2019-2205

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

NEVRO CORP.,

Plaintiff-Appellee,

v.

STIMWAVE TECHNOLOGIES, INC.,

Defendant-Appellant.

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE IN CASE NO. 19-CV-325, JUDGE COLM F. CONNOLLY

CORRECTED NON-CONFIDENTIAL OPENING BRIEF OF APPELLANT STIMWAVE TECHNOLOGIES, INC.

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November 1, 2019

CERTIFICATE OF INTEREST

Counsel for Appellant certifies the following:

1. Full name of every party represented by me is:

Stimwave Technologies, Inc.

2. Name of the real party in interest represented by me is:

Stimwave Technologies, Inc.

3. Parent corporations and publicly held companies that own 10% or more of stock in the party:

None.

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court (including those who have not or will not enter an appearance in this case) are:

FISH & RICHARDSON P.C.: Frank. E. Scherkenbach, Proshanto Mukherji, Todd G. Miller, Corrin N. Drakulich, Douglas McCann, and Kelly A. Del Dotto

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5. The title and number of any case known to counsel to be pending in this or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. *See* Fed Cir. R. 47.4(a)(5) and 47.5(b):

Nevro Corp. v. Stimwave Technologies, Inc., USDC-D. DE Case 19-325-CFC.

Nevro Corp. v. Boston Scientific Corp., Fed. Cir. Case Nos. 18-2220, 18-2349.

Dated: November 1, 2019 Respectfully submitted,

By: */s/ Proshanto Mukherji*

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CONFIDENTIAL MATERIAL OMITTED

The material omitted on pages 11 and 36 contains sensitive business data and metrics about the performance of Stimwave's products.

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STATEMENT OF RELATED CASES

This is an appeal from *Nevro Corp. v. Stimwave Technologies, Inc.*, USDC-D. DE Case No. 19-CV-325-CFC. Related cases pending before the Federal Circuit Court of Appeals are *Nevro Corp. v. Boston Scientific Corp.*, Nos. 18-2220, 18-2349. Counsel is unaware of any other pending case that will directly affect or be directly affected by this court's decision in this pending appeal.

STATEMENT OF JURISDICTION

The United States District Court for the District of Delaware had subject-matter jurisdiction over this case under 28 U.S.C. §§ 1331 and 1338(a). This appeal is from the grant, in part, of a preliminary injunction issued on July 24, 2019. Appx47-48 (Order at 1-2). A timely notice of appeal was filed the next day on July 25, 2019. D.I. 1-2 at 1. This Court has appellate jurisdiction over this interlocutory order pursuant to 28 U.S.C. §§ 1292(c)(1) and 1295(a)(1).

STATEMENT OF THE ISSUES

The district court has entered a preliminary injunction that prevents Stimwave from providing patients with an FDA cleared pain-relief therapy. The issues on appeal are:

1. Whether the district court clearly erred by finding that Nevro was irreparably harmed;

2. Whether the district court erred legally by not holding the term "non-paresthesia-producing . . . signal" to be indefinite;

3. Whether the district court erred legally or clearly erred factually by finding the claims at issue not anticipated by, or obvious over, prior art to Royle;

4. Whether the district court clearly erred by finding that the preliminary injunction would not injure the public interest; and

5. Whether the injunction is overbroad in scope.

INTRODUCTION

The district court entered a preliminary injunction that prevents Stimwave from providing patients who suffer crippling pain with a unique, effective, and FDA cleared pain-relief therapy. "A preliminary injunction is a drastic and extraordinary remedy that is not to be routinely granted," *Nat'l Steel Car, Ltd. v. Canadian Pac. Ry., Ltd.*, 357 F.3d 1319, 1324 (Fed. Cir. 2004), especially where doing so might limit patients' medical choices. *Cordis Corp. v. Bos. Sci. Corp.*, 99 F. App'x 928, 935 (Fed. Cir. 2004) (non-precedential). Such an injunction "should not be granted unless the movant, ***by a clear showing***, carries the burden of persuasion." *Mazurek v. Armstrong*, 520 U.S. 968, 972 (1997) (emphasis in original).

This injunction rests instead upon clear errors of law and fact. The district court simply misread the clinical numbers when it found irreparable harm. It found that Stimwave's products' clinical performance "pale[s] in comparison" to Nevro's, Appx40, but the hard numbers prove otherwise. They show that it is ***Stimwave's*** products that reduce more pain in more patients. Here are the key numbers[1]:

[1] These numbers relate generally relate to patients suffering from back pain six months into the study. *See* Section IV below.

	RESPONDERS *(% who obtained significant (>50%) relief)*	REMISSIONS *(% whose pain was nearly eliminated)*	AVERAGE REDUCTION IN PAIN
Stimwave 10 kHz	92%	84%	77%
Nevro 10 kHz	76.4%	59.6%	67%

The district court compounded this error by finding, based on Nevro's witnesses' speculation, that physicians would confuse Nevro's products with Stimwave's and abandon ***Nevro*** because of hypothetical bad experiences with ***Stimwave***. Yet with years of real-world experience to draw from in Europe and Australia—where both parties' products have been on sale for years—Nevro could not find a single physician who has ever done such a thing.

The district court also erred by finding no substantial question of invalidity. The claims are indefinite because a skilled artisan cannot determine if an act infringes the claims except by actually performing the act and seeing if infringement occurs. They are also anticipated and obvious: the prior art undisputedly "discloses each element of the asserted claims." Appx35 (Op.at 34). Finally, the injunction is overbroad and harms the public by depriving patients of the medical care they may need, and for which Nevro's products are no substitute.

Stimwave respectfully submits that the drastic remedy entered in this case requires far more solid support than Nevro has here. The injunction should be vacated.

STATEMENT OF THE CASE

I. SCS THERAPY AND ITS HISTORY

This appeal relates to high-frequency spinal cord stimulation ("SCS") therapy. SCS therapy treats chronic pain by implanting electrodes to deliver electrical stimulation directly to targeted areas of the patient's spinal column, disrupting the signal to the brain that would result in a pain response. Appx1417 (Pless) ¶ 23; Appx4931-4932 (North) ¶¶ 34-36. SCS therapy is an improvement over conventional pain treatments, such as opioids, which can have side effects that include addiction and possible death. Appx4932 (North) ¶ 35. Electrical stimulation, by contrast, "is a drug free, long term solution for the treatment of chronic pain." *Id.*

The benefits of SCS therapy have long been known. Dr. Norman Shealy performed the first SCS electrode placements over fifty years ago, in 1967. Appx1417 (Pless) ¶ 24; Appx4932 (North) ¶ 36. Since then, numerous medical device companies, including Medtronic and Cordis, have developed and marketed implantable SCS devices, including, more recently, ones with implanted pulse generators (IPGs), which we discuss further below. Appx1417 (Pless) ¶ 24; Appx4932, Appx4939-4940 (North) ¶¶ 36, 54.

SCS therapy signals delivered from the electrodes traditionally had three parameters that defined the waveform being delivered to the patient: frequency, pulse

width, and amplitude. Appx1418 (Pless) ¶ 26. The most effective combination of parameters to achieve pain relief varies from patient to patient, and so SCS systems are configured so they can operate at wide ranges of parameters. For example, some SCS systems are configured to operate at lower frequencies (typically under 1.5 kHz), *see* Appx3616 ¶ 68, others at higher frequencies, Appx4494, and still others at both higher and lower frequencies. For instance, SCS products have been capable of using high frequencies up to 14,000 Hz since the 1970s, Appx3604, and the use of SCS products using frequencies between 10 kHz and 30 kHz were shown to be effective in animals in 2005. Appx3593.

Patients sometimes respond to SCS therapy signals by experiencing "paresthesia." While descriptions of this side effect can vary, the district court described it as "a sensation usually described as tingling, pins and needles, or numbness."[2] Appx3. Whether treatment at a particular frequency will induce paresthesia depends on, among other things, (i) the signal parameters used (including amplitude); (ii) the specific patient's anatomy; and (iii) the specific device being used. Appx4871,

[2] Stimwave applies the district court's interpretation of "paresthesia" for purposes of this appeal only. Stimwave reserves the right to revisit this interpretation at later stages of the case, as well as to propose constructions for other terms, including "non-paresthesia producing … signal" and related terms.

Appx4872, Appx4874 (Aberle) ¶¶ 89, 93, 98. To determine what signals may potentially cause a paresthesia response, physicians deliver a variety of signals and ask the patient to report what he or she feels in response to each one. Appx4942 (North) ¶ 59.

It has long been known that the use of signals with higher frequencies (e.g., above 3 kHz) and lower amplitudes may reduce or eliminate the side effect of paresthesia in some patients. Appx3616-3617 ¶ 75; Appx4935-4938 (North) ¶¶ 46, 51. United States Patent Application 2006/0009820 to Royle ("Royle") disclosed one such system that produced such outcomes. Appx3608-3620. According to Royle, "most applications" will use frequencies of 2-3 kHz and higher frequencies—up to 10 kHz—can be applied to provide pain relief to patients. *Id.* ¶¶ 46, 68. Royle explains that the use of these higher frequencies is preferable because they do not stimulate the peripheral nerves, "so that the subject (i.e. patient) feels no sensation," including paresthesia. *Id.* ¶ 75.

II. NEVRO'S SENZA SYSTEMS

Nevro currently markets two fully implantable SCS systems, called "Senza" and "Senza II." Appx4492. These systems use an "implantable pulse generator (IPG)." *Id.* An IPG is an implant that generates the signal pulses and delivers them to elec-

trodes implanted in the patient. Appx4813-4814 (Perryman) ¶ 8. The IPG is implanted via surgery in which a pocket is created at the IPG implant site, which may include, for example, the patient's buttock, large enough to accommodate the IPG. Appx4514.

Nevro refers to its 10 kHz high-frequency treatment as "HF10 therapy." Appx1520 (Caraway) ¶ 13. According to Nevro, 97% of its patients receive exclusively HF10 therapy. Appx7376 (Tr.) 100:14-20. HF10 therapy always utilizes a frequency of 10 kHz at a fixed pulse width of 30 μs. Appx7416 (Tr.) 140:20-25. However, because the signal amplitude at which a patient will feel sensation varies from patient to patient, the HF10 amplitude setting may be varied so as to not produce paresthesia in the particular patient being treated. Appx7417 (Tr.) at 141:1-21.

Nevro's systems, like other fully implantable systems, are not adequate for all patients. Specifically, Nevro's systems are not suitable for patients who are too slender to accept the bulk of a battery or who will need frequent MRI scans. Appx4933-4934 (North) ¶¶ 40-41. Nevro's systems are not FDA-cleared for use with full-body 3T MRI scans, and using them may "result in severe patient injury or device malfunction." Appx4495; Appx7424 (Tr.) 148:11-13. Nevro also cautions that its systems are not suitable for patients who are "poor surgical candidates." Appx4498.

III. STIMWAVE'S MICRO-SIZED WIRELESS SCS SYSTEM

Stimwave SCS devices are different from Nevro's in both form and structure. They are unique in the marketplace because they are wireless and miniature. Appx4939 (North) ¶ 53. They use novel micro-sized electronic elements and do not have an implantable pulse generator or battery, Appx4938-4939 (North) ¶¶ 52–53, with the result that their implants are less than 5% the size of conventional SCS systems'. *See* Appx3792. Stimwave's products are also implanted using a less invasive surgical procedure than Nevro's, Appx3447; Appx4816, Appx4818-4819 (Perryman) ¶¶ 12, 14: without the IPG, they are so small that they can be introduced through a needle while the patient is awake. Appx4939 (North) ¶ 53. Stimwave was recently named to Fast Company's list of the World's Most Innovative Companies. Appx3472; Appx4815-4816 (Perryman) ¶ 11.

Stimwave targets its systems at patients who are unwilling or unable to use other companies' bulkier and more intrusive systems, such as those who are unwilling to have an IPG lithium-ion battery (the same type of batteries used in cell phones) implanted in their body, those in need of regular 3T MRI spinal scans, those who are unwilling or unable to undergo general anesthesia, and those with low body mass index or other conditions that may make it risky to perform the intrusive surgery needed to implant an IPG. Appx4933-4934 (North) ¶¶ 40-41.

Stimwave's devices are safer than Nevro's. IPGs are associated with a number of medical complications, including pain at the site of the IPG (a phenomenon known as "pocket pain"). Studies have found such complications in up to 64% of IPG-based SCS patients. Appx4104; Appx4822-4823 (Perryman) ¶19. Accordingly, the FDA classifies Stimwave's products as "Class II" devices and Nevro's as riskier "Class III" devices. Appx4823-4824 (Perryman) ¶ 21; Appx1520-1521 (Caraway) ¶14. This classification is based on both the device's intended use and the "risk the device poses to the patient and/or the user." Appx4080-4081. A recent analysis of the FDA's Manufacturer and User Facility Device Experience ("MAUDE") database confirms the superior safety of Stimwave's "Freedom" systems. For example, only [ ] of Stimwave's Freedom systems sold between 2016 and 2018 showed "lead migration" (an undesirable event where the stimulator leads move from the proper position), and only [ ] of them led to infection. Appx4113. These rates were far below those reported for SCS Systems marketed by competitors—in the case of infection, ten times less. *Id*.

Stimwave's SCS systems have long been FDA cleared for use at frequencies up to and including 1,500 Hz (1.5 kHz). Appx4830-4832 (Perryman) ¶ 31. On March 29, 2019, Stimwave received clearance to operate its SCS systems at higher frequencies, up to 10 kHz. Appx2581-85; Appx4825-4826.

IV. CLINICAL STUDIES

Nevro and Stimwave have both sponsored clinical studies of their respective high-frequency treatments. Nevro's "SENZA-RCT" study compared Nevro's 10 kHz SCS devices against a commercially available, low-frequency device made by Boston Scientific, Appx1566, and Stimwave's "SURF-RCT" study compared Stimwave's 10 kHz therapy against its own low frequency therapy. Appx4160. Both studies evaluated (among other things) for each system: (1) how many patients "responded" to the treatment, defined as obtaining at least 50% pain relief, Appx4162 (SURF-RCT); Appx1567 (SENZA-RCT); (2) how many experienced "remission" of pain, meaning that their pain was reduced to low levels ($\leq$ 2.5 on the VAS pain scale), Appx4163; Appx1567; and (3) the average pain reduction in treated patients, Appx4162; Appx1569. The results for patients suffering from back pain six months after treatment began (the primary endpoint of the SURF-RCT study) are as follows:

	RESPONDERS *(% who obtained significant relief)*	REMISSIONS *(% whose pain was nearly eliminated)*	AVERAGE REDUCTION IN PAIN
Stimwave 10 kHz	92%[3]	84%[4]	77%[5]
Nevro 10 kHz	76.4%[6]	59.6%[7]	67%[8]
Stimwave LF	82%[9]	47%[10]	64%[11]
BSC LF	51.9%[12]	36.7%[13]	44%[14]

The numbers show that Stimwave's 10 kHz treatment produced more respond-

[3] Appx1698 (SURF-RCT) (At six months, "92% [] of the subjects with HF stimulation were responders, as compared with 82% [] of subjects who responded to LF ….").

[4] Appx1699 (SURF-RCT) (Figure 5. "Frequency of subjects reporting remission for back pain following six months of stimulation was 84% and 47%, respectively, for the high-frequency and low-frequency arms.").

[5] Appx1698 (SURF-RCT) ("At the six-month primary end point, the mean back pain VAS reduction for the HF arm [] was 77% … and the LF arm was 64%.").

[6] See Appx1570 (SENZA-RCT) (Table 2, "Month 6" column, showing "responder" rates and "remitter" rates after six months in the HF and LF tests).

[7] *Id.*

[8] Appx1569 (SENZA-RCT) ("Mean back pain VAS [showed] … a 67% decrease[] over 12 months with HF10 therapy compared with … a 44% decrease[] for traditional SCS."). These figures are from the twelve-month rather than the six-month mark because the SENZA-RCT study did not expressly report pain reduction percentages at six months. However, the HF10 six-month figures would likely be marginally lower (i.e. worse) than the twelve-month figures: the study includes a graph showing mean pain numbers at six and twelve months, which show that pain reduction was slightly worse at six months for the HF10 therapy. Appx1570.

