

**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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**PETITION FOR *INTER PARTES* REVIEW  
OF U.S. PATENT NO. 7,587,241**

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Patent Trial and Appeal Board  
U.S. Patent & Trademark Office  
P.O. Box 1450  
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**EXHIBIT LIST**

<b>Exhibit No.</b>	<b>Description</b>
1001	U.S. Patent No. 7,587,241 to Parramon <i>et al.</i>
1002	U.S. Patent No. 7,587,241 File History
1003	Declaration of Dr. Mark W. Kroll
1004	<i>Curriculum Vitae</i> of Dr. Mark W. Kroll
1005	U.S. Patent No. 6,453,198 to Torgerson <i>et al.</i>
1006	U.S. Patent No. 7,167,756 to Torgerson <i>et al.</i>
1007	U.S. Patent No. 6,456,883 to Torgerson <i>et al.</i>
1008	U.S. Patent No. 6,647,298 to Abrahamson <i>et al.</i>
1009	U.S. Patent Publication No. 2002/0019928 to Saulsbury

## **I. Introduction**

Petitioner Nevro Corp. (“Nevro”) requests *inter partes* review of claims 1-20 of U.S. Patent No. 7,587,241<sup>1</sup> (“the ’241 patent”) (Ex. 1001), which is assigned to Boston Scientific Neuromodulation Corporation (“BSNC”).

### **A. The ’241 patent**

The ’241 patent is directed to a “method for controlling an implantable medical device.” Ex. 1001, Abstract. Implantable medical devices (“IMDs”) of the type described in the ’241 patent—namely, “implantable microstimulators”—were well known in the art by June 2002, the earliest possible priority date of the ’241 patent. The ’241 patent itself candidly acknowledges this by describing in the background section no less than a dozen exemplary prior-art microstimulators. Ex. 1001, 1:25-2:54.

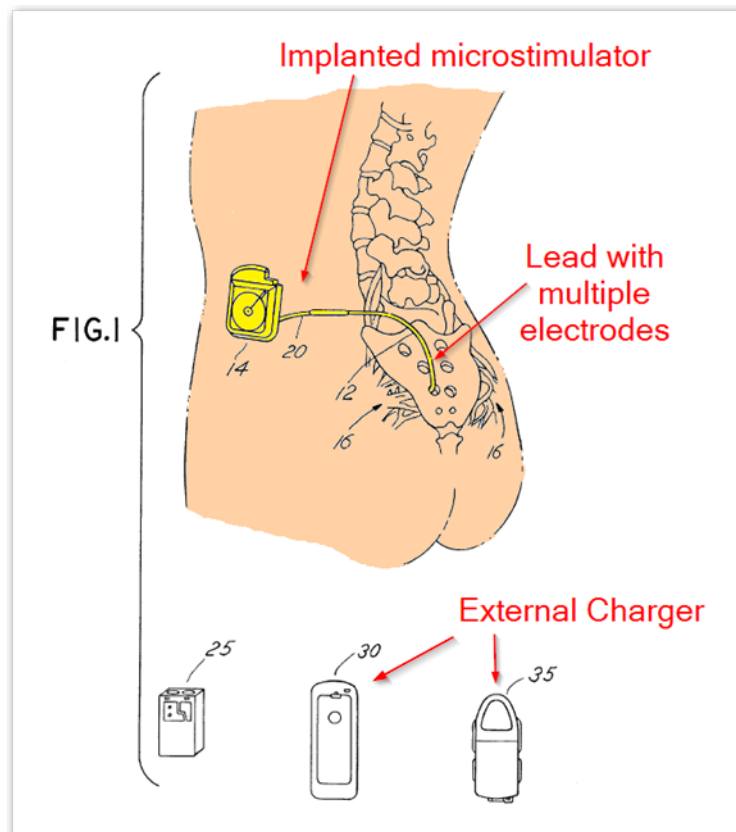
The described microstimulators, once implanted in a patient, generate electrical currents that are delivered via electrodes to the patient’s nerve or muscle tissue. Ex. 1003, ¶ 30; Ex. 1001, 1:25-42, 2:32-45. Those electrical currents stimulate the tissue electrically and provide therapy for various disorders including,

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<sup>1</sup> The ’241 patent was issued prior to the enactment of the America Invents Act (“AIA”). Accordingly this petition applies the pre-AIA versions of 35 U.S.C. §§ 102, 103.

for example, urinary urge incontinence or neurological disorders caused by injury or stroke. Ex.1003 ¶ 30; Ex. 1001, 1:25-42, 2:32-45.

To generate such electrical currents, microstimulators also contain a power source such as a rechargeable battery that can be recharged wirelessly using an external charger that is placed outside and near the patient's body. Ex. 1003, ¶ 30; Ex. 1001, 2:1-2:31. An exemplary depiction of such a device is shown below:



Ex. 1005, Fig. 1, 4:16-43, 4:59-5:3, 5:65-6:3; Ex. 1006, 8:40-61.<sup>2</sup>

<sup>2</sup> In this paper, colors in figures have been added to provide annotations and emphasis unless otherwise indicated.

Because IMDs are designed to be implanted in a human body, there are strong motivations to avoid the need to extract and re-implant the device. As such, device designers naturally place importance on maintaining the reliability and life of the power source, and retaining the ability to communicate with the implanted device. Ex. 1003, ¶ 47. The claimed methods thus focus on monitoring the voltage of the IMD's internal power source, and then enabling or disabling certain features based on that voltage to protect the device's power source and preserve the ability to communicate.

To that end, the '241 patent claims methods that operate on a certain category of well-known IMDs—namely, those that (1) include a power source such as a rechargeable battery, (2) can listen for two different types of telemetry to communicate with external devices, and (3) can provide therapy to a patient such as by providing stimulation through electrodes. Ex. 1003, ¶¶ 35, 37. The claimed methods are directed to controlling the telemetry and stimulation features based on power source capacity. Ex. 1001, claims 1, 8, 14. The power source capacity, in turn, is determined by measuring the voltage of the rechargeable battery.

**B. The prior art: Torgerson and Abrahamson patents**

The prior art, however, discloses and teaches methods for controlling telemetry and stimulation features of an IMD operation based on the IMD's power

source capacity. Specifically, at least three related prior-art patents, plus one additional patent, combine to render all of the claims obvious.

- Ex. 1005 - U.S. Patent No. 6,453,198 (“Torgerson198”)
- Ex. 1006 - U.S. Patent No. 7,167,756 (“Torgerson756”)
- Ex. 1007 - U.S. Patent No. 6,456,883 (“Torgerson883”)
- Ex. 1008 - U.S. Patent No. 6,647,298 (“Abrahamson”)

During the original prosecution of the application that led to the ’241 patent, the examiner did not consider any of these four references. *See* Ex. 1002.

**1. Three related Torgerson patents and the Abrahamson patent together disclose an IMD in which the claimed methods of the ’241 patent can be applied.**

Like the ’241 patent, the Torgerson patents are directed to various aspects of power management, battery recharge management, and reliable communication for IMDs. To be more specific, Torgerson198 and Torgerson756 together disclose an implantable neural stimulator (“INS”) that can operate the claimed methods of the ’241 patent. That is, they disclose an IMD (*i.e.*, Torgerson198 and Torgerson756’s INS) that provides therapy to a patient by providing stimulating currents through electrodes. The INS includes a rechargeable battery. And they include telemetry circuitry that utilizes two different types of telemetry to communicate with external devices. Ex. 1003, ¶¶ 35, 37.

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Together, Torgerson198 and Torgerson756 lack only two specific features of the '241 patent claims under their broadest reasonable interpretation —(1) they disclose two telemetry types and only explicitly disclose that one type is used for bi-directional communications while leaving it ambiguous as to whether the second telemetry type is also used for bi-directional communication. It is thus not clear that the INS receives or listens for both types of telemetry as required by independent claims 1, 8, and 14 of the '241 patent; and (2) they do not disclose the specific use of frequency-shift keying (FSK) for one of the telemetry types and on-off keying (OOK) for the other telemetry type as required by dependent claims 2, 9, and 15 of the '241 patent. However, Torgerson883 evidences that it would have been obvious for a POSA to ensure that the second telemetry type is also used for bi-directional communication. And Abrahamson evidences that it would have been obvious for a POSA to utilize FSK and OOK as the two telemetry types as required in the dependent claims. The prior art thus evidences that the IMDs that are the subject of the claimed methods would have been obvious prior to the earliest priority date of the '241 patent.

**2. One of the Torgerson patents discloses the methods claimed by the '241 patent for controlling such an IMD disclosed by the Torgerson and Abrahamson patents**

Torgerson198 discloses all the methods of operating an IMD as claimed by the '241 patent. Torgerson198 discloses a power management technique that

enables and disables various features of the INS based on the voltage of the INS's internal power source. *Id.*, ¶¶ 62-64.

