IN THE UNITED STATES PATENT AND TRACEMARK 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.: 1014.0248AB1

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

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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 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. 1001) 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

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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 No. 5,776,170 (Electrotherapeutic Apparatus") to A. J. R. MacDonald *et al*., issued July 7, 1998 (Ex. 1002, hereafter "MacDonald").
2. U.S. Patent No. 6,246,912 (Modulated High Frequency Tissue Modification) to M. E. Sluijter *et al*., issued June 12, 2001 (Ex. 1003, hereafter "Sluijter").

3. U.S. Patent Publication No. 2006/0009820 (Apparatus for the Application of Electrical Pulses to the Human Body) to J. Royle, published January 12, 2006 (Ex. 1004, hereafter "Royle").

4. U.S. Patent Publication No. 2011/0184488 (Spinal Cord Stimulation to Treat Pain) to D. De Ridder, published July 28, 2011 (Ex. 1005, hereafter "De Ridder").

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, Ex. 1015, the citations in the Claim Charts and the remarks provided below, Petitioners respectfully contend 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.

D. Statement of Material Facts

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, 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. 1001, front page and Ex. 1006, p. 5. 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 (Ex. 1007), the examiner rejected the claims for being anticipated. Following that rejection, an in-person interview was held on February 1, 2012. The Interview Summary (Ex. 1008) 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.

See Ex.1008, p. 2.

The applicants submitted an amendment in the '450 application (Ex. 1009) on February 7, 2012, allegedly making amendments as described in the Interview Summary. *See* Ex. 1009. 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. 1010, 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, in which claim 1 was amended to cover a method of treating a patient by delivering an electrical signal in a frequency range similar to that allowed in U.S. Patent No. 8,170,675, while not creating paresthesia in the patient. *See* Ex. 1011, p. 2.

On October 15, 2012, in the first action on the merits of the application, 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. *See* Ex. 1012. The Examiner also listed 11 prior art references that discussed stimulation without paresthesia. *See* Ex. 1012, pp. 6-7.

On November 28, 2012, the applicants responded with a terminal disclaimer and an amendment cancelling some of the claims. *See* Ex. 1013. The '102 patent was issued on January 22, 2013.

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. 1001, 1:21-22. The Background of the '102 patent acknowledges 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. The '102 patent alleges that the latter, high frequency therapy reduced pain by 42% compared to standard SCS therapy and had other benefits reflected in Figures 3-6. *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 was 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: delivering or instructing delivery of 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.	26. A method for treating a patient, comprising: 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.

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 type of 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. 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. 1014).

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. 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. 1001, 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. 1001, 4:44 – 5:10.

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

"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. 1015, ¶ 14.

C. Level of Ordinary Skill in the Art

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. 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. 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. *Id*., ¶ 11.

VII. GROUNDS FOR CHALLENGE

Ground 1: claims 1, 2, 11-14, 17-22, 25 and 26 of the '102 patent are anticipated by MacDonald.

Ground 2: claims 1, 2, 15, 17, 18, 25 and 26 are anticipated by Sluijter.

Ground 3: claims 1, 2, 17-23, 25 and 26 are anticipated by Royle.

Ground 4: claims 1, 2, 11-15, 17-23, 25 and 26 are obvious over MacDonald, either alone or in view of De Ridder, Sluijter and/or Royle.

Ground 5: claims 1, 2, 11-15, 17-23, 25 and 26 are obvious over Sluijter, either alone or in view of De Ridder, MacDonald and/or Royle.

Ground 6: claims 1, 2, 11-15, 17-23, 25 and 26 are obvious over Royle, either alone or in view of De Ridder, MacDonald and/or Sluijter.

VIII. IDENTIFICATION OF HOW THE CLAIMS ARE UNPATENTABLE

A. Ground 1: Claims 1, 2, 11-14, 17-22, 25 and 26 Are Anticipated By MacDonald

MacDonald (Ex. 1002) issued on July 7, 1998 and is prior art to the '102 patent under 35 U.S.C. § 102(b).[1] While MacDonald is one of the roughly 200 references listed on the front of the '102 patent as having been considered during prosecution of the '102 patent, there no indication that the Examiner recognized the relevance of MacDonald. This is evidenced by the fact that the Examiner omitted MacDonald from the references identified in the *Ex Parte* Quayle Action of October 15, 2012 as showing spinal stimulation without paresthesia, *see* Ex. 1010, pp. 6-7, even though MacDonald clearly contains such a disclosure, *infra*.

[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.

MacDonald is directed to an apparatus for producing pain relief by applying electrical stimulation to the spine. *See* Ex. 1002, Abstract; 2:22-43. The apparatus includes a stimulator that is attached by cables to at least two electrodes. *Id.*, 3:33-40; 7:5-11. 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 stimulation should take place in a range of 100 Hz to 250 kHz and notes that faster analgesic effects can be achieved using higher stimulation frequencies. *Id.,* 4:1-24; 5:24-31. MacDonald discusses a specific example of stimulation at 5 kHz, which is squarely within the range claimed in the '102 patent. *Id.*, 8:39-43.

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.

MacDonald presents results from two clinical trials. In the first study, the stimulation voltage was maintained sub-threshold for those patients who could perceive the "spinal cord stimulation." *Id.* 9:58 –10:3. The patients suffered from a variety of painful conditions, and a large majority of them achieved substantial pain relief. *Id.*; *see also* cols. 12-16, Tables 1-2. The average pain relief for this first group of patients was 70%. *Id.*, 9:59-63.

1. Comparison of MacDonald 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	**US 5,776,170 to MacDonald (Ex. 1002)**
1. A method for treating a patient, comprising:	"An apparatus for producing analgesia through electrical stimulation…" Abstract. "The present invention provides an apparatus for producing electrical stimulation…such that analgesic effects tend to be stimulated in the central nervous system…" 2:21-30.
delivering or instructing delivery of an electrical signal to the patient's spinal cord via at least one implantable signal delivery device; and	"One embodiment of the present invention employs a single pair of electrodes…Usually one electrode is placed on…the mid-line of the back overlying one end of the portion of the spinal cord that requires stimulation while the second is placed at the other end. In a similar manner, however, more than two electrodes could be arranged over the spinal cord." 3:33-39. "In order to stimulate the spinal cord without producing discomfort, we have studied the effects of a TSE stimulator designed to produce…pulses having both rapid rise and fall phases.… Both monopolar and bipolar pulses having rapid rise and

	fall phases can be applied to a patient via the electrodes." 3:53-67. "Although in general electrodes are placed on the surface of a body, in some circumstances it may be desirable to implant the electrodes." 3:49-51. "If required, the electrodes may be implanted in the body either in tissues near the spine or within the spinal canal itself." 8:55-57.
wherein the electrical signal has a frequency of from about 1.5 kHz to about 50 kHz	"[W]hen applied at the normal TENS frequency of 100 Hz the amplitude of the pulse produced by the TSE stimulator is higher than that of the conventional TENS machines…. The narrow 1-10 μs TSE pulses can be delivered at higher frequencies than is possible with the broader TENS pulses (typically 50-500 μs). Typically it is possible to use signals having a frequency up to about 250 kHz. We have made the unexpected discovery that the higher the frequency we deliver to the patient with TSE, the more rapid the onset of analgesia; for example frequencies in the region of 150 KHz produce analgesia within 5-30 minutes, whereas 100 Hz takes 40-60 minutes." 4:9-21. "At higher frequencies, unwanted heating effects begin to occur, so the voltage has to be decreased; for example, with a 1.5 μs pulse width and a frequency of 5KHz, 150V are sufficient, while at 150 KHz a voltage of 25V was found to be effective." 8:39-43.
and does not create paresthesia in the patient.	"However, if the electrodes were separated by a distance of 10 cms or so the levels between T1 and T12 could be perceived and described by the trained observer at a lower threshold than the tingling. It was a continuous feeling of warmth and painless, light pressure. However, this sensation is so mild in intensity, that many patients distracted by their aches and pains are unable to perceive it. Nevertheless amongst those that report this sensation, the most striking observation about it is its continuity; the

	discrete sensations produced by each pulse are not detectable, as it is when tingling is present. This new feeling may be called `spinal cord sensation` as it is only obtained when the electrodes are placed in the immediate vicinity of the spinal cord itself." 5:51-63. "When the electrodes were located over the spinal cord, amplitudes capable of producing the spinal cord sensation were always lower than those capable of producing tingling sensation provided the stimulation was continuous and had a fast rise and fall time." 6:8-12. "The voltage need not be sufficient to cause tingling associated with Aβ fibre excitation; thus it may be subthreshold for the selected pulse width." 8:31-34.

