetry type after it has been discontinued if the voltage of the power source later exceeds the claimed "first threshold." *Id.* Similarly, claim 10 recites that the implantable medical device is configured to provide electrical stimulation to a patient, and the method comprises enabling stimulation while listening for the first telemetry type, and disabling stimulation if the voltage falls below the first threshold. *Id.* Whenever the voltage of INS 14's power supply 315 falls below ST, INS 14 will transition to the "power off" state in which therapy module 350 (*i.e.*, stimulation therapy) and telemetry unit 305 (*i.e.*, reception of the first telemetry type) are disabled. EX1005, 9:30-60; EX1003, ¶110.

Thereafter, whenever INS 14's power supply is recharged such that the voltage of power supply 315 exceeds ST, INS 14 will transition back to the "normal operation" state again. EX1005, 9:30-60; EX1003, ¶111. In the "normal operation" state, both therapy module 350 (*i.e.*, stimulation therapy) and telemetry unit 305 (*i.e.*, reception of the first telemetry type) of INS 14 will be re-enabled. EX1005, 9:30-60; EX1003, ¶111. Accordingly the two-state method of operating INS 14 discloses dependent claims 5 and 10 of the '071 patent when ST is considered the claimed "first threshold." EX1003, ¶¶109-111.

**(c) Remaining dependent claims**

Other dependent claims 4, 8, and 9 only narrow the types of IMDs operated on by the methods of the independent claims, and that programming and recharging is received by a clinician (claim 8). As discussed above in Section III.A, those IMDs are disclosed by the INS 14 of Torgerson198 and Torgerson756 in view of Torgerson883. Thus, the obvious two-state method of operating INS 14 as taught by the combination of Torgerson198, Torgerson756, and Torgerson883 discloses claims 1, and 4-10 of the '071 patent.

### C. Independent claim 1

Having shown that the prior art (1) discloses an IMD that operable by the claimed methods, and (2) discloses or renders obvious the claimed method, Petitioner now specifically maps the claims to the cited art. This mapping supplements the arguments and proof outlined above in Section VI.A-B.

#### 1. "A method for controlling an implantable medical device, the device having telemetry circuitry to receive both a first type of telemetry and to receive a second type of telemetry, the method comprising:"

Torgerson198/756 discloses that INS 14 is a device, which when implanted within a patient, provides "precise, electrical pulses to the spinal cord, brain, or neural tissue to provide […] therapy." EX1005, 2:13-15, 4:38-40; EX1006, 2:25-27, 4:34-36; EX1003, ¶114. Accordingly INS 14 is an implantable medical device. Torgerson756 also discloses two modules – telemetry module 305 and recharge module 310 – each of which has separate telemetry circuitry for communicating independently with external modules for different purposes. *See* Section VI.A.1 *supra*. Torgerson198, in turn, discloses a method for controlling the operation of INS 14. In particular, Torgerson198 discloses a power management method, which controls the overall operation of INS 14 by enabling and disabling various components of INS 14 based on the energy level of the INS 14's internal power source 315. *See* Section VI.B *supra*. Torgerson198 and Torgerson756, in view of

Torgerson883, thus meet every limitation of the preamble of independent claim 1. EX1003, ¶¶114-119.

### 2. "listening for the first … telemetry type[];"

Torgerson198 and Torgerson756 disclose that INS 14 includes a telemetry unit 305 (EX1005, 6:12-20) that listens for a first type of telemetry from an external physician programmer 30 and patient programmer 35. *See* Section VI.A.1(a) *supra*; EX1003, ¶¶120-125; EX1006, 6:50-52.

### 3. "listening for the … second telemetry type[]"

Torgerson198 and Torgerson756 disclose that INS 14 includes a recharge module 310, EX1005, 6:12-20, that includes a recharge regulation control unit 525, EX1006, 7:41-59, that communicates with external devices using a different communications technique than the one provided by telemetry unit 305, EX1006, 9:46-53. *See* Section VI.A.1(b) *supra*; EX1003, ¶¶126-130. Torgerson198 and Torgerson756, however, do not disclose explicitly that recharge module 310 of INS 14 listens for  telemetry (*i.e.*, data or communications) from such an external device. *Id.* But because Torgerson756 explains that a POSA would have "appreciate[d] that other communication techniques" other than that utilized by telemetry unit 305 can be employed by the recharge regulation control unit 525 of recharge module 310, EX1006, 9:35-53, a POSA would have considered other such techniques for recharge module 310. EX1003, ¶126.

Torgerson883 discloses one such communication technique utilized by a charging circuit of an IMD. *Id*. *See* Section VI.A.2 *supra*. Torgerson883 discloses a charging circuit 20 that can receive telemetry signals from an external device and charge a supplemental power source 25 when the IMD's main power source has been depleted. EX1003, ¶128-129; Ex.1007, 5:17-57, 7:24-48, 12:53-65. By charging the supplemental power source 25, the charging circuit 20 allows the IMD to have sufficient power to perform bi-directional communications with an external device even when its main power source has been depleted. Ex.1007, 5:17-57, 7:24-48, 12:53-65; Ex.1003, ¶128-129. As discussed in Section VI.A.2 above, it would have been obvious for a POSA to incorporate such teachings of Torgerson883 into the recharge module 310 of INS 14.

