IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

In re U.S. Patent No.: 8,359,102 B2	Trial Number: _____
Filed: April 13, 2012	Attorney Ref.: 1014.0248AB2
Issued: January 22, 2013	Petitioner: Boston Scientific Neuromodulation Corporation

Inventors: Konstantinos Alataris, Andre B. Walker, Jon Parker, Youganth Chitre, Sangsoo W. Park, James R. Thacker

Patent Owner: Nevro Corp.

Title: Selective high frequency spinal cord modulation for inhibiting pain with reduced side effects, and associated systems and methods

---

Mail Stop PATENT BOARD
Patent Trial and Appeal Board
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

PETITION FOR *INTER PARTES* REVIEW OF CLAIMS 1, 2, 11-15, 17-23, 25 AND 26 OF U.S. PATENT NO. 8,359,102

TABLE OF CONTENTS

I. MANDATORY NOTICES

Pursuant to 37 C.F.R. § 42.8(b), Petitioner submits the following mandatory notices.

A. Real Party-In-Interest

The real party in interest is Boston Scientific Neuromodulation Corporation, 25155 Rye Canyon Loop, Valencia CA 91355.

B. Related Matters

There is no related litigation. This Petition is being filed and served concurrently with another Petition for *Inter Partes* Review, which also challenges the patentability of claims 1, 2, 11-15, 17-23, 25 and 26 of U.S. Patent No. 8,359,102 ("the '102 patent," Ex. 1101), but on different grounds.

C. Lead and Backup Counsel

Petitioner's counsel are:

Lead Counsel: J. Derek Vandenburgh (Reg. No. 32,179).

Backup Counsel: Iain A. McIntyre (Reg. No. 40,337).

Pursuant to 37 C.F.R. § 42.10(a), a Power of Attorney is submitted with this Petition.

D. Service Information

Lead Counsel

Electronic mail address: dvandenburgh@carlsoncaspers.com

Postal mailing and hand delivery address: Mr. D. Vandenburgh, Carlson Caspers, 225 South Sixth Street, Suite 4200, Minneapolis, MN 55402

Telephone number: 612 436 9618

Facsimile number: 612 436 9605

Backup Counsel

Electronic mail address: imcintyre@carlsoncaspers.com

Postal mailing and hand delivery address: Mr. I. McIntyre, Carlson Caspers, 225 South Sixth Street, Suite 4200, Minneapolis, MN 55402

Telephone number: 612 436 9610

Facsimile number: 612 436 9605

II. SERVICE

Petitioner has served by FedEx, on even date herewith, the Petition and supporting evidence on (i) the correspondent attorney of record of the patent owner as listed on USPTO PAIR and (ii) the patent owner as listed in the USPTO Assignment database. A certificate of service is attached at the end of this Petition, pursuant to 37 C.F.R. § 42.6(e)(4)(i).

III. FEES

Pursuant to 37 C.F.R. § 42.15(a)(i), Petitioners enclose the associated fee of $9000 with this Petition.

IV. GROUNDS FOR STANDING

Pursuant to 37 C.F.R. § 42.104, Petitioner certifies that the '102 patent is available for review under 35 U.S.C. § 311(c), because this Petition is filed more than nine months after issuance of the '102 patent, and no post-grant review of the '102 patent has been instituted under chapter 32 of 35 U.S.C. Furthermore, Petitioner is not barred or estopped from requesting an *inter partes* review challenging claims of the '102 patent on the grounds set forth below.

V. INTRODUCTION TO THE CHALLENGE AND RELIEF REQUESTED

Pursuant to 37 C.F.R. §§ 42.22(a) and 42.104(b), Petitioner challenges claims 1, 2, 11-15, 17-23, 25 and 26 of the '102 patent as being anticipated, or obvious over, the following patents and publications, either individually or in combination as described in more detail below.

A. Prior Art Patents and Printed Publications

1. U.S. Patent Publication No. 2007/0073354 (Neural Blocking Therapy) to M. B. Knudson *et al*, published on March 29, 2007 (Ex. 1102, hereafter "Knudson").
2. U.S. Patent Publication No. 2011/0184488 (Spinal Cord Stimulation to Treat Pain) to D. DeRidder, published on July 28, 2011 (Ex. 1103, hereafter "DeRidder").

3. U.S. Patent No. 5,776,170 (Electrotherapeutic Apparatus") to A. J. R. MacDonald *et al*., issued July 7, 1998 (Ex. 1104, hereafter "MacDonald").4.

B. Reasonable Likelihood That Claims 1, 2, 11-15, 17-23, 25 and 26 are Unpatentable

In view of the Exhibits attached hereto, including a Declaration by Prof. C. McIntyre, Exhibit 1115, the citations in the Claim Charts and the remarks provided below, Petitioner respectfully contends that there is more than a reasonable likelihood that at least one of claims 1, 2, 11-15, 17-23, 25 and 26 of the '102 patent are unpatentable under 35 U.S.C. §§ 102 and/or 103.

C. Relief Requested

Petitioner respectfully requests under 35 U.S.C. § 311-319 and 37 C.F.R. §42.100 *et seq.* institution of a trial under 37 C.F.R. Part 42 and cancellation/ invalidation of claims 1, 2, 11-15, 17, 19-23, 25 and 26 of the '102 patent as unpatentable under 35 U.S.C. §§ 102 and/or 103.

VI. IDENTIFICATION OF THE CHALLENGE

A. The '102 Patent and its Claims

The '102 patent is directed to "selective high frequency spinal cord modulation for inhibiting pain." *See* Ex. 1101, 1:21-22. The Background of the patent states that it is known to implant neurological devices for the purpose of

spinal cord stimulation ("SCS") to treat pain. *Id.* 1:28-50. Such devices have electrodes placed at a desired location in the vicinity of the spinal cord, and an electrical signal is applied to the electrodes that mask or otherwise alter the patient's sensation of pain. *Id.* According to the '102 patent, traditional SCS in many cases results in paresthesia, a tingling sensation that is perceived as pleasant for some patients, but may be less beneficial for other patients. *Id.*, 1:50-56.

The specification describes the technology of the patent as systems and methods for inhibiting pain "via waveforms with high frequency elements or components…, generally with reduced or eliminated side effects." *Id.* 2:53-57. The patent asserts that this pain inhibition can be achieved without therapy-induced paresthesia. *Id.* 3:15-23. The system includes a pulse generator coupled to one or more leads that are implanted in the spinal region. *Id.* 3:28-53. The pulse generator provides signals via the lead(s) that can up-regulate (e.g., stimulate or excite) and/or down-regulate (e.g., block or suppress) target nerves. *Id.* 3:54-57.