'102 patent, Claim 26	**US 5,776,170 to MacDonald (Ex. 1002)**
26. A method for treating a patient, comprising:	Same as for claim 1 above.
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	"One embodiment of the present invention employs a single pair of electrodes…Usually one electrode is placed on…the mid-line of the back overlying one end of the portion of the spinal cord that requires stimulation while the second is placed at the other end. In a similar manner, however, more than two electrodes could be arranged over the spinal cord." 3:33-39. "In order to stimulate the spinal cord without producing discomfort, we have studied the effects of a TSE stimulator designed to produce…pulses having both rapid rise and fall phases.… Both monopolar and bipolar pulses having rapid rise and fall phases can be applied to a patient via the electrodes." 3:53-67. "[E]lectrodes were attached to a stimulator that produced a square wave…" 5:33-34.

	"Although in general electrodes are placed on the surface of a body, in some circumstances it may be desirable to implant the electrodes." 3:49-51. "If required, the electrodes may be implanted in the body either in tissues near the spine or within the spinal canal itself." 8:55-57.
wherein the electrical signal has a frequency of from about 1.5 kHz to about 50 kHz	"[W]hen applied at the normal TENS frequency of 100 Hz the amplitude of the pulse produced by the TSE stimulator is higher than that of the conventional TENS machines…. The narrow 1-10 μs TSE pulses can be delivered at higher frequencies than is possible with the broader TENS pulses (typically 50-500 μs). Typically it is possible to use signals having a frequency up to about 250 kHz. We have made the unexpected discovery that the higher the frequency we deliver to the patient with TSE, the more rapid the onset of analgesia; for example frequencies in the region of 150 KHz produce analgesia within 5-30 minutes, whereas 100 Hz takes 40-60 minutes." 4:9-21. "At higher frequencies, unwanted heating effects begin to occur, so the voltage has to be decreased; for example, with a 1.5 μs pulse width and a frequency of 5KHz, 150V are sufficient, while at 150 KHz a voltage of 25V was found to be effective." 8:39-43.
and does not create paresthesia in the patient.	"However, if the electrodes were separated by a distance of 10 cms or so the levels between T1 and T12 could be perceived and described by the trained observer at a lower threshold than the tingling. It was a continuous feeling of warmth and painless, light pressure. However, this sensation is so mild in intensity, that many patients distracted by their aches and pains are unable to perceive it. Nevertheless amongst those that report this sensation, the most striking observation about it is its continuity; the discrete sensations produced by each pulse are not detectable, as it is when tingling is present. This new feeling may be called `spinal cord sensation` as it is

	only obtained when the electrodes are placed in the immediate vicinity of the spinal cord itself." 5:51-63. "When the electrodes were located over the spinal cord, amplitudes capable of producing the spinal cord sensation were always lower than those capable of producing tingling sensation provided the stimulation was continuous and had a fast rise and fall time." 6:8-12. "The voltage need not be sufficient to cause tingling associated with Aβ fibre excitation; thus it may be subthreshold for the selected pulse width." 8:31-34.

As these claim charts show, MacDonald describes all the elements of claims 1 and 26. *See* Ex. 1015, ¶¶ 45-54. Accordingly, there is more than a reasonable likelihood that independent claims 1 and 26 are unpatentable under 35 U.S.C. § 102.

2. Comparison of MacDonald to Dependent Claims 2, 11-14, 17-22 and 25

The following claim chart compares dependent claims 2, 11-14, 17-22 and 25 to the disclosure of MacDonald:

'102 Patent	**US 5,776,170 to MacDonald (Ex. 1002)**
2. The method of claim 1 wherein the electrical signal is delivered to the patient to treat pain in the patient.	"An apparatus for producing analgesia through electrical stimulation…" Abstract. "The present invention provides an apparatus for producing electrical stimulation…such that analgesic effects tend to be stimulated in the central nervous system…" 2:21-30. "These observations suggest that TSE produces pain relief without introducing numbness in the manner of

	local anaesthesia." 9:37-39. "In a study of 23 patients suffering from a number of painful, chronic, subacute and acute conditions, TSE produced an average of 70% pain relief for an average of 50 hours following the first treatment of no more than 45 minutes stimulation." 9:58-62.
11. The method of claim 2 wherein the pain in the patient includes at least one of low-back pain and leg pain.	"Despite the fact that the electrodes are always located over the spinal cord, these changes occur wherever the tender region lies, be it in the foot, hip, back, wrist, shoulder or head or all of these regions simultaneously." 9:33-36. Those patients treated for back or leg pain are highlighted in Table 1, below. TABLE 1 RESULTS OF FIRST TSE TREATMENT on a group of 23 patients No Sex / Severity (0 nil - 10 agony) / Duration (months) / Diagnosis / % Relief (0 nil-100 total) / Duration of relief (hrs) 1 F / 7 / 3 / Hip Pain / 50 / 72 2 F / 8 / 180 / Fused C5/6 / 50 / 2 3 M / 5 / 240 / Polymalgia rheumatica / 50 / 16 4 F / 9 / 3 / Shoulder pain / 50 / 4 5 F / 3 / 1 / TMJ (jaw) pain / 60 / 17 6 M / 3 / 0.5 / Ankle pain / 20 / 24 7 F / 5 / 0.5 / Foot pain / 80 / 12 8 F / 3 / 4 / RA hand / 100 / 70 9 F / 8 / 132 / Cervical spondylosis / 100 / 120 10 F / 4 / 360 / RA feet, wrists / 50 / 2 11 F / 4 / 84 / Sarcoid, back abdomen & shoulders / 50 / 168 12 F / 6 / 21 / Back pain / 50 / 1.5 13 M / too distressed to give an opinion as to severity / 0.04 / Post-op pain resection of lower ⅓rd oesophagus / 100 / 7 14 F / 5 / 6 / Cervical spondylitis / 75 / 96

	TABLE 1-continued RESULTS OF FIRST TSE TREATMENT on a group of 23 patients No Sex Severity (0 nil - 10 agony) Duration (months) Diagnosis % Relief (0 nil-100 total) Duration of relief (hrs) 15 F Aged 92: unable to quantify pain numerically - described it as 'nasty'. 9 Cervical spondylitis Better 120 16 M 4 1 2° Ca spine 100 96 17 F 6 5 L5/S1 PID 50 120 18 F 2 12 Achilles tendonitis 80 72 19 M 8 0.001 Ischaemic pain in the calves - running while unfit 90 NFP 20 M 10 1 Collapse of vertebral body c steroid therapy 90 9 21 M 2 120 Cervical spondylitis 80 24 22 F 3 3 Shoulder pain 100 72 23 F 8 0.03 Fractured humerus 90 48 Average 5 56 71 53 Key: NFP no further pain; RA rheumatoid arthritis; c associated with; 2° secondary carcinomatous deposits. 12:43 – 13:28. Table 1 is provided in its entirety in Ex. 1015, ¶ 57. See also Table 2, 13:29 – 16:19 and Ex. 1014, ¶ 59.
12. The method of claim 2 wherein the pain in the patient includes both low-back pain and leg pain.	TABLE 2 The number of TSE treatments required to produce a successful outcome in the next 50 consecutive patients. Key: c means associated with OA means osteoarthritis RTA road traffic accident Success means pain relief at 60% or more (0, no relief; 100, complete relief) No Condition years duration number of treatments required for long term success contd treat-ment reqd * * * * 59 Athlete with back and leg pains 0.5 4 15:43-44
13. The method of claim 2 wherein the pain in the patient includes nociceptive pain.	TABLE 1 RESULTS OF FIRST TSE TREATMENT on a group of 23 patients No Sex Severity (0 nil - 10 agony) Duration (months) Diagnosis % Relief (0 nil-100 total) Duration of relief (hrs) * * * * 23 F 8 0.03 Fractured humerus 90 48 13:1-29