As argued above in Section VI.A.2, the proposed combination thus listens for a "second telemetry type," irrespective of whether the second telemetry type is defined by a different modality of energy transfer (e.g., a wake up burst transmitted via an inductive telemetry link) or by a different type of transmitted information or data (e.g., information related to charging operations).

#### 4. "monitoring a voltage of a power source within the implantable medical device; and"

Torgerson198 discloses that INS 14 includes a processor 335 and a power source measurement unit 515, EX1005, 6:12-20, 7:26-29, that monitors the voltage of its internal power source 315, which can be for example a rechargeable battery, *id.*, 3:18-29, 6:12-20, 7:48-8:2. EX1003, ¶¶132-135. Torgerson198 explains that "power source measurement unit 515 measures the power source 315 and […] provides that information to the processor 335 [… which] in turn, determines how the energy from the power source 315 will be allocated […] as a function of the [power source 315] battery voltage." EX1005, 7:57-8:2.

Although Torgerson198 discloses that processor 335 is put to sleep when the voltage of power source 315 falls below a level that does not allow for normal operation, *id.*, 8:10-14, 8:33-34, a POSA would have recognized from other disclosures in Torgerson198 that processor 335 would still have been woken from time to time to monitor the voltage of power source 315. EX1003, ¶134. For example, Torgerson198 discloses that when the recharging process of INS 14 has stopped, processor 335 is woken to check whether the power source 315 has been sufficiently charged to allow for normal operation to be resumed. *Id.*; EX1005, 10:18-19. Torgerson198 also discloses that if the energy level of INS 14's power source drops further after normal operation cannot be supported, the processor of INS 14 must operate to prepare a shutdown of INS 14. EX1005, 3:18-29; EX1003, ¶135. Thus a POSA would have understood that even when processor 335 is placed into sleep mode, processor 335 would have been made operational from time to time to monitor the voltage of power source 315 and control the operation of INS 14. EX1003, ¶135.

### 5. "if the voltage falls below the first threshold, discontinuing listening for the first telemetry type while continuing listening for the second telemetry type."

Torgerson198 discloses a method of operating INS 14 in three operating states. As explained above in Section VI.B.1(a), Torgerson198 discloses two transition points T1 and T2 that are compared against the voltage of INS 14's power source 315 to place INS 14 into one of the three operating states. EX1005, 8:30-9:16; EX1003, ¶136. Table B of Torgerson198 (reproduced below) depicts the three operating states of INS 14.

TABLE B

| State of Operation | Components On | Components Off | |
|---|---|---|---|
| Normal Operation | All | None | T1 |
| Low Power | Power Management 320<br>Recharge 310<br>Telemetry 305<br>Oscillator 330<br>Calendar Clock 325<br>Volatile Memory<br>High Freq Protection Circuit<br>High Energy Protection Circuit<br>System Shutdown/ POR 345 | Therapy 350<br>Measurement 355<br>Permanent Memory<br>Non-volatile Memory<br>EEPROM<br>Memory Management<br>System Bus 327<br>Processor 335 | T2 |
| Power Off | Recharge 310<br>High Freq. Protection Circuit<br>High Energy Protection Circuit | Therapy 350<br>Measurement 355<br>Permanent Memory<br>Non-volatile Memory<br>EEPROM<br>Memory Management<br>System Bus 327<br>Processor 335<br>Power Management 320<br>Telemetry 305<br>Oscillator 330<br>Calendar Clock 325<br>Volatile Memory<br>System Shutdown/POR 345 | |

EX1005, 9:34-59.

Torgerson198 discloses that if the voltage of power source 315 falls below both transition points T1 and T2, INS 14 is made to operate in the "power off" state. EX1005, 8:30-9:16; EX1003, ¶137. In the "power off" state, therapy module 350 and telemetry unit 305 are both disabled while recharge module 310 remains enabled, and thus still listens for the second telemetry type. *Id*; *see also* Section VI.B.1(a). This is because telemetry unit 305 listens for a first type of telemetry, recharge module 310 listens for a second type of telemetry, and therapy module 350 provides stimulation. Section VI.A.1(a)-(b). Thus if either T1 or T2 is considered the claimed "first threshold" of this limitation, Torgerson198 discloses that if the voltage of power source 315 falls below the claimed "first threshold," INS 14 discontinues listening for a first type of telemetry, while recharge module 310 continues listening for the second type of telemetry. EX1003, ¶138.

And to the extent that the Board determines that claim 1 requires only two states of operation, Torgerson198's obvious two-state method of operating INS 14 also discloses this step. For ease of reference, modified Table B is depicted below to illustrate the obvious two-state variant.

Modified Two State TABLE B

| State of Operation | Components On | Components Off |
|---|---|---|
| Normal Operation | All | None |
| Power Off | Recharge 310<br>High Freq. Protection Circuit<br>High Energy Protection Circuit | Therapy 350<br>Measurement 355<br>Permanent Memory<br>Non-volatile Memory<br>EEPROM<br>Memory Management<br>System Bus 327<br>Processor 335<br>Power Management 320<br>Telemetry 305<br>Oscillator 330<br>Calendar Clock 325<br>Volatile Memory<br>System Shutdown/POR 345 |

ST

*See supra*, Section VI.B.2.