The '102 patent describes two clinical studies that were performed using the allegedly new device. In the first study, two leads were initially implanted on either side of spinal cord midline in the region of vertebral levels T7-T8, and patients were given standard SCS treatment with frequency in the range of 60-80Hz, a pulse width of 100-200 μsec, a duty cycle of 100% and an amplitude in the range of 3-10 mA. *Id.* 6:18-55. After completing that therapy, the leads were then

moved to the region of T9-T12, and therapy was provided at a higher frequency in the range of 3-10 kHz, with a duty cycle of 50-100%, a pulse width of 30-35μsec, and an amplitude of 1-4 mA. *Id.*, 6:56 – 7:10. According to the '102 patent, the latter, high frequency, therapy reduced pain by 42% compared to standard SCS therapy and had other benefits reflected in Figures 3-6 of the patent. *Id.*, 7:11 – 11:8. The high frequency therapy was alleged to be preferred by the patients because it did not produce paresthesia. *Id.*, 9:5-20. The second study did not include a comparison to low frequency SCS therapy, but again is relied on in the '102 patent to show substantial reduction in pain. *Id.* 12:9 – 14:18.

The '102 patent contains 26 claims, including two independent claims. The independent claims are reproduced below:

1. A method for treating a patient, comprising:	26. A method for treating a patient, comprising:
delivering or instructing delivery of an electrical signal to the patient's spinal cord via at least one implantable signal delivery device; and	activating or instructing activation of a signal generator to apply an electrical signal to the patient's spinal cord via at least one implantable signal delivery device; and
wherein the electrical signal has a frequency of from about 1.5 kHz to about 50 kHz and does not create paresthesia in the patient.	wherein the electrical signal has a frequency of from about 1.5 kHz to about 50 kHz and does not create paresthesia in the patient.

The two independent claims are very similar, and broadly recite a method involving a single step of delivering or applying an electrical signal to a patient's spinal cord that has a frequency between 1.5 kHz and 50 kHz, without creating paresthesia. The dependent claims add limitations relating to features such as the specific pain being treated, the specific location in the spine where therapy is applied and the use of patient feedback to identify that location, and narrower ranges of signal frequency, among others.

B. Relevant Prosecution History

The '102 patent issued from Application Serial No. 13/446,970 ("the '102 application") filed on April 13, 2012. The '102 application claims priority as a continuation of Application Serial No. 13/245,450 ("the '450 application") filed on September 26, 2011, which claims priority as a continuation of Application Serial No. 12/765,747 ("the '747 application"), filed on April 22, 2010, which in turn claims priority from two provisional applications, 61/176,868, filed on May 8, 2009 and 61/171,790, filed on April 22, 2009. *See* Ex. 1101, front page. Accordingly, the earliest asserted priority date for the '102 patent is April 22, 2009.

In an office action issued on November 18, 2011 in the parent '450 application, the examiner rejected the claims for being anticipated. Exhibit 1105.

Following that rejection, an in-person interview was held on February 1, 2012. The Interview Summary described the substance of that interview as follows:

> Applicant presented an overview of conventional spinal cord stimulation techniques and the different results achieved by Nevro as disclosed in the present application. Discussed the claim elements of epidural stimulation, the specific frequency range, and the association with not inducing paresthesia. Agreed that the not creating paresthesia is an unexpected result tied to the specific frequency range and that the prior art of record does not explicitly disclose stimulating at the claimed frequencies with the result of not creating paresthesia. Proposed claim amendments are to limit the claimed subject matter to the range of frequencies as previously claimed and not creating paresthesia with the electrical signal.

Exhibit 1106, p. 2.

The applicants submitted an amendment in the ‘450 application on February 7, 2012, allegedly making amendments as described in the Interview Summary. Exhibit 1107. The Examiner allowed the ‘450 application on March 14, 2012, and it subsequently issued as U.S. Patent No. 8,170,675. In the Notice of Allowability, the Examiner identified five pieces of prior art as showing stimulation without causing paresthesia. *See* Ex. 1108, p. 2.

On April 13, 2012, the applicants filed the ‘102 application as a continuation of the ‘450 application. A preliminary amendment was filed on May 18, 2012 that,

inter alia, broadened claim 1 by removing the limitation that the treatment reduces or inhibits pain. Exhibit 1109, p. 2.

On October 15, 2012, the Examiner issued an Ex Parte Quayle Office Action that included an objection to one independent claim, a rejection of two dependent claims under 35 U.S.C. §101 and a provisional obviousness-type double patenting rejection. Exhibit 1110. The Examiner indicated that the rejected claims contained allowable subject matter if modified to overcome the rejections and/or objections. The Examiner also listed 11 prior art references as being pertinent to the disclosure. *See* Ex. 1110, pp. 6-7. One of those references was Knudson, which the Examiner described as showing "blocking neural activity along the spinal cord using high frequency stimulation." *Id.*

On November 28, 2012, the applicants responded with a terminal disclaimer and an amendment cancelling some of the claims. Exhibit 1111. The '102 patent was issued on January 22, 2013.

While no rejection was made in the '102 application based on Knudson, prosecution of the grandparent '747 application continued beyond the issuance of the '102 patent. In an Office Action dated July 25, 2013, six months after the '102 patent issued, the examiner rejected claims of the '747 application as anticipated by Knudson. Exhibit 1112, p. 3. In an Amendment dated January 24, 2014, the

applicants distinguished the claims of the ‘747 application over Knudson based on the “no paresthesia” limitation:

> A. Knudson
>
> As discussed during the January 13 interview, Knudson discloses electrodes positioned at the spinal cord and/or roots (see Figures 12 and 13). Paragraph [0083] of Knudson discloses that the electrodes are implanted in the subarachnoid space and have applied to them a blocking signal that "preferably, has a frequency in excess of 3,000 Hz and more preferably about 5,000 Hz or more."
>
> The parties further discussed scientific publications by Dr. Kevin L. Kilgore, et al., including an article titled "Simulation of High-Frequency Sinusoidal Electric Block of Mammalian Myelinated Axons" (Bhadra, et al., J. Comput. Neurosci. (2007), hereinafter "Bhadra 2007"), and an article titled "Reversible Nerve Conduction Block Using Kilohertz Frequency Alternating Current" (Kilgore, et al., Neural Modulation: Technology at the Neural Interface (2013), hereinafter "Kilgore 2013"). The foregoing references are attached hereto. The parties also discussed a presentation given by Dr. Kilgore at the North American Neuromodulation Society (NANS) Annual Meeting on December 6, 2013.[1]
>
> As discussed and agreed upon during the January 13 interview, Bhadra 2007, Kilgore 2013, and Dr. Kilgore's presentation at the NANS Annual Meeting provide scientific support for the conclusion that the term "block" as used in Knudson (and/or other references), as well as the term “high frequency” stimulation (as used in certain references), cannot inherently mean therapy without paresthesia. Specific reference was made to Figure 3 of Bhadra 2007, and pages 7, 8, and 11 of Kilgore 2013, to show that applying a block signal to one area of the spinal cord would likely activate other nerve fibers in the spinal cord of different diameters and at different distances from the “blocked” nerve fibers, and would thus generate paresthesia. Kilgore 2013, in fact, states on page 11 that the “lack of paresthesia [in Nevro’s SCS system] is an unexpected result, as it may indicate that the onset response, if present, does not produce a conscious effect when delivered to the spinal cord with the parameters utilized in this trial."
>
> The parties also discussed an article by Perruchoud, et al.,[2] titled "Analgesic Efficacy of High-Frequency Spinal Cord Stimulation: A Randomized Double-Blind Placebo-Controlled Study" (Neuromodulation: Technology at the Neural Interface (2013), hereinafter "Perruchoud", attached hereto).[3] The parties discussed and agreed that Perruchoud shows that stimulation applied to a patient's spinal cord at a frequency