More specifically, Torgerson198 discloses a method of operating an INS in one of three states (normal operation, low power, power off states) depending on the voltage level of its internal power source. *Id.*, ¶¶ 65-78. In the “normal operation” state, Torgerson198's method operates the INS with all of its features enabled including stimulation and listening for two different types of telemetry. *Id.* In the “power off” state, Torgerson198's method operates the INS with stimulation and listening for one of the two telemetries disabled. *Id.* These and other aspects of Torgerson198's method of operating an INS discloses all the methods claimed by the '241 patent. *Id.*

Thus the three Torgerson and Abrahamson patents disclose both the claimed methods of the '241 patent and the IMDs operated on by those claimed methods. If the PTO had considered the three Torgerson and Abrahamson patents, it would not have issued the '241 patent.

## **II. Grounds for the Unpatentability of the '241 patent**

Nevro requests *inter partes* review of claims 1-20 of the '241 patent and a determination that those claims are unpatentable based on the following grounds:



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<b>Ground</b>	<b>Prior Art</b>	<b>Basis</b>	<b>Claims Challenged</b>
1	Torgerson198 (Ex. 1005) Torgerson756 (Ex. 1006) Torgerson883 (Ex. 1007)	35 U.S.C. § 103	1, 3-8, 10-14 , and 16-20
2	Torgerson198 (Ex. 1005) Torgerson756 (Ex. 1006) Torgerson883 (Ex. 1007) Abrahamson (Ex. 1008)	35 U.S.C. § 103	2, 9, 15

The prior art references cited for each ground above qualifies as prior art to the '241 patent for the following reasons:

- Torgerson198 (Ex. 1005) is U.S. Patent No. 6,453,198 and qualifies as a prior art patent under 35 U.S.C. § 102(e) because it was filed on April 28, 2000, which precedes the earliest priority date (June 28, 2002) of the '241 patent.
- Torgerson756 (Ex. 1006) is U.S. Patent No. 7,167,756 and qualifies as a prior art patent under 35 U.S.C. § 102(e) because it was filed on April 28, 2000, which precedes the earliest priority date (June 28, 2002) of the '241 patent.
- Torgerson883 (Ex. 1007) is U.S. Patent No. 6,456,883 and qualifies as a prior art patent under 35 U.S.C. § 102(e) because it was filed on April 26, 2000, which precedes the earliest priority date (June 28, 2002) of the '241 patent.
- Abrahamson (Ex. 1008) is U.S. Patent No. 6,647,298 and qualifies as a prior art patent under 35 U.S.C. § 102(e) because it was filed on June 4, 2001, which precedes the earliest priority date (June 28, 2002) of the '241 patent.

The three Torgerson references are related. They share the same named first inventor, Nathan Torgerson. Ex. 1005; Ex. 1006, Ex. 1007. Torgerson198 and Torgerson756 were filed on the same day and incorporate each other by reference, in their entireties. Ex. 1005, 8:53-59; Ex. 1006, 10:22-31. Torgerson883 was filed two days earlier and is also referenced by Torgerson756. Ex. 1006, 1:21-27.

### **III. The claimed inventions of '241 patent**

The '241 patent includes three sets of claims: claims 1-7, 8-13, and 14-20. All three claim sets are directed to a “method for controlling an implantable medical device” as recited in their preambles. Claim 1 is illustrative and is reproduced below with labels [a] through [i] added to demarcate the various limitations in the body of the claim:

1. A method for controlling an implantable medical device, comprising:
  - [a] monitoring a voltage of a power source within the implantable medical device;
  - [b] if the voltage is above a first threshold, enabling the following functions:
    - [c] listening for a first type of telemetry from a first external component;
    - [d] listening for a second type of telemetry from an external charging component, wherein the external charging component is used to wirelessly charge the power source; and
    - [e] providing stimulation to device electrodes using the power source; and
    - [f] if the voltage falls below the first threshold,

[g] discontinuing listening for the first type of telemetry from the first external component and

[h] discontinuing providing stimulation to device electrodes using the power source,

[i] while continuing listening for the second type of telemetry.

As stated in the preamble, claim 1 (as well as all the other claims of the '241 patent) is a method of operating an implantable medical device. Ex. 1001, 1:17-21.

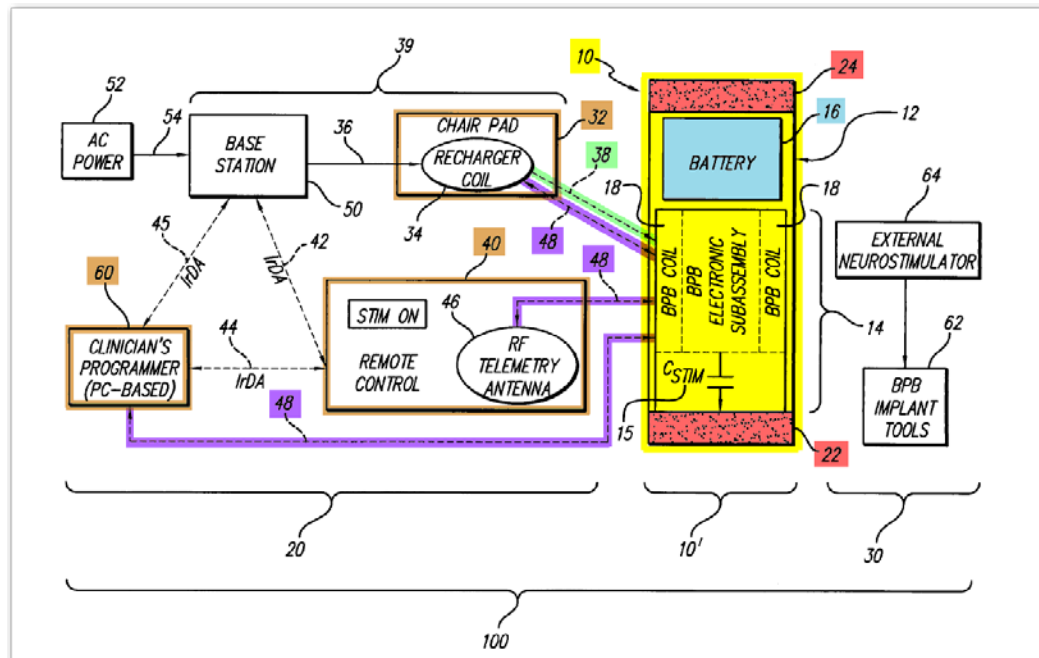
The claims thus define both the methods and the IMDs that are suitable for the methods.

For example, claim 1 defines an IMD that includes a power source (*see* [a] above), is capable of listening for two types of telemetry (*see* [c], [d], [g], [i] above) and can provide stimulation therapy through electrodes (*see* [e], [h] above). *See also*, Ex. 1001, claims 8, 14; Ex. 1003 ¶ 35. Claim 1 covers a method of controlling certain features of such IMDs. That method involves (1) measuring the voltage of an IMD's power source (*see* [a] above), (2) enabling stimulation and listening for two types of telemetry if the power source voltage is above a first threshold (*see* [b]-[e] above), and (3) discontinuing both stimulation and listening for one of the two telemetry types if the power source voltage falls below the first threshold (*see* [f]-[i] above). *See also*, Ex. 1001, claims 8, 14; Ex. 1003, ¶ 41.

In the sections that follow, the IMDs defined by the claims of the '241 patent are discussed first and then the claimed methods that operate on such IMDs are discussed next.

**A. Claims operate on an implantable medical device**

As discussed with respect to claim 1 above, all of the independent claims of the '241 patent operate on an IMD that (1) includes a power source, (2) is capable of listening for two different types of telemetry from external devices and (3) can provide therapy via stimulation through electrodes. Ex. 1001, claims 1, 8, 14; Ex. 1003, ¶ 35.



Ex. 1001, Fig. 1.

Such an IMD (which is operable by the independent claims) is shown in Figure 1 of the '241 patent (reproduced above) as BPB<sup>3</sup> device 10 (highlighted in yellow). 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. Ex. 1001, 5:52-57, 8:29-35, 11:23-28, 12:19-35; Ex. 1003, ¶ 36. The electronics of the implantable device 10 is capable of listening for two different types of telemetry—telemetry 38 (shown in green) and telemetry 48 (shown in purple)—from various external devices such as a chair pad 32 of a recharging system, a remote control 40, and a clinician programmer 60 (shown in brown). Ex. 1001, 8:36-42, 8:48-54, 8:56-65; Ex. 1003, ¶ 36. 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. Ex. 1001, 1:47-51, 3:60-4:4, 11:29-33; Ex. 1003, ¶ 36.