[9] *See supra* n. 3.

[10] *See supra* n. 4.

[11] *See supra* n. 5.

[12] *See supra* n.6.

[13] *See supra* n.6.

[14] *See supra* n. 8.

ers (92% vs. 76.4%), more remissions (84% vs. 59.6%), and more average pain reduction (77% vs. 67%) than Nevro's.[15] They also show that Stimwave's low frequency treatment was in the same range as both parties' 10 kHz treatments.

V. THE '222 PATENT

Claims 24 and 28 of U.S. Patent No. 8,874,222 ("the '222 patent") are at issue in this appeal. The '222 patent issued October 28, 2014 and is titled "Selective High Frequency Spinal Cord Modulation for Inhibiting Pain with Reduced Side Effects, and Associated Systems and Methods." Appx83. The '222 patent is "directed generally to spinal cord modulation and associated systems and methods for inhibiting pain via waveforms with high frequency elements or components (e.g., portions having high fundamental frequencies), generally with reduced or eliminated side effects." Appx102 at 2:52-56.

The '222 patent's purported invention is programming a device to deliver "non-paresthesia-producing therapy signals" at frequencies between 1.5 kHz and 100 kHz. *See* Appx106 at 10:20-28, Appx114 at Claim 23. Claims 24 and 28 of the

[15] The pattern is similar for patients suffering from leg pain, rather than back pain. There, the average pain reduction was: Stimwave HF: 76%, Appx1698, Appx1700 Figure 7; Nevro HF: 70%, Appx1569 (at 12 months, which again is an overestimate of the six-month number); Stimwave LF: 64%, Appx1698; BSC LF: 49%. Appx1569. The SURF-RCT does not separately report responder and remission rates for leg-pain patients, but the SENZA-RCT study reported similar rates as for back pain (80.9% responders, 68.6% remitters). Appx1570, Table 2.

'222 patent are directed to methods of "programming" a signal generator. Appx114-115. Both claims depend from independent claim 23. All three claims are reproduced below:

Claim 23:

> A method for configuring a signal generator to deliver a therapy signal to a patient's spinal cord, the method comprising:
>
> programming the signal generator to
>
> (1) generate a non-paresthesia-producing therapy signal, wherein at least a portion of the therapy signal has a frequency in a frequency range of from 1.5 kHz to 100 kHz; and
>
> (2) deliver the therapy signal to the patient's spinal cord via a signal delivery device implanted in the patients epidural space.

> **Claim 24**: The method of claim 23, wherein the frequency is 10 kHZ.

> **Claim 28**: The method of claim 23 wherein the frequency range is from 3 kHz to 10 kHz.

Appx114-115 at 26:52–27:10-11.

Claim 23 thus has a single "programming" step that requires (among other things): (1) generating a signal in the frequency range of 1.5–100 kHz; (2) the signal must be a "non-paresthesia-producing therapy signal"; and (3) the signal must be

delivered to an implanted signal delivery device, such as an electrode.[16] Claims 24 and 28 narrow the claimed frequency range to 10 kHz and 3–10 kHz, respectively.

VI. THE DISTRICT COURT PROCEEDINGS

Shortly after filing suit, Nevro filed a motion for a preliminary injunction alleging infringement of claims 22 and 23 of Patent No. 9,327,127 and claims 24, 28 and 48 of the '222 patent. Appx8-12. After a hearing, the district court granted Nevro's motion with respect to claims 24 and 28 of the '222 patent only. Appx46. In its ruling, the district court made findings related to, *inter alia*, irreparable harm, invalidity, public interest, and the scope of the injunction.

Irreparable Harm—The district court found that Nevro would be irreparably harmed absent an injunction. Appx38-42. The district court did not adopt Nevro's primary irreparable-harm argument—a straightforward contention of loss of market share and price-erosion, Appx1402-1405—but instead found irreparable harm under a "customer confusion" theory. Appx37-43.

To reach this conclusion, the district court first found that Stimwave's clinical results at 10 kHz "pale in comparison" to Nevro's, Appx40, on the ground that

[16] Both Stimwave's and Nevro's devices implant electrodes in the patient's body. But as discussed, the Nevro systems also implant the program generator and batter into the patient, whereas Stimwave's miniature wireless systems do not. Appx4938-4939 (North) ¶¶ 52–53.

Nevro's SENZA-RCT study found Nevro's HF system to be "superior[]" to ***its*** low-frequency baseline, Appx39—which was a Boston Scientific device—whereas "Stimwave's SURF study showed only that Stimwave's high frequency … therapy is '***noninferior***' to ***its*** traditional, low-frequency" baseline, Appx40, which was a Stimwave device operating at lower frequencies. The district court made no findings to account for the fact that the studies used different baselines. Appx37-43. It also did not attempt to reconcile these findings with the studies' reported numbers, Appx37-43, which indicate that Stimwave's 10 kHz treatment actually produced more responders (92% vs. 76.4%), more remissions (84% vs. 59.6%), and more average pain reduction (77% vs. 67%) than Nevro's.

The district court next concluded that, in light of the Stimwave devices' supposed inferior performance, there could be "consumer confusion between [Nevro's] product and [Stimwave's] product," Appx41, and that if "a skeptical physician were to try [Stimwave's 10 kHz product] . . . but . . . has a negative experience, . . . Nevro could forever lose this physician as a potential customer." *Id.* The district court cited no evidence of any doctor who actually did these things, but instead acknowledged that it was relying on testimony that "involve[d] speculation." Appx41-42.

Invalidity—The district court also found that Stimwave had not raised a substantial question of invalidity for the '222 patent. Appx23. In doing so, it rejected Stimwave's arguments regarding indefiniteness, anticipation and obviousness.

The district court found that the term "non-paresthesia producing … signal" was not indefinite. Appx24-27. While the district court agreed that "paresthesia is a subjective assessment that can vary from patient to patient," Appx25, meaning that the determination of whether a signal produces paresthesia or not would have to be made separately for each patient and for each therapy session, it still found the term not indefinite on the ground that "a POSITA would be able to determine easily from patient interactions whether a signal produces paresthesia for ***any given patient***." Appx27.

As to anticipation, the district court analyzed U.S. Patent Application No. 2006/0009820 to Royle ("Royle"). *See* Appx34. Despite determining that Royle "discloses each element of the asserted claims," the district court found that Royle did not anticipate them. Appx35. It found that, although Royle disclosed that high-frequency signals would result in paresthesia-free therapy, it only did so in the context of electrodes placed on the skin, rather than implanted electrodes. Appx35. Royle, however, elsewhere discloses that "[i]f desired, the electrodes could be implanted within the body, including within the skin." Appx3618 ¶ 104.

As to obviousness, the district court determined that although Royle disclosed the use of high-frequency signals to provide paresthesia-free therapy using electrodes placed on the skin, it would not be obvious to deliver the same therapy through an implanted electrode. Appx35. The district court noted that Royle expressly disclosed that "[i]f desired, the electrodes could be implanted within the body, including within the skin," *id.* (quoting Royle ¶ 104), but held that Royle taught away from implanting them when it said that "it is more preferable" to place them on the skin. Appx35-36 (quoting Royle ¶ 104).

***Public Interest*—**The district court also found that the public interest would not be harmed by an injunction against Stimwave's high-frequency SCS treatment. Appx44-45. It held that patients could simply use Nevro's products or Stimwave's low-frequency products instead. *Id.*

***Injunction*—**The district court then issued a broad preliminary injunction that prevents Stimwave from "programming Stimwave's SCS systems to deliver its recently introduced high-frequency, paresthesia-free SCS therapy, or any other SCS therapy that is not more than colorably different from it." Appx48. The "high frequenc[ies]" here are all those from 3–10 kHz, which are identified in the claims at issue. *See* Appx114-115 at Claim 24, 28. Stimwave promptly filed the present appeal.

SUMMARY OF THE ARGUMENT

The preliminary injunction is grounded in error and should be vacated. "[Preliminary] injunctive relief is an extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 22 (2008) (citations omitted). "[C]ase law and logic both require that a movant cannot be granted a preliminary injunction unless it establishes ***both*** … likelihood of success on the merits and irreparable harm." *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1350 (Fed. Cir. 2001). Nevro has established neither. The injunction also disserves the public by depriving patients of the medical care they may need, and sweeps so broadly that it covers many non-infringing activities.

Irreparable Harm—The district court's finding of irreparable harm is clear error. The district court did not adopt Nevro's primary irreparable-harm argument—a straightforward, albeit incorrect, contention of loss of market share and price-erosion, Appx1387 at Appx1402-1405—but instead found irreparable harm under a "customer confusion" theory. Appx37-43. This finding rests upon three premises, all of them necessary, and none of them supported by the record: (1) that Stimwave's high-frequency SCS systems' clinical performance "pales in comparison" to Nevro's; (2) that physicians could "confus[e]" Nevro's product with Stimwave's;

and (3) that if "a skeptical physician were to try [***Stimwave's*** high frequency product] … but … has a negative experience," the physician might "forever" refuse to use ***Nevro's*** products. Appx41.

Each of these premises is clearly erroneous. Premise 1 (Nevro's clinical superiority) is based on a simple misreading of the clinical results; the numbers themselves show that, if anything, Stimwave's results are better that Nevro's. And Premises 2 and 3 (physicians' confusion leading them to abandon Nevro because of bad experiences with Stimwave devices) are based only on naked speculation. Both Nevro and Stimwave have been selling 10 kHz devices in Europe and Australia for years, and yet there is no evidence that any physician has ever conflated the parties' products, which are entirely different in form and structure, or abandoned Nevro owing to a bad experience with Stimwave.

Likelihood of Success—The district court also made errors of law and clear errors of fact when it found that Nevro was likely to succeed on the merits. Appx22-27; 31-36. Stimwave raised at least a substantial question that the claims at issue are invalid. ***First***, it showed that the term "non-paresthesia-producing … signal," which appears in all asserted claims, is indefinite. The district court found that any given signal will produce paresthesia in some patients but not others, Appx25, and that "it is impossible to know whether paresthesia will be induced until after the signal is

applied" to the patient. Appx27.[17] Thus, the claim is indefinite because (1) it "requires that an artisan make a separate infringement determination for every set of circumstances [i.e. every patient] in which [it] may be used, and … such determinations are likely to result in differing outcomes (sometimes infringing and sometimes not)," *Halliburton Energy Servs., Inc. v. M-I LLC*, 514 F.3d 1244, 1255 (Fed. Cir. 2008); and (2) one cannot tell whether a signal infringes the claim except by applying it to the patient, and thus risking infringement. "[T]he notion that one reasonably skilled in the art would have to infringe the patent claim in order to discern the boundaries of the claim is repugnant to long-standing principles of patent jurisprudence." *STX, Inc. v. Brine, Inc.*, 37 F. Supp. 2d 740, 755 (D. Md. 1999), *aff'd on other grounds*, 211 F.3d 588 (Fed. Cir. 2000).

[17] *See also* Appx7417 (Tr.) at 141:14-21 (Nevro's witness testifying that "for all forms of spinal cord stimulation in every frequency," including for Nevro's own HF10 therapy, "there isn't any way to tell before you start the process of adjusting the amplitude setting in the therapy when a given patient is going to feel something."). *See also* Appx4945-4946 (North) ¶¶ 66–67 ("[I]t was not possible to ascertain whether a given set of parameters would cause paresthesia in a particular patient until after the SCS device was implanted, the parameters set, and the signal was applied. This uncertainty is due to a number of factors, including where the electrodes are placed in relation to the spinal cord, where the electrodes are placed in relation to each other, the inherent variability of a patient's neural response to the stimulation, and the amount of scar tissue and cerebrospinal fluid in the area.")

Second, the district court made an error of law when it concluded that the Royle reference does not anticipate the claims or at least render them obvious. It erred by finding no anticipation despite acknowledging that "Royle discloses each element of the asserted claims." Appx35. And as to obviousness, it erred on the law by treating Royle's specific teaching that electrodes could be implanted in the body as "teaching away" from doing that very thing simply because Royle expressed a general preference for non-implanted electrodes. As a matter of law, "[a] reference that 'merely expresses a general preference for an alternative invention … does not teach away." *Meiresonne v. Google, Inc.*, 849 F.3d 1379, 1382 (Fed. Cir. 2017); *see also Syntex LLC* v. *Apotex, Inc.*, 407 F.3d 1371, 1380 (Fed. Cir. 2005) ("A statement that a particular combination is not a preferred embodiment does not teach away absent clear discouragement of that combination.").

Public Interest—The preliminary injunction injures the public interest because it denies some patients the medical care that is best for them. The district court clearly erred when it concluded that patients could just use Nevro devices instead, or else use Stimwave devices at low frequencies.

Stimwave's high-frequency treatment is the medically superior option for some patients, as the SURF-RCT study shows. Denying these patients treatment at this preliminary stage, before Stimwave has even had the opportunity to defend itself

on the merits, is against the public interest. Where different products offer different options for different patients, the public's interest is in providing physicians with a wide variety of treatment options. *Cordis Corp. v. Bos. Sci. Corp.*, 99 F. App'x 928, 935 (Fed. Cir. 2004) (non-precedential).

Scope of the Injunction—Lastly, the injunction is plainly overbroad. ***First***, it enjoins Stimwave from using its Freedom SCS Systems to deliver "paresthesia-free" SCS therapy at frequencies from 3 kHz to 10 kHz, even though there is no evidence that Stimwave (or for that matter Nevro) has used frequencies other than 10 kHz and there are no findings as to which, if any, signals at those frequencies would satisfy the "non-paresthesia producing ... signal" element of the claims. ***Second***, and relatedly, the injunction's effect sweeps far beyond the scope of the claims, to cover the use of signals that ***do*** produce paresthesia, and thus do not infringe. As "it is impossible to know whether paresthesia will be induced until after [a] signal is applied …," Appx27, Stimwave cannot tell whether this limitation is met except by delivering the signal to the patient and thus risking violating the injunction if paresthesia does not occur. So Stimwave has no choice but to cease providing therapy at these frequencies altogether. Stimwave submits that this is manifestly unjust.

Accordingly, this court should vacate the preliminary injunction.

STANDARDS OF REVIEW

"[A] preliminary injunction is an extraordinary and drastic remedy, one that should not be granted unless the movant, ***by a clear showing***, carries the burden of persuasion." *Mazurek v. Armstrong*, 520 U.S. 968, 972 (1997) (citations omitted) (emphasis in original). Thus, "[t]he district court's discretion [to grant an injunction] is not absolute," *Hybritech Inc. v. Abbott Labs.*, 849 F.2d 1446, 1451 (Fed. Cir. 1988) but "must be measured against the standards governing the issuance of an injunction." *Id.*

The Court reviews preliminary injunctions under the law of the regional circuit, here the Third Circuit. *See Tinnus Enters., LLC v. Telebrands Corp.*, 846 F.3d 1190, 1202–03 (Fed. Cir. 2017). "However, [it] … gives dominant effect to Federal Circuit precedent insofar as it reflects considerations specific to patent issues." *Murata Mach. USA v. Daifuku Co.*, 830 F.3d 1357, 1363 (Fed. Cir. 2016). The Court "review[s] factual findings for clear error, conclusions of law de novo, and the exercise of a district court's discretion for a clear error of judgment in weighing relevant factors." *Nat'l Steel Car, Ltd. v. Canadian Pac. Ry.*, 357 F.3d 1319, 1325 (Fed. Cir. 2004).

"A plaintiff seeking a preliminary injunction must establish [1] that he is likely to succeed on the merits, [2] that he is likely to suffer irreparable harm in the absence

of preliminary relief, [3] that the balance of equities tips in his favor, and [4] that an injunction is in the public interest." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). "[C]ase law and logic both require that a movant cannot be granted a preliminary injunction unless it establishes ***both*** . . . likelihood of success on the merits and irreparable harm." *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1350 (Fed. Cir. 2001).