> of 5,000 Hz can produce paresthesia (Perruchoud at pg. 3). Accordingly, the parties agreed that Knudson's disclosure of stimulation at the spinal cord at frequencies in excess of 3,000 Hz and "more preferably about 5,000 Hz or more" cannot inherently disclose providing therapy at such frequencies, without generating paresthesia.
>
> The parties also discussed U.S. Patent No. 8,224,453 to De Ridder ("De Ridder"), which explicitly states that high frequency stimulation generates paresthesia. More specifically, in column 1, lines 52-58, De Ridder states: "Specifically, high frequency stimulation has been observed to prevent the perception of certain types of pain by patients. Instead of perceiving pain, the high frequency electrical stimulation causes other sensation signals to reach the thalamus **whereby the patient experiences a tingling sensation known medically as paresthesia**." (emphasis added).

Exhibit 1113, pp. 13-15. The '747 application was subsequently allowed and issued as U.S. Patent No. 8,712,533 on April 29, 2014.

C. Definition of Certain Claim Terms

In this proceeding, the claims of the '102 patent are to be given their "broadest reasonable construction in light of the specification." 37 C.F.R. § 42.100(b). Petitioner has used that standard to produce the following definitions of certain claim terms.

"implantable signal delivery device." As used in claims 1 and 26, this term refers to an implantable lead and electrode(s) that deliver(s) the electrical signal to the patient.

First, "implantable" simply means capable of being inserted in a living site (implant: to insert in a living site. *See* Merriam Webster's Collegiate Dictionary, 10th ed. Ex. 1114).

Second, the terms "signal delivery device" and "signal delivery element" are used interchangeably in the specification to describe element 110 of the drawings, shown in FIG. 1A, reproduced below.

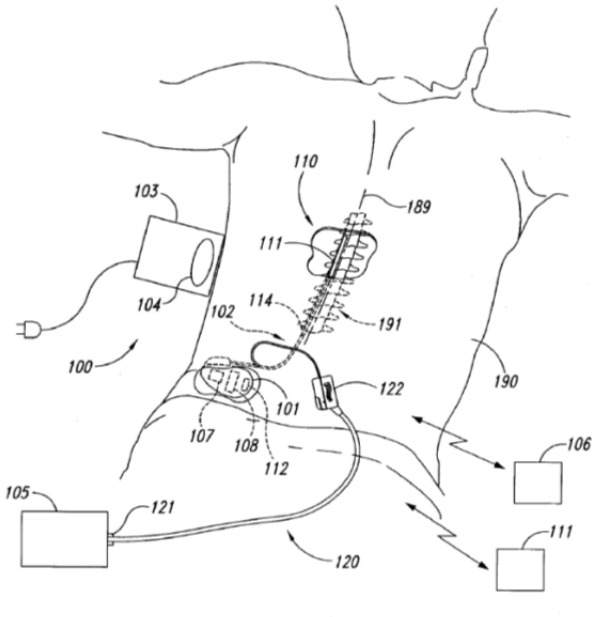

Fig. 1A

FIG. 1A from the '102 Patent

For example:

> "[t]he practitioner can test the efficacy of the **signal delivery element 110** in an initial position. The practitioner can then disconnect the cable assembly 120, reposition the **signal delivery element 110**, and reapply the electrical modulation. This process can be performed iteratively until the practitioner obtains the desired position for the **signal delivery device 110**."

Ex. 1101, 4:64- 5:3 (emphasis added).

The ‘102 patent distinguishes between a “signal delivery device” and a pulse generator. For example, the ‘102 patent discusses how a pulse generator 101 is coupled to the “signal delivery device” and can send signals to the “signal delivery device” to stimulate or excite, or to block or suppress, target nerves. *Id.* 3:28-4:6 Furthermore, the “signal delivery device” can include “a lead or lead body 111 that carries features for delivering therapy to a patient 190 after implantation.” *Id*. 3:34-36. The ‘102 patent also describes how a practitioner can temporarily couple an external programmer to the “signal delivery device” during the implantation procedure to find the correct location for the “signal delivery device.” *See* Ex. 1101, 4:44 – 5:10.

Thus, the broadest reasonable construction of an “implantable signal delivery device” is that it includes at least a lead, having one or more electrodes, that is capable of being inserted into a living site to deliver a signal.

“spinal cord.” Claims 1 and 26 of the ‘102 patent recite delivering or supplying an electrical signal to the “spinal cord” of the patent. As used in the ‘102 patent, the “spinal cord” includes “the dorsal column, dorsal horn, dorsal root, dorsal root entry zone and/or other particular regions of the spinal column.” *Id.*, 2:67 – 3:6.

“paresthesia.” As used in claims 1 and 26, paresthesia refers to a sensation experienced by some patients undergoing spinal cord stimulation (SCS). The

sensation is perceived as a tingling or prickling feeling. This definition is supported the '102 patent. For example, "in many cases, patients report a tingling or paresthesia that is perceived as more pleasant and/or less uncomfortable than the underlying pain sensation." *Id.* 1:50-52.

This construction of "paresthesia" as a tingling sensation induced by spinal cord stimulation is supported by the Declaration submitted by Dr. C. McIntyre. *See* Ex. 1115, ¶ 21.

"**nociceptive pain**" As used in claim 13, this means pain that that results from a mechanical or other physical effect. The '102 patent provides a definition of "nociceptive pain" as referring "generally to pain that is properly sensed by the patient as being triggered by a particular mechanical or other physical effect (e.g., a slipped disc, a damaged muscle, or a damaged bone)." *See* Ex. 1101, 13:51-55. Nociceptive pain is contrasted in the '102 patent with "neuropathic pain," which is "pain resulting from a dysfunction in the neural mechanism for reporting pain, which can produce a sensation of pain without an external neural trigger." *Id*. 13:48-51; *see* also Ex. 1115, ¶ 22. Thus, "nociceptive pain" is properly construed as a pain that is properly sensed as being triggered by a particular mechanical or other physical effect and not one that arises from a dysfunction of the neural pain reporting apparatus.