Dependent claims 2, 9, and 15 further limit the IMDs operable by the independent claims by requiring that the two telemetry types that the IMD listens for be specifically frequency shift keying (FSK) and on-off keying (OOK). FSK

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<sup>3</sup> The '241 patent discloses an IMD that it refers to as a battery-powered BION (“BPB”) device. Ex. 1001, 1:17-21, 1:52-55, 5:46-51, 8:10-19.

and OOK, which were well known prior to the '241 patent, are two different techniques for encoding data into a signal. Ex. 1003, ¶ 37. As its name suggests, frequency shift keying encodes data into a signal (such as a wireless radio frequency signal used for telemetry) by modulating (*i.e.*, altering) the frequency of the signal. *Id.* In contrast, on-off keying encodes data into a signal by modulating the amplitude of the signal. *Id.*

Dependent claims 6, 13, and 19 limit the IMDs operable by the independent claims by requiring that the IMD's internal power source include a lithium ion battery. Dependent claims 7 and 20 limit the IMDs operable by the independent claims by requiring that the IMD be capable of listening for the two different telemetry types from a single external device. Finally, dependent claims 3, 10, and 16 require the IMD defined by the independent claims to include a register for holding a threshold value used for performing the claimed methods of the '241 patent. *Id.*, ¶¶ 37-40. Those methods are described next in the section below.

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

All of the claims of the '241 are directed to controlling the operation of an IMD. More specifically, the claims cover methods for enabling and disabling the stimulation and telemetry features of an IMD. The steps of those methods are provided in independent claims 1, 8, and 14, and additionally in two sets of

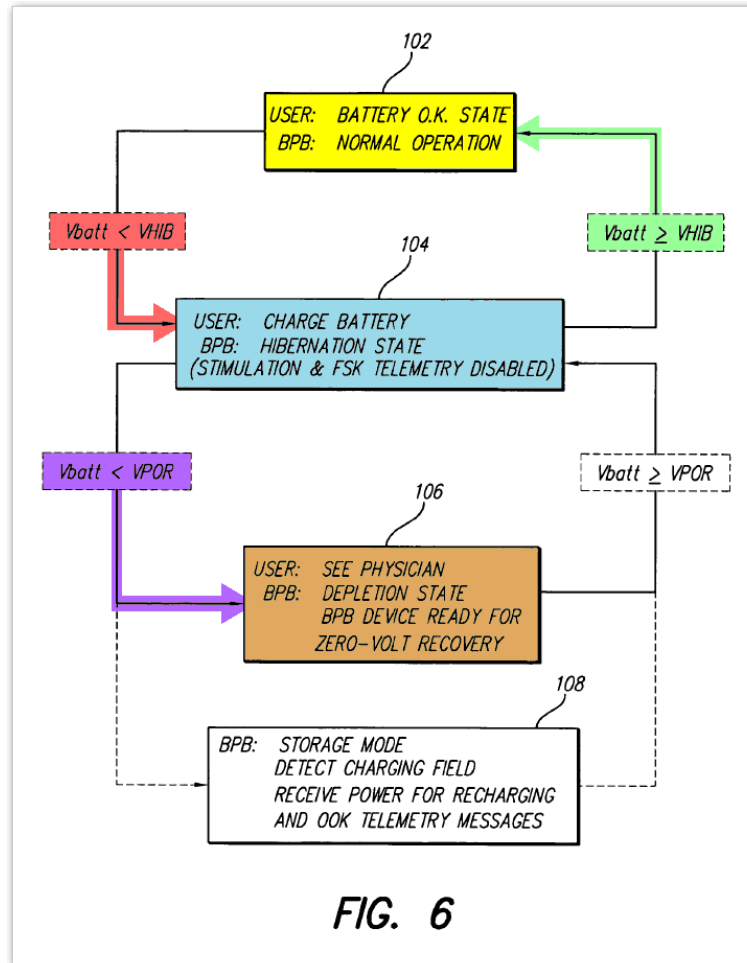
dependent claims: 4, 11, 17 and 5, 12, 18. The remaining dependent claims only further define the IMDs operable by the methods of the independent claims.

The methods of the independent claims entail: (1) measuring the voltage of the IMD's internal power source, (2) enabling stimulation and listening for two different types of telemetry if the power source voltage is above a first threshold, and (3) discontinuing stimulation as well as discontinuing listening for one of the two types of telemetry if the voltage later falls below the first threshold. *See also*, Ex. 1001, claims 1, 8, 14; Ex. 1003 ¶ 41.

Dependent claims 4, 11, and 17 further specify that the methods of the independent claims require: resuming stimulation and listening for both types of telemetry if the voltage later increases above the first threshold.

Finally dependent claims 5, 12, and 18 further specify that the methods of the independent claims require: keeping stimulation and listening for one of the two telemetry types discontinued until the IMD is recharged if the voltage falls below a second threshold, which is lower than the first threshold.

The above methods of the '241 patent claims are depicted in Figure 6 of the '241 patent, which is reproduced below.



Ex. 1001, Fig. 6.

As shown in Figure 6 above, the '241 patent contemplates operating an IMD in one of three different states (shown in yellow, blue and brown above). Ex. 1001, 13:11-47; Ex. 1003, ¶ 45. 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. Ex. 1001, 13:11-47; Ex. 1003, ¶ 45. 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 (FSK) disabled. Ex. 1001, 13:11-47; Ex. 1003, ¶ 45. State 106 (shown in brown) represents the



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“depletion state,” in which stimulation and listening for one of the two telemetry types (FSK) remain discontinued until the IMD is recharged, for example, by a clinician. Ex. 1001, 13:11-47; Ex. 1003, ¶ 45.

The claims of the '241 patent cover methods for controlling an IMD to cause the IMD to operate in one of the three states based on the voltage level of the IMD's internal power source. Those steps of the '241 claims can be seen in Figure 6 above highlighted in green, red, and purple. Ex. 1001, 13:11-47; Ex. 1003, ¶ 46. As shown highlighted in green, if the voltage of the IMD's power source  $V_{batt}$  is above a first threshold  $V_{HIB}$ , 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. Ex. 1001, 13:11-47; Ex. 1003, ¶ 46. As shown highlighted in red, if the IMD's power source voltage  $V_{batt}$  falls below the first threshold  $V_{HIB}$ , 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. Ex. 1001, 13:11-47; Ex. 1003, ¶ 46. Finally, as shown highlighted in purple, if the IMD's power source voltage  $V_{batt}$  falls below the second threshold  $V_{POR}$ , 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. Ex. 1001, 13:11-47; Ex. 1003, ¶ 46.

As detailed below in discussing the challenged grounds, a POSA would have found all of the claimed methods of the '241 patent and the IMDs operated on by those methods to have been obvious prior to earliest priority date (June 28, 2002) of the '241 patent.

#### **IV. Level of Ordinary Skill in the Art**

A POSA in the context of the '241 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. Ex. 1003, ¶ 22. A POSA of the '241 patent would have had general knowledge of implantable medical devices and various related technologies as of June 28, 2002. *Id.*, ¶ 21.

#### **V. Claim Construction**

In considering the scope and meaning of the claims of an unexpired patent (such as the '241 patent) in an *inter partes* review, the claim terms are to be given their broadest reasonable interpretation as understood by a POSA in light of the specification. *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144-46 (2016); 37 C.F.R. § 42.100(b). Under this standard, absent any special definitions, claim terms or phrases are given their ordinary and customary meaning, as would be

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understood by a POSA in the context of the entire specification. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007).

In this petition, Nevro challenges the claims of the '241 patent under their broadest reasonable interpretations. 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 under the broadest reasonable interpretation. The patentee did not provide a glossary, and the patentee does not appear to have acted as its own lexicographer for any term.

If the patent owner BSNC asserts that any term specifically requires construction, Nevro reserves the right to challenge such construction, if necessary. And if the Board believes, after reviewing the patent owner's preliminary response, that any claim term requires additional briefing, Nevro is willing to provide supplemental briefing.

Petitioner Nevro also reserves the right to challenge in a different forum, such as in a U.S. District Court, that one or more claims of the '241 patent are indefinite or have a claim scope that differ from their broadest reasonable interpretations.

**VI. GROUND 1: Claims 1, 3-8, 10-14, and 16-20 of the '241 Patent are Unpatentable under 35 U.S.C. § 103 over Torgerson198 and Torgerson756 in view of Torgerson883**

We begin by showing that the Torgerson references together disclose all of the features of an IMD that can operate in accordance with the methods of claims 1, 3-8, 10-14, and 16-20 of the '241 patent. We then show that Torgerson198 discloses the claimed methods for controlling the telemetry and stimulation features of the IMD based on the IMD's power source capacity. We end with a detailed mapping of the claims to the Torgerson references.