To establish likelihood of success on the merits, a patentee must demonstrate that, *inter alia*, the patent is likely to withstand challenges to its validity. *Tinnus*, 846 F.3d at 1202. Thus, "[a]n accused infringer can defeat a showing of likelihood of success on the merits by demonstrating a substantial question of validity . . . ." *Trebo Mfg., Inc. v. Firefly Equip., LLC*, 748 F.3d 1159, 1165 (Fed. Cir. 2014).

A patent claim is invalid as indefinite under 35 U.S.C. § 112 where "a patent's claims, viewed in light of the specification and prosecution history, inform those skilled in the art about the scope of the invention with reasonable certainty." *Nautilus, Inc. v. Biosig Instr. Inc.*, 572 U.S. 898, 910 (2014). Though absolute certainty is not required, the claims, when read in light of the intrinsic record, "must provide objective boundaries for those of skill in the art." *Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1371 (Fed. Cir. 2014). Indefiniteness is a question of law, which

is reviewed *de novo*, except for subsidiary fact-findings, which are reviewed for clear error. *Berkheimer v. HP Inc.*, 881 F.3d 1360, 1363 (Fed. Cir. 2018).

A claim is invalid as anticipated under 35 U.S.C. § 102 "if each and every element is found within a single prior art reference, arranged as claimed." *Summit 6, LLC v. Samsung Elecs. Co.*, 802 F.3d 1283, 1294 (Fed. Cir. 2015). Anticipation is a factual question. *Id.*

A patent claim is invalid as obvious under 35 U.S.C. § 103 where the difference between the claim and the relevant prior art would have been obvious to a person of ordinary skill in the art. *Graham v. John Deere Co.*, 383 U.S. 1, 37 (1966). "Obviousness is a question of law based on underlying facts." *Id.* at 1047.

The existence of irreparable harm is reviewed for abuse of discretion. *Metalcraft of Mayville, Inc.*, 848 Fed. Cir. 1358, 1368–69 (Fed. Cir. 2017). "An abuse of discretion may be established by showing that the court made a clear error of judgment in weighing relevant factors or exercised its discretion based upon an error of law or clearly erroneous factual findings." *Id.* at 1363 (internal quotation marks and citation omitted). The facts underlying this determination must be substantially certain. "[N]either the difficulty of calculating losses in market share, nor speculation that such losses might occur, amount to proof of special circumstances

justifying the extraordinary relief of an injunction prior to trial." *Nutrition 21 v. United States*, 930 F.2d 867, 871 (Fed. Cir. 1991).

The determination that an injunction is in the public interest are reviewed for abuse of discretion. *Metalcraft*, 848 F.3d at 1369. Equity will not support an injunction that harms the public. *See Benisek v. Lamone*, 138 S. Ct. 1942, 1944 (2018). "In considering whether the public interest favors the grant of an injunction, the district court should focus on whether a critical public interest would be injured by the grant of injunctive relief." *Metalcraft*, 848 F.3d at 1369.

"Every order granting an injunction must 'state the reasons why it issued,' 'state its terms specifically,' and 'describe in reasonable detail—and not by referring to the complaint or other document—the act or acts restrained or required.'" *Macom Tech. Sol'ns Holdings v. Infineon Tech.*, 881 F.3d 1323, 1331–32 (Fed. Cir. 2018) (quoting Rule 65(d), Fed. R. Civ. P.). Whether the terms of an injunction comply with these requirements "is a question of law that [this Court] review[s] without deference." *Int'l Rectifer Corp. v. IXYS Corp.*, 383 F.3d 1312, 1315–16 (Fed. Cir. 2004); *see also Macom Tech.*, 881 F.3d at 1332.

ARGUMENT

VII. THE DISTRICT COURT'S IRREPARABLE HARM FINDING IS CLEAR ERROR.

This is the rare case where the district court's finding of irreparable harm is clear error. "[A] preliminary injunction is an extraordinary and drastic remedy, one that should not be granted unless the movant, ***by a clear showing***, carries the burden of persuasion." *Mazurek v. Armstrong*, 520 U.S. 968, 972 (1997) (citations omitted) (emphasis in original). Thus, "[t]he district court's discretion [to grant an injunction] is not absolute," *Hybritech Inc. v. Abbott Labs.*, 849 F.2d 1446, 1451 (Fed. Cir. 1988) but "must be measured against the standards governing the issuance of an injunction." *Id.* Accordingly, "speculation that . . . losses might occur [does not] amount to proof of special circumstances justifying the extraordinary relief of an injunction prior to trial." *Nutrition 21 v. United States*, 930 F.2d 867, 871 (Fed. Cir. 1991) (vacating preliminary injunction).

Here, the district court's irreparable harm finding rests on three premises, all of them necessary, and none of them supported by the record. The district court did not adopt Nevro's primary irreparable-harm argument—a straightforward, albeit incorrect, contention of loss of market share and price-erosion, Appx1402-1405—but instead found irreparable harm under a "customer confusion" theory. Appx37-43. Relying on *Tinnus Enterprises, LLC v. Telebrands Corporation*, 846 F.3d 1190 (Fed.

Cir. 2017), where irreparable harm arose because customers confused the defendant's brand of water-balloon toy with patentee's, the district court found irreparable harm as follows:

[Premise 1] "Nevro's HF10 [i.e. high-frequency 10 kHz] therapy offers clinically superior results" to Stimwave's high-frequency therapy, Appx40;

[Premise 2] there could be "consumer confusion between [Nevro's] product and [Stimwave's] product," Appx41; and

[Premise 3] if "a skeptical physician were to try [Stimwave's high frequency product] . . . but . . . has a negative experience, . . . Nevro could forever lose this physician as a potential customer." *Id.*

Each of these premises is clear error. Premise 1 (Nevro's clinical superiority) is based on a simple misreading of the clinical results; the numbers themselves show that, if anything, Stimwave's results are better than Nevro's. And Premises 2 and 3 (physician confusion leading them to abandon ***Nevro*** because of bad experiences with ***Stimwave*** devices) are based only on pure speculation. Both parties have been selling their 10 kHz devices in Europe and Australia for years, and yet there is no evidence that any physician has ever conflated the parties' products or abandoned Nevro owing to a bad experience with Stimwave.

A. The district court clearly erred in finding that Nevro's high frequency products were clinically superior to Stimwave's.

The district court's finding on Premise 1—that "Nevro's HF10 therapy offers clinically superior results" to Stimwave's, Appx40—is wrong as a matter of arithmetic. The district court simply misread two clinical studies, the Stimwave-sponsored "SURF-RCT" study and the Nevro-sponsored "SENZA-RCT" study. Appx40. It concluded that "[t]he results Stimwave obtained in its 10 kHz clinical trial pale in comparison to the results Nevro obtained in the SENZA-RCT study," *id.*, but the hard numbers show that the opposite is true.

Here are the numbers. Nevro's SENZA-RCT study compared Nevro's 10 kHz SCS devices against a low frequency device made by Boston Scientific. Appx1566. Stimwave's SURF-RCT study compared Stimwave's 10 kHz therapy against Stimwave's own low frequency therapy—a ***different baseline***. Appx4160. Both studies evaluated (among other things) for each system: (1) how many patients "responded" to the treatment, defined as obtaining at least 50% pain relief, Appx4162 (SURF-RCT); Appx1567 (SENZA-RCT); (2) how many experienced "remission" of pain, meaning that their pain was reduced to low levels (≤ 2.5 on the VAS pain scale), Appx4163; Appx1567; and (3) the average pain reduction in treated patients,

Appx4162; Appx1569. The results for patients suffering from back pain six months after treatment began are as follows[18]:

	RESPONDERS *(% who obtained significant relief)*	REMISSIONS *(% whose pain was nearly eliminated)*	AVERAGE REDUCTION IN PAIN
Stimwave 10 kHz	92%	84%	77%
Nevro 10 kHz	76.4%	59.6%	67%
Stimwave LF	82%	47%	64%
BSC LF	51.9%	36.7%	44%

Stimwave's 10 kHz results plainly do not "pale in comparison" to Nevro's. If anything, they are better. Stimwave's 10 kHz treatment produced more responders (92% vs. 76.4%), more remissions (84% vs. 59.6%), and more average pain reduction (77% vs. 67%). The numbers also show that Stimwave's low frequency treatment was in the same range as both parties' 10 kHz treatments (with statistically insignificant differences reported between the high- and low-frequency Stimwave treatments on most metrics). The outlier was the Boston Scientific low frequency device, which produced weaker results across the board.

The district court's error arose because it missed the fact that the two studies measured the performance of their respective 10 kHz systems against different baselines. The district court reasoned that Stimwave's 10 kHz results must "pale in comparison" to Nevro's because (1) the SENZA-RCT study found Nevro's HF system

[18] *See* Section IV above.

to be "***superior***[]" to ***its*** low-frequency baseline, Appx39, whereas (2) "Stimwave's SURF study showed only that Stimwave's high frequency . . . therapy is '***noninferior***' to ***its*** traditional, low-frequency" baseline. Appx40. But these baselines are different. SENZA-RCT's baseline was Boston Scientific's low frequency product, and the numbers above show that Nevro's 10 kHz product was indeed "superior" to that. However, SURF-RCT's baseline was Stimwave's (much more effective) low frequency product, and as the numbers also show, Stimwave's 10 kHz system was in the same range as that, and thus "noninferior." As a matter of logic and mathematics, this provides no basis to conclude that Nevro's 10 kHz system was better than Stimwave's. The numbers show that it is not.

The district court also made a finding (at Appx40) that the studies showed that "patients experienced [more] complications" with Stimwave's 10 kHz systems than Nevro's, although it later indicated that it was "unclear" whether this was still the case and the court seemed to disclaim reliance upon it. *Id.* n. 12. Regardless, this

too is an incorrect reading of the studies. Both studies report how many complications—called "adverse events" (AEs)—arose, and also how many of these AEs were "serious" (SAEs). Here are the numbers for the parties' respective 10 kHz systems:

	SERIOUS ADVERSE EVENTS	ALL ADVERSE EVENTS
Stimwave 10 kHz	0%[19]	24%[20]
Nevro 10 kHz	4%[21]	27.7%[22]

Again, Stimwave's 10 kHz results do not "pale in comparison" to Nevro's and are, if anything, better. Stimwave's 10 kHz treatment produced fewer serious adverse events (0% vs. 4%) and fewer adverse events overall (24% vs. 28%). The district court did not address these facts.

The district court also erred in two other ways. ***First***, at Nevro's urging, it cherry picked the few types of adverse events where Nevro happened to show better results, and ignored without explanation the events that went the other way. Appx40. "A reviewing court must consider the record as a whole, including that which fairly

[19] Appx1701 (SURF-RCT) (Table 2, showing treatment-related SAEs in 0% of subjects for the high frequency treatment).

[20] *Id.* (Table 2, showing 24% treatment-related AEs for the high frequency treatment).

[21] Appx1570 (SENZA-RCT) ("4.0% of HF10 therapy subjects had a study-related serious AE.").

[22] *Id.* ("Nonserious study-related AEs were reported in . . . 27.7% [of] . . . HF10 therapy . . . subjects."). This number is an underestimate of Nevro's total AEs because it counts only nonserious AEs and excludes serious ones.

detracts from [the] weight" of the findings below. *Nippon Steel Corp. v. United States*, 458 F.3d 1345, 1351 (Fed. Cir. 2006). Here, the district court focused only on complications (lead migration, lead fracture, and resulting loss of stimulation) where Stimwave's systems allegedly performed worse than Nevro's. Appx40. But it made no findings that these complications are more serious or important than the complications where Nevro's systems performed worse than Stimwave's. *Id.* For example, as the SENZA-RCT study explains, "the most common study-related AE [for Nevro's 10 kHz product] w[as] ***implant site pain*** [] in ***11.9%*** of HF10 therapy subjects…" Appx1570. The corresponding number for Stimwave's 10 kHz therapy was ***4%***. Appx1701 (Table 2, "Incisional pain"). The district court ignored this, even though an adverse event involving pain rather than lead migration/loss of stimulation would plainly be important to studies whose goal is pain relief.[23]

Second, undisputed evidence shows that Stimwave has improved its fixation techniques since the SURF-RCT study, so that even its migration rates today are lower than Nevro's (and indeed nearly zero). This is important evidence to consider in the context of a forward-looking preliminary injunction. It is undisputed that in 2017 Stimwave obtained FDA clearance for its SandShark Anchor, Appx4824-4825 (Perryman) ¶ 22, which has wings that lock into place to help prevent migration. *Id.*;

[23] By contrast, device migration does not inherently mean loss of pain relief.

Appx4076. Stimwave also recently analyzed migration and other adverse events in a Quality Management System Analysis, and found that migration accounted for only [ ] of Freedom SCS Systems sold from 2016-2018, Appx4113—one tenth the number reported for Nevro devices in the SENZA-RCT study. Appx40. The district court's finding on Premise 1 is clearly wrong.[24]

B. The district court clearly erred in finding that physicians would confuse Nevro's products with Stimwave's or abandon the former because of bad experiences with the latter.

The district court's findings on Premises 2 and 3 (physician confusion leading them to abandon Nevro because of bad experiences with Stimwave devices) were

[24] The district court said in a footnote that "Stimwave conceded at oral argument that Nevro's therapy is clinically superior." Appx40 n. 12 (*citing* Appx7575-7576 (Tr.) at 299:4-300:6). It is unclear what the court meant: Stimwave certainly conceded, for purposes of the preliminary injunction hearing, that Nevro's therapy was superior to the baseline of its SENZA-RCT study—i.e. the low-frequency Boston Scientific device. But it certainly did not concede that Nevro's therapy was superior to Stimwave's low- or high-frequency system. On the contrary, Stimwave's witness specifically testified by declaration that, based on the SENZA-RCT and SURF-RCT studies, "both Stimwave's Low Frequency and High Frequency results were ***on par with the results reported by Nevro in their published data set (64% pain relief)***." Appx4833 (Perryman) ¶ 33. Stimwave then presented a graph showing the "Percentage Pain Relief 6-Month Results" from the studies, which showed Stimwave's systems providing somewhat more pain relief than Nevro's, as we have discussed in this brief. *Id.* The portion of the transcript that the court cited has Stimwave's attorney discussing the message ***Nevro*** uses in the marketplace to try and differentiate its products, namely, that Nevro has "improved clinical results as … shown through randomized clinical evidence [i.e. SENZA-RCT] that they are better than ***low frequency therapy*** [used in that study]." Appx7575-7576 (Tr.) 299:24–300:1.

also independently clear error. It court cited no evidence other than admitted ungrounded speculation for these conclusions. Appx40-41.

The absence of evidence on these points is striking. Both parties have been selling their high-frequency products in Europe and Australia for years, Appx4823-4824 (Perryman) ¶ 21, and so there are years of real-world data to show how often—if it all—physicians confuse the parties' products or refuse to buy Nevro's products because of problems with Stimwave's. But Nevro has identified ***zero*** physicians, in all of this time, who did either of these things—not a single one. *See* Appx38-42. Nor did Nevro introduce any surveys showing a likelihood of confusion. *See id.* And there are no "conversations and reviews from confused customers," as there were in in *Tinnus*, 846 F.3d at 1201, showing physicians penalizing Nevro for bad experiences with Stimwave's products. *See id.* In short, there are no ***facts*** to support the district court's contention—only speculation, which we will discuss below.

By contrast, the record contains many undisputed facts that go the other way. ***First***, Nevro did provide evidence (albeit hearsay) of several US physicians who used Stimwave's high-frequency system; but none of them had negative experiences that turned them against high-frequency SCS, and all of them apparently liked the Stimwave product so much that they started using it long term. Appx42 (describing alleged "instances where physicians who were once loyal Nevro customers switched

to Stimwave" for 10 kHz SCS therapy); Appx5290-5291 (Bledsoe) ¶¶ 5-6, 9; Appx5295 (Lenahan) ¶¶ 5-6; Appx5381-5381 (Purkey) ¶¶ 3-6; Appx1525 (Caraway) ¶ 25; Appx7389-7397 (Tr.) at 113:20-121:10.