In the obvious method of operating INS 14 in two states, whenever the voltage of power source 315 falls below ST, INS 14 operates in the "power off" state. *See supra,* Section VI.B.2. As shown above, in the "power off" state, therapy module 350 and telemetry unit 305 are disabled while recharge module 310 remains enabled and thus remains listening for the second type of telemetry. Thus if ST is considered the claimed "first threshold" of this limitation, the obvious method of Torgerson198 discloses that whenever the voltage of power source 315 falls below the claimed "first threshold," INS 14 operates in the "power off" state, which discontinues listening for a first type of telemetry. *See supra,* Section VI.B.2.

*   *   *

In summary, Torgerson198 discloses a method of operating INS 14 in three states. EX1003, ¶¶136-138. For the three-state method, Torgerson198 discloses this limitation when either T1 or T2 is considered the claimed "first threshold." *Id.* Torgerson198 also discloses an obvious method of operating INS 14 in only two states. EX1003, ¶¶139-140. For the two-state method, this limitation is satisfied when the ST is considered the claimed "first threshold." *Id.* Either way, the limitation is satisfied.

### D. Claim 4

#### 1. "The method of claim 1,"

*See supra,* Section VI.C.

#### 2. "wherein the first threshold is stored in a first register in the implantable medical device."

Whether Torgerson's INS 14 is operating in three states or two states, its processor 335 would need to periodically compare the claimed "first threshold" value with the voltage of the power source 315 in order to determine whether INS 14 needs to be transitioned from one operating state to another. EX1003, ¶145. For a processor to perform such a comparison operation, the processor would need to be supplied with the claimed "first threshold" value as an operand—i.e., the part of a computer instruction that specifies data that is to be operating on or manipulated.

*Id.* A POSA would have recognized that such operands are typically stored in some form of memory such as a register. *Id.*

To the extent that evidence is needed to support a POSA's understanding on this point, it is found in the Saulsbury reference, EX1009. Saulsbury is directed to "a processing core that executes a compare instruction." EX1009, Saulsbury, Abstract. Among the set of instructions that a processor executes, Saulsbury explains that such "[i]nstruction sets typically include one or more compare instructions" that "compare[] two input registers so that decisions can be made based upon the result." EX1009, Background, ¶6; EX1003, ¶146. Accordingly at the very least, Saulsbury is evidence that a POSA would have found it obvious to store the claimed "first threshold" value at least temporarily in a register so that processor 335 could access the "first threshold" value to make a comparison against the measured voltage value of power source 315. EX1003, ¶146.

Thus Torgerson198 discloses to a POSA that the claimed "first threshold" (T1, T2, or ST voltage values) would be stored in a register of INS 14. *Id.*, ¶¶146-147. Alternatively, a POSA would have found it obvious to store the claimed "first threshold" value in a register of INS 14 in view the state of the art at the time of invention, as evidenced by Saulsbury. *Id.*

## E. Claim 5

### 1. "The method of claim 1, further comprising"

*See supra,* Section VI.C.

### 2. "if the voltage later exceeds the first threshold after falling below the first threshold, resuming listening for the first telemetry type."

Again, Torgerson198 discloses a method of operating INS 14 in three operating states. And Torgerson198 discloses two transition points T1 and T2 that are compared against the voltage of INS 14's power source 315 to place INS 14 into one of the three operating states. EX1005, 8:30-9:16; EX1003, ¶149. Table B of Torgerson198 (reproduced below) depicts the three operating states of INS 14.

TABLE B

| State of Operation | Components On | Components Off | |
|---|---|---|---|
| Normal Operation | All | None | |
| | | | T1 |
| Low Power | Power Management 320<br>Recharge 310<br>Telemetry 305<br>Oscillator 330<br>Calendar Clock 325<br>Volatile Memory<br>High Freq Protection Circuit<br>High Energy Protection Circuit<br>System Shutdown/ POR 345 | Therapy 350<br>Measurement 355<br>Permanent Memory<br>Non-volatile Memory<br>EEPROM<br>Memory Management<br>System Bus 327<br>Processor 335 | |
| | | | T2 |
| Power Off | Recharge 310<br>High Freq. Protection Circuit<br>High Energy Protection Circuit | Therapy 350<br>Measurement 355<br>Permanent Memory<br>Non-volatile Memory<br>EEPROM<br>Memory Management<br>System Bus 327<br>Processor 335<br>Power Management 320<br>Telemetry 305<br>Oscillator 330<br>Calendar Clock 325<br>Volatile Memory<br>System Shutdown/POR 345 | |

EX1005, 9:34-59.

As shown above, if the voltage of power source 315 falls to a value below transition point T2, INS 14 operates in the "power off" state in which telemetry unit 305 and therapy module 350 are disabled while recharge module 310 remains enabled. *See supra,* Section VI.C.5. Thereafter, if power source 315 is recharged to operate in the "normal operation" state such that the voltage of power source 315 exceeds transition point T2, all of the components are re-enabled as shown above in Table B. *See supra,* Section VI.B.1(b); EX1003, ¶150. Thus if T2 is considered the claimed "first threshold" of this claim, Torgerson198 discloses resuming listening for the first telemetry type (via re-enabling of telemetry unit 305) if the voltage of power source 315 later exceeds the claimed "first threshold." *See supra,* Section VI.B.1. The stimulation therapy (via re-enabling therapy module 350) may also be resumed in this case.

And to the extent that the claims require that the IMD enable and discontinue stimulation and telemetry features whenever the power supply voltage is above or below the claimed "first threshold," Torgerson198's obvious two-state method of operating INS 14 also discloses dependent claim 5. For ease of reference, the two-state variation is depicted below in a modified Table B.