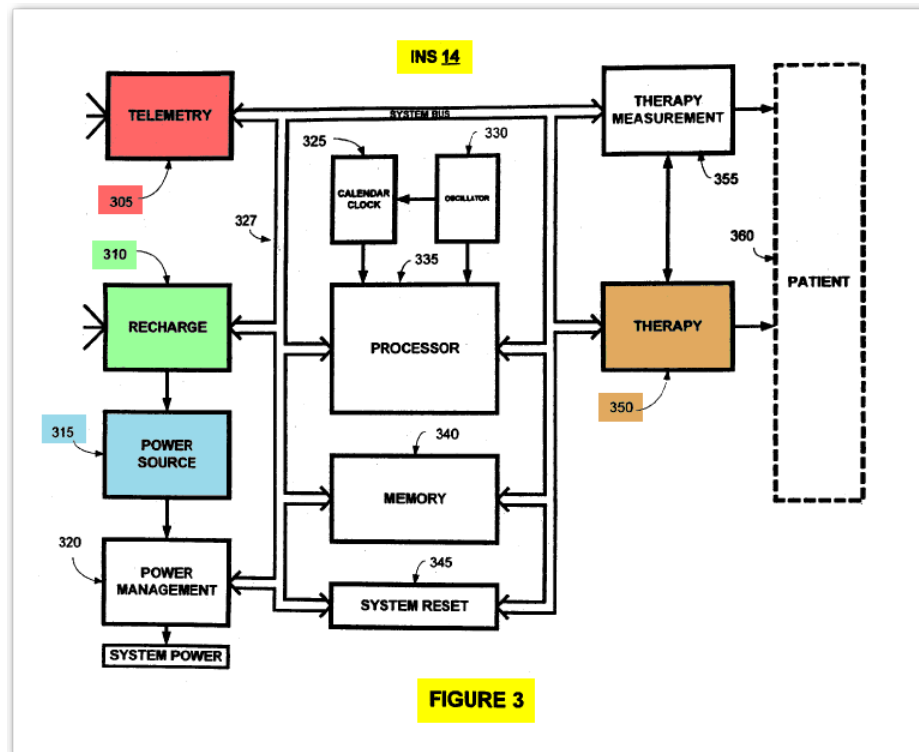
**A. Torgerson198 and Torgerson756 in view of Torgerson883 disclose an IMD that is operable by claims 1, 3-8, 10-14, and 16-20 of the '241 patent**

Torgerson198 and Torgerson756 disclose every feature of the IMD required by claims 1, 3-8, 10-14, and 16-20 of the '241 patent under their broadest reasonable interpretation except one—they are silent as to whether the second type of telemetry used by the Torgerson198 INS provides bi-directional communications. The Torgerson883 reference evidences that it would have been obvious for the second type of telemetry of the INS to be bi-directional.

**1. Torgerson198 and Torgerson756 disclose the required IMD of the '241 patent except for one feature.**

Torgerson198 and Torgerson756 together disclose an IMD in the form of an implantable neural stimulator (INS) 14. Ex. 1003, ¶ 50; Ex. 1005, 4:16-17, 4:25-28; Ex. 1006, 4:4-5, 4:22-24. Torgerson198 and Torgerson756 incorporate each

other by reference in their entireties and were filed on the same day on April 28, 2000. Ex. 1005, 8:53-59; Ex. 1006, 10:22-31. In describing INS 14, Torgerson198 and Torgerson756 utilize the same Figures 1-4 in their specifications. A block diagram of INS 14 is provided in their Figure 3, which is reproduced below:



Ex. 1005, Fig. 3.

Like the IMDs defined by the claims of the '241 patent (*see supra*, Section III.A), INS 14 of Torgerson198 and Torgerson756 includes an internal power source 315 (highlighted in blue in Fig. 3 above) (Ex. 1005, 6:12-20; Ex. 1006, 6:10-19), provides stimulation therapy, and communicates with external devices using two different types of telemetry.

More specifically, 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. Ex. 1003, ¶ 52; Ex. 1005, 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. Ex. 1003, ¶ 52; Ex. 1005, 2:13-19, 4:37-43, 4:59-5:9.

INS 14 further 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. Ex. 1003, ¶ 53; Ex. 1005, 6:12-20; Ex. 1006, 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. Ex. 1003, ¶ 53; Ex. 1005, 2:13-19, 5:15-24, 5:63-6:6.

INS 14 also includes a recharge module 310 (highlighted in green in Fig. 3 above), which includes a recharge regulation control unit 525 that can—separately from the telemetry unit 305—communicate with an external charger such as physician programmer 30 or patient programmer 35. Ex. 1003, ¶ 54; Ex. 1005, 6:12-20; Ex. 1006, 7:41-45, 8:40-61, 9:35-53. Such external chargers are used to recharge the internal power source 315 of INS 14. Ex. 1003, ¶ 54; Ex. 1006, 8:40-61, 9:23-53. Torgerson<sup>756</sup> explains that a POSA would have appreciated that

recharge module 310 (via recharge regulation control unit 525) would be able to communicate with such external chargers without utilizing telemetry unit 305 and by implementing a different communications technique. Ex. 1003, ¶ 54; Ex. 1006, 9:35-53.

Although Torgerson756 discloses that telemetry unit 305 performs bi-directional communication (Ex. 1006, 6:50-52), neither Torgerson198 nor Torgerson756 discloses explicitly 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. Ex. 1003, ¶ 55. But given that Torgerson756 indicates that various communication techniques could be implemented by recharge module 310 (Ex. 1006, 9:35-53), a POSA would have considered implementing such other known techniques for recharge module 310. Torgerson883 evidences one such known bi-directional communication technique utilized by a charging circuit of an IMD. Ex. 1003, ¶ 55; Ex. 1007, 5:17-57.

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

Torgerson883 is identified by Torgerson756 as a related patent (Ex. 1006, 1:21-27) and was filed on April 26, 2000, two days before the Torgerson198 and Torgerson756 patents were filed. Ex. 1005; Ex. 1006; Ex. 1007. A POSA reviewing the Torgerson198 and Torgerson756 patents would have been alerted to

other members of the Torgerson patent family, such as Torgerson883, because they alert the reader to those family members. Ex. 1003, ¶ 56; Ex. 1005, 1:5-19; Ex. 1006, 1:6-28.

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. Ex. 1003, ¶ 57; Ex. 1007, 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. Ex. 1003, ¶ 57; Ex. 1007, 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. Ex. 1003, ¶ 57; Ex. 1007, 2:24-39, 10:57-67.

To benefit from such advantages, it would have been obvious for a POSA to incorporate such teachings of Torgerson883 into the recharge module 310 of INS 14. Ex. 1003, ¶ 58. That would have enabled recharge module 310 of INS 14 to perform bi-directional communications with an external charger even when its main internal power source 315 becomes depleted. *Id.* Such bi-directional



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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.*; Ex. 1007, 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. Ex. 1003, ¶ 59. For example, Torgerson756 discloses that recharge module 310 of INS 14 should operate similarly to the recharging circuit 20 of Torgerson883. Ex. 1006, 8:62-9:2; Ex. 1003, ¶ 59. 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. Ex. 1006, 8:62-9:2; Ex. 1003, ¶ 59.

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. Ex. 1003, ¶ 59. Including a supplemental power source would have enabled recharge module 310 to charge the supplemental power source (such as a small capacitor) to wake up quickly and perform its functions even when INS 14's power source 315 was depleted. *Id.* As taught by Torgerson883, recharge module 310 would then have been able to perform such advantageous functions as

providing bi-directional communications with an external charger even when power source 315 becomes depleted to enable medical personnel to always interrogate and obtain data from INS 14. *Id.*

In sum, the INS 14 of Torgerson198 and Torgerson756 as modified by the above teachings of Trogerson883 disclose an IMD that includes (1) a power source 315, (2) a telemetry unit 305 that performs bi-directional communications with an external device, which programs the stimulation therapy provided by INS 14, (3) a recharge module 310 that performs a different type of bi-directional communications with an external charger, which wirelessly recharges the internal power source 315 of INS 14, and (4) a therapy module 350 that provides the programmed electrical stimulation therapy to the patient through INS 14's electrodes.

The resulting INS 14 of Torgerson198, Torgerson756 and Torgerson883 is therefore the type of IMD that is operable by the claimed methods of the '241 patent.

**B. Torgerson198 discloses the claimed methods of the '241 patent**

The claims of the '241 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 under their broadest reasonable

interpretation. 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.

**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. Ex. 1003, ¶ 65; Ex. 1005, 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). Ex. 1003, ¶ 65; Ex. 1005, 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). Ex. 1003, ¶ 65; Ex. 1005, 9:31-60.

**TABLE B**

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

Ex. 1005, 9:34-60.

As shown in Table B above, when INS 14 operates in the “normal operation” state, all of its components are enabled. Ex. 1003, ¶ 66; Ex. 1005, 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 the first telemetry type) are disabled while recharge module 310 (*i.e.*, reception of the second telemetry type) remains enabled. Ex. 1003, ¶ 66; Ex. 1005, 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. Ex. 1003, ¶ 66; Ex. 1005, 9:31-60.

Torgerson198 further discloses that INS 14 transitions between the three operating states based on the voltage of its power source 315. Ex. 1003, ¶ 67; Ex. 1005, 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. Ex. 1003, ¶ 67; Ex. 1005, 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. Ex. 1003, ¶ 67; Ex. 1005, 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. Ex. 1003, ¶ 67; Ex. 1005, 8:47-49, 9:14-30.

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. Ex. 1003, ¶ 68; Ex. 1005, 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. Ex. 1003, ¶ 68; Ex. 1005, 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. Ex. 1005, 9:14-19.