Second, it is undisputed that the physicians who implant SCS systems—unlike the toy buyers in *Tinnus*—are sophisticated and knowledgeable about SCS products, and are therefore unlikely to be confused. *See* Appx5160 (Kidder) ¶ 157. They are thus well aware of the different SCS brands, their products, and their points of distinction.

Third, it is undisputed that the Stimwave SCS products are substantially different in form and structure than Nevro's. This creates core differences between the products that the physicians who implant them certainly know about. To begin with, SCS's products are undisputedly unique in the marketplace because they are wireless and miniature. Appx4939 (North) ¶ 53. This means they work without the need to implant a host of bulky components, such as an implantable pulse generator, batteries and connectors, into the patient's body. *Id.* ¶¶ 52–53. In addition, Stimwave's smaller products are implanted using a different and less invasive surgical procedure than Nevro's, Appx3447; Appx4816, Appx4818-4819 (Perryman) ¶¶ 12, 14, because there are fewer components that need to be implanted. Appx4492, Appx4514; Appx4939-4940 (North) ¶¶ 54-55. Furthermore, the FDA classifies them differently

from Nevro's products, as Class II rather than Class III devices. Appx4823-4824 (Perryman) ¶ 21; Appx1520-1521 (Caraway) ¶14. Finally, Stimwave markets these differences—the reduction in size and avoidance of implanted components—as some of its products' key distinguishing features. Appx4830-4832 (Perryman) ¶ 31. It is not plausible that the physicians who prescribe and implant SCS systems will confuse them with Nevro's products.

Fourth, the district court cited nothing but speculation to support its findings. It relies (at Appx41) upon statements by two of Nevro's witnesses, Drs. Caraway and Rosenberg, that are plainly no more than conjecture that a long sequence of hypothetical events could possibly occur someday, with no evidence that they ever have. They pile speculation upon speculation:

CARAWAY TESTIMONY	ROSENBERG TESTIMONY

• "**[I]f**
  • there is another company saying that they can do the exact same thing as Nevro,
  • but then their implementation does not support doing the exact same thing as Nevro,
  • it **could be conflated** with that's how our therapy is. …
  • It **could** draw a negative reputation upon the therapy as a whole."
	• "**If**
	  • another company were to offer high frequency paresthesia-free therapy
	  • that does not perform as well as Nevro's technology,
	  • and a skeptical physician were to try it, . . .
	  • but the skeptic has a negative experience,
	  • the skeptic would find confirmation for their skepticism,

CARAWAY TESTIMONY	ROSENBERG TESTIMONY
	• and Nevro **could forever lose this physician** as a potential customer."
Appx7380 (Tr.) at 104:15–23.	Appx1485 (Rosenberg) ¶ 60.

The district court conceded that "Dr. Rosenberg's statement and Dr. Caraway's testimony . . . involve speculation," but actually relied on that as a reason to grant the injunction, asserting that "the need to speculate [about] the extent of such harm supports the conclusion that the harm cannot be readily quantified and is therefore irreparable." Appx42. Stimwave submits that this turns the law upside down. *See Nutrition 21*, 930 F.2d at 871 (vacating preliminary injunction because "speculation that [] losses might occur [does not] amount to proof of special circumstances justifying the extraordinary relief of an injunction prior to trial."). "[A] preliminary injunction … should not be granted unless the movant, by a clear showing, carries the burden of persuasion.'" 520 U.S. at 972 (quotation omitted). Here, Nevro had no need to rely on speculation—it had years of sales in Europe and Australia to draw upon for actual evidence for its theory, if any existed—and the pure conjecture it adduced cannot justify the extraordinary remedy it obtained. *See Nutrition 21*, 930 F.2d at 871; *Automated Merch. Sys., Inc. v. Crane Co.*, 357 F. App'x 297, 301 (Fed. Cir. 2009) (vacating preliminary injunction where there was "no evidence . . . that [the alleged price erosion harm] would be likely to occur.").

* * *

"A preliminary injunction is a drastic and extraordinary remedy that is not to be routinely granted," *Nat'l Steel Car, Ltd. v. Canadian Pac. Ry., Ltd.*, 357 F.3d 1319, 1324 (Fed. Cir. 2004), especially where it might deprive people in crippling pain of the medical treatment that works best for them. Stimwave respectfully submits that this drastic remedy requires far more solid support than Nevro has here, with its mistakes of fact, cherry-picked data, and ungrounded speculation. The injunction should be vacated.

VIII. THE DISTRICT COURT ERRED IN FINDING A LIKELIHOOD OF SUCCESS ON THE MERITS

The district court also made errors of law and clear errors of fact when it found that Nevro was likely to succeed on the merits. Appx22-27; Appx31-36. These errors require reversal. "If the accused infringer 'raises a substantial question concerning either infringement or validity,' then the patentee has not established that it is likely to succeed on the merits, and a preliminary injunction is not appropriate." *LifeScan Scotland, Ltd.* v. *Shasta Techs., LLC*, 734 F.3d 1361, 1366 (Fed. Cir. 2013).

Here, Stimwave raised at least a substantial question that the claims at issue are invalid. ***First***, it showed that the term "non-paresthesia-producing . . . signal," which appears in all the claims at issue, is indefinite. ***Second***, Stimwave showed that the Royle reference anticipates the claims or at least renders them obvious.

A. The term "non-paresthesia-producing . . . signal" is indefinite

1. A skilled artisan must separately determine for each patient whether an SCS "signal" produces paresthesia or not

The term "non-paresthesia-producing . . . signal" in claims 24 and 28 is at least substantially likely to be indefinite. SCS signals themselves are neither "paresthesia producing" nor "non-paresthesia producing": paresthesia is the subjective response of patients to whom the signals are applied, and a separate determination of "paresthesia-produc[tion]" has to be made for each individual patient and for each individual signal. A claim is indefinite when it "requires that an artisan make a separate infringement determination for every set of circumstances in which [it] may be used, and when such determinations are likely to result in differing outcomes (sometimes infringing and sometimes not)." *Halliburton*, 514 F.3d at 1255. Here, as we discuss below, it is undisputed that a given SCS signal may result in no paresthesia in one patient and have the opposite result in another, so that a separate infringement analysis must be done for each one. Appx25.

Halliburton fits this case like a glove. The court there found indefinite a similar claim to a "method for conducting a drilling operation . . . using a ***fragile gel*** drilling fluid . . . ." 514 F.3d at 1246. The patent defined a "fragile gel" as one that, among other things, "is capable of suspending drill cuttings." *Id.* at 1250. This court held the term indefinite because "an artisan would not know from one well to the

next whether a certain drilling fluid was within the scope of the claims," *id.* at 1254–55, since "a given fluid might be adequate to suspend drill cuttings in some formations and/or well configurations, whereas in others it would not be." *Id.* at 1255. As with the claims here, a skilled artisan would have to "make a separate infringement determination for every set of circumstances in which the composition may be used." *Id.* That rendered the claim indefinite. *Id.*

Claims 24 and 28 have the same problem as the claim in *Halliburton*. Both claims depend from claim 23, which recites "programming the signal generator to generate a ***non-paresthesia-producing*** therapy ***signal*** . . . ." Appx114. As in *Halliburton*, "an artisan [here] would not know from one [patient] to the next whether a certain [signal] was within the scope of the claims." 514 F.3d at 1255. As the district court found, "[i]t is undisputed that paresthesia is a subjective assessment that can vary from patient to patient," Appx25, and "it is impossible to know whether paresthesia will be induced until after the signal is applied" to the patient. Appx27.[25] Accordingly, the claims at issue are at least substantially likely to be indefinite.

[25] *See also* Appx7417 (Tr.). at 141:14-21 (Nevro's witness testifying that "for all forms of spinal cord stimulation in every frequency," including for Nevro's own HF10 therapy, "there isn't any way to tell before you start the process of adjusting the amplitude setting in the therapy when a given patient is going to feel something.").

2. The district court's rationale for finding no indefiniteness is legal error

The district court's rationale for finding "non-paresthesia-producing . . . signal" not indefinite is legally erroneous for two reasons. ***First***, the court erred by assuming that the claim avoids indefiniteness simply because a skilled artisan can tell whether a given signal produces paresthesia ***in one particular patient***:

> Although the wave attributes that would result in a signal that does not create paresthesia may vary among patients, a POSITA would be able to determine easily from patient interactions whether a signal produces paresthesia for any ***given patient***.

Appx27. The court gave no reason for this interpretation, *id.*, and it contradicts *Halliburton*. In *Halliburton* too, there was no dispute that tests could tell if a gel could suspend drill cuttings "adequate[ly] for the circumstances" in a ***given*** well, but invalidity arose because these circumstances would vary between different wells. *See* 514 F.3d 1244–55. The same applies here.

Second, if "non-paresthesia-producing . . . signal" did mean not producing paresthesia in a particular patient, then the term is plainly indefinite, because then the very process of determining ***whether*** a therapy infringes is ***itself*** an infringement. Under this interpretation, the only way to tell whether a particular programming step will infringe (i.e. if the signal used will produce paresthesia in the particular patient) is to perform it (program and deliver the signal), thereby risking infringement. The

district court held that "it is ***impossible*** to know whether paresthesia will be induced until after the signal is applied . . .," Appx27 and that "the method taught by claim 23 is not completed until it is known whether the signal induces paresthesia." *Id.* Similarly, both parties' experts testified that to determine whether a signal will induce paresthesia, skilled artisans apply it and ask the patient what they feel. *Id.* (describing Stimwave's expert's testimony); Appx1489 (Rosenberg) ¶ 70 (Nevro's expert); Appx5794 (Stimwave's expert). In short, a skilled artisan trying to avoid infringement by using only high-frequency signals that ***are*** paresthesia-producing would be unable to do so, because the very act of determining whether a signal produces paresthesia is itself a potential infringement of the claim.

This is the epitome of indefiniteness. As one district court correctly held, "the notion that one reasonably skilled in the art would have to infringe the patent claim in order to discern the boundaries of the claim is repugnant to long-standing principles of patent jurisprudence." *STX, Inc. v. Brine, Inc.*, 37 F. Supp. 2d 740, 755 (D. Md. 1999), *aff'd on other grounds*, 211 F.3d 588 (Fed. Cir. 2000). Definiteness, the Supreme Court has instructed, requires a patent to be "precise enough to afford clear notice of what is claimed, thereby apprising the public of what is still open to them in a manner that ***avoids a zone of uncertainty which enterprise and experimentation may enter only at the risk of infringement claims***." *Nautilus, Inc. v. Biosig*

Instruments, Inc., 572 U.S. 898, 899 (2014) (internal quotations and citations omitted) (emphasis added). The claims here create this zone of uncertainty in extreme form, since they prevent the very act of determining whether they are infringed.

The injustice of this approach is manifest in the present case. The district court relied on the "non-paresthesia producing signal" claim element to avoid invalidity over Royle, *see* Appx35, yet issued an injunction that effectively prevented Stimwave from using even high-frequency signals that ***do*** produce paresthesia. As Stimwave cannot tell whether this element is met except by actually delivering the signal to the patient, thus risking violating the injunction if paresthesia does not occur, the claims' "zone of uncertainty"—and the injunction's zone of exclusion—sweeps far beyond the claim's own scope. Stimwave submits that this is manifestly unjust.

B. Claims 24 and 28 Are Anticipated and/or Obvious

The district court erred legally and factually by finding that Stimwave had not shown a substantial likelihood that Royle anticipates claims 24 and 28, or at least renders them obvious.

1. Royle anticipates claims 24 and 28

Royle anticipates the claims of the '222 patent. Here, the district court correctly found that "Royle discloses each element of the asserted claims." Appx35. Briefly, Royle discloses: a signal generator that is programmed to deliver a therapy

signal for pain relief (analgesia) to a patient's spinal cord, Appx3614 ¶ 4 ("Spinal Electroanalgesia"), Appx34; that the signal can use the frequencies that are listed in the claims, Appx3616 ¶ 68 (For "most applications 2 kHz -3 kHz will be used and ***for medical uses 10 kHz*** may be the upper frequency limit"); that these signals often will not produce paresthesia, especially when a fast signal rise time is used, Appx3616-3617 ¶ 75 ("[U]se of a fast rise time . . . 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***."); and that the signals can be delivered by electrodes that are either on the patient's skin or implanted. Appx3618 ¶ 104 ("If desired, the electrodes could be ***implanted within the body***, including within the skin.").

The district court erred when it found that, despite disclosing each claim element, Royle did not "disclose these elements as arranged . . . in the same way as in the asserted claims." Appx34-35. The court held that the disclosure of paresthesia-free therapy was "in the context of placing the electrodes on the patient's skin[,] rather than implanted within the patient's body" as the claims require. *Id.*

This was an error. While the specific discussion of the fast rise time leading to "no sensation" was made in the context of non-implanted electrodes, Royle elsewhere expressly says that "***[i]f desired, the electrodes could be implanted within the***

body, including within the skin, but it is more preferable that they are designed to simply be placed in contact with the skin surface." Appx3618 ¶ 104. This sentence on its face applies to all other embodiments, and discloses using implanted electrodes instead of non-implanted ones for them all. Moreover, the mechanism by which the signals produce "no sensation"—i.e. by using a "fast rise time" so as to "not stimulat[e] the peripheral nerves"—applies equally in implanted electrodes as in non-implanted ones. Stimwave's expert confirmed this, Appx4967-4968 (North) ¶ 114 ("There is nothing in Royle that would lead a person of ordinary skill to believe that the peripheral nerves would be stimulated, and thus cause the patient to feel the stimulation (i.e., paresthesia), if the electrodes were implanted."); Nevro's expert did not rebut it, Appx5327-5328 (Pless) ¶¶ 84–85[26]; and in any case the district court made no express findings on this point. Appx35.

Therefore, the district court's conclusion that Royle only taught paresthesia-free therapy in the context of placing electrodes on the patient's skin is clear error, or at least requires the injunction to be vacated and the case remanded for fact-finding on this issue.

[26] Dr. Pless only testified that Royle did not *expressly* state that a 10 kHz signal administered by an implant would not produce paresthesia, and that Royle did not expressly provide parameters for the implants. *See* Appx5327-5328 (Pless) ¶¶ 84-85.

2. Royle renders claims 24 and 28 obvious

The district court also erred as a matter of law by not finding claims 24 and 28 obvious over Royle. It erred by construing Royle's teaching that electrodes ***could*** be implanted, albeit as a less preferred choice, as teaching away from implantation. Under established law, "[a] reference that merely expresses a general preference for an alternative invention but does not criticize, discredit, or otherwise discourage investigation into the claimed invention does ***not*** teach away." *Meiresonne v. Google, Inc.*, 849 F.3d 1379, 1382 (Fed. Cir. 2017); *see also Syntex LLC* v. *Apotex, Inc.*, 407 F.3d 1371, 1380 (Fed. Cir. 2005) ("A statement that a particular combination is not a preferred embodiment does not teach away absent clear discouragement of that combination."). Here, Royle's statement is legally not a teaching away from implantation, but rather a teaching and suggestion ***to*** implant.

Based solely on this alleged teaching away, the district court found no obviousness over Royle. As discussed above, the district court found that "Royle discloses each element of the asserted claims," Appx35, but still does not anticipate because the high-frequency non-paresthesia-producing signal was not disclosed in the specific context of implanted electrodes.[27] Appx34-35. Even if this were correct,

[27] The claims of '222 patent claim a signal delivery device, which includes (but is not necessarily limited to) "electrodes."

Royle specifically teaches and suggests that the electrodes ***could*** alternatively be implanted:

> "If desired, the electrodes ***could*** be implanted within the body, including within the skin, but it is ***more preferable*** that [they] are designed to simply be placed in contact with the skin surface"

Appx3618 ¶ 104. It would thus at least have been obvious from Royle's own teaching to substitute implanted electrodes for non-implanted electrodes.

The district court found no obviousness purely because it construed Royle's disclosure as teaching away from implanting the electrodes:

> "***Because Roy[le] teaches away from implanting the electrodes***, I also conclude that it does not render the asserted claims obvious."