14. The method of claim 2 wherein the pain in the patient includes pain from surgery.	TABLE 1 RESULTS OF FIRST TSE TREATMENT on a group of 23 patients * * * * 13 M — too distressed to give an opinion as to severity — 0.04 — Post-op pain resection of lower ⅓rd oesophagus — 100 — 7 TABLE 2 The number of TSE treatments required to produce a successful outcome in the next 50 consecutive patients. Key: c means associated with OA means osteoarthritis RTA road traffic accident Success means pain relief at 60% or more (0, no relief; 100, complete relief) * * * * 31 — Post-viral fatigue & post-operative cardiac bypass pain — 3.0 — 12 * * * * 33 — Post-operative pain (cholecystectomy) and a fall fracturing ribs — 4.25 — 2 * * * * 35 — Post-operative eye pain c correction of squint & drug addiction — 5.25 — 10 12:43-65 and 13:30-65
17. The method of claim 1, further comprising placing or instructing placement of the at least one signal delivery device at a position	"However, if the electrodes were separated by a distance of 10 cms or so the levels between T1 and T12 could be perceived and described by the trained observer at a lower threshold than the tingling." 5:51-54.

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.	"This will be seen from the following two experiments where the anode was placed at T1 and the cathode at T12." 6:13-14. "However on all occasions the electrodes separated from each other by being placed at T1 and T12 produced more sensation than the pair of electrodes placed closer together at a given amplitude." 7:18-21. "Chronic myofascial or osteoarthritic pains in almost every region of the body such as knees, elbows or shoulders, also tend to do well with the electrodes placed at T1 and T12." 10:40-42.
18. The method of claim 17 wherein placing or instructing placement includes placing or instructing placement of the 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.	See as for claim 17, above.
19. The method of claim 1 wherein the electrical signal has a frequency of from about 5 kHz to about 15 kHz.	"Typically it is possible to use signals having a frequency up to about 250 kHz. We have made the unexpected discovery that the higher the frequency we deliver to the patient with TSE, the more rapid the onset of analgesia; for example frequencies in the region of 150 KHz produce analgesia within 5-30 minutes, whereas 100 Hz takes 40-60 minutes." 4:9-21.

	"At higher frequencies, unwanted heating effects begin to occur, so the voltage has to be decreased; for example, with a 1.5 μs pulse width and a frequency of 5KHz, 150V are sufficient, while at 150 KHz a voltage of 25V was found to be effective." 8:39-43.
20. The method of claim 1 wherein the electrical signal has a frequency of from about 3 kHz to about 15 kHz.	Same as for claim 19, above.
21. The method of claim 1 wherein the electrical signal has a frequency of from about 3 kHz to about 20 kHz.	Same as for claim 19, above.
22. The method of claim 1 wherein the electrical signal has a frequency of from about 3 kHz to about 10 kHz.	Same as for claim 19, above.
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.	"If required, the electrodes may be implanted in the body either in tissues near the spine or within the spinal canal itself." 8:55-57 "Chronic myofascial or osteoarthritic pains in almost every region of the body such as knees, elbows or shoulders, also tend to do well with the electrodes placed at T1 and T12." 10:40-42.

The subject matter of claims 2, 11-14, 17-22 and 25 is also disclosed by MacDonald. Claim 2 is directed to treatment being delivered to the patient to treat pain. MacDonald's device is described multiple times as being used for treating pain, or producing analgesia. *Id.* 2:21-30, 9:37-39, 9:58-62, 10:7-11. Thus, MacDonald teaches the elements of claim 2.

Claim 11 is directed to the pain in the patient including at least one of low-back pain and leg pain, and claim 12 is directed to the pain including both low-back pain and leg pain. MacDonald's therapy is applied over the spinal cord, regardless of where the pain is located in the patient, including the foot, hip, back, wrist, shoulder or head. *Id.* 9:33-36. In Tables 1 and 2, MacDonald describes the results of clinical trials on 73 different patients, many of whom had back or leg pain. *Id*. 12:43 – 16:18. For example, patient numbers 1, 2, 11, 12, 17, 19, 25, 26, 28, 29, 30, 37, 41, 43, 49, 51, 56-59, 63, and 70 were treated for back or leg pain, and patient 59 was specifically treated for back and leg pains. *Id*. Thus, MacDonald teaches the elements of claims 11 and 12.

Claim 13 is directed to the treatment of nociceptive pain. Nociceptive pain is pain that is properly sensed as being triggered by a particular mechanical or other physical effect. *See* Ex. 1015, ¶ 62. The '102 patent gives "slipped disc, damaged muscle or **damaged bone**" as examples of nociceptive pain. *See* Ex. 1001, 13:54-55 (emphasis added). Tables 1 and 2 describe examples of patients being treated for nociceptive pain, including at least patient 23, treated for a fractured humerus. *See* Ex. 1002, 12:43 – 16:18. Thus, MacDonald teaches the elements of claim 13.

Claim 14 is directed to the treatment of pain arising from surgery. MacDonald describes several examples of this in Tables 1 and 2, including patient nos. 13, 31, 33 and 35. *Id.* Thus, MacDonald teaches the elements of claim 14.

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. MacDonald indicates that the treatment is effective using electrodes placed at T1 and T12. *Id.* 5:51-54, 6:13-14, 7:18-21, 10:40-42. The placement of the electrodes at selected vertebra is performed by a practitioner without requiring patient feedback, and one of ordinary skill would understand MacDonald to teach a method that did not require the practitioner to use patient feedback for electrode placement. *See* Ex. 1015, ¶ 65. Thus, MacDonald teaches the elements of claims 17 and 18.

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. MacDonald teaches that his device can operate over a range of frequencies of 100 Hz to 250 kHz, and provides specific information for operation at, *inter alia*, 5 kHz. *Id.* 4:9-21, 8:39-43. MacDonald's value of 5 kHz falls within the ranges claimed in claims 19-22, i.e. about 5 kHz to about 15 kHz (claim 19), about 3 kHz to about 15 kHz (claim 20), about 3 kHz to about 20 kHz (claim 21) and about 3 kHz to about 10 kHz (claim 22). Thus, MacDonald teaches the elements of claims 19-22.

Claim 25 is directed to the at least one signal delivery device being implanted at a position along the patient's spinal cord. MacDonald teaches placement of the electrodes along the spinal cord, e.g. at T1 and T12. *Id.*, 10:40-42. Furthermore, MacDonald discusses implanting the electrodes along the spine, "in the body either in tissues near the spine or within the spinal canal itself." *Id.* 8:55-57. Thus, MacDonald teaches the elements of claim 25.

Accordingly, there is more than a reasonable likelihood that dependent claims 2, 11-14, 17-22, and 25 are unpatentable under 35 U.S.C. § 102.

B. Ground 2: Claims 1, 2, 15, 17, 18, 25 and 26 Are Anticipated By Sluijter

Sluijter (Ex. 1003) issued on June 12, 2001 and is prior art to the '102 patent under the under 35 U.S.C. § 102(b). Sluijter is one of the roughly 200 references listed on the '102 patent as having been considered by the Examiner during prosecution of the '102 patent. The Examiner overlooked the relevance of Sluijter, since the Examiner omitted Sluijter from the references in the *Ex Parte* Quayle Action of October 15, 2012 (Ex. 1012) that discuss spinal stimulation without paresthesia, even though Sluijter contains such a disclosure, *infra*.

Sluijter is directed to a method and apparatus for altering a function or other characteristics of neural tissue in a patient. *See* Ex. 1003, 1:12-17. One embodiment of Sluijter's apparatus, illustrated in FIG. 4, includes a high frequency generator 120 coupled to a "catheter-like" applicator 110 that is provided with

multiple electrode contacts 112, 114, 116 along its length. *Id.* 7:59-62. This embodiment of generator 120 is described as being inductively powered, via external apparatus 130 and transmitter element 126. *Id.* 7:62-8:29.