**(a) Independent claims 1, 8 and 14.**

Torgerson198’s method of operating INS 14 in one of three different states discloses the methods of the independent claims 1, 8, and 14 of the ’241 patent

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under their broadest reasonable interpretation. Ex. 1003, ¶ 69. The independent claims of the '241 patent cover methods that control the operation of an IMD by (1) enabling stimulation and listening for two different types of telemetry if the voltage level of its internal power source is above a first threshold, and (2) discontinuing both stimulation and listening for one of the two telemetry types if the voltage level of its internal power source falls below that first threshold. *Id.* Torgerson198's method of operating INS 14 in three operating states discloses the independent claims of the '241 patent under their broadest reasonable interpretation 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. *Id.*, ¶ 70. 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.*; Ex. 1005, 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 as required by the independent claims of the '241 patent under their broadest reasonable interpretation. Ex. 1003, ¶ 70.

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. Ex. 1003, ¶ 71. 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) remain 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,” stimulation and listening for one of the two types of telemetry will be disabled as required by the independent claims of the '241 patent under their broadest reasonable interpretation. *Id.*

Accordingly Torgerson198's method of operating INS 14 in three operating states discloses, at least, the independent claims of the '241 patent under their broadest reasonable interpretation when either the transition points T1 or T2 is considered the claimed “first threshold.” *Id.*, ¶ 72.

**(b) Dependent claims 4, 11, and 17**

Torgerson198's method of operating INS 14 in three different states also discloses the methods of the dependent claims 4, 11, and 17 under their broadest reasonable interpretation when the transition point T2 is considered the claimed "first threshold." *Id.*, ¶¶ 73-74. As discussed in Section III.B above, dependent claims 4, 11, and 17 specify a fourth step of the methods of the independent claims. That fourth step requires that stimulation and listening for the first telemetry type be resumed after they have been discontinued if the voltage of the power source later exceeds the claimed "first threshold." *Id.*, ¶ 73. 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.*, ¶ 74; Ex. 1005, 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. Ex. 1003, ¶ 74. Thus Torgerson198's method of operating INS 14 in three operating states discloses the dependent claims 4, 11, and 17 of the '241 patent under their broadest



reasonable interpretation when the transition point T2 is considered the claimed “first threshold.” *Id.*

**(c) Dependent claims 5, 12, and 18**

Torgerson198’s method of operating INS 14 in three different states additionally discloses the methods of the dependent claims 5, 12, and 18 under their broadest reasonable interpretation. *Id.*, ¶¶ 75-76. As discussed in Section III.B above, dependent claims 5, 12, and 18 specify a different fourth step of the methods of the independent claims. *Id.*, ¶ 75. That fourth step requires that stimulation and listening for the first telemetry type remain discontinued until the IMD is recharged if the voltage of its power source falls below a second threshold lower than the first threshold. *Id.*

Torgerson198’s method of operating INS 14 in three operating states discloses dependent claims 5, 12, and 18 under their broadest reasonable interpretation when transition point T1 is considered the claimed “first threshold” and transition point T2 is considered the claimed “second threshold.” *Id.*, ¶ 76. 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.*; Ex. 1005, 9:30-60. Thereafter, if INS 14’s power supply is recharged 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. Ex. 1005, 9:30-60; Ex. 1003, ¶ 76. Thus Torgerson198’s method of operating INS 14 in three operating states discloses discontinuing both stimulation and listening for the first telemetry type until INS 14 is recharged (as required by dependent claims 5, 12, and 18) when T1 is considered the claimed “first threshold” and T2 is considered the claimed “second threshold.” Ex. 1003, ¶ 76.

**(d) Remaining dependent claims**

Other dependent claims 3, 6, 7, 10, 13, 16, 19 and 20 only narrow the types of IMDs operated on by the methods of the independent claims. 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, 3-8, 10-14, and 16-20 of the ’241 patent. Ex. 1003, ¶ 78.

**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. Ex. 1005, 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. Ex. 1003, ¶ 79. 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. *Id.* 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. *Id.*, ¶ 80.

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

ST

Ex. 1005, 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. Ex. 1003, ¶ 81. 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.*, ¶ 82. For example, for a certain type of 4V battery disclosed by Torgerson<sup>198</sup> 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.*; Ex. 1005, 2:47-58. Doing so would have enabled INS 14 to provide stimulation in the “normal operation” state without damaging the battery. Ex. 1003, ¶ 82; Ex. 1005, 2:47-58.

**(a) Independent claims 1, 8, and 14**

This obvious two-state method of operating INS 14 also discloses the methods of the independent claims 1, 8, and 14 of the '241 patent. Ex. 1003, ¶ 83. As discussed in Section III.B above, the independent claims of the '241 patent cover methods that control the operation of an IMD by (1) enabling stimulation and listening for two different types of telemetry if the voltage of its internal power source is above a first threshold, and (2) discontinuing both stimulation and listening for one of the two telemetry types if the voltage of its internal power source falls below the first threshold. *Id.*

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The obvious two-state method of operating INS 14 discloses the independent claims of the '241 patent when the transition point ST is considered the claimed “first threshold.” *Id.* 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.*, ¶ 84; Ex. 1005, 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. Ex. 1005, 9:30-60. Accordingly the two-state method of operating INS 14 discloses the independent claims of the '241 patent when ST is considered the claimed “first threshold.”

**(b) Dependent claims 4, 11, and 17**

The obvious two-state method of operating INS 14 also discloses dependent claims 4, 11, and 17 when the transition point ST is considered the claimed “first threshold.” Ex. 1003, ¶¶ 85-86. As discussed in Section III.B above, dependent claims 4, 11, and 17 add a fourth step to the methods of the independent claims. That fourth step requires that stimulation and listening for the first telemetry type

be resumed after they have been discontinued if the voltage of the power source later exceeds the claimed “first threshold.” *Id.*, ¶ 85. As discussed above, 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. Ex. 1005, 9:30-60; Ex. 1003, ¶ 86.

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. Ex. 1005, 9:30-60; Ex. 1003, ¶ 86. 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. Ex. 1005, 9:30-60; Ex. 1003, ¶ 86. Accordingly the two-state method of operating INS 14 discloses dependent claims 4, 11, and 17 of the ’241 patent when ST is considered the claimed “first threshold.” *Id.*

**(c) Remaining dependent claims**

Other dependent claims 3, 6, 7, 10, 13, 16, 19 and 20 only narrow the types of IMDs operated on by the methods of the independent claims. 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, 3-4, 6-8, 10-11, 13-14, 16-17, 19-20 of the '241 patent.

\* \* \*

In summary, the combination of Torgerson198, Torgerson756, and Torgerson883 discloses both a three-state method of operating INS 14 and an obvious two-state method of operating INS 14 that render obvious most of the method claims of the '241 patent. In Sections VI.C through VI.S that follow, a detailed mapping is provided showing how Torgerson198 and Torgerson756 in view of Torgerson883 render obvious claims 1, 3-8, 10-14, and 16-20 of the '241 patent.

**C. Independent claim 1**

**1. “A method for controlling an implantable medical device, comprising:”**

Torgerson198 and Torgerson756 in view of Torgerson883 disclose a method for controlling an IMD as claimed in the '241 patent. More specifically,

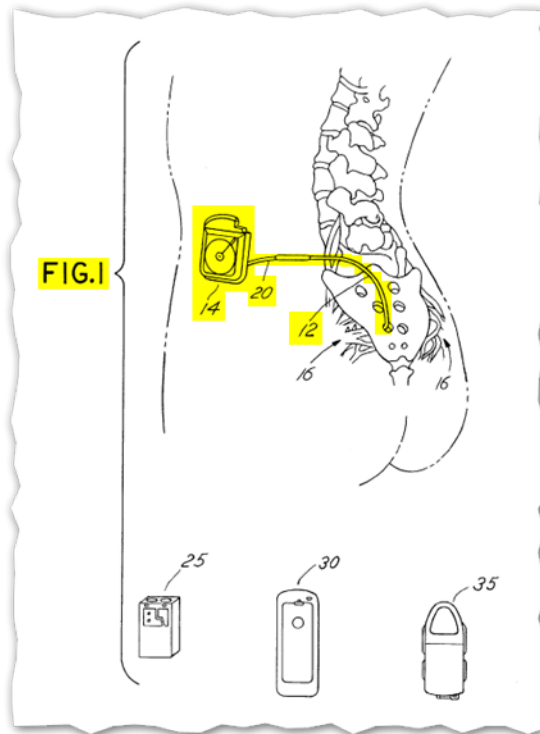
Torgerson198 and Torgerson756 in view of Torgerson883 disclose an implantable neuro stimulator (“INS”) 14. *See supra*, Section VI.A; Ex. 1005, 4:16-28.

Torgerson198 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*.”<sup>4</sup> *Id.*, 4:37-41, 5:29-51; Ex. 1003, ¶ 91. Accordingly INS 14 is an IMD. Ex. 1003, ¶ 91.

Figure 1 of Torgerson198 (reproduced below) shows an INS 14 along with lead 12 and lead extension 20 implanted within a patient. *Id.*, ¶ 92. Lead 12 includes “one or more electrodes” and is connected to INS 14 via a lead extension 20. *Id.*; Ex. 1005, 4:59-5:9. INS 14 delivers its electrical stimulation therapy to the patient’s tissue via the electrodes of lead 12. Ex. 1005, 4:59-5:9; Ex. 1003, ¶ 92.