D. Level of Ordinary Skill in the Art

The level of ordinary skill in the art is relatively high. A person of ordinary skill in the art to which the '102 patent pertains would have a degree, typically a graduate degree, in a science or engineering discipline related to neural stimulation, such as neuroscience or electrical or biomedical engineering, along with some relevant experience. If the person had a Ph.D., they would have at least 2-3 years of experience in neural stimulation or, if the person had with a master's degree, 3-5 years of experience in neural stimulation. Someone with a bachelor's degree would have more than 5 years of experience in neural stimulation, along with direct exposure to scientific research in neural stimulation. Alternatively, the person of ordinary skill would have an M.D. and experience practicing as neurologist, neurosurgeon or anesthesiologist, again with 2-3 years of experience in neural stimulation, along with direct exposure to scientific research in neural stimulation. The person would regularly peruse the relevant literature including, but not exclusively, peer-reviewed publications, books, monographs and patents, and would know how to use library resources to find out more information about areas being researched. Exhibit 1115, ¶ 11.

VII. GROUNDS FOR CHALLENGE

Ground 1: claims 1, 2, 17-22, 25 and 26 are anticipated by Knudson.

Ground 2: claims 1, 2, 11-15, 17-23, 25 and 26 are invalid as obvious over Knudson either alone or in view of DeRidder and/or MacDonald.

VIII. IDENTIFICATION OF HOW THE CLAIMS ARE UNPATENTABLE

A. Ground 1: Claims 1, 2, 17-22, 25 and 26 Are Anticipated By Knudson

Knudson (Ex. 1102) was published on March 29, 2007 and, therefore, is prior art to the '102 patent under 35 U.S.C. § 102(b).[1] Knudson is one of the references that was identified as being pertinent to the disclosure of the '102 application in the October 15, 2012 *Ex parte Quayle* action. Exhibit 1110.) However, the Examiner did not have the benefit of the McIntyre Declaration filed herewith that explains how those skilled in the art would interpret the "blocking" therapy described in Knudson relative to the presence or absence of paresthesia.

Knudson is entitled "Neural Blocking Therapy," and is directed to methods and apparatus for treating a variety of disorders associated with neural activity. *See* Ex. 1102, Abstract. The disclosure begins by describing several prior art treatments that involve applying stimulation signals to nerves. *Id.*, ¶¶ 4-8. The publication then describes the difference between such "stimulation" therapies and "blocking" therapies. *Id.*, ¶¶ 10-11. With stimulation therapies, the stimulation parameters are selected "to initiate neural action potentials to be propagated along

[1] Because the '102 patent was filed prior to March, 2013, it is governed by the pre-AIA version of 35 U.S.C. § 102.

the nerve to an organ (e.g., brain or stomach)." *Id.* In contrast, a blocking signal "blocks the propagation of action potentials along the nerve." *Id.*

According to Knudson, a waveform suitable for the disclosed therapy will have a frequency in excess of 200 Hz and, "more preferably, 5,000 Hz or higher." *Id.*, ¶ 66. "A 5,000 Hz signal will have a pulse width of about 100 microseconds. A representative amplitude for such signals would be 0.2 to 8 mA." *Id.* Knudson describes this signal as a "blocking" waveform. *Id.*

One of the uses for the therapy disclosed in Knudson is spinal cord treatment. *Id.*, ¶¶ 80-86. In the embodiment of Figures 11-12, an electrode E is inserted within the dural layer of the spine in the region of a dorsal root. *Id.*, ¶ 83. The electrode is electrically connected via a lead to an "implantable or external pulse generator." *Id.*, ¶ 85. "Application of a blocking signal to the electrode E blocks signals such as pain signals from the dorsal root [to] the spinal cord SC." *Id.*, ¶ 83. The signal in this embodiment "preferably, has a frequency in excess of 3,000 Hz and more preferably about 5,000 Hz or more." *Id.*

In a second spinal cord embodiment shown in Figure 13, an electrode is placed over a desired location of the spinal column itself. *Id.*, ¶ 86; Figure 13. The desired location in Figure 13 is an ascending pathway AP. *Id.* Application of the disclosed signal to the ascending pathways "block[s] transmission of neural signals to the brain." *Id.*

1. Comparison of Knudson to Independent Claims 1 and 26

The following claim charts compare independent claims 1 and 26 of the '102 patent to the disclosure of MacDonald:

'102 patent, Claim 1	**Knudson (U.S. Patent Pub. No. 2007/0073354)**
1. A method for treating a patient, comprising:	Knudson is directed to treating a variety of conditions in the human body. Exhibit 1102, Abstract.
delivering or instructing delivery of an electrical signal to the patient's spinal cord via at least one implantable signal delivery device; and	"For treating a condition associated with neural activity of a spinal cord, the method includes placing an electrode to create a field near a nerve associated with the spinal cord, and creating the field with parameters selected to at least partially block neural activity within the nerve." *Id.*, ¶ 36. Beginning at ¶80, Knudson describes "Spinal Cord Treatment." Figures 11 and 12 show an implanted electrode E encircling a dorsal root of the spine and connected to a lead L. *Id.*, ¶¶ 83, 85. Figure 13 shows an electrode E implanted adjacent a targeted ascending pathway to the brain. *Id.*, ¶ 86. An electrical blocking signal is applied to the electrode by an "implantable or external pulse generator." *Id.*, ¶ 85.
wherein the electrical signal has a frequency of from about 1.5 kHz to about 50 kHz	"For spinal treatments, such blocking signal may be as previously described and, preferably has a frequency in excess of 3,000 Hz and more preferably about 5,000 Hz or more." *Id.*, ¶ 83
and does not create paresthesia in the patient.	The electrical signal applied to the spine is a "blocking" signal." *Id.*, ¶83. Knudson describes a blocking signal as one that "blocks the propagation of action potentials along the nerve," and distinguishes a blocking signal from a stimulation signal that causes neural action signals to be "propagated along the nerve." *Id.*, ¶¶ 10-11. One skilled in the art would be familiar with the term "block." Exhibit 1120, ¶ 45. One skilled in the art would understand that, since the

	term "block" is used to describe a signal that prevents the transmission of signals along a nerve, Knudson was teaching application of a signal that would not create paresthesia. *Id.*