Modified Two State TABLE B

| State of Operation | Components On | Components Off | |
|---|---|---|---|
| Normal Operation | All | None | |
| | | | ST |
| Power Off | Recharge 310<br>High Freq. Protection Circuit<br>High Energy Protection Circuit | Therapy 350<br>Measurement 355<br>Permanent Memory<br>Non-volatile Memory<br>EEPROM<br>Memory Management<br>System Bus 327<br>Processor 335<br>Power Management 320<br>Telemetry 305<br>Oscillator 330<br>Calendar Clock 325<br>Volatile Memory<br>System Shutdown/POR 345 | |

*See supra,* VI.B.2(a)-(b); EX1005, 9:34-60.

In the obvious method of operating INS 14 in two states, whenever the voltage of power source 315 falls below ST, INS 14 operates in the “power off” state in which telemetry unit 305 and therapy module 350 are disabled while recharge module 310 remains enabled. EX1003, ¶¶152-153; *see supra,* Section VI.B.2(a)-(b). Thereafter, if power source 315 is recharged to operate in the “normal operation” state such that the voltage of power source 315 exceeds ST, all of the components are re-enabled as shown in the above modified Table B. *Id.* Thus if ST is considered the claimed “first threshold” of this limitation, the obvious method of Torgerson198 discloses that whenever the voltage of power source 315 later exceeds the claimed “first threshold,” INS 14 operates in the "normal operation" state, which resumes listening for the first telemetry type (via re-enabling of telemetry unit 305). *Id. see supra,* Section VI.B.2(a)-(b). Stimulation therapy (via re-enabling therapy module 350) may also be enabled in this case.

*  *  *

In summary, Torgerson198 discloses a method of operating INS 14 in three states. For the three-state method, Torgerson198 discloses this limitation when T2 is considered the claimed "first threshold." Torgerson198 also discloses an obvious method of operating INS 14 in only two states. For the two-state method, this limitation is satisfied when the ST is considered the claimed "first threshold."

### F. Claim 6

#### 1. "The method of claim 1, further comprising:"

*See supra,* Section VI.C.

#### 2. "if the voltage falls below a second threshold lower than the first threshold, detecting a charging field and continuing to listen for the second telemetry type."

Once again, Torgerson198 discloses a method of operating INS 14 in three operating states. *See* Section VI.B.1. And Torgerson198 discloses two transition points T1 and T2 that are compared against the voltage of INS 14's power source 315 to place INS 14 into one of the three operating states. EX1005, 8:30-9:16; EX1003, ¶156.

For ease of reference, Table B of Torgerson198 (reproduced below) depicts the three operating states of INS 14.

TABLE B

| State of Operation | Components On | Components Off | |
|---|---|---|---|
| Normal Operation | All | None | |
| Low Power | Power Management 320<br>Recharge 310<br>Telemetry 305<br>Oscillator 330<br>Calendar Clock 325<br>Volatile Memory<br>High Freq Protection Circuit<br>High Energy Protection Circuit<br>System Shutdown/ POR 345 | Therapy 350<br>Measurement 355<br>Permanent Memory<br>Non-volatile Memory<br>EEPROM<br>Memory Management<br>System Bus 327<br>Processor 335 | T1 |
| Power Off | Recharge 310<br>High Freq. Protection Circuit<br>High Energy Protection Circuit | Therapy 350<br>Measurement 355<br>Permanent Memory<br>Non-volatile Memory<br>EEPROM<br>Memory Management<br>System Bus 327<br>Processor 335<br>Power Management 320<br>Telemetry 305<br>Oscillator 330<br>Calendar Clock 325<br>Volatile Memory<br>System Shutdown/POR 345 | T2 |

EX1005, 9:34-60.

Torgerson198 discloses that if the voltage of power source 315 falls below both transition points T1 and T2, INS 14 operates in the "power off" state in which telemetry unit 305 and therapy module 350 are disabled while recharge module 310 remains enabled. EX1003, ¶¶157-158. If power source 315 is then recharged to operate in the "normal operation" state, all of the components are re-enabled as shown above in Table B. *Id.* Thus if T1 and T2 are considered the claimed "first threshold" and "second threshold," respectively, Torgerson198 discloses that if the voltage of power source 315 falls below the claimed "second threshold," listening for the first telemetry type is discontinued (via disabling of telemetry unit 305) and stimulation therapy is discontinued (via disabling therapy module 350) until INS 14 is later recharged. *Id.*; *see also supra,* Section VI.B.1. In this way, during the "power off" state, the recharge module 310 listens for the second telemetry type, and detects a charging field. EX1003, ¶¶158-160.

Lest there be any doubt that recharge unit 310 detects a charging field, that feature is also disclosed in Torgerson883. *See* Section VI.A.2. There, the recharging field takes the form of the "wake-up burst." EX1007, 7:51-65. That wake up burst transmits both power and telemetry. *Id.* Indeed, Torgerson883 has a separate "wake up burst detector" in its telemetry detector. *See, e.g.*, EX1007, FIG.4. So the combination of Torgerson198/756 and Torgerson883 set forth above in Section VI.A.1-2 discloses this feature.

## G. Claim 7

### 1. "The method of claim 1, further comprising:"

*See supra,* Section VI.C.

### 2. "if the voltage falls below a second threshold lower than the first threshold, disabling circuitry in the implantable medical device except circuitry required for recharging the battery."