Another embodiment of Sluijter's apparatus, illustrated in FIG. 9, includes a pulsed high frequency generator 242 connected via a catheter 240 to electrical contacts 222, 224, 226 that are positioned in proximity to the spinal cord C. Sluijter describes the application of bipolar pulses between different electrodes. *Id.* Figure 9, 12:14-39.

Sluijter discusses a high frequency generator that applies a pulsed radiofrequency signal to the electrodes. *Id.*, 4:44-61. One type of waveform modulation, referred to as "interrupted" or "burst" is described with reference to FIG. 12, reproduced below.

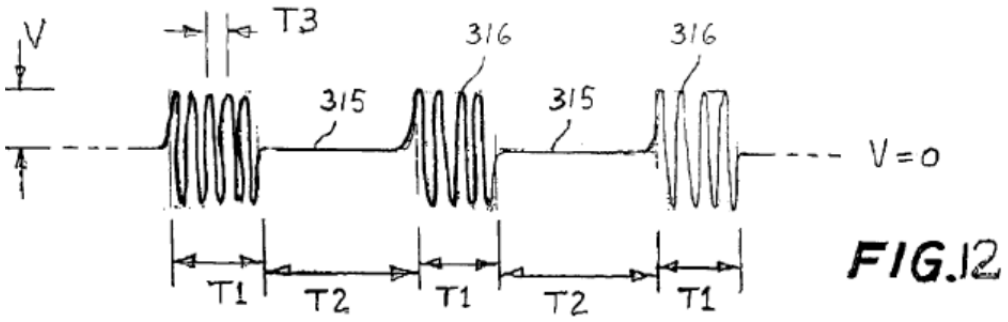


FIG.12

The signal in this case has "a high frequency output of voltage amplitude V and of burst duration T1 between which on-time bursts there are illustrated periods of zero voltage of duration T2. During the on-time T1, the RF signal output is oscillatory with time period T3 between maximum voltages V. The reciprocal of

T3 is proportional to the value of the radiofrequency." *Id.* 15:54-62. Sluijter states that an advantage of this burst mode of operation is to reduce the overall energy deposition in the tissues so that there is no excessive heating. *Id.* 16: 2-15.

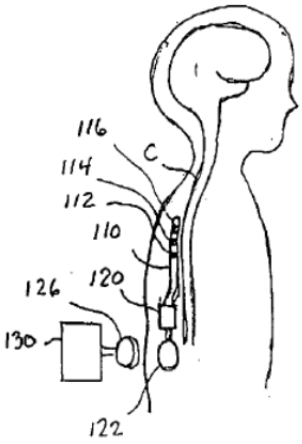
Sluijter teaches a wide variation of frequency of the applied electrical signal. *Id.* 18:65-67. "[T]he high frequency characteristic of 1/T3…can be above the so-called physiologic stimulation frequency range of about 0 to about 300 Hertz. This high frequency may also range up into the radiofrequency or microwave range (viz. 50 Kilo Hertz to many Mega Hertz)." *Id.* 18:67 – 19:6. Sluijter further distinguishes what is meant by "high frequency" and "low frequency," stating that a signal could include a mixture "of "high frequencies" (above the physiologic stimulation range (of about 0 to 300 Hertz) and lower frequencies (within that stimulation range of about 0 to 300 Hertz)." *Id.* 19:11-15. Thus, Sluijter teaches that the lower frequency limit of the applied electrical waveform lies above about 300 Hz, and that the upper frequency is as high as 50 kHz or even into many MHz.

Among the types of prior art devices discussed in the Background section of Sluitjer are neural stimulators. *Id.*, 1:54-2:10. Such "low frequency" stimulators operate in a frequency range that stimulates neural function. *Id.* In contrasting these with his invention, Sluijter teaches that an advantage of high frequency stimulation is that it "will avoid the stimulation effects that are typical for stimulator system applications described above." *Id.*, 15:50-53. One of ordinary

skill would have understood that avoiding the "stimulative effects" of low frequency stimulation systems would have included avoiding tingling/paresthesia. Ex. 1015, ¶ 33-34. This is confirmed by technical articles describing testing performed using Sluijter's methodologies, which note that patients typically did not feel anything during stimulation. *See* Ex. 1015, ¶35, Ex. 1016, p. 113 and Ex. 1017, p. 438.

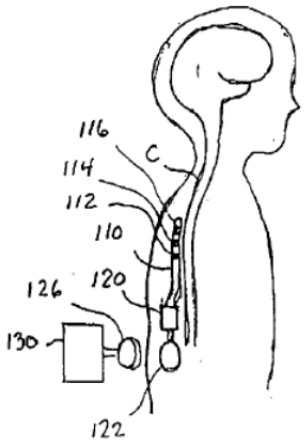
1. Comparison of Sluijter to Independent Claims 1 and 26

The following claim chart compares independent claims 1 and 26 of the '102 patent to the disclosure of Sluijter:

'102 patent, Claim 1	**Sluijter (U.S. Patent No. 6,246,912, Ex. 1003)**
1. A method for treating a patient, comprising:	"A method and apparatus are provided for altering a function of tissue in a patient." Abst.
delivering or instructing delivery of an electrical signal to the patient's spinal cord via at least one implantable signal delivery device; and	 FIG. 4 "FIG. 4 shows an embodiment of the present invention which a catheter-like application 110 with multiple electrode contact, illustrated by 112, 114, 116 is

	implanted near to the spinal cord C." 7:59-62 "FIG. 9 shows an epidural catheter connected to a pulsed high frequency generator for neural modification of the spinal cord in accordance with another embodiment of the invention." 4:19-22. "Referring to FIG. 9, another embodiment of the present invention includes an epidural catheter applicator 220 inserted so that electrical contacts 222, 224, and 226 are in proximity to the spinal cord C." 12:14-17.
wherein the electrical signal has a frequency of from about 1.5 kHz to about 50 kHz	"The frequency range for the so-called high frequency waveforms, as shown for instance in FIGS. 12-15 can be used over a wide range. For example, the "high frequency" characteristic of 1/T3, which may be only one of many high frequency components, can be above the so-called physiologic stimulation frequency range of 0 to about 300 Hertz. This high frequency may also range up into the radiofrequency or microwave range (viz. 50 Kilo Hertz to many Mega Hertz)." 18:65 –19:6.
and does not create paresthesia in the patient.	"In addition, the high frequency waveform from the generator 305 may or may not be free from substantial stimulative components in the 0 to about 300 to 400 Hertz range, which is lower than radiofrequencies. If the waveform is without stimulative frequencies, it will avoid the stimulation effects that are typical for stimulator system applications as described above." 15:47-53.

'102 patent, Claim 26	**Sluijter (U.S. Patent No. 6,246,912, Ex. 1003)**
26. A method for treating a patient, comprising:	"A method and apparatus are provided for altering a function of tissue in a patient." Abst.
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	 FIG. 4 "FIG. 4 shows an embodiment of the present invention which a catheter-like application 110 with multiple electrode contact, illustrated by 112, 114, 116 is implanted near to the spinal cord C. The connections within the applicator 110 connect to a high frequency generator 120." 7:59-62 "FIG. 9 shows an epidural catheter connected to a pulsed high frequency generator for neural modification of the spinal cord in accordance with another embodiment of the invention." 4:19-22. "Referring to FIG. 9, another embodiment of the present invention includes an epidural catheter applicator 220 inserted so that electrical contacts 222, 224, and 226 are in proximity to the spinal cord C…The catheter is connected to a pulse high frequency generator 242." 12:14-28.
wherein the electrical signal has a frequency of from about 1.5 kHz to about 50 kHz	"The frequency range for the so-called high frequency waveforms, as shown for instance in FIGS. 12-15 can be used over a wide range. For example, the "high frequency" characteristic of 1/T3, which may be only one of many high frequency components, can be above the so-called physiologic stimulation frequency range of 0 to about 300 Hertz. This high frequency may also

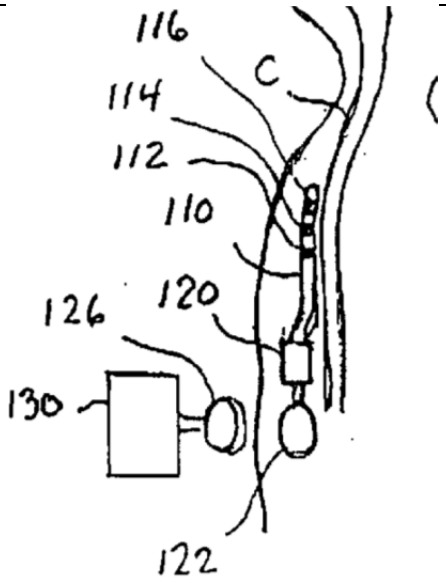
	range up into the radiofrequency or microwave range (viz. 50 Kilo Hertz to many Mega Hertz).” 18:65 –19:6.
and does not create paresthesia in the patient.	“In addition, the high frequency waveform from the generator 305 may or may not be free from substantial stimulative components in the 0 to about 300 to 400 Hertz range, which is lower than radiofrequencies. If the waveform is without stimulative frequencies, it will avoid the stimulation effects that are typical for stimulator system applications as described above.” 15:47-53.