'102 patent, Claim 26	**Knudson (U.S. Patent Pub. No. 2007/0073354)**
26. A method for treating a patient, comprising:	Knudson is directed to treating a variety of conditions in the human body. Exhibit 1102, Abstract.
activating or instructing activation of a signal generator to apply an electrical signal to the patient's spinal cord via at least one implantable signal delivery device; and	"For treating a condition associated with neural activity of a spinal cord, the method includes placing an electrode to create a field near a nerve associated with the spinal cord, and creating the field with parameters selected to at least partially block neural activity within the nerve." *Id.*, ¶ 36. Beginning at ¶80, Knudson describes "Spinal Cord Treatment." Figures 11 and 12 show an implanted electrode E encircling a dorsal root of the spine and connected to a lead L. *Id.*, ¶¶ 83, 85. Figure 13 shows an electrode E implanted adjacent a targeted ascending pathway to the brain. *Id.*, ¶ 86. An electrical blocking signal is applied to the electrode by an "implantable or external pulse generator." *Id.*, ¶ 85.
wherein the electrical signal has a frequency of from about 1.5 kHz to about 50 kHz	"For spinal treatments, such blocking signal may be as previously described and, preferably has a frequency in excess of 3,000 Hz and more preferably about 5,000 Hz or more." *Id.*, ¶ 83
and does not create paresthesia in the patient.	The electrical signal applied to the spine is a "blocking" signal." *Id.*, ¶83. Knudson describes a blocking signal as one that "blocks the propagation of action potentials along the nerve," and distinguishes a blocking signal from a stimulation signal that causes neural action signals to be "propagated alone the nerve." *Id.*, ¶¶ 10-11. One skilled in the art would be familiar with the term "block." Exhibit 1120, ¶ 45. One skilled in the art would understand that, since the term "block" is used to describe a signal that prevents

	the transmission of signals along a nerve, Knudson was teaching application of a signal that would not create paresthesia. *Id.*

As the above charts show, Knudson anticipates independent claims 1 and 26. Knudson expressly discloses the step of delivering/applying an electrical signal to the spinal cord of a patient and expressly discloses stimulation frequencies that are squarely in the range of claims 1 and 26. While Knudson does not expressly use the words "no paresthesia" in describing his blocking therapy, one skilled in the art would understand that, by describing his therapy signal as applying a "blocking" signal, Knudson was teaching application of a signal that would not cause the patient to perceive paresthesia. Exhibit 1115, ¶ 45. As Knudson states, the purpose of a block is to "block the propagation of action potentials along the nerve." Exhibit 1102, ¶ 11. If no action potentials are traveling along a nerve, the patient will not feel paresthesia. Exhibit 1115, ¶ 45.

As noted above, in later prosecution of the grandparent '747 application that occurred after the '102 patent issue, the applicants argued that Knudson does not disclose treatment without paresthesia. *See, e.g.*, Exhibit 1113, pp. 13-15. However, the McIntyre Declaration filed herewith explains why applicants' argument is incorrect. Exhibit 1115, ¶¶ 46-55.

In their argument, applicants point to two technical articles as teaching that, if one were to attempt to block nerve fibers in one area of the spinal cord, it would

likely cause stimulation of other nerve fibers in the spinal cord that are farther away from the stimulation source, which the applicants characterize as "paresthesia." Exhibit 1113 at 14. These cited articles actually support Petitioner's position that "blocking" refers to a therapy that does not cause paresthesia, because they confirm that, when a nerve block is successfully established, it prevents all signals from passing along the blocked nerve. Exhibit 1116 at 243 ("In true nerve conduction block, action potentials are arrested as they pass under the blocking electrode"). The fact that other nearby nerves may be stimulated and not blocked goes, not to whether or not a "blocked" nerve causes paresthesia, but rather go to whether Knudson correctly understood the mechanism by which his proposed therapy operated. In this regard, the '102 patent also suggests that the therapy functioned through blocking of nerves, thus showing the applicants also may not have correctly understood the mechanism of action through which the claimed therapy works. Exhibit 1101, 14:38-49; 3:15-23. That Knudson (and the '102 patent inventors) may have been mistaken about the mechanism of action, however, does not change the conclusion that persons skilled in the art would have interpreted Knudson's use of the term "block" as describing a therapy that did not cause the patient to feel paresthesia. Exhibit 1115, ¶ 50.

This is particularly true considering that Knudson teaches essentially the same stimulation parameters and stimulation locations as those taught in the '102

patent. Knudson's preferred spinal stimulation frequency is 3-5 kHz, which is squarely within the preferred range of the '102 patent. *Compare* Exhibit 1101, 10:23-29 *with* Exhibit 1102, ¶ 83. Knudson discloses a stimulation amplitude in the range of 0.2 to 8 mA, which corresponds very closely to the preferred range of stimulation amplitudes disclosed in the '102 patent (0.2 to about 6 mA). *Compare* Exhibit 1101, 13:22-27 *with* Exhibit 1102, ¶ 66. Knudson discloses a preferred pulse width of 100 μs, which also corresponds closely to the pulse widths disclosed in the '102 patent. *Compare* Exhibit 1101 at 6:60 – 7:10 *with* Exhibit 1102, ¶66.[2] And Knudson discloses stimulating at the dorsal root and/or ascending pathways of the dorsal column – two locations also identified in the '102 patent for stimulation. *Compare* Exhibit 1101, Figure 1B *with* Exhibit 1102, Figures 11-13. Thus, regardless of the terminology being used to describe the therapy or the mechanism by which the therapy works, Knudson is teaching the same therapy as that claimed in the '102 patent. Exhibit 1120, ¶¶ 51-53.

In applicants' argument in the '747 application, applicants also cited to a 2013 article from Perruchoud et al. as teaching that it is possible to generate paresthesia with a 5 kHz stimulation signal. Exhibit 1113, pp. 14-15. This

[2] While the '102 patent does not expressly disclose a range of pulse widths, the applicants have taken the position in the grandparent '747 application that the disclosure of the '102 patent discloses a pulse width range of 25-166 microseconds. *See* Patent No. 8,712,533, claim 19, Exhibit 1122. Petitioner does not concede that the '102 disclosure adequately discloses this range.

argument misses the point. Petitioners do not dispute that it is possible to induce paresthesia with a 5 kHz signal. However, Knudson does not just teach to apply a 5kHz signal; it teaches to do so in a way that *blocks* the nerve. As discussed above, one skilled in the art would have understood Knudson's use of the term "blocking" as referring to a therapy that did not cause paresthesia. Exhibit 1115, ¶ 54. The Perruchoud article makes no reference to blocking, nor does it teach that the 5 kHz signal referred to in the article was applied in such a way as to induce blocking of nerves. *See* Exhibit 1117. Thus, it is not relevant to the teaching of Knudson.

Finally the applicants in the '747 application pointed to U.S. Patent No. 8,224,453 to DeRidder as teaching that "high frequency" stimulation causes paresthesia. Exhibit 1113, p. 15. Again, however, the cited DeRidder patent is not referring to a high frequency signal that is applied for the purpose of inducing nerve block, as in Knudson.[3] Indeed, when DeRidder refers to "high frequency," it is not even talking about the frequency ranges taught by the '102 patent and by Knudson. This is confirmed by the fact that DeRidder states that "high frequency" operation is described in U.S. Patent Publication No. 2006/0259098, which was incorporated in DeRidder by reference. Exhibit 1103, ¶ 56. The '098 publication, in turn, describes "high frequency" stimulation as being on the order of 600 Hz.

[3] The DeRidder patent referred to by applicants corresponds to the published patent application relied on herein that is attached as Exhibit 1103.