Once again, Torgerson198 discloses a method of operating INS 14 in three operating states. And Torgerson198 discloses two transition points T1 and T2 that are compared against the voltage of INS 14's power source 315 to place INS 14 into one of the three operating states. EX1005, 8:30-9:16; EX1003, ¶162.

For ease of reference, Table B of Torgerson198 (reproduced below) depicts the three operating states of INS 14.

TABLE B

| State of Operation | Components On | Components Off | |
|---|---|---|---|
| Normal Operation | All | None | |
| Low Power | Power Management 320<br>Recharge 310<br>Telemetry 305<br>Oscillator 330<br>Calendar Clock 325<br>Volatile Memory<br>High Freq Protection Circuit<br>High Energy Protection Circuit<br>System Shutdown/ POR 345 | Therapy 350<br>Measurement 355<br>Permanent Memory<br>Non-volatile Memory<br>EEPROM<br>Memory Management<br>System Bus 327<br>Processor 335 | T1 |
| Power Off | Recharge 310<br>High Freq. Protection Circuit<br>High Energy Protection Circuit | Therapy 350<br>Measurement 355<br>Permanent Memory<br>Non-volatile Memory<br>EEPROM<br>Memory Management<br>System Bus 327<br>Processor 335<br>Power Management 320<br>Telemetry 305<br>Oscillator 330<br>Calendar Clock 325<br>Volatile Memory<br>System Shutdown/POR 345 | T2 |

EX1005, 9:34-60.

Torgerson198 discloses that if the voltage of power source 315 falls below both transition points T1 and T2, INS 14 operates in the "power off" state in which telemetry unit 305 and therapy module 350 are disabled while recharge module 310 remains enabled. EX1003, ¶¶163-164. If power source 315 is then recharged to operate in the "normal operation" state, all of the components are re-enabled as shown above in Table B. *Id.* Thus if T1 and T2 are considered the claimed "first threshold" and "second threshold," respectively, Torgerson198 discloses that if the voltage of power source 315 falls below the claimed "second threshold," listening for the first telemetry type is discontinued (via disabling of telemetry unit 305) and stimulation therapy is discontinued (via disabling therapy module 350) until INS 14 is later recharged. EX1003, ¶¶165-166; *see also supra,* Section VI.B.1. In this way, during the "power off" state, the recharge module 310 listens for the second telemetry type, and detects a charging field. And in the "power off" state, all circuitry is disabled in the implantable medical device except circuitry required for recharging the battery (e.g., recharge module 310, and the high frequency and high energy protection circuits). EX1005, 9:30-60; EX1003, ¶166.

A POSA would have also recognized that the high frequency and high energy protection circuits are required for charging operations. They protect the battery from inadvertent damage. Damage to a battery in an implantable medical device would be exceedingly dangerous for the patient in whom the device is implanted. EX1003, ¶¶166-167. Thus Torgerson198's method of operating INS 14 in three operating states discloses detecting a charging field and continuing to listen for the second telemetry type, and disabling circuitry in the implantable medical device except circuitry required for recharging the battery until INS 14 is recharged when T1 is considered the claimed "first threshold" and T2 is considered the claimed "second threshold." EX1003, ¶169.

### H. Claim 8

#### 1. "The method of claim 1, further comprising:"

*See supra,* Section VI.C.

#### 2. "receiving programming and recharging by a clinician."

Torgerson198 expressly discloses that device may receive programming and recharging by a clinician. *See, e.g.*, EX1005, 1:63-67, 2:15-19, 4:25-43, 5:15-24, 5:63-6:6, 7:1-21; EX1003, ¶171.

### I. Claim 9

#### 1. "The method of claim 1,"

*See supra,* Section VI.C.

#### 2. "wherein the power source comprises a lithium ion battery."

Torgerson198 expressly discloses that its internal power source 315 can be a lithium ion battery. EX1005 at 7:51-54; EX1003, ¶173.

### J. Claim 10

#### 1. "The method of claim 1,"

*See supra,* Section VI.C.

#### 2. "wherein the implantable medical device is configured to provide electrical stimulation to a patient, and further comprising enabling stimulation while listening for the first telemetry type, and disabling stimulation if the voltage falls below the first threshold."

INS 14 includes a therapy module 350 (highlighted in brown in Fig. 3 above) that provides stimulation therapy to a patient once INS 14 has been implanted. EX1003, ¶175; EX1005, 5:29-50, 8:23-26. INS 14 provides such stimulation therapy by sending precise, electrical pulses via electrodes to targeted neural tissue of the patient in order to electrically stimulate such tissue. EX1003, ¶175; EX1005, 2:13-19, 4:37-43, 4:59-5:9.

Torgerson198 discloses a method of operating INS 14 in three operating states. And Torgerson198 discloses two transition points T1 and T2 that are compared against the voltage of INS 14's power source 315 to place INS 14 into one of the three operating states. EX1005, 8:30-9:16; EX1003, ¶¶175-176. Torgerson's implantable medical device is configured to provide electrical stimulation to a patient via therapy module 350, when it is enabled and when the INS 14 is listening for the first type of telemetry in both the "normal operation" and "low power" modes. Table B of Torgerson198 (reproduced below) depicts the three operating states of INS 14.