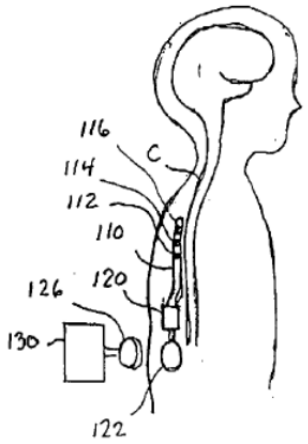
As these claim charts show, Sluijter teaches all the elements of independent claims 1 and 26. *See* Ex. 1015, ¶¶ 78-86. Accordingly, there is more than a reasonable likelihood that these claims are unpatentable under 35 U.S.C. § 102.

2. Comparison of Sluijter to Dependent Claims 2, 15, 17, 18 and 25

The following claim chart compares dependent claims 2, 15 and 17 to the disclosure of Sluijter:

‘102 Patent	**Sluijter (U.S. Patent No. 6,246,912, Ex. 1003)**
2. The method of claim 1 wherein the electrical signal is delivered to the patient to treat pain in the patient.	“Pain relief or neural modification, for instance, can be achieved by the inventive system.” 2:48-50. “Some applications of this invention include relief of back, head, and facial pain…” 3:13-14.
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.	FIG. 4, a portion of which is presented below, shows an implanted “catheter-like applicator 110,” which is a single lead, “with multiple electrode contacts 112, 114, 116.” 7:59-62. The electrodes 112, 114, 116 are shown to be axially placed along the applicator 110:

	 FIG. 9, described at 12:14-28, shows a similar arrangement.
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.	"The insertion guide needle may be, e.g., a Tuoy needle with curved or adapted tip and stylet to be percutaneously pushed through the skin near the epidural space. With removal of the stylet, the catheter structure 220 can be slid in such that the electrode contacts 222, 224, and 226 can be put into proximity of the spinal cord at a level corresponding to associated neurological disease." 12:21-28
18. The method of claim 17 wherein placing or instructing placement includes placing or instructing placement of the at least one signal delivery device at a position having an axial	Same as for claim 17, above

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.	
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.	"FIG. 4 shows an embodiment of the present invention in which a catheter-like applicator 110 with multiple electrode contacts, illustrated by 112, 114, and 116, is implanted near to the spinal cord C." 7:59-62  FIG. 4 FIG. 9 shows similar placement of the electrodes. 12:14-17.

The subject matter of claims 2, 15, 17, 18 and 25 is clearly disclosed by Sluijter. Claim 2 is directed to treatment being delivered to the patient to treat pain. Sluijter's device is described multiple times as being used for treating pain,

or producing analgesia. *Id.* 2:48-50, 3:13-14, 2:66 – 3:5, 21:43 – 22:5. Thus, Sluijter teaches all the elements of claim 2.

Claim 15 is directed to the signal delivery device being a single lead having a single axial row of electrical contacts. Sluijter shows two implanted signal delivery devices in FIGs. 4 and 9. In the embodiment of FIG. 4, the signal delivery device is a "catheter-like applicator with multiple electrode contacts 112, 114, 116." *Id.* 7:59-62. In the embodiment of FIG. 9, the signal delivery device is "an epidural catheter applicator 220 inserted so that electrical contacts 222, 224 and 226 are in proximity to the spinal cord." *Id*. 12:14-17. In both cases, the "applicator" is a single lead, and the electrodes are shown to be spaced axially along the applicator in a row. Moreover, this general lead/electrode structure is similar to the examples of signal delivery device shown in FIGs. 9 and 10A-C of the '102 patent. Thus, Sluijter teaches all the elements of claim 15.

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 either the axial or lateral position of the signal delivery device. Sluijter provides no indication that patient feedback is required or desirable for locating the electrodes. Sluijter merely states that "the electrode contacts…can be put into proximity of the spinal cord at a level corresponding to associated neurological disease." *Id.* 12:26-28. The placement of

the electrodes at a selected site along the spinal cord at a level corresponding to the associated neurological disease is easily performed by a practitioner without requiring patient feedback, and one of ordinary skill would understand that Sluijter discloses a method that did not require the practitioner to use patient feedback for electrode placement. *See* Ex. 1015, ¶¶ 90-92. Thus, Sluijter teaches all the elements of claims 17 and 18.

Claim 25 is directed to the signal delivery device being implanted at a position along the patient's spinal cord. Sluijter clearly shows, in FIGs. 4 and 9, and describes a signal delivery device implanted along the patient's spinal cord. *Id.* FIGs. 4, 9; 7:59-62; 12:14-17 and Ex. 1015, ¶ 93. Thus, Sluijter teaches all the elements of claim 25.

Accordingly, there is more than a reasonable likelihood that at least one of claims 2, 15, 17, 18 and 25 is unpatentable under 35 U.S.C. § 102.

C. Ground 3: Claims 1, 2, 17-23, 25 and 26 are anticipated by Royle

Royle published on January 12, 2006, and, therefore, is prior art to the '102 patent under 35 U.S.C. § 102(b). *See* Ex. 1004. Royle was not considered during prosecution of the '102 patent. *See* Ex. 1001.

Royle is directed to an apparatus for applying electrical pulses to a patient's body. *See* Ex. 1004, Abstract, ¶ 10. The apparatus includes a pulse generating unit that is connectable to two electrodes placed at respective locations of the patient's

body. *Id.*, ¶ 10. The electrodes are placed over the central nervous system (which is defined to include the spinal cord) and may be implanted if desired. *Id.*, ¶ 104-105.

Royle teaches that stimulation takes place within a range of 100 Hz to 250 kHz, that for most applications a range of 2 kHz – 3 kHz will be used, and that for medical uses, the upper frequency limit may be 10 kHz. *Id.*, ¶ 68.

Royle states that the use of pulses with a fast rise time preferable, so that the subject feels no sensation, and that voltage decay back to zero ensures that peripheral nerves are not stimulated. *Id.*, ¶ 75-76. Royle also argues that the pulse length of a prior art unit was limited to around 4 μs, because longer pulses led to a tingling feeling in the patient. According to Royle, the newly disclosed apparatus uses positive and negative impulses and so can comfortably deliver longer pulses to a patient, up to about 30 μs, but preferably around 15 μs. The longer pulse length is alleged in Royle to increase the electrical charge delivered to the patient, which enables a greater range of therapies. *Id.*, ¶ 78.

1. Comparison of Royle to Independent Claims 1 and 26

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

'102 patent, Claim 1	**Royle (U.S. Patent Pub. No. 2006/0009820, Ex. 1004)**
1. A method for treating a patient, comprising:	Royle is titled "Apparatus for the application of electrical pulses to the human body."