Appx35 (citing Royle ¶ 104, quoted above). But Royle's statement is not teaching away as a matter of law; it is plainly a specific teaching that the electrodes "could be implanted," coupled with a "general preference," *Meiresonne*, 849 F.3d at 1382, for using electrodes on the skin instead. Nowhere does Royle "criticize, discredit, or otherwise discourage" a skilled artisan from implanting electrodes and delivering signals at 10 kHz in order to provide a "no sensation" therapy.[28]

[28] Neither Nevro nor Dr. Pless made any showing that Royle "criticize[s], discredit[s], or otherwise discourage[s]" implanting electrodes. *See* Appx5278-5279; Appx5325-5328 (Pless) ¶¶ 81-87. Dr. North also provided unrebutted testimony that a POSITA would have a reasonable expectation of success in implanting the electrodes. Appx4968 (North) ¶ 115.

Royle's disclosure, indeed, is like the disclosures that were found not to teach away in *Meiresonne* and *Galderma Labs. v. Tolmar*, 737 F. 3d 731, 739 (Fed. Cir. 2013). In *Galderma Labs*, references disclosed that a lower concentration of the chemical adapalene than in the claims was "the standard or optimal concentration of adapalene for the treatment of acne." 737 F.3d at 739. This court found that this did not teach away from the claimed concentrations because the references did not "criticize, discredit, or otherwise discourage investigation into other compositions." *Galderma Labs*, 737 F.3d at 339. Similarly, in *Meiresonne*, the Court found that a prior art reference did not teach away where it referred to a feature—"descriptive text"—as "cryptic," but not "'unreliable,' 'misleading,' 'wrong,' or 'inaccurate.'" 849 F.3d at 1383. Similarly, Royle's disclosure only states that it "is more preferable" to place electrodes in contact with the skin, but does not "criticize, discredit, or otherwise discourage investigation" into implanted electrodes. *See* Appx3618. Accordingly, the district court's finding that there was no substantial likelihood that Stimwave would prove obviousness over Royle should be reversed.

IX. THE BROAD INJUNCTIVE RELIEF GRANTED IN THIS CASE HARMS THE PUBLIC

The preliminary injunction in this case harms the public. Stimwave's high-frequency treatment is the best medical option for some patients. Denying these pa-

tients treatment at this preliminary stage, before Stimwave has even had the opportunity to fully defend itself on the merits, is against the public interest. Equity will not support an injunction that harms the public. *See Benisek v. Lamone*, 138 S. Ct. 1942, 1944 (2018). Where different products offer different options for different patients, the public's interest is in providing physicians with a wide variety of treatment options. *Cordis Corp. v. Bos. Sci. Corp.*, 99 F. App'x 928, 935 (Fed. Cir. 2004) (non-precedential). In such cases, a "strong public interest supports a broad choice of medical options." *Id.*; *see Kimberly-Clark Worldwide v. Tyco Healthcare Grp*, 635 F. Supp. 2d 870, 882 (E.D. Wis. 2009).

The broad injunctive relief granted here injures the public interest by eliminating needed variety in treatment options provided by Stimwave's SCS Systems. Appx4814 (Perryman) ¶ 9. The district court erred in finding otherwise. ***First***, it was an error to hold that "for those patients that desire high frequency, paresthesia-free therapy, they will have access to Nevro's products." *See* Appx45. Nevro's SCS system is not a complete substitute for Stimwave's devices. For one thing, as the district court elsewhere correctly held, there are some "chronic pain patients who cannot, or will not, be treated with [Nevro-like] IPG-based systems." *Id.* at Appx43. These patients, at least, will lose access to high frequency therapy under the injunction. Dr. North, who over thirty years has implanted more than 4,000 SCS devices,

testified that he encountered patients who would not be able to use Nevro's SCS system. Appx4933-4934 (North) ¶ 40. By contrast, Nevro's employee, Dr. Caraway—on whose testimony the district court relied—did not affirmatively testify that Nevro's device could be implanted in all patients who needed high frequency SCS therapy, but only that he was personally "unaware" of such patients. Appx7400 (Tr.) 124:7-11; Appx7409 (Tr.) 133:10-34:3. This testimony does not contradict Dr. North's; at most it fails to corroborate it.[29]

Moreover, there are specific classes of patients for whom Nevro's SCS devices are not adequate substitutes. For one thing, they are not substitutes for patients who need 3T MRI imaging. Appx4934 (North) ¶ 41. For example, Nevro's devices, unlike Stimwve's, are not approved for full-body 3T MRI scans, which produce high-resolution images using a strong magnetic field. Appx7403 (Tr.) 127:2-12 (3T MRI scans), Appx7424 (Tr.) 148:11-13 (Nevro's products are not approved for 3T MRI); Appx3791 (Stimwave products can be used for 3T MRI). Moreover, Nevro's devices are not adequate substitutes for patients who are too slender to accept the bulk of a battery or have other medical conditions prohibiting placement of a battery Appx4933-4934 (North) ¶ 40. Stimwave's system works for these patients since it

[29] Dr. North's credibility is not at issue; the district court made no credibility determination as to his testimony. *See* Appx27, Appx29.

is only 5% the size of Nevro's system and does not have an implanted signal generator or battery. *See* Appx3791.

Stimwave's products are also safer than Nevro's products. The FDA classified Nevro's products as "Class III." Appx1520-1521 (Caraway) ¶ 14. By contrast, the FDA classified Stimwave's products as "Class II." *Id.* According to FDA guidelines, this classification is risk-based, with Class III products having the greatest risk, and Class I products having the lowest risk. Appx2025-2026. Thus, the district court's injunction forces patients into choosing a product that may present a greater risk to their health. This is not in the public interest.

Second, the district court erred when it determined that patients who could not or would not use Nevro's devices could just use Stimwave's devices at low frequencies instead. *See* Appx45. Though low frequency therapy delivered via the Stimwave form factor is effective in the majority of patients, some patients respond better to high frequency treatment, as shown by the study results discussed above. *See* Section VI above. (discussing results of SENZA-RCT and SURF-RCT studies that show Stimwave 10 kHz SCS producing better results than Stimwave low-frequency SCS). Therefore, there are patients who are and will continue to be deprived of the most effective medical treatment for their pain by the injunction in this case.

Considering all the relevant evidence, eliminating Stimwave's high-frequency treatment option prevents those patients who suffer from chronic pain and who "cannot, or will not, be treated with IPG-based systems" from obtaining SCS treatment at high frequencies. Appx45. This forces patients to make needless, difficult decisions regarding their health, including potentially being forced to use opioids, which is not in the public interest. *See* Appx4932 (North) ¶ 35.

X. THE DISTRICT COURT'S INJUNCTION IS OVERLY BROAD

In addition to the problems explained above, the district court's injunction is impermissibly broad. This Court "do[es] not uphold vague or overly broad injunctions because 'those against whom an injunction is issued should receive fair and precisely drawn notice of what the injunction actually prohibits.'" *Metalcraft of Mayville, Inc. v. Toro Co.*, 848 F.3d 1358, 1369 (Fed. Cir. 2017) (quotation omitted). This Court has also rejected as overly broad an injunction which did not "use specific terms or describe in reasonable detail the acts sought to be restrained," and did not state which acts constituted infringement. *Additive Controls & Measurement Sys., Inc. v. Flowdata, Inc.*, 986 F.2d 476, 479 (Fed. Cir. 1993). That is the case here.

First, the injunction is overly broad because it effectively prevents Stimwave from a wide range of ***noninfringing*** activities—in particular, high-frequency therapies that ***do*** result in paresthesia.[30] As we have discussed, whether a given signal results in paresthesia varies on a per-patient and per-therapy-session basis, Appx27, and it is impossible to determine whether a given signal will cause paresthesia without first delivering it to the patient. *See* Section VIII.A.1 above. Thus, Stimwave risks violating the injunction (and being held in contempt) if it even attempts to provide non-infringing, high-frequency therapies. Consequently, the district court's injunction effectively bars Stimwave from ***any*** high-frequency SCS therapy, not just paresthesia-free therapy. That is plainly overbroad.

Second, while the injunction covers all frequencies in the broad 3–10 KHz range, *see* Appx48, there is no evidence or finding as to whether or in what circumstances signals at frequencies other than exactly 10 kHz would satisfy the "non-paresthesia-producing …signal limitation." As the district court found, "there is no evidence that [Stimwave's] SCS systems have been programmed to administer a therapy signal with a frequency of between 3 kHz and 9.999 kHz." Appx21. Nevro's evidence relates to 10 kHz signals only. *See, e.g.*, Appx1565, Appx1569; Appx1425

[30] Solely for purposes of this appeal, the parties agree that "high frequency" includes the range of frequencies between 3 kHz and 10 kHz.

(Pless) ¶ 45; *see also* Appx1529 (Caraway) ¶ 37 (referring to "10 kHz" therapy).[31] With no record evidence as to the proper range to be enjoined, the district court went beyond the scope of an appropriate remedy. *See Allergan, Inc. v. Athena Cosmetics, Inc.*, 738 F.3d 1350, 1160 (Fed. Cir. 2013) (vacating an injunction where it improperly prevented the defendant from permissible activity).

Finally, the district court's injunction is overbroad because—by enjoining all signals in the 3–10 kHz range—it covers actions that undisputedly have never been shown to infringe. Appx21 ("[T]here is no evidence that [Stimwave's] SCS systems have been programmed to administer a therapy signal with a frequency of between 3 kHz and 9,999 kHz.").

Because the district court's injunction lacks clarity as to which activities are enjoined, enjoins non-infringing activities, and enjoins uses that were never shown to infringe, the injunction is impermissibly overbroad.

CONCLUSION

This Court should vacate the preliminary injunction for the reasons above.

[31] Nevro also programs its own systems to provide signals only at 10 kHz. *See* Appx1520 (Caraway) ¶ 13 ("Nevro's Senza system provides electrical pulses to the spinal cord at a rate of . . . 10 kHz."); Appx7416 (Tr.) 140:3-11.

Dated: November 1, 2019 Respectfully submitted,

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CERTIFICATE OF SERVICE AND FILING

I hereby certify that I electronically filed the foregoing document using the Court's CM / ECF filing system on November 1, 2019. All counsel of record were served with the non-confidential version of this brief via the Court's CM / ECF filing system on November 1, 2019. All counsel of record were served two paper copies of the confidential brief via FedEx on November 1, 2019.

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CERTIFICATE OF COMPLIANCE

The undersigned attorney certifies that the foregoing document complies with the type-volume limitation set forth in Fed. R. App. P. 27. The relevant portions of the brief, including all footnotes, contain 12,366 words, as determined by Microsoft Word.

Dated: November 1, 2019

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UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

CERTIFICATE OF COMPLIANCE MOTIONS OR BRIEFS CONTAINING MATERIAL SUBJECT TO A PROTECTIVE ORDER

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(Signature of Attorney)

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Appellant Stimwave Technologies, Inc.
(State whether representing appellant, appellee, etc.)

November 1, 2019
(Date)

ADDENDUM

ADDENDUM
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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

NEVRO CORP.,	:	
	:	
Plaintiff,	:	
	:	
v.	:	Civil Action No. 19-325-CFC
	:	
STIMWAVE TECHNOLOGIES, INC.,	:	
	:	
	:	
Defendant.	:	

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MEMORANDUM OPINION

July 24, 2019
Wilmington, Delaware

COLM F. CONNOLLY
UNITED STATES DISTRICT JUDGE

Plaintiff Nevro Corp. has filed a motion for a preliminary injunction to enjoin Defendant Stimwave Technologies, Inc. "from infringing two of Nevro's patents, U.S. Patent No. 8,874,222 ('the [#]222 patent') and U.S. Patent No. 9,327,127 ('the [#]127 patent')[.]" D.I. 18 at 1. I have reviewed the parties extensive briefing, supporting declarations, and exhibits (*see* D.I. 19, 20, 21, 22, 23, 24, 41, 42, 43, 44, 48, 77, 78, 79, 80, 81, 82, 83, 84, 85, 87, 111, 112, 113, 114, 115, 116, 117, 118, 120, 121, 125, 126, 135, 137, 138, 139, 140, 141, 142, 143, 144, 145), and held a full-day evidentiary hearing on June 27, 2019 ("Tr.") in connection with the motion. For the reasons stated below, I will grant in part and deny in part the motion. This opinion constitutes my findings of fact and conclusions of law pursuant to Federal Rule of Civil Procedure 52(a).

I. BACKGROUND

Nevro and Stimwave are medical device companies and direct competitors in the field of spinal cord stimulation ("SCS"), a technology used to treat pain by delivering short electrical pulses to the spinal cord through electrical leads implanted in the body. *See* D.I. 21 at ¶¶ 13, 18; D.I. 84 at ¶ 34. Although there are several types of SCS systems, they all have three main parts: (1) a pulse generator with a battery that creates an electrical signal; (2) leads on an implanted wire that

deliver the signal to the spinal cord; and (3) a hand-held remote control that turns the pulse generator on and off and adjusts its settings. *See* D.I. 85 at ¶ 21.

SCS technology is well-established; the oldest SCS systems date back to 1967. D.I. 20 at ¶ 24; D.I. 84 at ¶ 36. Innovations in SCS systems since that time have primarily focused on making the electrical devices smaller, more reliable, and more programmable. *Id.* at ¶ 29. The therapeutic strategy of SCS, however, remained largely unchanged until 2015, when Nevro introduced its "HF10" SCS therapy, which is covered by the patents asserted in this case. *Id.* at ¶¶ 29, 31, 43.

Traditional SCS therapy delivers low frequency electrical stimulation, generally under 1.5 kHz, and induces paresthesia—a sensation usually described as tingling, pins and needles, or numbness—that masks the patient's pain. *See id.* at ¶ 25; *see also* #222 patent at 1:47-52, 6:37-48; D.I. 21 at ¶ 15; Tr. 96:23-24. To ensure that the paresthesia overlays the area in which the patient has been experiencing pain, a mapping procedure is typically conducted at the time the leads are surgically implanted. *Id.*; *see also* #222 patent at 18:20-31. This process of paresthesia mapping involves changing the patient's level of sedation and conversing with him to determine his perceived sensations. *See id*; *see also* D.I. 21 at ¶¶ 14, 46. Based on the patient's description of the paresthesia, the physician may have to move the leads and a technician may need to adjust the programming

of the SCS system to optimize paresthesia distribution and the patient's comfort. D.I. 21 at ¶ 14; *see also* #222 patent at 18:20-31.

Although traditional SCS therapy provides sufficient pain relief for many patients, a significant number of patients dislike paresthesia. D.I. 20 at ¶ 30; *see also* #222 patent at 9:3-17. Nevro's HF10 SCS therapy solved that problem. D.I. 21 at ¶¶ 18-19.

The two distinguishing features of Nevro's SCS therapy—high frequency stimulation, typically at a rate of 10 kHz, and the absence of paresthesia—bucked conventional wisdom. D.I. 22 at ¶ 13. SCS practitioners generally did not see any benefit in high frequency stimulation and many questioned whether stimulating the spinal cord at frequencies like 10kHz—more than one hundred times higher than traditional frequencies—could be safe. D.I. 20 at ¶ 36. For its part, paresthesia was generally deemed "an absolute requirement" for reliable, effective pain relief. D.I. 22 at ¶ 11; *see also* D.I. 24, Ex. 3 at 0002 (2007 article stating that "[p]atient-perceived concordant paresthesia overlapping the area of pain is *essential* for success of [SCS] therapy") (emphasis added).