TABLE B

| State of Operation | Components On | Components Off |
|---|---|---|
| Normal Operation | All | None |
| Low Power | Power Management 320<br>Recharge 310<br>Telemetry 305<br>Oscillator 330<br>Calendar Clock 325<br>Volatile Memory<br>High Freq Protection Circuit<br>High Energy Protection Circuit<br>System Shutdown/ POR 345 | Therapy 350<br>Measurement 355<br>Permanent Memory<br>Non-volatile Memory<br>EEPROM<br>Memory Management<br>System Bus 327<br>Processor 335 |
| Power Off | Recharge 310<br>High Freq. Protection Circuit<br>High Energy Protection Circuit | Therapy 350<br>Measurement 355<br>Permanent Memory<br>Non-volatile Memory<br>EEPROM<br>Memory Management<br>System Bus 327<br>Processor 335<br>Power Management 320<br>Telemetry 305<br>Oscillator 330<br>Calendar Clock 325<br>Volatile Memory<br>System Shutdown/POR 345 |

T1

T2

EX1005, 9:34-59.

As shown above, if the voltage of power source 315 falls to a value below transition point T2, INS 14 operates in the "power off" state in which telemetry unit 305 and therapy module 350 are disabled while recharge module 310 remains enabled. *See supra,* Section VI.C.4; EX1003, ¶176. Thereafter, if power source 315 is recharged to operate in the "normal operation" state such that the voltage of power source 315 exceeds transition point T2, all of the components are re-enabled as shown above in Table B. *See supra,* Section VI.B.1; EX1003, ¶176. Thus if T2 is considered the claimed "first threshold" of this claim, Torgerson198 discloses resuming listening for the first telemetry type (via re-enabling of telemetry unit

305) if the voltage of power source 315 later exceeds the claimed "first threshold" as required by this limitation. *Id.*

And to the extent that the claims require that the IMD enable and discontinue stimulation and telemetry features whenever the power supply voltage is above or below the claimed "first threshold," Torgerson198's obvious two-state method of operating INS 14 also discloses dependent claim 10. For ease of reference, the two-state variation is depicted below in a modified Table B.

Modified Two State TABLE B

| State of Operation | Components On | Components Off |
|---|---|---|
| Normal Operation | All | None |
| | | ST |
| Power Off | Recharge 310<br>High Freq. Protection Circuit<br>High Energy Protection Circuit | Therapy 350<br>Measurement 355<br>Permanent Memory<br>Non-volatile Memory<br>EEPROM<br>Memory Management<br>System Bus 327<br>Processor 335<br>Power Management 320<br>Telemetry 305<br>Oscillator 330<br>Calendar Clock 325<br>Volatile Memory<br>System Shutdown/POR 345 |

*See supra,* Section VI.B.2; EX1005, 9:34-60.

In the obvious method of operating INS 14 in two states, whenever the voltage of power source 315 falls below ST, INS 14 operates in the "power off" state in which telemetry unit 305 and therapy module 350 are disabled while recharge module 310 remains enabled. EX1003, ¶177-178; *see supra,* Section VI.B.2. Thereafter, if power source 315 is recharged to operate in the "normal operation" state such that the voltage of power source 315 exceeds ST, all of the components are re-enabled as shown in the above modified Table B. EX1003, ¶178. Thus if ST is considered the claimed "first threshold" of this limitation, the obvious method of Torgerson198 discloses that whenever the voltage of power source 315 later exceeds the claimed "first threshold," INS 14 operates in the "normal operation" state, which resumes listening for the first telemetry type (via re-enabling of telemetry unit 305). *See supra,* Section VI.B.2. Stimulation therapy (via re-enabling therapy module 350) may also be enabled in this case.

## VII. GROUND 2: CLAIMS 2 AND 3 OF THE '071 PATENT ARE UNPATENTABLE UNDER 35 U.S.C. § 103 OVER TORGERSON198 AND TORGERSON756 IN VIEW OF TORGERSON883 AND FURTHER IN VIEW OF ABRAHAMSON

### A. Overview

Claim 2 depends from independent claim 1, and claim 3 depends from claim 2. These dependent claims further define the IMDs operated on by the independent claims of the '071 patent. More specifically, if the "type of telemetry" could encompass the particular modulation scheme (which it should), these dependent claims require that the two different types of telemetry used by such IMDs be frequency shift keying (FSK) and on-off keying (OOK). *See supra,* Section V.B (construing "type of telemetry"). The Torgerson references do not specifically identify the particular modulation schemes used in operating INS 14.

The Abrahamson reference, however, proves that it would have been obvious for a POSA to utilize FSK and OOK for the telemetries used by INS 14, and because telemetry unit 305 and recharge module 310 both engage in bidirectional telemetry in the proposed combination, they would necessarily include the recited transmitters/receivers recited in dependent claim 3. EX1003, ¶182.

Consistent with those disclosures, a POSA would have been aware of a variety of well-known telemetry techniques that could be employed in an IMD such as INS 14. EX1003, ¶¶183-187. A POSA would have understood that those telemetry techniques include FSK and OOK modulation schemes as evidenced by Abrahamson. *Id.*; EX1008, 1:14-25, 5:9-15. Thus it would have been obvious for a POSA to select any one of these well-known telemetry techniques such as FSK for the first type of telemetry used by telemetry module 305 and OOK for the second type of telemetry used by recharge module 310. EX1003, ¶¶189-191.