	"An apparatus is described for applying electrical pulses to a patient's body." Abstract
delivering or instructing delivery of an electrical signal to the patient's spinal cord via at least one implantable signal delivery device; and	"at least two electrodes arranged for connection to [a] generating unit for supplying electrical pulses to respective locations on the patient's body." ¶44 "the electrodes are normally applied to the surface of a body overlying the central nervous system, such that analgesic effects tend to be effected in the central nervous system whilst stimulating peripheral nerves that lie between the electrodes and the central nervous system to a lesser extent or not at all. If desired, the electrodes could be implanted within the body… the term "central nervous system" should be interpreted to include the brain and the spinal cord." ¶¶ 104-105.
wherein the electrical signal has a frequency of from about 1.5 kHz to about 50 kHz	"Preferably, the impulses are delivered at a predetermined frequency (i.e. 1/T.sub.1) lying within the range 100 Hz to 250 kHz. For most applications 2 kH-3 kHz will be used and for medical uses 10 kHz may be the upper frequency limit." ¶ 68
and does not create paresthesia in the patient.	"The use of a fast rise time (the transition time from 0 volts to the peak voltage) of the pulses is preferable, as it is understood to lower the electrical resistance of the skin without stimulating the peripheral nerves, so that the subject (i.e. patient) feels no sensation." ¶ 75 "It is also preferable that the voltage decays from the respective positive or negative peak voltage to zero volts, so as to ensure that the peripheral nerves are not stimulated." ¶ 76 "By utilising positive and negative voltage impulses as described above, the impulse width can be increased dramatically compared with the impulse width of a rectangular pulse. For instance, typical known rectangular impulses are limited to a width of about 4 μs, as longer rectangular impulses lead to a tingling feeling within the patient. However, using positive and negative voltage impulses, longer pulse widths can be comfortably utilised on a patient e.g.

	pulses of widths of up to 30 μs, although preferably within the range 10 to 20 μs, and more preferably of a width of substantially 15 μs. This very significant discovery allows a greatly increased electrical charge to be applied to a patient, enabling a range of therapies to be provided for the patient." ¶ 78

'102 patent, Claim 26	**Royle (U.S. Patent Pub. No. 2006/0009820, Ex. 1004)**
26. A method for treating a patient, comprising:	Royle is titled "Apparatus for the application of electrical pulses to the human body." "An apparatus is described for applying electrical pulses to a patient's body." 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	"at least two electrodes arranged for connection to [a] generating unit for supplying electrical pulses to respective locations on the patient's body." ¶44 "the electrodes are normally applied to the surface of a body overlying the central nervous system, such that analgesic effects tend to be effected in the central nervous system whilst stimulating peripheral nerves that lie between the electrodes and the central nervous system to a lesser extent or not at all. If desired, the electrodes could be implanted within the body… the term "central nervous system" should be interpreted to include the brain and the spinal cord." ¶¶ 104-105
wherein the electrical signal has a frequency of from about 1.5 kHz to about 50 kHz	"Preferably, the impulses are delivered at a predetermined frequency (i.e. 1/T.sub.1) lying within the range 100 Hz to 250 kHz. For most applications 2 kH-3 kHz will be used and for medical uses 10 kHz may be the upper frequency limit." ¶ 68
and does not create paresthesia in the patient.	"[a] patient will normally experience a sensation if a square wave impulse wider than 10 μs is utilized. Other, preferred waveforms are described below that allow longer width impulses to be utilized." ¶ 68 "The use of a fast rise time (the transition time from 0 volts to the peak voltage) of the pulses is preferable, as it is understood to lower the electrical resistance of the skin without stimulating the peripheral nerves, so

	that the subject (i.e. patient) feels no sensation." ¶ 75 "It is also preferable that the voltage decays from the respective positive or negative peak voltage to zero volts, so as to ensure that the peripheral nerves are not stimulated." ¶ 76 "By utilising positive and negative voltage impulses as described above, the impulse width can be increased dramatically compared with the impulse width of a rectangular pulse. For instance, typical known rectangular impulses are limited to a width of about 4 μs, as longer rectangular impulses lead to a tingling feeling within the patient. However, using positive and negative voltage impulses, longer pulse widths can be comfortably utilised on a patient e.g. pulses of widths of up to 30 μs, although preferably within the range 10 to 20 μs, and more preferably of a width of substantially 15 μs. This very significant discovery allows a greatly increased electrical charge to be applied to a patient, enabling a range of therapies to be provided for the patient." ¶ 78

As the above charts show, Royle teaches all the elements of independent claims 1 and 26. *See* Ex. 1015, ¶¶ 108-118. Accordingly, there is more than a reasonable likelihood that these claims are unpatentable under 35 U.S.C. § 102.

2. Comparison of Royle to Dependent Claims 2, 17-23 and 25

The following claim chart compares dependent claims 2, 17-23 and 25 to the disclosure of Royle.

'102 Patent	**Royle (U.S. Patent Pub. No. 2006/0009820, Ex. 1004)**
2. The method of claim 1 wherein the electrical signal is delivered to the	"Preliminary examination of [clinical trial] data demonstrates that patients are reporting pain relief after each treatment." ¶109

patient to treat pain in the patient.	
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.	"Typically, the electrodes are spaced apart by a distance of around 10 cm, and are always over the central nervous system, irrespective of the location of the pain." ¶ 104 "In the context of this invention, the term "central nervous system" should be interpreted to include the brain and the spinal cord, and also include the other neural tissues which may otherwise be classed as part of the peripheral nervous system, but are in close anatomical proximity to the central nervous system, such as the ganglia, autonomic or somatic, such as the dorsal root ganglia." ¶ 105
18. The method of claim 17 wherein placing or instructing placement includes placing or instructing placement of the 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.	See claim 17
19. The method of claim 1 wherein the electrical signal has a frequency of from about 5 kHz to about 15 kHz.	"Preferably, the impulses are delivered at a predetermined frequency (i.e. $1/T_1$) lying within the range 100 Hz to 250 kHz. For most applications 2 kH-3 kHz will be used and for medical uses 10 kHz may be the upper frequency limit." ¶ 68

20. The method of claim 1 wherein the electrical signal has a frequency of from about 3 kHz to about 15 kHz.	Same as for claim 19, above.
21. The method of claim 1 wherein the electrical signal has a frequency of from about 3 kHz to about 20 kHz.	Same as for claim 19, above.
22. The method of claim 1 wherein the electrical signal has a frequency of from about 3 kHz to about 10 kHz.	Same as for claim 19, above.
23. The method of claim 1 wherein the signal has a frequency of about 10 kHz	Same as for claim 19, above.
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.	"Typically, the electrodes are spaced apart by a distance of around 10 cm, and are always over the central nervous system, irrespective of the location of the pain." ¶ 104 "In the context of this invention, the term "central nervous system" should be interpreted to include the brain and the spinal cord, and also include the other neural tissues which may otherwise be classed as part of the peripheral nervous system, but are in close anatomical proximity to the central nervous system, such as the ganglia, autonomic or somatic, such as the dorsal root ganglia." ¶ 105

Claim 2 is directed to the method being used to treat pain. Royle discloses preliminary results of a clinical trial of his apparatus for relieving pain. *Id.*, ¶ 109. Thus, Royle teaches the elements of claim 2.

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 either the axial or lateral position of the signal delivery device. Royle teaches nothing about using patient feedback to locate the electrodes. Instead, Royle states that "the electrodes are spaced apart by a distance of around 10 cm, and are always over the central nervous system, irrespective of the location of the pain." *Id.*, ¶ 104. The central nervous system includes the spinal cord, *id.*, ¶ 105, and, based on Royle's frequent references to MacDonald, one of ordinary skill would have understood that the electrodes could be positioned by the spinal cord, particularly at T1 and T12 . *See* Ex. 1015, ¶¶ 65, 122. Thus, Royle teaches the elements of claims 17 and 18.

Claims 19-23 are directed to the frequency of the electrical signal delivered to the patient's spinal cord having a specific value or falling within a specific range narrower than the range of 1.5 kHz to 50 kHz set forth in claim 1. Royle states that the electrical pulses are delivered at a frequency "lying within the range 100 Hz to 250 kHz," and that "[f]or most applications 2 kHz-3 kHz will be used." *See* Ex. 1004, ¶ 68. All of the ranges and frequencies defined in claims 19-23 fall within Royle's range of 100 Hz to 250 kHz, and the ranges set forth in claims 20-22, *viz*., about 3 kHz to about 15 kHz, about 3 kHz to about 20 kHz, and about 3 kHz to about 10 kHz, all overlap with Royle's narrower range of 2 kHz to 3 kHz.