Ex. 1005, Fig. 1.

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<sup>4</sup> In this paper, emphasis in quotes have been added unless otherwise indicated.

Torgerson198 and Torgerson756 in view of Torgerson883 disclose a method for controlling the operation of INS 14. *See supra*, Section VI.B. 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. Ex. 1005, Abstract, 8:3-10:33; Ex. 1003, ¶ 93.

Thus Torgerson198 and Torgerson756 in view of Torgerson883 disclose a method for controlling an IMD such as an INS 14, which provides therapy to a patient. Ex. 1003, ¶ 94.

**2. “monitoring a voltage of a power source within the implantable medical device;”**

Torgerson198 discloses that INS 14 includes a processor 335 and a power source measurement unit 515 (Ex. 1005, 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). Ex. 1003, ¶¶ 95-96. 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.” Ex. 1005, 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. Ex. 1003, ¶ 97. 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.*; Ex. 1005, 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. Ex. 1005, 3:18-29; Ex. 1003, ¶ 97. 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. Ex. 1003, ¶ 97.

**3. “if the voltage is above a first threshold, enabling the following functions:”**

As discussed in Section VI.B.1, Torgerson198 discloses that depending on the voltage of INS 14's internal power source 315, INS 14 is made to operate in one of three different operating states: “normal operation,” “low power,” and

“power off.” Ex. 1005, 8:3-9:16; Ex. 1003, ¶ 98. For each operating state, Torgerson198 discloses that a different set of components within INS 14 are enabled as shown in Table B of Torgerson198 (reproduced below with annotations added). Ex. 1003, ¶ 98; Ex. 1005, 9:14-60.

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

Ex. 1005, 9:34-59.

Torgerson198 further discloses transition points T1 and T2 (as discussed in Section VI.B.1 above) that are compared against the monitored voltage of power source 315 to place INS 14 into one of the three operating states. *Id.*, 8:3-9:16; Ex. 1003, ¶ 99. If the voltage of power source 315 is above transition point T1, INS 14 is made to operate in the “normal operation” state. Ex. 1003, ¶ 99; Ex. 1005, 8:3-19, 9:14-16. If the voltage of power source 315 is between transition points T1 and

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T2, INS 14 is made to operate in a “low power” state. *Id.*; Ex. 1003, ¶ 99. Finally, if the voltage of power source 315 is below transition point T2, INS 14 is made to operate in a “power off” state. Ex. 1003, ¶ 99; Ex. 1005, 8:47-50, 9:14-16.

As shown in Table B above, when INS 14 is in the “normal operation” state, all of its components are enabled including telemetry unit 305, recharge module 310, and therapy module 350. Ex. 1003, ¶ 100. In that state, 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 as required by the claims of the '241 patent. *Id.*

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 is above the claimed “first threshold” so that INS 14 is operating in the “normal operation” state, INS 14 enables providing stimulation and listening for a first and a second type of telemetry as required by the claims of the '241 patent under their broadest reasonable interpretation. *Id.*, ¶ 101.

To the extent that the broadest reasonable interpretation of the claims requires enabling and discontinuing stimulation and telemetry features whenever the power supply voltage is above or below the claimed “first threshold,” a POSA would have found it obvious to modify Torgerson198 to simplify its method to operate in only two states: “normal operation” and “power off.” *Id.*, ¶ 102. Also as

discussed in Section VI.B.2, a POSA would have selected a transition point ST so that when the voltage of power source 315 is above ST, INS 14 would operate in the “normal operation” state, and when the voltage of power source 315 falls below ST, INS 14 would operate in the “power off” state. *Id.* Torgerson198’s obvious two-state method of operating INS 14 is depicted below in a modified Table B. *Id.*

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

ST

*See supra*, Section VI.B.2; Ex. 1005, 9:34-60.

In the obvious method of operating INS 14 in two states, whenever the voltage of power source 315 is above ST, all of the components of INS 14 would be enabled including telemetry unit 305, recharge module 310, and therapy module 350. Ex. 1003, ¶ 103. 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 is above the claimed “first threshold,” INS 14 operates in the “normal operation” state, which enables providing stimulation and listening for a first and a second type of telemetry as required by the claims of the ’241 patent. *Id.*

\* \* \*

In summary, Torgerson198 discloses a method of operating INS 14 in three states. *Id.*, ¶ 104. For the three-state method, Torgerson198 discloses this limitation under its broadest reasonable interpretation 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. *Id.* For the two-state method, this limitation is satisfied when the transition point ST is considered the claimed “first threshold.” *Id.* Either way, the limitation is satisfied.

**(a) “listening for a first type of telemetry from a first external component;”**

Torgerson198 and Torgerson756 disclose that INS 14 includes a telemetry unit 305 (Ex. 1005, 6:12-20) that listens for (*i.e.*, receives) a first type of telemetry from an external physician programmer 30 and patient programmer 35 (Ex. 1006, 6:50-52). Ex. 1003, ¶ 105. More specifically, Torgerson756 discloses that “telemetry module 305 provides *bi-directional communications* between INS 14

and external [physician programmer] 30 or [patient programmer] 35.” Ex. 1006, 6:50-52, 8:44-57; Ex. 1003, ¶ 105.

Torgerson198 further discloses that physician programmer 30 is an external device that can be used to program the stimulation therapy provided by INS 14. Ex. 1003, ¶ 105; Ex. 1005, 2:13-19, 5:15-24, 5:63-6:6. Torgerson198 explains that “physician programmer 30, also known as a console programmer, uses telemetry to communicate with the implanted INS 14, so a physician can program and manage a patient’s therapy stored in the INS 14.” Ex. 1005, 5:15-24.

Torgerson198 additionally discloses that patient programmer 35 is an external device that can be used to make adjustments to the stimulation therapy provided by INS 14. *Id.*, 5:15-24, 5:63-6:6; Ex. 1003, ¶ 106. Torgerson198 explains that “patient programmer 35 also uses telemetry to communicate with the INS 14” and that the “patient uses the patient programmer 35 to communicate with the implanted INS 14 to make therapy adjustment that have been programmed by the physician.” Ex. 1005, 5:15-24, 5:63-6:6.

Accordingly, physician programmer 30 and patient programmer 35 are external devices that use telemetry to communicate with the telemetry module 305 of INS 14 to program the parameters of the stimulation therapy provided by INS 14 to a patient. Ex. 1003, ¶ 108.



- (b) “listening for a second type of telemetry from an external charging component, wherein the external charging component is used to wirelessly charge the power source; and”**

Torgerson198 and Torgerson756 disclose that INS 14 includes a recharge module 310 (Ex. 1005, 6:12-20) that includes a recharge regulation control unit 525 (Ex. 1006, 7:41-45) that communicates with external devices using a different communications technique than the one provided by telemetry unit 305. Ex. 1003, ¶ 110. More specifically, Torgerson756 explains that while recharge regulation control unit 525 can communicate with an “external component via telemetry unit 305,” a POSA would have appreciated that other communication techniques may be implemented for such a purpose. *Id.*; Ex. 1006, 9:35-53.

Torgerson756 further discloses that recharge module 310 (via its recharge regulation control unit 525) communicates with an external component such as a physician programmer 30 or a patient programmer 35 to recharge the INS 14’s internal power source 315 using a wireless magnetic field. Ex. 1006, 8:40-61, 9:23-34, 9:35-53; Ex. 1003, ¶ 111. Thus, Torgerson198 and Torgerson756 disclose (1) that the recharge module 310 of INS 14 communicates with an external device using a second telemetry technique that is different from the one utilized by telemetry unit 305, and (2) that the external device includes a physician

programmer 30 and a patient programmer 35, which are used to wirelessly charge INS 14's internal power source 315. Ex. 1003, ¶ 112.

Torgerson198 and Torgerson756, however, do not disclose explicitly that recharge module 310 of INS 14 listens for (*i.e.*, receives) telemetry (*i.e.*, communications) from such an external device. *Id.*, ¶ 113. 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 (Ex. 1006, 9:35-53), a POSA would have considered other such techniques for recharge module 310. Ex. 1003, ¶ 113. Torgerson883 discloses one such communication technique utilized by a charging circuit of an IMD. *Id.*

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. *Id.*, ¶ 115; 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, ¶ 115.

Torgerson883 discloses that it is advantageous for an IMD to have a bi-directional communication system that can function even when its main power source is

depleted so that medical personnel can always interrogate the IMD and obtain crucial information from the device. Ex. 1003, ¶ 115; Ex. 1007, 2:24-39, 10:62-67. And as discussed in 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.

Thus Torgerson198 and Torgerson756 in view of Torgerson883 disclose an INS 14 that includes a recharge module 310 that performs bi-directional communications with (which includes receiving or listening for communications from) an external charging component (such as physician programmer 30 or patient programmer 35) using a second telemetry technique that differs from the one used by telemetry unit 305. Ex. 1003, ¶ 117.