Exhibit 1118, ¶¶ 86, 91. The fact that a signal of 600 Hz can be applied to produce paresthesia is irrelevant to the 3-5 kHz *blocking* signal taught by Knudson.

Thus, contrary to applicants' arguments in the '747 application, Knudson does disclose a treatment that one skilled in the art would interpret as resulting in no paresthesia. Because the other limitations of independent claims 1 and 26 are unquestionably disclosed in Knudson, these claims are anticipated by Knudson.

2. Comparison of Knudson to Dependent Claims 2, 17-22 and 25

The following claim chart compares dependent claims 2, 17-22 and 25 to the disclosure of Knudson:

'102 Patent	**Knudson**
2. The method of claim 1 wherein the electrical signal is delivered to the patient to treat pain in the patient.	"Application of a blocking signal to the electrode E blocks signals such as pain signals from the dorsal root [to] the spinal cord SC." Exhibit 1102, ¶ 83.
17. The method of claim 1, further comprising placing or instructing placement of the at least one signal delivery device at a position along the patient's spinal cord as at least part of a placement process without using or instructing use of patient feedback during the placement process to at least assist in selecting the position.	Knudson teaches to place the electrode around a dorsal root or adjacent a desired area of the spinal column, and gives no indication that patient feedback is used to select the electrode location. ¶¶ 82-86.
18. The method of claim 17 wherein placing or instructing placement includes placing or instructing placement of the	See claim 17.

at least one signal delivery device at a position having an axial location and a lateral location without using or instructing use of patient feedback to adjust one of (a) the axial location of the at least signal delivery device, or (b) the lateral location of the at least one signal delivery device.	
19. The method of claim 1 wherein the electrical signal has a frequency of from about 5 kHz to about 15 kHz.	"For spinal treatments, such blocking signal may be as previously described and, preferably has a frequency in excess of 3,000 Hz and more preferably about 5,000 Hz or more." ¶ 83.
20. The method of claim 1 wherein the electrical signal has a frequency of from about 3 kHz to about 15 kHz.	See claim 19.
21. The method of claim 1 wherein the electrical signal has a frequency of from about 3 kHz to about 20 kHz.	See claim 19.
22. The method of claim 1 wherein the electrical signal has a frequency of from about 3 kHz to about 10 kHz.	See claim 19.
25. The method of claim 1, further comprising implanting or instructing implantation of the at least one signal delivery device at a position along the patient's spinal cord.	"According to the present invention, an electrode E is advanced either through open surgical or minimally invasive techniques into the subanachroid space SAS and positioned on a root such as the right dorsal root RDR." ¶ 83. "FIG. 13 illustrates an electrode E (the upper electrode E in the view of FIG. 13) placed on a dorsal root either surgically or through catheter delivery as previously described." ¶86.

As with the independent claims, the subject matter of claims 2, 17-22 and 25 is also clearly disclosed by Knudson. Claim 2 is directed to treatment being delivered to the patient to treat pain. Knudson's device is described as being used for treating pain. Exhibit 1102, ¶ 83.

Claim 17 is directed to positioning the signal delivery device along the patient's spinal cord without the use of patient feedback, while claim 18 is directed to not using patient feedback to adjust one of axial or lateral location on the patient's back. Knudson teaches to place the electrode around a dorsal root or adjacent a desired area of the spinal column, and gives no indication that the patient feedback is used to select the electrode location. *Id.*, ¶¶ 82-86. One of ordinary skill would thus understand Knudson to teach a method that did not require the practitioner to use patient feedback for electrode placement. *See* Ex. 1120, ¶¶ 59-60.

Claims 19-22 are directed to the frequency of the electrical signal delivered to the patient's spinal cord having specific value or falling within a specific range narrower than the range set forth in claim 1. Knudson teaches applying a blocking signal for spinal cord treatment that "has a frequency in excess of 3,000 Hz and more preferably about 5,000 Hz or more." Exhibit 1102, ¶ 83. Thus, Knudson discloses frequencies that fall within the ranges of claims 19-22.

Claim 25 is directed to the signal delivery device being implanted at a position along the patient's spinal cord. Knudson teaches placement of the electrodes along the spinal cord. *Id.*, ¶¶ 83, 86. Thus, claim 25 is also anticipated.

Since MacDonald discloses all the elements in claims 1, 2, 17-22, 25 and 26, these claims are anticipated by MacDonald and should be found invalid.

B. Ground 2: Claims 1, 2, 11-15, 17-23, 25 and 26 Are Invalid as Obvious Over Knudson Alone Or In View of DeRidder and/or MacDonald

1. Analysis of Independent Claims 1 and 26

As discussed in the previous section, persons skilled in the art would understand Knudson's statement that the disclosed therapy results in "blocking" of neural transmissions as indicating that the therapy would not result in paresthesia. Since Knudson unquestionably discloses the remaining limitations of independent claims 1 and 26, it anticipates these claims.

However, even if the Board were to find that this understanding of those skilled in the art is insufficient to anticipate claims 1 and 26, these claims would have been obvious in view of Knudson. Assuming applicants were correct in the '747 application that high frequency therapy of the type taught by Knudson might or might not result in paresthesia, a person skilled in the art implementing Knudson's blocking therapy would be faced with two options relative to paresthesia: (1) apply the therapy in a way that causes paresthesia; and (2) apply

the therapy in a way that does not cause paresthesia. Moreover, the therapy taught by Knudson is not dependent in any way on the presence of paresthesia. *See generally* Exhibit 1102; *see also* Ex. 1115, ¶ 67. Knudson operates under a theory of relieving pain by blocking the transmission of signals along a nerve, not by causing paresthesia to mask pain. *Id.* Therefore, it would have been an obvious design choice for one of ordinary skill in the art to implement the blocking therapy of Knudson in a way that does not cause paresthesia. *Id.*; *see also KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 420 (2007) ("When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp.").

This is particularly true when Knudson is combined with other prior art that teaches that paresthesia is an undesired side effect that should be avoided if possible. DeRidder (Exhibit 1103) and MacDonald (Exhibit 1104).[4] DeRidder is directed to a "system and method for treating pain without paresthesia by spinal cord stimulation." Exhibit 1103, Abstract. De Ridder teaches that paresthesia "can

[4] DeRidder was published on July 28, 2011 based on an application filed on March 12, 2008. Hence, it is prior art to the '102 patent under 35 U.S.C. 102(e). DeRidder also claims priority to a Provisional Application No. 60/895,061 filed on March 14, 2007, which discloses the same subject matter as the DeRidder publication. Therefore, the effective date of DeRidder for 102(e) purposes is March 15, 2007. MacDonald issued on July 7, 1998 and is prior art to the '1092 patent under 35 U.S.C. 102(b).

be uncomfortable or even painful in patients" and is considered to be "an acceptable negative side-effect" of existing spinal cord stimulation therapy. *Id.*, ¶ 4. DeRidder describes tests that were performed on patients using spinal cord stimulation parameters that successfully treated pain without causing paresthesia. *Id.*, ¶¶ 41-44. The absence of paresthesia, according to DeRidder, "was felt as a bonus to the patient." *Id.*, ¶ 44.