Furthermore, the range defined in claim 19, about 5 kHz to about 15 kHz, encompasses Royle's preferred upper frequency for medical use, 10 kHz. Lastly, the frequency set forth in claim 12, about 10 kHz, is identical with Royle's preferred upper frequency for medical use, 10 kHz. Thus, Royle teaches the elements of claims 19-23.

Claim 25 is directed to implanting the electrodes at a position along the patient's spinal cord. Royle's disclosure describes an apparatus for treating patients in which a stimulator (signal generator) applies electrical signals via electrodes to the patient's central nervous system, which is defined as including the spinal cord. *Id.*, ¶ 104-105. Also, given that Royle claims his apparatus provides improved therapy compared to the apparatus disclosed by MacDonald through the use of positive and negative impulses, one of ordinary skill would understand that Royle's electrodes could be placed over the spinal cord in the same manner as taught by MacDonald. Thus Royle teaches the elements of claim 25.

Accordingly, there is more than a reasonable likelihood that dependent claims 2, 17-23, and 25 are unpatentable under 35 U.S.C. § 102.

D. Ground 4: Claims 1, 2, 11-15, 17-23, 25 and 26 are Invalid as Obvious Over MacDonald in view of Sluijter, Royle and/or De Ridder

As discussed in Section V.A, a person of skill in the art would understand MacDonald's statement that the patient felt a "spinal cord sensation" instead of

"tingling" to mean that MacDonald treated patients without paresthesia. Since MacDonald 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 MacDonald. A person skilled in the art implementing MacDonald's 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 MacDonald is not dependent in any way on the presence of paresthesia and, in fact, he teaches away from operation in a "tingling" mode. *See generally* Exhibit 1102; *see also* Ex. 1015, ¶ 52-53. It would have been an obvious design choice for one of ordinary skill in the art to implement MacDonald's therapy 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 MacDonald is combined with other prior art that teaches that paresthesia is an undesired side effect that should be avoided if

possible. DeRidder (Ex. 1005)[2] DeRidder is directed to a "system and method for treating pain without paresthesia by spinal cord stimulation." Ex. 1005, Abstract. De Ridder teaches that paresthesia "can 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.

Thus, DeRidder teaches that paresthesia is an undesirable side effect that should be avoided if possible.[3] Given that MacDonald's therapy is not dependent on creating paresthesia in the patient, it would have been obvious in view of DeRidder to implement MacDonald's therapy in a way that that did not create paresthesia in the patient. Exhibit 1115, ¶ 138-141.

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

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[2] 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.

[3] 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 (Ex. 1018) and U.S. Patent Publication No. 2006/0015153 to Gliner *et al*. (Ex. 1019).

As discussed in the previous section, MacDonald also discloses the limitations of dependent claims 2, 11-14, 17-22 and 25. Therefore, under the alternative basis of obviousness based on MacDonald alone or MacDonald in view of DeRidder, these dependent claims would have been obvious as well.

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. MacDonald does not describe any specific arrangement of implantable electrodes used with his device. 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 common in the art at this time. *See* Ex. 1015, ¶ 71. Examples of this are shown in FIG. 4 and FIG. 9 of Sluijter, which disclose a single implanted electrical lead with a row of electrical contacts axially placed along the lead. For example, in the portion of FIG. 4 presented in the claim chart immediately above, the catheter-like applicator 110 is a single lead, and has a single row of axially-disposed electrical contacts 112, 114, 116. Ex. 1003, 7:59-62.[4]

[4] Examples of other prior art references showing a spinal stimulation lead having a single axial row of electrical contacts, which could also be combined with

One of ordinary skill would have been motivated to employ an electrode configuration as disclosed by Sluijter, 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 MacDonald's system could successfully delivery an electrical signal to a patient's spine. *See* Ex. 1015, ¶ 73. For these reasons, claim 15 would have been obvious based on MacDonald alone, or MacDonald and De Ridder in view of Sluijter.

Regarding claim 23, the claimed value of around 10 kHz is squarely within the frequency range taught by MacDonald (100 Hz up to 250kHz), and is very close to one of the specific stimulation frequencies taught by MacDonald (5 kHz). Ex. 1002, 4:9-21 and 8:39-43. Furthermore, it is exactly the frequency specified in Royle as being a likely upper frequency limit for medical uses. Ex. 1004, ¶ 68. As such, claim 23 is *prima facie* obvious in view of MacDonald. *In re Harris*, 409 F.3d 1339, 1341 (Fed. Cir. 2005).

The '102 patent reports results that are purported to be an improved result as compared to stimulation at very low frequency, i.e., 60-80 Hz. Ex. 1001, 6:12 –

MacDonald to render claim 15 obvious, are shown in Exhibit 1018, FIGs. 6A-6F and ¶¶ 51-52.

8:9. However, one of ordinary skill would have known that patients could be treated at the various frequencies taught by MacDonald and Royle. *See* Ex. 1013, ¶¶ 74-75. For example, one of ordinary skill would have been aware that Royle teaches operation at a frequency of 10 kHz. Accordingly, there is no basis to conclude that the frequency recited in claim 23 provides unexpected results, and the frequency value claimed in claim 23 would have been obvious to one of ordinary skill.

For these reasons, there is more than a reasonable likelihood that claims 1, 2, 11-15, 17-23, 25 and 26 are unpatentable under 35 U.S. C. § 103.

E. Ground 5: Claims 1, 2, 11-15, 17-23, 25 and 26 Are Invalid as Obvious Over Sluijter in view of De Ridder, MacDonald and/or Royle

As discussed above, a person of skill in the art would understand that Sluijter's suggestions to avoid stimulation effects (*see* Ex. 1003, 15:47-53) meant that Sluijter treated patients without paresthesia. Since Sluijter 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 is insufficient to anticipate claims 1 and 26, these claims would have been obvious in view of Sluijter. A person skilled in the art implementing Sluijter's 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, Sluijter's therapy is not dependent in any way on the presence of paresthesia and, in fact, he teaches away from using "stimulation effects." *See generally* Exhibit 1003; *see also* Ex. 1015, ¶ 85. It would have been an obvious design choice for one of ordinary skill in the art to implement Sluijter's therapy in a way that does not cause paresthesia. *Id.*; *see also KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 420 (2007).

This is particularly true when Sluijter is combined with other prior art that teaches that paresthesia is an undesired side effect that should be avoided if possible. DeRidder is directed to a "system and method for treating pain without paresthesia by spinal cord stimulation." Ex. 1005, Abstract. De Ridder teaches that paresthesia "can 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. Also, MacDonald teaches the use of a "spinal cord stimulation" rather than paresthesia. *See* Ex. 1002 5:51-63 and Section V.A, *supra*.

Thus, DeRidder and MacDonald teach that paresthesia is an undesirable side effect that should be avoided if possible.[5] Given that Sluijter's therapy is not dependent on creating paresthesia in the patient, it would have been obvious in view of DeRidder and MacDonald to implement Sluijter's therapy in a way that that did not create paresthesia in the patient. Exhibit 1115, ¶ 138-141.

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

As discussed in the previous section, Sluijter also discloses the limitations of dependent claims 2, 15, 17, 18 and 25. Therefore, under the alternative basis of obviousness based on Sluijter alone or Sluijter in view of DeRidder, these dependent claims would have been obvious as well.

Dependent claims 11-14 of the '102 patent 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. Sluijter states that applications of the invention include relief from back pain, *See* Ex. 1003, 3:13-14, but does not describe specific treatments.

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[5] Other examples of prior art teaching that paresthesia is an undesirable and/or unnecessary side effect of electroneural therapy include Ex. 1018 and Ex. 1019.