In particular, a POSA would have chosen the FSK modulation scheme for the communication between the telemetry module 305 and an external device for programming the INS 14 because FSK provides a higher bandwidth and thus a higher capacity to transmit useful information. *Id.*, ¶189. And a POSA would have chosen the OOK modulation scheme for the communication between the recharge module 310 and an external device used for recharging the INS 14 because that communication is typically simpler and can be fully achieved with the simpler OOK modulation scheme. *Id.*, ¶191.

### B. Claim 2

#### 1. "The method of claim 1,"

*See supra,* Sections VI.C.

#### 2. "wherein the first telemetry type comprises Frequency Shift Keying (FSK), and wherein the second telemetry type comprises On/Off Keying (OOK)."

As discussed in Section VII.B above, a POSA would have found it obvious to select any one of the well-known telemetry types such as FSK for the first type of telemetry used by telemetry module 305 and OOK for the second type of telemetry used by recharge module 310. EX1003, ¶¶189-194. During cross-examination, Dr. Berger actually confirmed that these two particular modulation schemes would have been the obvious choices to a POSA. EX1011, 125:19-127:6.

##### (a) Patent Owner's expert Dr. Berger confirmed that a POSA would have found it obvious to use FSK for use with the first type of telemetry in Torgerson756's telemetry module 305.

With respect to selecting FSK for the first telemetry type, Patent Owner's expert Dr. Berger confirmed during cross examination in the related '1899IPR on the '241 patent (1) that FSK was a known modulation scheme used in IMDs during the relevant timeframe, (2) that FSK was an appropriate modulation scheme for IMDs, and (3) that a POSA would have believed that FSK was likely to work as a modulation scheme in an IMD. EX1011, 106:18-4–107:25.

Dr. Berger further confirmed that for telemetry where power transfer is not important—e.g., for Torgerson756's telemetry module 305 (EX1011, 136:9-18)—a POSA would have wanted a faster transfer of information and higher signal-to-noise ratio, and that FSK would have been a good choice:

> Q. And [for Torgerson756] what type of keying or modulation schemes would be better if you are, if you are not using it for the transfer of power?
>
> ….
>
> THE WITNESS: If one is using telemetry, if one is using this link entirely for telemetry, and only for telemetry, and not also for the transfer of power, then one makes a decision about how much information, how quickly that information is to be communicated, and what sort of signal-to-noise ratio is tolerable. If one wants a higher signal-to-noise ratio, *one would be better off with frequency shift keying*.

EX1011, 125:19-127:6 (emphasis added).

Dr. Berger's candid answer is again consistent with the opinion of Petitioner's expert Dr. Kroll, who testified that "FSK modulation scheme for the communication between the telemetry module 305 and an external device for programming the INS 14 because FSK provides a higher bandwidth and thus a higher capacity to transmit useful information." EX1003, ¶189.

#### (b) Under Patent Owner's own explanation, Torgerson883 listens for a wake up burst from the external charger, which is transmitted via OOK.

The "wake up burst" described in detail in Torgerson883, and also referenced in Torgerson756, is a dual purpose signal in that it can carry both power and telemetry in the form of a command. EX1011, 102:4-103:18. The telemetry portion of the wake up burst is transmitted via OOK because Torgerson883's wake up burst detector simply responds to the presence of the wake-up burst. EX1003, ¶¶192-194.

Specifically, Torgerson883 discloses that "[t]he wake-up burst, or RF signal 10, will then be detected by the wake-up burst detector 65, which will send an interrupt to the controller 95." EX1007, 8:48-50. Torgerson883 goes on to explain that "[a]t this point, the electrical connection interrupt line 66 to the controller 95 enters a high or active state due to the RF transmissions 10 from the RF programmer 1," which controller 95 interprets as a command to "assemble and send device and status information relating to the [IMD]" back to the RF programmer 1. *Id.*, *citing* EX1007, 8:51-9:1. Then, "[w]hen the wake-up burst signal 10 is no longer being delivered … the interrupt line 66 from the wake-up burst detector 65 will be in a low or inactive state." EX1007, 8:48-58; *see* POR, 35; EX1003, ¶¶192-194.

This simple modulation scheme, whereby Torgerson883's wake up burst detector 65 on telemetry IC 60 responds to the presence (or absence) of the wake-up burst, is a form of OOK modulation. EX1011, 50:8-51:5 (confirming OOK could be as simple as the presence or absence of a signal), 102:21-103:9 (confirming that Torgerson883's wake burst "might be" transmitted using OOK telemetry). So a POSA would have recognized that the wake-up burst command, itself, is transmitted via OOK.

In any event, Dr. Berger again conceded in the related '1899IPR that a POSA would have chosen OOK even without Torgerson883's disclosure:

> Q. [D]oes the Torgerson '756 patent require any particular type of keying or modulation?
>
> A. I think that to the extent that Torgerson is trying to accomplish not just telemetry with the transmitted signal, but it is also trying to transmit power to recharge the power source. That is likely to work best if it uses a, an inductive transfer of energy. And that works best when the modulation scheme is confined to a narrow frequency band. And that would work best with a scheme that sticks to a certain frequency and modulates the amplitude rather than modulating the frequency. *And so, that would probably work best with ASK or OOK.*

EX1011, 125:19-126:14 (emphasis added).

Patent Owner's expert Dr. Berger thus confirmed that with respect to Torgerson756's second type of telemetry, which is inductive telemetry (EX1006, 9:49-53), a POSA would have realized that it works "best with ASK or OOK."[1] *See also*, EX1011, 136:9-18 (confirming that recharge module 310 is primarily responsible for receiving energy transfer).