**(c) “providing stimulation to device electrodes using the power source; and”**

Torgerson198 discloses that INS 14 includes a therapy module 350 for providing stimulation therapy to a patient. *Id.*, ¶ 118; Ex. 1005, 5:29-50, 8:23-26. Such therapy is provided by INS 14 by sending precise, electrical pulses through electrodes to provide electrical stimulation to the targeted neural tissue of the patient. Ex. 1005, 2:13-19, 4:37-43, 4:59-5:9; Ex. 1003, ¶ 118. Those electrical pulses are generated via the electronics and the internal power source 315 contained within INS 14. Ex. 1003, ¶ 118; Ex. 1005, 4:37-43. Torgerson198

further discloses that the stimulation therapy provided by INS 14 is based on a desired treatment therapy programmed in INS 14 for a particular patient using an external programming device such as a physician programmer 30 or patient programmer 35. Ex. 1005, 2:13-19, 4:37-43, 5:15-24; Ex. 1003, ¶ 118; *see supra*, Section VII.C.3.a.

Thus Torgerson198 discloses that INS 14 includes a therapy module 350 that provides stimulation therapy via electrodes to a patient's tissue in accordance with the desired treatment therapy programmed (using external devices such as physician programmer 30 and patient programmer 35) and stored in INS 14. Ex. 1003, ¶ 119.

4. **“if the voltage falls below the first threshold, discontinuing listening for the first type of telemetry from the first external component and discontinuing providing stimulation to device electrodes using the power source, while continuing listening for the second type of telemetry.”**

Torgerson198 discloses a method of operating INS 14 in three operating states. As explained above, 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. Ex. 1005, 8:30-9:16; Ex. 1003, ¶ 120. Table B of Torgerson198 (reproduced below) depicts the three operating states of INS 14.

**TABLE B**

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

Ex. 1005, 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. Ex. 1005, 8:30-9:16; Ex. 1003, ¶ 121. In the “power off” state, therapy module 350 and telemetry unit 305 are disabled while recharge module 310 remains enabled. *Id.* As discussed in Sections VI.B.1, VI.C.3.a, VI.C.3.b, and VI.C.3.c, 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 as required by the claims of the ’241 patent. Ex. 1003, ¶ 121.

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

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below the claimed “first threshold,” INS 14 discontinues listening for a first type of telemetry and discontinues providing stimulation while continuing to listen for a second type of telemetry as required by this limitation under its broadest reasonable interpretation. *Id.*, ¶ 122.

And to the extent that the broadest reasonable interpretation of the claims requires that the IMD enable and discontinue stimulation and telemetry features whenever the power supply voltage is above or below the claimed “first threshold,” Torgerson 198’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	<b>Recharge 310</b> High Freq. Protection Circuit High Energy Protection Circuit	<b>Therapy 350</b> Measurement 355 Permanent Memory Non-volatile Memory EEPROM Memory Management System Bus 327 Processor 335 Power Management 320 <b>Telemetry 305</b> Oscillator 330 Calendar Clock 325 Volatile Memory 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. *Id.*, ¶ 124; *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. 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 and discontinues providing stimulation while continuing to listen for a second type of telemetry as required by this limitation. Ex. 1003, ¶ 124; *see supra*, Section VI.B.2.

\* \* \*

In summary, Torgerson198 discloses a method of operating INS 14 in three states. *Id.*, ¶ 125. For the three-state method, Torgerson198 discloses this limitation under its broadest reasonable interpretation 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. *Id.* 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 3**

**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. Ex. 1003, ¶ 129. 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, Ex. 1009. 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.” Ex. 1009, Abstract, ¶¶ 3, 6; Ex. 1003, ¶ 129. 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. Ex. 1003, ¶ 129.

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.*, ¶ 130. Alternatively, a POSA would have found it obvious to store the claimed “first threshold” value in a register of INS 14. *Id.*

**E. Claim 4**

**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 and resuming providing stimulation to device electrodes using the power source.”**

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. Ex. 1005, 8:30-9:16; Ex. 1003, ¶ 132. Table B of Torgerson198 (reproduced below) depicts the three operating states of INS 14.

**TABLE B**

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

Ex. 1005, 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; Ex. 1003, ¶ 133. 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.C.3; Ex. 1003, ¶ 133. 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) and resuming stimulation therapy (via re-enabling therapy module 350) if the

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voltage of power source 315 later exceeds the claimed “first threshold” as required by this limitation under its broadest reasonable interpretation. *See supra*, Section VI.B.1.

And to the extent that the broadest reasonable interpretation of 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 4. 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
Power Off	Recharge 310 High Freq. Protection Circuit High Energy Protection Circuit	Therapy 350 Measurement 355 Permanent Memory Non-volatile Memory EEPROM Memory Management System Bus 327 Processor 335 Power Management 320 Telemetry 305 Oscillator 330 Calendar Clock 325 Volatile Memory System Shutdown/POR 345

ST

*See supra*, VI.B.2; Ex. 1005, 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. Ex. 1003, ¶ 135; *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. Ex. 1003, ¶ 135. 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) and stimulation therapy (via re-enabling therapy module 350). *Id.*, ¶ 135; *see supra*, Section VI.B.2.

\* \* \*

In summary, Torgerson198 discloses a method of operating INS 14 in three states. *Id.*, ¶ 136. For the three-state method, Torgerson198 discloses this limitation under its broadest reasonable interpretation when T2 is considered the claimed “first threshold.” *Id.* Torgerson198 also discloses an obvious method of operating INS 14 in only two states. *Id.* For the two-state method, this limitation is satisfied when the ST is considered the claimed “first threshold.” *Id.*

**F. Claim 5**

- 1. “The method of claim 1, further comprising:”**

*See supra*, Section VI.C.

- 2. “if the voltage falls below the first threshold, and later falls below a second threshold lower than the first threshold, discontinuing listening for the first telemetry type and discontinuing providing stimulation to device electrodes using the power source until the device is recharged.”**

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. Ex. 1005, 8:30-9:16; Ex. 1003, ¶ 138.

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

Ex. 1005, 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. Ex. 1003, ¶ 139. 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 under the broadest reasonable interpretation of the claims 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 summary, Torgerson198 discloses a method of operating INS 14 in three states, which discloses this limitation under its broadest reasonable interpretation when T1 is considered the claimed “first threshold” and T2 is considered the claimed “second threshold.” Ex. 1003, ¶ 140.

**G. Claim 6**

**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. Ex. 1005 at 7:51-54.

**H. Claim 7**

**1. “The method of claim 1,”**

*See supra*, Section VI.C.

**2. “wherein the first external component and the external charging component are the same component.”**

As discussed in Section VI.C.1, Torgerson198 discloses a “first external component” in the form of either a physician programmer 30 or a patient programmer 35. As discussed in Section VI.C.2, Torgerson198 also discloses an “external charging component” in the form of either a physician programmer 30 or

patient programmer 35. Thus Torgerson198 discloses that the claimed “first external component” and the claimed “external charging component” can be the same. Ex. 1003, ¶ 144.

**I. Independent claim 8**

Independent claim 8 is nearly identical, substantively, to independent claim

1. It is narrower in certain aspects, which are explained below.

- 1. “A method for controlling an implantable medical device, comprising:”**

*See supra*, Section VI.C.1.

- 2. “monitoring a voltage of a power source within the implantable medical device;”**

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

- 3. “if the voltage is above a first threshold, enabling the following functions:”**

*See supra*, Section VI.C.3.

- (a) “listening for a first type of telemetry from a first external component, wherein the first external component is used to program stimulation parameters for the implantable medical device;”**

*See supra*, Section VI.C.3.a. This element narrower than independent claim 1 because it specifies that the claimed “first external component is used to program stimulation parameters for the implantable medical device.” Torgerson198 discloses that physician programmer 30 is an external device that can be used to program the stimulation therapy provided by INS 14. Ex. 1003, ¶ 105; Ex. 1005,



2:13-19, 5:15-24, 5:63-6:6. Torgerson198 thus meets this limitation as further discussed in Section VI.C.3.a.

- (b) **“listening for a second type of telemetry from an external charging component, wherein the external charging component is used to wirelessly charge the power source; and”**

*See supra*, Section VI.C.3.b

- (c) **“providing stimulation to device electrodes using the power source and in accordance with the stimulation parameters; and”**

*See supra*, Section VI.C.3.c. This element differs from independent claim 1 only in that the provided stimulation is “in accordance with the stimulation parameters.” Torgerson198 discloses this feature as discussed in Section VI.C.3.c.

4. **“if the voltage falls below the first threshold, discontinuing listening for the first telemetry type and discontinuing providing stimulation to device electrodes using the power source, while continuing listening for the second telemetry type so that the power source can be recharged.”**

*See supra*, Section VI.C.4. This element differs from independent claim 1 only in that it specifies that the device continues to listen to the second telemetry type “so that the power source can be recharged.” As explained above, Torgerson198’s telemetry unit 305 listens for a first type of telemetry while recharge module 310 listens for a second type of telemetry. Ex. 1003, ¶ 121. The recharge module 310 is responsible for recharging the power source so this feature is thus satisfied as further discussed in Section VI.C.4.