One of ordinary skill, however, would have been aware of the many types of pain that can be treated with spinal stimulation. For example, one of ordinary skill would have been aware of the treatments disclosed in Tables I and II of MacDonald, shown in the claim chart and discussed in Section V.A.2, *supra*, and would have understood that such symptoms as were treated by the MacDonald system were also amenable to treatment by the Sluijter system. *See*. Ex. 1013, ¶ 97. 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. 1002, 12:43-16:19, Tables 1 and 2.

One of ordinary skill would have understood that Sluijter's system could be used to treat these sources of pain also and, indeed 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 MacDonald and Sluijter systems, in terms of electrode placement and frequency of operation, a person of ordinary skill would reasonably have expected that use of Sluijter's system to treat such sources of pain would have had similar success to MacDonald's system. Accordingly, claims 11-14 would have been obvious based on Sluijter in view of MacDonald.

Claims 19-23 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.

Sluijter discloses that the lower limit of the frequency of the signal applied to the patient is above 300 Hz, *Id.* 19:1-3, and suggests two different upper limits to the frequency range, namely 50 kHz and many MHz. *Id*. 19:4-6. Thus Sluijter teaches two frequency ranges, i) above 300 Hz to about 50 kHz and ii) above 300 Hz to many MHz. The claimed frequency ranges and values all fall within each of Sluijter's disclosed ranges. Where claimed ranges "are completely encompassed by the prior art, the conclusion that the claims are *prima facie* obvious is even more compelling than in cases of mere overlap." *In re Harris*, 409 F.3d at 1341 (citing *In re Peterson*, 315 F.3d 1325, 1330 (Fed. Cir. 2003)). Since the claimed frequency ranges and values all fall within both of the frequency ranges taught by Sluijter, they are *prima facie* obvious. Additionally, MacDonald and Royle teach the provision of therapy over the range of 100 Hz – 250 kHz, and Royle specifically states that a range of 2 kHz – 3 kHz will be adequate for most applications. This range overlaps with the ranges of claims 20-22. Royle also states that 10 kHz is the likely upper frequency limit for medical use, a value that lies squarely within the range of claim 19 and that is identical to that of claim 23.

Accordingly, one of ordinary skill would have known to provide therapy at the frequencies taught in the prior art.

For these reasons, there is more than a reasonable likelihood that claims 1, 2, 11-15, 17-23, 25 and 26 are unpatentable under 35 U.S.C. § 103.[6]

F. Ground 6: Claims 11-15 Are Invalid as Obvious Over Royle in view of MacDonald and/or Sluijter

As discussed in Section V.C, *supra*, a person of skill in the art would understand that Royle teaches a method of treatment that avoids producing a sensation in the patient. *See* Ex. 1015, ¶¶113-117. Since Royle 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. A person skilled in the art implementing Royle's 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, Royle's therapy is not dependent in any way on the presence of paresthesia. *See generally* Exhibit 1004; *see also* Ex. 1015, ¶ 113-117. It would have been an obvious design choice for one of ordinary skill in the art to

[6] In the event the Board concludes that the ranges taught by Sluijter are not sufficient to anticipate independent claims 1 and 26, then the obviousness analysis discussed above with respect to claims 19-23 would be equally applicable to claims 1, 2, 15, 17, 18, 25 and 26.

implement Royle's therapy in a way that does not cause paresthesia. *Id.*; *see also KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 420 (2007).

This is particularly true when Royle is combined with other prior art that teaches that paresthesia is an undesired side effect that should be avoided if possible. DeRidder is directed to a "system and method for treating pain without paresthesia by spinal cord stimulation." Ex. 1005, Abstract. De Ridder teaches that paresthesia "can 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. Also, MacDonald teaches the use of a "spinal cord stimulation" rather than paresthesia. *See* Ex. 1002 5:51-63 and Section V.A, *supra*.

Thus, DeRidder and MacDonald teach that paresthesia is an undesirable side effect that should be avoided if possible.[7] Given that Royle's therapy is not dependent on creating paresthesia in the patient, it would have been obvious in view of DeRidder and MacDonald to implement Royle's therapy in a way that that did not create paresthesia in the patient. Exhibit 1015, ¶ 141.

[7] Other examples of prior art teaching that paresthesia is an undesirable and/or unnecessary side effect of electroneural therapy include Ex. 1018 and Ex. 1019.

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

As discussed in Section V.C, Royle also discloses the limitations of dependent claims 2, 17-23 and 25. Therefore, under the alternative basis of obviousness based on Royle alone or Royle in view of DeRidder, these dependent claims would have been obvious as well.

Dependent claims 11-14 of the '102 patent 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.

One of ordinary skill would have been aware of the many types of pain that can be treated with spinal stimulation. For example, one of ordinary skill would have been aware of the treatments disclosed in Tables I and II of MacDonald, shown in the claim chart and discussed in Section V.A.2, *supra*, and would have understood that the symptoms treated by the MacDonald system were also amenable to treatment by the Royle system. *See*. Ex. 1015, ¶ 130-132. 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. 1002, 12:43-16:19, Tables 1 and 2.

One of ordinary skill would have understood that Royle's system could be used to treat these sources of pain also and, indeed would have been motivated to do so, given that MacDonald's treatment led, in many cases, to significant pain relief, and that Royle argued his system provided even more effective treatment than MacDonald. Furthermore, based on the clinical results discussed in MacDonald and Royle, it would have been reasonable for one of ordinary skill to believe that treatment with such a system would be successful in providing pain relief. Accordingly, claims 11-14 would have been obvious based on Royle 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. Royle does not describe the arrangement of implantable electrodes used with his device. 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. 1013, ¶ 134. Examples of this are shown in FIG. 4 and FIG. 9 of Sluijter, which disclose a

single implanted electrical lead with a row of electrical contacts axially placed along the lead. For example, in the portion of FIG. 4 presented in the claim chart immediately above, the catheter-like applicator 110 is a single lead, and has a single row of axially-disposed electrical contacts 112, 114, 116. Ex. 1003, 7:59-62. One of ordinary skill would have been motivated to employ an electrode configuration disclosed by Sluijter with the Royle device, 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 Royle's system could successfully delivery an electrical signal to a patient's spine. *See* Ex. 1015, ¶ 134. Thus, claim 15 is obvious. [8]

For these reasons, there is more than a reasonable likelihood that claims 1, 2, 11-15, 17-23, 25 and 26 are unpatentable under 35 U.S.C. §103.

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,

[8] Examples of other prior art references showing a spinal stimulation lead having a single axial row of electrical contacts, which could also be combined with Royle to render claim 15 obvious, are shown in Figs. 6A-F of Exhibit 1005.

17-23 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 and 26 of the '102 patent.

Date: May 14, 2015

Respectfully submitted,

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EXHIBIT LIST

Exhibit No.	Description
1001	U.S. Patent No. 8,359,102
1002	U.S. Patent No. 5,776,170 (MacDonald)
1003	U.S. Patent No. 6,246,912 (Sluijter)
1004	U.S. Patent Publication No. 2006/0009820 (Royle)
1005	U.S. Patent Publication No. 2011/0184488 (De Ridder)
1006	'102 patent file history, Application Data Sheet
1007	Application 13/245,450 file history, Office Action, November 18, 2011
1008	Application 13/245,450 file history, Interview Summary, February 1, 2012
1009	Application 13/245,450 file history, Amendment, February 7, 2012
1010	Application 13/245,450 file history, Notice of Allowability, March 14, 2012
1011	Application 13/446,970 file history, Preliminary Amendment, May 18, 2012
1012	Application 13/245,450 file history, Ex Parte Quayle Action, October 15, 2012
1013	Application 13/245,450 file history, Amendment in Response to Ex Parte Quayle Office Action, November 28, 2012
1014	Merriam Webster's Collegiate Dictionary, 10th ed., p. 583
1015	Declaration of Prof. Cameron C. McIntyre Ph.D.
1016	Sluijter ME *et al.*, "The effects of pulsed radiofrequency fields applied to the dorsal root ganglion – a preliminary report," *The Pain Clinic* (1998) **11**(2) 109-117
1017	Munglani R, "The longer term effect of pulsed radiofrequency for neuropathic pain," *Pain* **80** (1999) 437-439
1018	U.S. Patent No. 8,280,515
1019	U.S. Patent Publication No. 2006/0015153

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:

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