Similarly, MacDonald is titled "Electrotherapeutic Apparatus," and is directed to an apparatus for producing pain relief by applying electrical stimulation to the spine. *See* Ex. 1104, Abstract; 2:22-43. The electrodes are preferably placed over the spinal cord and may be implanted if desired. *Id.*, 3:46-52. Implantation may be "near the spine or within the spinal canal itself." *Id.*, 8:55-57.

MacDonald teaches that the electrical stimulation is used to achieve what is called "spinal cord sensation." *Id.*, 5:51-63. This is a sensation of "warmth and painless, light pressure" achieved "at a lower threshold than the tingling" (i.e., below the paresthesia threshold). *Id.* MacDonald reports the results of experiments showing the threshold amplitudes (in volts) required to create spinal cord sensation and tingling as a function of pulse width. *Id.*, 6:33-48. Applying the spinal cord sensation for a period of time reduced pain without the need to cause tingling. *Id.*, 7:65 – 8:35.

Thus, both DeRidder and MacDonald teach that paresthesia is an undesirable side effect that should be avoided if possible.[5] Given that the therapy of Knudson is not dependent on creating paresthesia in the patient, it would have been obvious in view of DeRidder or MacDonald to implement the therapy of Knudson in a way that that did not create paresthesia in the patient. Exhibit 1115, ¶ 71.

Hence, independent claims 1 and 26 are also invalid as obvious based on Knudson alone or, alternatively, in view of DeRidder and/or MacDonald.

2. Analysis of Dependent Claims 2, 17-22 and 25

As discussed in the previous section, Knudson also discloses the limitations of dependent claims 2, 17-22 and 25. Therefore, under the alternative basis of obviousness based on Knudson alone or Knudson in view of DeRidder or MacDonald, these dependent claims would have been obvious as well.

3. Analysis of Dependent Claims 11-15 and 23

The following claim chart compares dependent claims 11-15 and 23 of the '102 patent to the prior art relied on herein:

'102 Patent	Knudson and Other Prior Art
11. The method of claim 2 wherein the pain in the patient includes at least one of low-back pain and	Knudson discloses spinal cord blocking therapy at the dorsal root or ascending pathway of the spinal column in order to treat pain. Exhibit 1102, ¶¶ 83, 86.

[5] Other examples of prior art teaching that paresthesia is an undesirable and/or unnecessary side effect of electroneural therapy are U.S. Patent No. 8,280,515 to Greenspan (Exhibit 1119) and U.S. Published Application No. 2006/0015153 to Gliner *et al*. (Exhibit 1120).

leg pain.	MacDonald teaches spinal cord treatment to treat pain "wherever the tender region lies, be it in the foot, hip, back, wrist, shoulder or head or all of these regions simultaneously." Exhibit 1104, 9:33-36. In the clinical studies reported by MacDonald, several patients were treated for leg or back pain, as reported in Tables 1 and 2. *Id.*, 12:43 – 16:19. Patient No. 59 in Table 2 was treated for both leg and back pain. *Id.*, 15:43-44.
12. The method of claim 2 wherein the pain in the patient includes both low-back pain and leg pain.	See claim 11.
13. The method of claim 2 wherein the pain in the patient includes nociceptive pain.	See claim 11. In addition, MacDonald reports that various patients were treated for pain that was nociceptive. *E.g.* Exhibit 1104, 13: Table 1, patient 23 (patient with "fractured humerus").
14. The method of claim 2 wherein the pain in the patient includes pain from surgery.	See claim 11. In addition, MacDonald reports that various patients were treated for "post-operative pain." *E.g.* Exhibit 1104, 12: Table 2, patents 31, 33 and 35.
15. The method of claim 1 wherein the at least one signal delivery device is a single electrical lead having a single axial row of electrical contacts.	Knudson teaches that, while a single electrode is shown in Figure 11, "it will be appreciated that multiple electrodes including bipolar electrodes may be placed on the roots." Exhibit 1102, ¶ 83. DeRidder shows spinal cord stimulation leads arranged in a single row of electrical contacts. Exhibit 1103, Figs. 6A-6F.
23. The method of claim 1 wherein the signal has a frequency of about 10 kHz	Knudson teaches that for spinal treatments, the blocking signal "preferably has a frequency in excess of 3,000 Hz and more preferably about 5,000 Hz or more." Exhibit 1102, ¶ 83.

Claims 11-14 of the '102 patent depend from claim 2 and are directed to treatment of specific types or categories of pain. Claim 11 is directed to treating

either low-back pain or leg pain, while claim 12 is directed to the treatment of both low-back pain and leg pain. Claim 13 is directed to the treatment of nociceptive pain and claim 14 is directed to the treatment of pain from surgery. Knudson discloses spinal cord blocking therapy at the dorsal root or ascending pathway of the spinal column in order to treat pain, but does not specifically disclose the type of pain treated.

One of ordinary skill in the art would have known, however, that certain dorsal roots and certain ascending pathways carry pain signals from the low-back and legs. Exhibit 1115, ¶ 75. One of ordinary skill would also have been aware of the many types of pain that can be treated with spinal stimulation. For example, one of ordinary skill in the art would have been aware of the treatments disclosed in Tables I and II of MacDonald, and would have understood that such symptoms as were treated by MacDonald's therapy were also amenable to treatment by Knudson's therapy. *Id.* MacDonald lists the results of treating a number of patients in Tables I and II, and specifically lists the treatment of leg or back pain (patient nos. 25, 26, 289, 29, 30, 37, 41, 42, 47, 49, 51, 55, 56, 57, 59, 62, 66, and 70), both leg and back pain (patient no. 59), nociceptive pain (patient no. 23), and post-operative pain (patient nos. 13, 31, 33 and 35). *See* Ex. 1104, 12:43-16:19, Tables 1 and 2.

One of ordinary skill would have understood that, by selecting the appropriate dorsal root or ascending pathway, the blocking therapy of Knudson could be used to block the type and location of pain described in MacDonald. Exhibit 1115, ¶ 75. One of ordinary skill would have been motivated to do so, since MacDonald's treatment led, in many cases, to significant pain relief. Furthermore, given the similarities between the Knudson and MacDonald systems in terms of electrode placement and frequency of operation, a person of ordinary skill would reasonably have expected that use of Knudson's system to treat such sources of pain would have had similar success to the MacDonald system. Accordingly, claims 11-14 would have been obvious based on Knudson in view of MacDonald.