Not surprisingly, then, Nevro's HF10 SCS therapy initially faced skepticism and criticism, D.I. 21 at ¶ 53; and the FDA required Nevro to test its SCS therapy in a randomized controlled trial, D.I. 22 at ¶ 14. That trial, referred to as the "SENZA-RCT," consisted of a head-to-head comparison between Nevro's HF10-

based SCS system and a commercially available low-frequency, paresthesia-based SCS system. *Id.* The results of SENZA-RCT showed that Nevro's SCS system with HF10 therapy was twice as effective as the traditional SCS system in providing pain relief and could be administered safely. *Id.* at ¶ 15; *see also* D.I. 24, Ex. 2 at 856-57. As a result of SENZA-RCT, on May 8, 2015, the FDA approved Nevro's SCS system and HF10 therapy with a "superiority" labeling. *Id.*

Nevro's superior and differentiated HF10 therapy enabled it to capture relatively quickly a significant share of what both parties call a "sticky" (or change resistant) SCS market historically dominated by three large medical device companies. *See* D.I. 21 at ¶¶ 57-61; D.I. 22 at ¶ 17; D.I. 85 at ¶¶ 23, 81. The SCS market is sticky because physicians are generally reluctant to change their medical device providers. *See id.* Nonetheless, by 2017—only two years after the FDA approved Nevro's HF10 therapy—Nevro had garnered approximately 16% of the U.S. SCS market. D.I. 23 at ¶ 24.

There can be little doubt that Nevro's market gains are attributable to its high frequency therapy. *See, e.g.*, D.I. 24, Ex. 36 at 2, Ex. 47 at 1, Ex. 51 at 2. Although Nevro's commercial embodiment of its invention can operate at traditional lower frequencies, about 97% of patients using Nevro's SCS systems receive therapy at 10 kHz. D.I. 117, Ex. 112 at 106:10-107:24; *see also* Tr. 100:14-20. There likewise can be little doubt that Nevro's economic success

(indeed, its existence) is traceable to its high frequency therapy. Nevro's SCS systems are its only products, and they all utilize Nevro's proprietary HF10 therapy. D.I. 22 at ¶ 16.

Shortly after Nevro received FDA approval for its 10 kHz SCS therapy, the FDA granted approval for Stimwave to market its Freedom-4A and Freedom 8-A SCS systems at frequencies up to 1.5 kHz. D.I. 79, Ex. 29. The distinguishing feature of Stimwave's systems is the absence of an implanted pulse generator (and battery). D.I. 82 at ¶ 12. Unlike traditional SCS systems and Nevro's SCS system, Stimwave's SCS systems use an external "Wearable Antenna Assembly" that transmits wirelessly stimulus parameters and power to an implanted receiver which relays the signals and power to a stimulator that sends the signal to the spinal cord. *Id.*; *see also* D.I. 83 at ¶ 48.

Stimwave touts the wireless nature of its systems as a significant competitive advantage because it requires the surgical implantation of only 5% of the material that must be implanted in traditional SCS systems and thereby reduces the invasiveness and risks associated with traditional SCS therapy. *Id.* at ¶¶ 6, 9, 14. It has enjoyed, however, only limited success with this marketing approach; perhaps because patients view the prospect of carrying an external power source as

a significant drawback. D.I. 20 at ¶ 49.[1] Stimwave's share of the U.S. SCS market stands at only 0.4%. D.I. 85 at ¶ 34.

On January 16, 2019, Stimwave issued a press release notifying the public that the FDA was reviewing "[t]he safety and effectiveness of the Freedom SCS system's high frequency stimulation parameters" for market clearance. D.I. 1 at ¶ 31. Stimwave also began reporting to the industry that FDA approval was imminent and that it intended to begin commercially marketing its SCS systems for high frequency, paresthesia-free therapy in the United States upon receiving FDA approval. *Id.* at ¶¶ 32-33.

In light of these public statements, Nevro filed the present action on February 14, 2019, alleging, among other things, infringement of the #222 and #127 patents. *See id.* at ¶¶ 84-109.

On March 29, 2019, the FDA granted approval for Stimwave to market its SCS systems for sale at frequencies up to 10 kHz in the United States. D.I. 80 at Ex. 39. Two days later, Stimwave issued a press release announcing that "FDA cleared [its] waveforms to 10,000 Hz available commercially in USA." D.I. 24 at Ex. 9. Stimwave followed its announcement with the dissemination of marketing

[1] The first SCS systems were powered by external batteries. D.I. 20 at ¶ 49. But once the FDA approved the first fully-implantable SCS system in 1984, SCS device manufacturers moved away from SCS systems with external batteries. D.I. 22 at ¶ 9.

materials that touted its high frequency therapy, *see, e.g.*, D.I. 24 at Ex. 16, and by congratulating individual providers on social media for programming Stimwave's SCS systems to treat patients at 10 kHz, *see* D.I. 24 at Exs. 10–15.

On April 17, 2019, Nevro filed its motion for a preliminary injunction, D.I. 18, as well as a motion to expedite discovery, D.I. 15. On April 23, 2019, I granted Nevro's motion to expedite discovery. D.I. 28. On June 27, 2019, I held a hearing for the parties to adduce evidence and make oral argument as they saw fit.

II. DISCUSSION

Pursuant to 35 U.S.C. § 283, a court in a patent case "may grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable." 35 U.S.C. § 283.[2] To obtain a preliminary injunction the moving party has the burden of showing (1) it is likely to succeed on the merits, (2) it is likely to suffer irreparable harm if the injunction is not granted, (3) that the balance of equities between the parties tips in its favor, and (4) that an injunction is in the public interest. *See*

[2] Because motions pursuant to 35 U.S.C. § 283 "involve[ ] substantive matters unique to patent law," they are governed by the law of the Federal Circuit. *Hybritech Inc. v. Abbott Labs.*, 849 F.2d 1446, 1451 n.12 (Fed. Cir. 1988); *see also Murata Mach. USA v. Daifuku Co.*, 830 F.3d 1357, 1363 (Fed. Cir. 2016) ("[T]he Federal Circuit has itself built a body of precedent applying the general preliminary injunction considerations to a large number of factually variant patent cases, and gives dominant effect to Federal Circuit precedent insofar as it reflects considerations specific to patent issues.") (internal quotation marks and citation omitted).

Winter v. Nat. Res. Def. Council, Inc., 555 U.S. 7, 20 (2008); *see also Tinnus Enters., LLC v. Telebrands Corp.*, 846 F.3d 1190, 1202 (Fed. Cir. 2017). I find that Nevro has met its burden of showing all four of these factors.

A. Likelihood of Success on the Merits

"[T]o demonstrate a likelihood of success on the merits, the patentee must demonstrate that it will likely prove infringement of one or more claims of the patents-in-suit, and that at least one of those same allegedly infringed claims will also likely withstand the validity challenges presented by the accused infringer." *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1351 (Fed. Cir. 2001). I find that Nevro has shown that it will very likely prove Stimwave infringed claims 24 and 28 of the #222 patent and that those claims will also likely withstand Stimwave's invalidity challenges.

In light of this conclusion, I find it unnecessary to address whether Nevro would likely succeed on the merits with respect to claims 22 and 23 of the #127 patent. The answer to that question would not affect my weighing of the other three factors I must consider in deciding whether to issue a preliminary injunction; and an injunction to enjoin Stimwave from infringing claims 24 and 28 of the #222 patent would have the same practical effect as an injunction enjoining Stimwave from infringing the #127 patent. I note that the two asserted claims of the #127 patent appear to present issues involving claim construction, inducement, and joint

infringement that I need not address in my review of the asserted claims of the #222 patent. I also have doubts about whether the expedited and abbreviated briefing and evidentiary record afford me a sufficient basis on which to make informed decisions about those issues.

1. Infringement

In evaluating whether Nevro is likely to succeed in proving infringement of the asserted claims of the #222 patent, I employ the same two-step process used to determine infringement at trial. *See Oakley, Inc. v. Sunglass Hut Int'l*, 316 F.3d 1331, 1339 (Fed. Cir. 2003) ("An assessment of the likelihood of infringement, like a determination of patent infringement at a later stage in litigation, requires a two-step analysis."). First, I must ascertain the meaning and scope of the asserted claims. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). Second, I must compare the accused device to the properly construed claims. *Id.*

Claim 45 of the #222 patent, from which claim 48 depends, recites as follows:

> A method for configuring a signal generator to deliver a therapy signal to a patient's spinal cord via an implantable signal delivery device, wherein the implantable signal delivery device is implantable in the patient's epidural space, the method comprising:
>
> programming the signal generator to generate and deliver a therapy signal to the patient's spinal cord,

> via the implantable signal delivery device, wherein at least a portion of the therapy signal has
>
> a frequency in a frequency range of from about 1.5 kHz to about 50 kHz,
>
> a current amplitude in an amplitude range of from about 0.1 mA to about 6 mA,
>
> a pulse width between about 10 microseconds and about 333 microseconds, and
>
> at least partially reduces the patient's sensation of pain without generating paresthesia.

Claim 48 recites "[t]he method of claim 45, wherein the frequency range is from about 3 kHz to about 20 kHz and the pulse width is between about 25 microseconds and about 166 microseconds."

Nevro presented no evidence that a patient who received Stimwave's SCS treatment experienced a reduction in the patient's "sensation of pain." It therefore failed to establish a likelihood of proving infringement of the last claim limitation of claim 45, and thus failed to establish a likelihood of proving infringement of claim 48 of the #222 patent.

Claims 24 and 28 of the #222 patent depend from independent claim 23, which teaches

> [a] method for configuring a signal generator to deliver a therapy signal to a patient's spinal cord, the method comprising:
>
> programming the signal generator to

(1) generate a non-paresthesia-producing therapy signal, wherein at least a portion of the therapy signal has a frequency in a frequency range of from 1.5 kHz to 100 kHz; and
(2) deliver the therapy signal to the patient's spinal cord via a signal delivery device implanted in the patient's epidural space.

Claim 24 recites: "The method of claim 23, wherein the frequency is 10 kHz." Claim 28 recites: "The method of claim 23[,] wherein the frequency range is from 3 kHz to 10 kHz."

The parties' infringement dispute with respect to the #222 patent is threefold. They disagree first about whether Stimwave infringes claim 23's limitation of "a non-paresthesia-producing therapy signal." Next, they dispute whether Stimwave uses a signal generator covered by the patent. And finally, they dispute whether Stimwave infringes the frequency range limitation of "from 3 kHz to 10 kHz."

a. "a non-paresthesia-producing therapy signal"

District courts are not required to construe every limitation in an asserted patent's claims; courts only have a duty to construe claim limitations when parties present "a fundamental dispute regarding the scope of a claim term." *O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1362 (Fed. Cir. 2008). Although the parties fundamentally dispute the scope of the "non-paresthesia-producing therapy signal" limitation, neither party argued or even suggested in its

briefing how I should construe "paresthesia." When pressed at oral argument, Nevro's counsel endorsed the construction of "paresthesia" adopted by the Northern District of California district court in *Nevro Corp. v. Boston Scientific Corp.*, 2018 WL 4676501, at *1 (N.D. Cal. July 24, 2018): "a sensation usually described as tingling, pins and needles, or numbness." Tr. 193:23-25. Stimwave's counsel stated at oral argument that the term is indefinite and "almost impossible, if not impossible, to define[.]" *Id.* at 205:4-5. Stimwave's infringement expert, however, provided a construction of "paresthesia" that is generally consistent with the construction adopted by the Northern District of California court: "the artificial sensation produced by electrical stimulation, commonly described as tingling or buzzing." D.I. 83 at ¶ 87. I will therefore adopt the construction of "paresthesia" adopted by the Northern District of California court.

Stimwave's discovery responses and the opinions of both sides' experts demonstrate that Nevro is very likely to prove at trial that Stimwave's SCS systems have been programmed to generate high frequency therapy signals that, when applied to patients, do not cause them to experience "a sensation usually described as tingling, pins and needles, or numbness."

(1) Stimwave's Discovery Responses

Nevro's second interrogatory in discovery reads as follows:

> Describe all instances in which a patient in the United States has received therapy from a Stimwave SCS

> System using a frequency above 1,500 Hz, including the programming parameters for pulse width, amplitude, and frequency used in providing the therapy, and whether the device was programmed to provide pain relief without generating paresthesia—other than for patients enrolled in the SURF randomized clinical trials during the period of that trial.

D.I. 44, Ex. 66 at 6. Although Stimwave "object[ed] to the phrase 'without generating paresthesia' as vague and ambiguous," *id.* at 7, it stated in its response to the interrogatory that "someone, typically the [Stimwave] Territory Manager/Clinical Specialist," works with the patient, "who remains awake during the implantation" of the Stimwave implantable stimulator and receiver, to "adjust[ ] programming parameters in order to identify the patient's perception threshold, discomfort threshold, *and area of paresthesia coverage*." *Id.* at 7–8 (emphasis added). "The goal" of this programming adjustment, Stimwave continued, "is to obtain complete *paresthesia coverage of the patient's pain area.*" *Id.* at 8 (emphasis added). Stimwave then noted:

> Because *paresthesia* may feel different to different patients, and may even feel different to the same patient over time given factors such as the development of scar tissue, the Territory Manager/Clinical Specialist tailors the programming parameters to the individual patient's needs to obtain the optimal amount of pain relief. *Th[e] process of mapping paresthesia coverage for the patient is performed for all patients*, including those treated before and after the March 29, 2019 FDA clearance of frequencies up to 10,000 Hz.

Id. (emphasis added).

In a supplemental response to the second interrogatory, Stimwave acknowledged that more than 50 patients who were treated with Stimwave's SCS "reported not feeling sensation(s) at 10 kHz." *See* D.I. 117, Ex. 100 at 19–33. These patient reports constitute compelling evidence that Stimwave has programmed its SCS systems to generate a therapy signal that, when applied to patients, does not cause them to experience "a sensation usually described as tingling, pins and needles, or numbness."

I agree with Nevro that Stimwave's use of "sensation" instead of "paresthesia" in its interrogatory responses is mere litigation obfuscation and is of no moment. The fact that Stimwave repeatedly uses "paresthesia coverage" in its interrogatory response to describe how its Territory Manager/Clinical Specialist works with the patient in programming Stimwave's SCS system belies the suggestion that "sensation" is anything other than "paresthesia."

Further evidence that outside of this litigation Stimwave equates "sensation" with "paresthesia" comes from three sources. First, a training video for Stimwave's sales representatives instructs them not to say "paresthesia-free" "because also there's litigation against Nevro . . . . We don't have to say the word paresthesia-free; we're just subthreshold." D.I. 117, Ex. 94 at 21:3-8. Consistent with that instruction, in a section explaining high frequency mode programming, Stimwave's Implant Procedure and Programming Reference Guide states that

"[h]igh frequency (HF) mode is a sub-threshold[,] meaning that the patient is not meant to feel stimulation while using this therapy." D.I. 44, Ex. 69 at 5.

Second, Stimwave's own SURF clinical study for its SCS HF programming noted that "HF SCS has been reported to be 'paresthesia-free,' since the resulting waveform is typically applied at amplitudes below the subject's level of perception." D.I. 24, Ex. 18 at 2. Thus, according to the authors of Stimwave's own clinical study, a patient does not experience paresthesia when the patient has no perception—i.e., no sensation[3]—of the waveform being applied to the patient. In other words, the authors understood that the perception of stimuli (i.e., sensation) that the patient experiences when the waveform is applied is paresthesia.

Third, the patently false deposition testimony of Stimwave's CEO, Ms. Perryman, that Stimwave's employees do not use the term "paresthesia-free" because "it is a made-up word," D.I. 137, Ex. A at 23:18-24:6, makes clear that Stimwave has adopted "sensation" in place of "paresthesia" as a litigation tactic. The fact that Ms. Perryman previously authored an article that uses the terms "paresthesia-free" and "paresthesia," *see* D.I. 24, Ex. 21 at 0023, and the fact that Stimwave's SURF clinical study also uses those terms, *see id.*, Ex. 18 at 2,

[3] *See Perception*, MERRIAM-WEBSTER.COM, http://merriam-webster.com/dictionary/perception (last visited July 24, 2019) (defining "perception" as "awareness of the elements of environment through physical *sensation*") (emphasis added).

contradict her testimony. Those inconsistencies along with Ms. Perryman's combative and dismissive demeanor during her deposition support my finding that her testimony lacks credibility.