**J. Claim 10**

Dependent claim 10 is not materially different from dependent claim 3.

**1. “The method of claim 8,”**

*See supra*, Section VI.I.

**2. “wherein the first threshold is stored in a first register in the implantable medical device.”**

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

**K. Claim 11**

Dependent claim 11 is not materially different from dependent claim 4.

**1. “The method of claim 8, further comprising”**

*See supra*, Section VI.I.

**2. “further comprising if the voltage later exceeds the first threshold after falling below the first threshold, resuming listening for the first telemetry type and resuming providing stimulation to device electrodes using the power source.”**

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

**L. Claim 12**

Dependent claim 12 is not materially different from dependent claim 5.

**1. “The method of claim 8, further comprising:”**

*See supra*, Section VI.I.

2. **“if the voltage falls below the first threshold, and later falls below a second threshold lower than the first threshold, discontinuing listening for the first telemetry type and discontinuing providing stimulation to device electrodes using the power source until the device is recharged.”**

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

**M. Claim 13**

Dependent claim 13 is not materially different from dependent claim 6.

1. **“The method of claim 8,”**

*See supra*, Section VI.I.

2. **“wherein the power source comprises a lithium ion battery.”**

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

**N. Claim 14**

Independent claim 14 is nearly identical, substantively, to independent claim

1. It is broader in certain respects, which are explained below.

1. **“A method for controlling an implantable medical device that provides therapy to a patient, comprising”**

*See supra*, Section VI.C.1.

2. **“monitoring a voltage of a power source within the implantable medical device;”**

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

3. **“if the voltage is above a first threshold, enabling the following functions:”**

*See supra*, Section VI.C.3.

- (a) **“listening for a first type of telemetry from a first external component;”**

*See supra*, Section VI.C.3.a.

- (b) **“listening for a second type of telemetry from an external charging component, wherein the external charging component is used to wirelessly charge the power source; and”**

*See supra*, Section VI.C.3.b.

- (c) **“providing therapy to the patient; and”**

*See supra*, Section VI.C.3.c. This feature of independent claim 14 is broader than independent claim 1 because it simply provides “therapy” to the patient, whereas independent claim 1 more specifically provides “stimulation to device electrodes using the power source.” As discussed in Section VI.C.3.c, the INS provides therapy by providing electrical stimulation via its electrodes. This limitation is thus satisfied if the analogous limitation in claim 1 is satisfied.

4. **“if the voltage falls below the first threshold, discontinuing listening for the first type of telemetry from the first external component and discontinuing providing therapy to the patient, while continuing listening for the second type of telemetry.”**

*See supra*, Section VI.C.4.

**O. Claim 16**

1. **“The method of claim 14,”**

*See supra*, Section VI.N.

2. **“wherein the first threshold is stored in a first register in the implantable medical device.”**

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

**P. Claim 17**

1. **“The method of claim 14, further comprising”**

*See supra*, Section VI.N.

2. **“if the voltage later exceeds the first threshold after falling below the first threshold, resuming listening for the first telemetry type and resuming providing therapy to the patient.”**

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

**Q. Claim 18**

1. **“The method of claim 14, further comprising:**

*See supra*, Section VI.N.

2. **“if the voltage falls below the first threshold, and later falls below a second threshold lower than the first threshold, discontinuing listening for the first telemetry type and discontinuing providing therapy to the patient until the device is recharged.”**

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

**R. Claim 19**

1. **“The method of claim 14,”**

*See supra*, Section VI.N.

2. **“wherein the power source comprises a lithium ion battery.”**

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

**S. Claim 20**

**1. “The method of claim 14,”**

*See supra*, Section VI.N.

**2. “wherein the first external component and the external charging component are the same component.”**

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

**VII. GROUND 2: Claims 2, 9, and 15 of the '241 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 of dependent claims 2, 9, and 15**

Claims 2, 9, and 15 depend from independent claims 1, 8, and 14, respectively. These dependent claims further define the IMDs operated on by the independent claims of the '241 patent. More specifically, these dependent claims require that the two different types of telemetry utilized by such IMDs be frequency shift keying (FSK) and on-off keying (OOK). *See supra*, Section VI.A.1. The Torgerson references do not specifically identify the types of telemetry used in operating INS 14. The Abrahamson reference evidences that it would have been obvious for a POSA to utilize FSK and OOK for the telemetries used by INS 14.

**B. Overview of Torgerson198 and Torgerson756 in view of Torgerson883 and further in view of Abrahamson**

As discussed in Sections VI.A, VI.C.3.a, and VI.C.3.b, Torgerson198 and Torgerson756 in view of Torgerson883 discloses an INS 14 that includes a

telemetry unit 305 and recharge module 310 that employ two different types of telemetry for bi-directional communications with external devices. Ex. 1003, ¶ 178.

The three Torgerson patents, however, do not explicitly disclose the specific types of telemetry used by either telemetry unit 305 or recharge module 310. *Id.*, ¶ 179. Instead Torgerson198 discloses that such “components are generally known in the art” (Ex. 1005, 6:12-20, 6:35-36) and Torgerson756 discloses that a POSA would have appreciated that different types of communication techniques can be used (Ex. 1006, 9:46-53).

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. Ex. 1003, ¶ 180. A POSA would have understood that those telemetry techniques include FSK and OOK modulation schemes as evidenced by Abrahamson. *Id.*; Ex. 1008, 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. Ex. 1003, ¶ 180.

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.*, ¶ 181. 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.*

**C. Claims 2, 9, and 15**

**1. “The method of claim [1, 8, 14],”**

*See supra*, Sections VI.C, VI.I, VI.N.

**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. Ex. 1003, ¶ 183.

**VIII. Nevro is unaware of any secondary considerations of non-obviousness**

BSNC has not provided any evidence of secondary indicia of non-obviousness as to the claims of the '241 patent. Additionally Nevro is unaware of any secondary indicia of non-obviousness as to the claims of the '241 patent. Ex. 1003, ¶¶ 184-186. Nevro reserves the right to respond to any assertion of secondary indicia of non-obviousness advanced by BSNC.



**IX. Conclusion**

For the reasons provided above, Nevro requests *inter partes* review of claims 1-20 of the '241 patent and a determination those claims are unpatentable as obvious under 35 U.S.C. § 103 according to the challenged grounds.

**X. Standing (37 C.F.R. § 42.104(a))**

Nevro certifies that the '241 patent is available for *inter partes* review, and that Nevro is not barred or estopped from requesting an *inter partes* review of the '241 patent.

The assignee of the '241 patent, BSNC, filed a complaint against Nevro in the District of Delaware (case no. 1:16-cv-01163) on December 9, 2016, alleging infringement of the '241 patent. The present petition is being filed within one year of Nevro being served with the complaint.

**XI. Mandatory Notices (37 C.F.R. § 42.8)**

**A. Real Party In Interest**

The real party-in-interest of this petition is Nevro Corp.

**B. Related Matters**

The '241 patent is the subject of one civil action: *Boston Scientific Corporation et al. v. Nevro Corp.*, Case No. 1:16-cv-01163 (D.E.D.), filed December 9, 2016.

*Petition for Inter Partes Review of  
U.S. Patent No. 7,587,241*

Nevro Corp. filed an *inter partes* review petition (IPR2017-01831) on July 21, 2017, challenging the claims of U.S. Patent No. 7,437,193, which is a divisional of the '241 patent.

**C. Lead and Back-up Counsel**

Pursuant to 37 C.F.R. § 42.8(b)(3) and 42.10(a), Petitioner Nevro appoints **Jon E. Wright** (Reg. No. 50,720, [jwright-PTAB@skgf.com](mailto:jwright-PTAB@skgf.com)) as its lead counsel and **Brian Lee** (Reg. No. 59,112, [blee-PTAB@skgf.com](mailto:blee-PTAB@skgf.com)) as its back-up counsel, both 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](mailto: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](mailto:tbroughan@sidley.com), 202-736-8314) and Sharon Lee<sup>5</sup> ([sharon.lee@sidley.com](mailto:sharon.lee@sidley.com), 202-736-8510), both at the address: Sidley Austin LLP, 1501 K Street N.W., Washington, DC 20005.

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<sup>5</sup> Nevro will file a motion for Sharon Lee to appear *pro hac vice* according to the Board's orders and rules.

**D. Service Information**

Petitioner consents to electronic service by email at:

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Respectfully submitted,  
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/Jon E. Wright/

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*Petition for Inter Partes Review of  
U.S. Patent No. 7,587,241*

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

The undersigned hereby certifies that on July 31, 2017, true and correct copies of the foregoing **PETITION FOR INTER PARTES REVIEW OF U.S. PATENT NO. 7,587,241**, Petitioner's Power of Attorney, and all associated exhibits were served in their entireties on the following parties via FedEx Express® or Express Mail:

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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 13,963 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.

Respectfully submitted,

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

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Date: July 31, 2017

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