Claim 15 depends from claim 1, and states that the at least one signal delivery device is a single electrical lead having a single axial row of electrical contacts. Knudson discloses that multiple electrodes may be used (Exhibit 1102, ¶ 83) but does not describe any specific arrangement of electrodes. However, one of ordinary skill would have been familiar with the different types of implantable electrode arrangement that could be used for applying electrical signals to the spinal cord that were known at the time of the alleged invention. The use of spinal cord stimulation leads with a single axial row of electrical contacts was very common in the art at this time. *See* Ex. 1115, ¶ 76. Examples of this are shown in

Figures 6A-6F of DeRidder. Exhibit 1103. One of ordinary skill would have been motivated to employ an electrode configuration as disclosed by DeRidder, as this type of electrode design was well known at the time for successfully delivering electrical signals when implanted in the body, and it could be implanted into the patient in a manner that was well-known and understood. Furthermore, due to the fact that such an electrode arrangement was well-known for implanted use, it would have been reasonable for one of ordinary skill to believe that use of such an electrode arrangement with Knudson's system could successfully deliver an electrical signal to a patient's spine. *See* Exhibit 1115, ¶ 76. Therefore, claim 15 would have been obvious based on Knudson in view of DeRidder.

Claim 23 depends from claim 1 and recites a stimulation frequency of "about 10 kHz." Knudson teaches a preferred blocking frequency of "about 5,000 Hz or more." Exhibit 1102, ¶ 83. Thus, the frequency of claim 23 is within the range taught by Knudson, and is very close to the specific 5 kHz frequency taught by Knudson. As such, claim 23 is *prima facie* obvious in view of Knudson. *In re Harris*, 409 F.3d 1339, 1341 (Fed. Cir. 2005).

A *prima facie* obviousness case can be rebutted by showing that the claimed value produces "a new and unexpected result which is different in kind and not merely in degree from the results of the prior art." *In re Huang*, 100 F.3d 135, 139 (Fed. Cir. 1996) (citations omitted). An improved result is not unexpected simply

because it is improved. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Applied Materials, Inc.*, 692 F.3d 1289, 2012 U.S. App. LEXIS 18349, at *11 (Fed. Cir. Aug. 29, 2012) (quoting *In re Aller*, 220 F.2d 454, 456 (C.C.P.A. 1955); *see also In re Boesch*, 617 F.2d 272, 276 (C.C.P.A. 1980) ("discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art."); *In re Peterson*, 315 F.3d at 1330 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination or percentages."). This is true regardless of whether the claimed range overlaps with the prior art, or is merely close. *Gentiluomo v. Brunswick Bowling and Billiards Corp.*, 36 Fed. Appx. 433, 438–39 (Fed. Cir. 2002); *In re Huang*, 100 F.3d at 136–37; *In re Woodruff*, 919 F.2d 1575, 1578 (Fed. Cir. 1990).

The '102 patent reports results that are purported to be an improved result as compared to stimulation at low frequency, i.e., 60-80 Hz. Ex. 1101, 6:12 – 8:9. There is no evidence, however, to suggest that the claimed frequency of 10 kHz is improved, much less unexpectedly improved, compared to the ranges and values taught by Knudson. Accordingly, there is no basis to conclude that the frequency recited in claim 23 provides unexpected results relative to Knudson, and the

frequency value claimed in claim 23 would have been obvious to one of ordinary skill. Exhibit 1115, ¶¶ 77-78.

IX. CONCLUSION

In view of the grounds set forth above, Petitioners respectfully submit that there is more than a reasonable likelihood that at least one of claims 1, 2, 11-15, 17-23, 25 and 26 of the '102 patent are unpatentable under 35 U.S.C. §§ 102 and/or 103. Accordingly, the Office is requested to institute an IPR of claims 1, 2, 11-15, 17-23, 25 and 26 of the '102 patent.

Date: May 14, 2015

Respectfully submitted,

/Iain McIntyre/

Iain McIntyre
USPTO Reg. No. 40,337
Carlson, Caspers, Vandenburgh
Lindquist and Schuman, P.A.
225 South Sixth Street
Minneapolis, MN 55402
612-436-9600
imintyre@carlsoncaspers.com

Attorneys for Petitioner
BOSTON SCIENTIFIC
NEUROMODULATION CORP.

EXHIBIT LIST

Exhibit No.	Description
1101	U.S. Patent No. 8,359,102
1102	U.S. Patent Publication No. 2007/0073354 (Knudson)
1103	U.S. Patent Publication No. 2011/0184488 (De Ridder)
1104	U.S. Patent No. 5,776,170 (MacDonald)
1105	Application 13/245,450 file history, Office Action, November 18, 2011
1106	Application 13/245,450 file history, Interview Summary, February 1, 2012
1107	Application 13/245,450 file history, Amendment, February 7, 2012
1108	Application 13/245,450 file history, Notice of Allowability, March 14, 2012
1109	Application 13/446,970 file history, Preliminary Amendment, May 18, 2012
1110	Application 13/245,970 file history, Ex Parte Quayle Action, October 15, 2012
1111	Application 13/245,970 file history, Amendment in Response to Ex Parte Quayle Office Action, November 28, 2012
1112	Application 12/765,747 file history, Office Action, July 25, 2013
1113	Application 12/765,747 file history, Amendment, January 24, 2014
1114	Merriam Webster's Collegiate Dictionary, 10th ed., p. 583
1115	Declaration of Prof. Cameron C. McIntyre Ph.D.
1116	Kilgore KL *et al*. "Reversible Nerve Conduction Block Using Kilohetrz Frequency Alternating Current," Neuromodulation (2013) **17** 242-255.
1117	Perruchoud et al., "Analgesic Efficacy of High-Frequency Spinal Cord Stimulation: A Randomized Double-Blind Placebo-Controlled Study," Neuromodulation (2013) **16** 363-369
1118	U.S. Patent Publication 2006/0259098
1119	U.S. Patent No. 8,280,515 (Greenspan)
1120	U.S. Patent No. 2006/0015153 (Gliner)
1121	Bhadra N *et al.* "Simulation of high-frequency sinusoidal electrical block of mammalian myelinated axons," J. Comput. Neurosci. (2007) **22** 313-326.
1122	U.S. Patent No. 8,712,533

CERTIFICATE OF SERVICE (37 C.F.R. §§42.6(e) and 42.105(a))

I hereby certify that, on the date indicated below, I caused the foregoing Petition, Exhibit List and Associated Exhibits to be served via Federal Express to the below addresses:

Nevro Corporation
4040 Campbell Avenue, Suite 210
Menlo Park, CA 94025

Perkins Coie
1201 Third Avenue, Suite 4900
Seattle, Washington 98101-3099

Date: May 14, 2015

Respectfully submitted,

/Iain McIntyre/

Iain McIntyre
USPTO Reg. No. 40,337
Carlson, Caspers, Vandenburgh
Lindquist and Schuman, P.A.
225 South Sixth Street
Minneapolis, MN 55402
612-436-9600
imintyre@carlsoncaspers.com

Attorneys for Petitioner
BOSTON SCIENTIFIC
NEUROMODULATION CORP.