(2) Expert Opinions

The opinions of both sides' experts also support a finding of infringement of the "non-paresthesia-producing therapy signal" limitation. Nevro's expert, Dr. Rosenberg, opined that "the vast majority, if not all" 10 kHz patients do not experience paresthesia at the ranges Stimwave has programmed. D.I. 43 at ¶ 4; *see also* D.I. 117, Ex. 110 at 46:2-24. Stimwave's expert, Dr. North, stated similarly a year ago that "SCS at 10 kHz, on the other hand, is paresthesia-free at amplitudes used clinically . . . ." D.I. 118, Ex. 164 at 594.

b. "a signal generator"

The method of claim 23 of the #222 patent uses "a signal generator to deliver" the therapy signal to the patient. Nevro asks me to give this limitation its plain and ordinary meaning. Stimwave argues that the "signal generator" in the #222 patent "should be construed to mean a fully implanted signal generator." D.I. 77 at 6. Infringement of this claim limitation rises or falls on whether I adopt Stimwave's proposed construction, as it is undisputed that Stimwave uses a non-implanted (i.e., wireless) signal generator in its SCS system.

Federal Circuit law requires the court to construe claim terms in accordance with their plain and ordinary meaning as understood by a person of ordinary skill in the art (POSITA) when read in the context of the written description and prosecution history. *Thorner v. Sony Comput. Entm't Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012).[4] "There are only two exceptions to this general rule: 1) when a patentee sets out a definition and acts as his own lexicographer, or 2) when the patentee disavows the full scope of the claim term either in the [written description] or during prosecution." *Id.* In either event, the lexicography or disavowal must be clear and unmistakable. *See id.* at 1367–68.

Stimwave's sole argument in support of its proposed construction is that the written description of the #222 patent discloses only a fully implantable signal

[4] The Court literally stated in *Thorner* that "[t]he words of a claim are generally given their ordinary and customary meaning as understood by a person of ordinary skill in the art when read in the context of the *specification* and prosecution history." *Id.* (emphasis added). Section 112(b) of Title 35 provides that "[t]he specification shall conclude with one or more claims[.]" This language makes clear that the specification includes the claims asserted in the patent, and the Federal Circuit has so held. *See Markman*, 52 F.3d at 979 ("Claims must be read in view of the specification, of which they are part"). The Federal Circuit and other courts, however, have also used "specification" on occasions such as in *Thorner* to refer to the written description of the patent as distinct from the claims. *See, e.g., Markman*, 52 F.3d at 979 ("To ascertain the meaning of claims, we consider three sources: The claims, the specification, and the prosecution history."). To avoid confusion, I will refer to the portions of the specification that are not claims as "the written description."

generator and says nothing about the wireless transmission of stimulation parameters from outside the body. *See* D.I. 77 at 5; D.I. 83 at ¶¶ 77-80, 140. But Stimwave's argument contradicts fundamental Federal Circuit precedent that "it is improper to read limitations from a preferred embodiment described in the [written description]—even if it is the only embodiment—into the claims absent a clear indication in the intrinsic record that the patentee intended the claims to be so limited." *Liebel–Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 913 (Fed. Cir. 2004); *see also Specialty Composites v. Cabot Corp.*, 845 F.2d 981, 987 (Fed. Cir. 1988) ("Where a [written description] does not require a limitation, that limitation should not be read from the [written description] into the claims.").

Here, there is no clear indication in the intrinsic record that the patentee intended to require an implanted signal generator. On the contrary, the language of claim 23 of the #222 patent itself makes clear that the patentee did not limit the signal generator to an implanted device. The claim teaches the programming of a "signal generator … to deliver the therapy signal … via a signal delivery device *implanted* in the patient's epidural space." The fact that the patentee placed an "implanted" limitation on the "signal delivery device" but did not do so for the signal generator device strongly suggests that there is no such limitation on the signal generator device. *See Power Mosfet Techs., L.L.C. v. Siemens AG*, 378 F.3d 1396, 1410 ("[I]nterpretations that render some portion of the claim language

superfluous are disfavored."); *see also Merck & Co. v. Teva Pharm. USA, Inc.*, 395 F.3d 1364, 1372 (Fed. Cir. 2005) ("A claim construction that gives meaning to all the terms of the claim is preferred over one that does not do so.") (citations omitted).

Relatedly, the doctrine of claim differentiation supports the conclusion that the signal generator need not be implanted. Under that doctrine, "the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1315 (Fed. Cir. 2005) (en banc). Claim 34 of the #222 patent, which is not asserted for purposes of Nevro's motion, states: "[t]he method of claim 23[,] wherein the signal generator is an implantable signal generator." The plain language of claim 34 requires an implantable signal generator, giving rise to a presumption that independent claim 23 is not limited to implantable signal generators. Nothing in the intrinsic or extrinsic evidentiary record suggests that Stimwave could rebut this presumption at a trial.

The patent's written description also demonstrates that the signal generator need not be implanted. For starters, it states that "the present disclosure and associated technology can encompass other embodiments not expressly shown or described herein." #222 patent at 25:44-46. Moreover, it expressly contemplates that the pulse generator need not be fully implanted. *See id.* at 3:30-33 ("a pulse

generator … *may be implanted* subcutaneously within a patient … and coupled to a signal delivery element") (emphasis added).

Because the written description does not show a clear intention to limit the claim's scope, the plain and ordinary meaning applies and the signal generator need not be implanted. *See Info-Hold, Inc. v. Applied Media Techs. Corp.*, 783 F.3d 1262, 1267 (Fed. Cir. 2015) (construing "transmit" in accordance with its plain and ordinary meaning because written description did not show "clear intention" to limit claims to preferred embodiment). Accordingly, there is a strong likelihood that Nevro will succeed on the merits in establishing Stimwave's infringement of the signal generator limitation.

c. "frequency range [of] from 3 kHz to 10 kHz"

As noted above, Stimwave admitted in its discovery responses that it has programmed its SCS systems to deliver patients a therapy signal with a frequency of 10 kHz. Stimwave argues, however, that because there is no evidence that its SCS systems have been programmed to administer a therapy signal with a frequency of between 3 kHz and 9.999 kHz, Nevro has failed to establish that Stimwave infringes claim 28 of the #222 patent, which recites "[t]he method of claim 23[,] wherein the frequency range is from 3 kHz to 10 kHz." *See* Tr. 81:7-24 (Stimwave's counsel arguing that "there needs to be allegations of infringement within the entire range").

The purpose of Stimwave's argument is obvious. It wants to limit an injunction to cover only a 10 kHz therapy signal so that it can continue to program its systems at frequencies just shy of 10 kHz, such as 9.9 kHz. But to adopt its argument, I would have to do one of two things, neither of which I can lawfully do: (1) rewrite claim 28 to cover a frequency range of "from 3 kHz to less than 10 kHz" or (2) ignore the fact that Stimwave admits that it has programmed its SCS systems to deliver to patients a therapy signal that falls within a range of 3 kHz to 10 kHz. Accordingly, I reject Stimwave's argument and do not accept that it creates a substantial question about whether Nevro can prove infringement of claim 28. Indeed, for the reasons explained above, I find it very likely that Nevro could establish at a trial that Stimwave programmed its SCS systems to deliver patients a therapy signal with a frequency that fell within the range of 3 to 10 kHz.

2. Invalidity

Having found that Nevro has met its burden with respect to infringement of claims 24 and 28 of the #222 patent, I next consider whether Nevro has established that it is likely to prevail at trial with respect to any invalidity defenses raised by Stimwave. Because an issued patent comes with a statutory presumption of validity under 35 U.S.C. § 282, an alleged infringer who raises invalidity as an affirmative defense has the burden at trial to prove invalidity by clear and convincing evidence. A patent "enjoys the same presumption of validity during

preliminary injunction proceedings as at other stages of litigation." *Titan Tire Corp. v. Case New Holland, Inc.*, 566 F.3d 1372, 1377 (Fed. Cir. 2009). "Thus, if a patentee moves for a preliminary injunction and the alleged infringer does not challenge validity, the very existence of the patent satisfies the patentee's burden of showing a likelihood of success on the validity issue." *Id.* But if the alleged infringer comes forward with some evidence of invalidity, then the patentee must present contrary evidence and argument to meet its burden to show that it is more likely than not that the alleged infringer will not be able to prove at trial, by clear and convincing evidence, that the patent is invalid. *Id.* at 1379. "Asking whether the [alleged infringer] has raised a substantial question of invalidity ... may be a useful way of initially evaluating the evidence, but the ultimate question ... remains that of the patentee's likelihood of success on the merits." *Id.*

In this case, Stimwave has raised invalidity defenses of indefiniteness, lack of enablement, anticipation, and obviousness. But I am persuaded that these defenses do not raise substantial questions about the #222 patent's validity and that Nevro has shown that it is unlikely that Stimwave could prove by clear and convincing evidence at trial that the asserted claims of the #222 patent are invalid.

a. Indefiniteness

The claims of a patent must "particularly point[ ] out and distinctly claim[ ] the subject matter" regarded as the invention. 35 U.S.C. § 112. In determining

whether challenged claims meet this requirement, the court must strike the "delicate balance" that tolerates "[s]ome modicum of uncertainty" necessitated by "the inherent limitations of language" yet at the same time ensures that "[the] patent [is] ... precise enough to afford clear notice of what is claimed[.]" *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 909 (2014) (citations omitted). Accordingly, "a patent is invalid for indefiniteness if its claims, read in light of the [written description] delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Id.* at 901.

In this case, the #222 patent informs a POSITA about the scope of the invention with reasonable certainty.[5] The patent's claims and written description disclose how to determine a patient's paresthesia threshold; and they provide sufficient guidance to achieve paresthesia-free therapy. *See* #222 patent at 1:47-54, 2:52-59, 4:43-5:30, 5:46-57, 5:63-6:8, 6:54-7:8, 12:23-32.

Stimwave asserts that "Nevro's claims are vulnerable to an indefiniteness challenge" because whether a patient experiences paresthesia is a subjective

[5] The parties agree that a POSITA would have "several years of experience developing active implantable medical devices, either from a technical or clinical side" and would have an educational background "in some relevant field, whether it's medicine, engineering, software development, something that would be used to develop the product." D.I. 83 at ¶ 22 (quoting D.I. 78, Ex. 3 at 6:7-7:7); *see also* D.I. 114 at ¶ 43.

assessment that varies from patient to patient and because the meaning of "non-paresthesia-producing therapy signal" is unclear. D.I. 77 at 8–11. It is undisputed that paresthesia is a subjective assessment that can vary from patient to patient. But that fact does not render the meaning of "non-paresthesia-producing therapy signal" unclear. The limitation is perfectly clear. It means: a therapy signal that does not produce "a sensation usually described as tingling, pins and needles, or numbness." *See supra* Section II.A.1.a (defining paresthesia); *see also Boston Sci.*, 2018 WL 4676501, at *3 (holding that phrases "such as 'does not produce paresthesia,'" in related Nevro patents "have a clear meaning. They mean: 'does not produce a sensation usually described as tingling, pins and needles, or numbness.'" (internal citation omitted)).[6]

Stimwave also argues that the #222 patent is indefinite because it is "impossible to know whether paresthesia will be induced until after the signal is applied." D.I. 138, Ex. F at 39; *see also* D.I. 77 at 11. But this argument misses the point. As Stimwave acknowledged at oral argument, "programming is the only

[6] As discussed above, *see supra* Section II.A.1.a(1), Stimwave's interrogatory responses and the words of its CEO and SURF clinical study also confirm that a POSITA would understand what is meant by "paresthesia" and "paresthesia-free." I note also that three other SCS companies have filed applications for patents that claim "paresthesia-free" treatment. D.I. 118, Exs. 144, 145; D.I. 81, Ex. 58. *See Mylan Instit. LLC v. Aurobindo Pharma Ltd.*, 857 F.3d 858, 871 (Fed. Cir. 2017) (finding no indefiniteness at preliminary injunction stage where "scientific literature and other patents" used similar terminology).

step of th[e] method" taught by claim 23. Tr. 213:6-7. And although the programming typically begins with the SCS company representative selecting the signal's initial wave attributes (i.e., pulse width, amplitude, and frequency) within recommended ranges, Dr. Caraway, Nevro's Chief Medical Officer, credibly testified that the programming inevitably includes testing the delivery of the signal and conversing with the patient to ensure the safe and efficacious delivery of the signal. *See id.* at 102:15-104:12. This interaction with the patient can occur in the operating room during or immediately after the implantation of the leads or at the physician's office or other location a week or so after the surgery when the patient's operating pain has subsided. D.I. 21 at ¶ 68; *see also* Tr. 103:5-13. But regardless of when it occurs, this interaction either confirms the safety and efficacy of the initial selection of the signal's wave attributes or prompts the physician or SCS company representative to adjust and reprogram those attributes as needed to obtain a safe and efficacious delivery of the signal.[7] *Id.* at ¶¶ 65-69.

[7] Nevro's counsel gave conflicting answers at oral argument about whether the method taught by claim 23 required a delivery of the signal. *See* Tr. 38:23-41:13. My sense is that his different answers were actually both correct. If the SCS company representative's initial selection of wave attributes were found after interaction with the patient to be safe and efficacious, then it could be said that the programming was completed before delivery of the signal. If, on the other hand, the patient's responses to testing of the signal required adjustment of the wave attributes, then the programming required the delivery of a signal.

Although the wave attributes that would result in a signal that does not create paresthesia may vary among patients, a POSITA would be able to determine easily from patient interactions whether a signal produces paresthesia for any given patient. *See id.* at ¶¶ 62-72. Indeed, Stimwave's own expert, Dr. North, admitted that he "routinely" determines a patient's paresthesia threshold by increasing the amplitude until the patient reports feeling a sensation believed to be attributable to the stimulation. D.I. 117, Ex. 108 at 14:4-14. In sum, the method taught by claim 23 is not completed until it is known whether the signal induces paresthesia. The fact that it is impossible to know whether paresthesia will be induced until after the signal is applied does not render the patent indefinite.

b. Enablement

Section 112 requires that a patent "contain a written description of the invention, and the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same[.]" 35 U.S.C. § 112(a). "To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1365 (Fed. Cir. 1997) (quoting *In re Wright*, 999 F.2d 1557, 1561 (Fed. Cir. 1993)). Although experimentation must not be "undue," enablement is not

precluded where a "reasonable" amount of "routine experimentation" is necessary to practice a claimed invention. *ALZA Corp. v. Andrx Pharm., LLC*, 603 F.3d 935, 940 (Fed. Cir. 2010). Furthermore, the specification need not teach what is well known in the art. *Koito Mfg. Co. v. Turn-Key-Tech, LLC*, 381 F.3d 1142, 1156 (Fed. Cir. 2004).

Stimwave argues that two circumstances create a substantial question about whether the #222 patent satisfies the enabling requirement. It contends first that #222 patent does not teach a POSITA how to program or use a system that is not fully implanted and that communicates wirelessly with the implanted portions of the SCS system. D.I. 77 at 14. This contention, however, ignores the fact that the asserted claims cover methods of configuring signal generators, not the manufacture of signal generators. *See Durel Corp. v. Osram Sylvania Inc.*, 256 F.3d 1298, 1306 (Fed. Cir. 2001) ("The dispositive question of enablement does not turn on whether the accused product is enabled."). Moreover, Stimwave's conclusory assertions that the patent lacks sufficient detail about non-implantable signal generators do not raise a substantial question about the patent's validity. It is undisputed that SCS devices with wireless programmers were well known within the prior art. *See* D.I. 77 at 14, D.I. 83 at ¶ 63; D.I. 84 at ¶ 37; D.I. 114 at ¶¶ 127-29. As the Federal Circuit has "repeatedly explained," a patent does not need to

include "that which is already known to and available to one of ordinary skill in the art." *Koito Mfg. Co.*, 381 F.3d at 1156.