Dr. Berger's candid answer is consistent with the opinion of Petitioner's expert Dr. Kroll, who testified "a POSA would have chosen the OOK modulation scheme for the communication between the recharge module 310 and an external device used for recharging the INS 14 because that communication is typically simpler and can be fully achieved with the simpler OOK modulation scheme." EX1003, ¶190.

### C. Claim 3

#### 1. "The method of claim 2,"

*See supra,* Sections VI.C and VII.C.

#### 2. "wherein the telemetry circuitry comprises an OOK receiver, an FSK receiver, and an FSK transmitter."

As discussed in Section VII.B above, a POSA would have found it obvious to select any one of the well-known telemetry types such as FSK for the first type

[1] Dr. Berger testified, correctly, that On/Off Keying (OOK) is merely a simple form of Amplitude Shift Keying (ASK). EX1011, 52:19–53:14.

of telemetry used by telemetry module 305 and OOK for the second type of telemetry used by recharge module 310. EX1003, ¶196.

Lest there be any doubt that the state of the art contemplated telemetry circuitry with the claimed features, Nevro's expert describes prior art telemetry circuitry having both FSK and OOK receivers. EX1003, ¶197.

# VIII. SECONDARY CONSIDERATIONS OF NON-OBVIOUSNESS

At this time, Petitioner is unaware of any secondary indicia of non-obviousness that would impact the above grounds of unpatentability.

# IX. CONCLUSION

For the reasons provided above, Nevro requests *inter partes* review of claims 1-10 of the '071 patent, and a determination that those claims are unpatentable as obvious under 35 U.S.C. § 103 according to the proposed grounds. Such a determination would be consistent with the determination in IPR2017-01899 on related U.S. Patent No. 7,587,241

# X. STANDING (37 C.F.R. § 42.104(A))

Nevro certifies that the '071 patent is available for *inter partes* review, and that Nevro is not barred or estopped from requesting an *inter partes* review of the '071 patent.

# XI. MANDATORY NOTICES (37 C.F.R. § 42.8(A)(1))

## A. Real Party In Interest (37 C.F.R. § 42.8(b)(1))

The real party-in-interest is Petitioner Nevro Corp.

### B. Related Matters (37 C.F.R. § 42.8(b)(2))

The ’071 patent is the subject of the following civil action: *Boston Scientific Corp. et al. v. Nevro Corp.*, Case No. 1:18-cv-00644 (D.E.D.), filed April 27, 2018. The ’071 patent is related to U.S. Patent No. 7,587,241 (the ’241 patent), which is the subject of civil action *Boston Scientific Corporation et al. v. Nevro Corp.*, Case No. 1:16-cv-01163 (D.E.D.), filed December 9, 2016, and PTAB proceeding no. IPR2017-01899, filed July 31, 2017.

### C. Lead and Back-up Counsel (37 C.F.R. § 42.8(b)(3))

Pursuant to 37 C.F.R. § 42.8(b)(3) and 42.10(a), Petitioner appoints **Jon E. Wright** (Reg. No. 50,720) as lead counsel, and **Ian Soule** (Reg. No. 74,290) and **Ross G. Hicks** (Reg. No. 56,374) as back-up counsel, all at the address: STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C., 1100 New York Avenue, N.W., Washington, D.C., 20005, phone number (202) 371-2600, and facsimile (202) 371-2540. Additional back-up counsel include **Ching-Lee Fukuda** (Reg. No. 44,334, clfukuda@sidley.com, 212-839-7364) at the address: Sidley Austin LLP, 787 Seventh Avenue, New York, New York 10019, and **Thomas A. Broughan, III** (Reg. No. 66,001, tbroughan@sidley.com, 202-736-8314) and **Sharon Lee**[2]

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[2] Nevro will file a motion for Sharon lee to appear *pro hac vice* according to the Board’s orders and rules.

(sharon.lee@sidley.com, 202-736-8510), both at the address: SIDLEY AUSTIN LLP, 1501 K Street N.W., Washington, DC 20005.

### D. Service Information (37 C.F.R. § 42.8(b)(4))

Petitioner consents to electronic service by email at: **jwright-PTAB@sternekessler.com**, **isoule-PTAB@sternekessler.com**, **PTAB@sternekessler.com**, **clfukuda@sidley.com, tbroughan@sidley.com,** and **sharon.lee@sidley.com**.

Respectfully submitted,
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/Jon E. Wright/

Date: July 15, 2019

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**CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATION, TYPEFACE REQUIREMENTS, AND TYPE STYLE REQUIREMENTS**

1. This Petition complies with the type-volume limitation of 14,000 words, comprising 13,976 words, excluding the parts exempted by 37 C.F.R. § 42.24(a).

2. This Petition complies with the general format requirements of 37 C.F.R. § 42.6(a) and has been prepared using Microsoft® Word 2010 in 14 point Times New Roman.

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

/Jon E. Wright/

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## CERTIFICATION OF SERVICE (37 C.F.R. §§ 42.6(e), 42.105(a))

The undersigned hereby certifies that on July 15, 2019, true and correct copies of the foregoing **PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 9,162,071**, Petitioner's Power of Attorney, and all associated exhibits were served in their entireties on the following parties via FedEx Express®:

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