Second, Stimwave argues that the #222 patent does not disclose various parameters that a POSITA would need to know to achieve paresthesia-free treatment at the full range of the claimed frequencies. D.I. 77 at 14. Although it is true that the patent does not disclose treatment parameters for the entire range of claimed frequencies (i.e. 3 kHz to 10 kHz),[8] the patent would enable a POSITA to practice the claimed invention with a "reasonable" amount of "routine experimentation." *ALZA Corp.*, 603 F.3d at 940. This conclusion is supported by both parties' experts. According to Dr. Rosenberg, "determining the sensory threshold at which a patient experiences paresthesia is a *routine part* of the procedure of implanting an SCS device." D.I. 21 at ¶ 70 (emphasis added). And Dr. North admitted that it is his practice to "*routinely*" (and "always") "determine[ ] the paresthesia threshold as part of treating a patient with spinal cord stimulation." D.I. 117, Ex. 108 at 14:4-14 (emphasis added). As Dr. Rosenberg

[8] Stimwave acknowledges that the patents disclose treatment parameters for 8 kHz, 9 kHz, and 10 kHz frequencies, but still contends that undue experimentation would be required because the patent states that "[t]he specific values selected for the foregoing parameters may vary from patient to patient." D.I. 77 at 14–15 (quoting #222 patent at 19:54-57). I agree with Dr. Rosenberg, however, that the patent enables a POSITA to provide paresthesia-free treatment without undue experimentation across the full range of claimed frequencies. *See* D.I. 21 at ¶¶ 70-78.

explained, a POSITA would be able to determine the parameters for generating paresthesia-free therapy using the frequency and amplitude ranges provided in the patent, D.I. 21 at ¶ 71, and the amount of experimentation needed to ensure paresthesia-free therapy would only take seconds to minutes because a POSITA would know (1) to start the procedure by working with lower power and gradually increasing upwards, and (2) that there are certain parameters that will very likely not generate paresthesia in any given patient. *Id.* at ¶ 72. Dr. North admitted that low amplitude stimulation "*at any frequency*, will not produce a paresthesia if it's low enough." D.I. 117, Ex. 108 at 11:6-14 (emphasis added).

According to Dr. Rosenberg, in the context of traditional, paresthesia-based SCS therapy, before setting the wave parameters, the physician will attempt to determine both the lowest settings at which a patient will experience paresthesia and the highest settings tolerable to the patient. D.I. 21 at ¶ 70. Stimwave acknowledged as much in its interrogatory responses when it confirmed that "[the] process of mapping paresthesia coverage for the patient is performed for all patients." D.I. 44, Ex. 66 at 8. Dr. Rosenberg further opined that the basic procedure for determining the sensory threshold at which a patient experiences paresthesia has not changed over the past twelve years. D.I. 21 at ¶ 70. Given that the experimentation process is "a fundamental and routine part of any SCS to determine thresholds (sensory, comfort) of combinations of parameters," *id.*, I find

that the state of the art, in conjunction with the #222 patent's written description, demonstrates that a POSITA would be able to practice the full scope of the claimed invention without undue experimentation. Accordingly, Stimwave's lack of enablement defense lacks substantial merit.

c. Anticipation & Obviousness

Finally, Stimwave argues that there are substantial questions as to whether the claims are anticipated and/or obvious. Stimwave's anticipation and obviousness arguments focus on three prior art sources. First, Stimwave argues that U.S. Patent Application Publication No. 2011/0184488 ("De Ridder") anticipates or renders obvious the asserted claims. D.I. 77 at 15–17. Second, Stimwave argues that U.S. Patent Application Publication No. 2006/0009820 ("Royle") anticipates or renders obvious the asserted claims. *Id.* at 17–18. Third, Stimwave argues that the CompuStim SCS System Clinical Manual from Advanced Neuromodulation Systems ("CompuStim"), in view of Royle, renders the asserted claims obvious. *Id.* at 18–19.

A patent claim is invalid as anticipated under 35 U.S.C. § 102 if "within the four corners of a single, prior art document . . . every element of the claimed invention [is described], either expressly or inherently, such that a person of ordinary skill in the art could practice the invention without undue experimentation." *Callaway Golf Co. v. Acushnet Co.*, 576 F.3d 1331, 1346 (Fed.

Cir. 2009) (alterations in original). "[U]nless a reference discloses within the four corners of the document not only all of the limitations claimed but also all of the limitations arranged or combined in the same way as recited in the claim, it cannot be said to prove prior invention of the thing claimed and, thus, cannot anticipate under 35 U.S.C. § 102." *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1371 (Fed. Cir. 2008).

"When more than one reference is required to establish unpatentability of the claimed invention," then "validity is determined under § 103[,]" not § 102. *Continental Can Co. USA v. Monsanto Co.*, 948 F.2d 1264, 1267 (Fed. Cir. 1991). Under § 103, a patent claim is invalid as obvious if "the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious . . . to a person having ordinary skill in the art to which the claimed invention pertains." 35 U.S.C. § 103(a). Whether claims of an asserted patent would have been obvious under 35 U.S.C. § 103 is a legal conclusion based on underlying factual determinations. *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17 (1966). "The underlying factual inquiries include (1) the scope and content of the prior art; (2) the differences between the prior art and the claims at issue; (3) the level of ordinary skill in the art; and (4) any relevant secondary considerations . . . ." *Western Union Co. v. MoneyGram*

Payment Sys., Inc., 626 F.3d 1361, 1370 (Fed. Cir. 2010) (citing *Graham*, 383 U.S. at 17–18).

At the outset, I note that Stimwave's first arguments for both anticipation and obviousness rely only on De Ridder; and its second arguments for both anticipation and obviousness rely only on Royle. Stimwave does not argue that the asserted claims are obvious in light of Royle *and* De Ridder. Because Stimwave only argues that the asserted claims are obvious in light of Royle *or* De Ridder, I decline to address whether a POSITA would have been motivated to combine the teachings of Royle and De Ridder to achieve the claimed invention and would have had a reasonable expectation of success in doing so. I also decline to consider the prior art references discussed only in the declaration of Stimwave's expert, Dr. North. *See* D.I. 84 at Section V.[9]

With respect to the anticipation and obviousness arguments Stimwave offered in its briefs, I find that these defenses lack substantial merit. First, I find it unlikely that Stimwave could prove by clear and convincing evidence at trial that De Ridder anticipates the claimed invention. It is true that De Ridder discloses "a system and method for treating pain without paresthesia by spinal cord

[9] I instructed the parties at the scheduling conference: "Now, I've got to really warn you on this. Do not circumvent page limits by having expert declarations where you are really making legal argument. I just really take umbrage with that practice, and you would risk me striking it." D.I. 108 at 54:18-22.

stimulation." D.I. 78, Ex. 13 at Abstract. But it does so only at low frequencies. *Id.* at ¶¶ 38-42, 45-47, Table 1. Moreover, De Ridder taught that higher frequency stimulation causes paresthesia. *See id.* at ¶ 4 (noting that "high frequency electrical stimulation causes other sensation signals to reach the thalamus whereby the patient experiences a tingling sensation known medically as paresthesia"). The fact that De Ridder teaches away from the invention disclosed in the #222 patent supports a finding that Stimwave would likely not be able to prove at trial by clear and convincing evidence an obviousness defense based on De Ridder. *See Meiresonne v. Google, Inc.*, 849 F.3d 1379, 1382 (Fed. Cir. 2017); *Impax Labs. Inc. v. Lannet Holdings, Inc.*, 893 F.3d 1372, 1380–81 (Fed. Cir. 2018).

Next, I find that Royle does not anticipate the claimed invention. Royle discloses an apparatus for applying electrical pulses to a patient's body by at least two electrodes placed on the patient's body in order to induce analgesic effects in the patient's central nervous system, which includes the patient's spinal cord. D.I. 78, Ex. 16 at Abstract, ¶¶ 46, 105. Of particular relevance here, Royle discloses preferred frequencies from 100 Hz to 250 kHz, including 10 kHz for medical purposes, *id.* at ¶¶ 35, 68, and discloses that the electrodes can be implanted within the patient's body, *id.* at ¶ 104. Royle also teaches that the use of a fast rise time of the pulses is preferred "so that the subject (i.e. patient) feels no sensation." *Id.* at ¶ 75. Although this statement purports to disclose paresthesia-free therapy, it does

so in the context of placing the electrodes on the patient's skin rather than implanted within the patient's body. *See id.* Thus, although Royle discloses each element of the asserted claims, Royle does not anticipate the claimed invention because Royle does not disclose these elements as arranged or combined in the same way as in the asserted claims. *See Net MoneyIN*, 545 F.3d at 1371 (holding that, to anticipate, a single prior art reference must not only disclose all the limitations claimed but also must disclose those limitations "arranged or combined in the same way as recited in the claim[.]"). Accordingly, I agree with Nevro that Royle does not achieve "no sensation" in the context of an implantable signal delivery device.[10]

Because Royal teaches away from implanting the electrodes, I also conclude that it does not render the asserted claims obvious. Royle states that "[i]f desired, the electrodes could be implanted within the body, including within the skin, but it is more preferable that [the electrodes] are designed to simply be placed in contact with the skin surface." D.I. 78, Ex. 16 at ¶ 104. "A reference teaches away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent

[10] The United States Patent and Trademark Office ("USPTO") also concluded that Royle did not anticipate a related Nevro patent based on the fact that the petitioner failed to adequately show that Royle achieves "no sensation" in the context of an implantable signal delivery device. D.I. 24, Ex. 32 at 16.

from the path that was taken in the claim." *Meiresonne*, 849 F.3d at 1382 (internal quotation marks omitted). Here, I find that Royle teaches away from implanting the electrodes because a POSITA, upon reading Royle, would choose to place the electrodes on the patient's skin rather than implant them in the patient's body.

Finally, I find that the CompuStim, in view of Royle, does not render the asserted claims obvious under § 103. First, CompuStim is limited to frequencies of 1.5 kHz or lower. D.I. 79, Ex. 17 at 41. The asserted claims, in contrast, claim frequencies of 3 kHz to 10 kHz. Second, CompuStim repeatedly refers to the need for paresthesia to relieve pain. *Id.* at 1, 33, 43–44. Because both Royle and CompuStim teach away from paresthesia-free SCS therapy, I conclude that a POSITA would not be motivated to combine Royle and CompuStim to achieve the claimed invention. Accordingly, CompuStim, in view of Royle, does not render the asserted claims obvious. As a result, Nevro has shown that Stimwave is not likely to prove by clear and convincing evidence that the #222 patent is invalid as obvious.[11]

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[11] Although I have already rejected all of Stimwave's affirmative § 103 arguments, I will briefly examine relevant secondary considerations of nonobviousness (i.e. objective indicia of nonobviousness) because I am required to do so. *See, e.g., Ruiz v. A.B. Chance Co.*, 234 F.3d 654, 667 (Fed. Cir. 2000) ("Our precedents clearly hold that secondary considerations, when present, *must* be considered in determining obviousness.") (emphasis added). Stimwave's brief fails to address objective indicia of nonobviousness, and Dr. North's declaration contains a single, bare-bones paragraph addressing objective indicia of nonobviousness. *See* D.I. 84 at ¶ 286. In contrast, Nevro has offered strong objective indicia of

B. Irreparable Harm

A party seeking a preliminary injunction must make a "clear showing" that it is likely to suffer irreparable harm in the absence of preliminary relief. *Winter*, 555 U.S. at 22; *Apple, Inc. v. Samsung Elecs., Co.*, 678 F.3d 1314, 1325 (Fed. Cir. 2012) ("*Apple I*"). "[T]o satisfy the irreparable harm factor in a patent infringement suit, a patentee must establish both of the following requirements: 1) that absent an injunction, it will suffer irreparable harm, and 2) that a sufficiently

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nonobviousness. First, Nevro has achieved commercial success, as evidenced by its significant growth in market share since it introduced its HF10 therapy. Contrary to Dr. North's assertions, Nevro does not need a majority share of the SCS market to show commercial success. In fact, Nevro does not even need to prove a higher market share to show commercial success. *See. PPC Broadband, Inc. v. Iancu*, 739 F. App'x 615, 626 (Fed. Cir. 2018) (stating there is "no authority" for the proposition that a patentee must prove higher market share to show commercial success). Not only has Nevro shown evidence of commercial success, I also find that Nevro has received significant industry praise for its high frequency, paresthesia-free therapy, *see, e.g.*, D.I. 24, Exs. 2, 5–7, and that Nevro's therapy addressed a long-felt but unsolved need for technology to overcome the limitations of traditional SCS therapy. *See, e.g.*, D.I. 21 at ¶¶ 43-48. In fact, in a publication he co-authored just last year, Dr. North praised 10 kHz, paresthesia-free therapy as providing "pain relief superior to that afforded by 'conventional/traditional' SCS [therapy.]" D.I. 118, Ex. 164 at 594. I give this evidence substantial weight because there is a nexus between Nevro's objective evidence of nonobviousness and the merits of the claimed invention (i.e. high frequency, paresthesia-free SCS therapy). *See Merck & Cie v. Gnosis S.P.A.*, 808 F.3d 829, 837 (Fed. Cir. 2015) ("For objective evidence of secondary considerations to be accorded substantial weight, its proponents must establish a nexus between the evidence and the merits of the claimed invention.") (citation omitted).

strong causal nexus relates the alleged harm to the alleged infringement." *Apple Inc. v. Samsung Elecs., Co.*, 695 F.3d 1370, 1374 (Fed. Cir. 2012) ("*Apple II*").

1. Irreparable Harm

Nevro has demonstrated that Stimwave's entry into the high frequency, paresthesia-free market will likely result in irreparable harm to its goodwill and reputation. Nevro has built its brand on its high-frequency, paresthesia-free therapy. According to Dr. Caraway, whom I found to be a credible witness because of the internal consistency and cogency of his testimony and the manner in which he handled his cross-examination, Nevro's HF10 therapy "was the basis for founding the company" and "the focus of the company's strategy for penetrating the market." D.I. 22 at ¶ 39. In Dr. Caraway's words, "the successful implementation of HF10 therapy by Nevro has been the whole reason [the] company is around," Tr. 104:13-23, and losing Nevro's exclusivity over its high frequency, paresthesia-free therapy "would be devastating" because it "is [Nevro's] reason for being." *Id.* at 123:2-7.

Nevro's only products are its SCS systems and 97% of Nevro's patients are using HF10 as their therapy. *Id.* at 100:14-20; D.I. 22 at ¶ 16. Dr. Caraway convincingly explained that Nevro has spent hundreds of millions of dollars to bring its therapy to market and to support it, and that all of Nevro's research and development is directed towards high frequency, paresthesia-free therapy. Tr.

123:13-24. Nevro has never licensed its patented technology, D.I. 22 at ¶ 39, and it publicizes in all of its marketing material and in its press releases the fact that its HF10 therapy is patented. Tr. 95:16-23.

Before 2015, the SCS market primarily consisted of three large companies. D.I. 23 at ¶ 27; Tr. 95:5-15. Because the SCS market is "sticky," "very little market share change took place as physicians tended to remain with their preferred SCS device provider." D.I. 116 at ¶ 114. By developing and marketing its high frequency, paresthesia-free therapy, however, Nevro was able to persuade doctors to try its unique system and by 2017 it captured nearly 16% of the market. *Id.*; D.I. 23 at ¶ 24. In the words of one of Stimwave's own internal documents, Nevro "did a lot of amazing things that really shifted the industry." D.I. 117, Ex. 94 at 24:6-8.

Nevro's success is likely attributable in part to the "superiority" label it received from the FDA based on the results of the SENZA-RCT clinical study. That study directly compared Nevro's SCS system to a traditional SCS system. It found that 84.3% of the patients who received Nevro's HF10 therapy experienced at least a 50% reduction in back pain after three months, as compared to 43.8% of the patients treated with traditional SCS therapy. *See* D.I. 24, Ex. 2 at 856. Similar results were obtained for patients with leg pain. Approximately 83% of patients treated with Nevro's HF10 SCS therapy experienced at least a 50%

reduction in leg pain as compared to 55% of patients treated with traditional SCS therapy. *See id.*

The results Stimwave obtained in its 10 kHz clinical trial pale in comparison to the results Nevro obtained in the SENZA-RCT study. Stimwave's SURF study showed only that Stimwave's high frequency, paresthesia-free therapy is "noninferior" to its traditional, low-frequency therapy. D.I. 24, Ex. 18 at 4, 7. Additionally, the SURF clinical trial showed that patients experienced complications with Stimwave's system: 15% of the patients suffered lead migration and 2% suffered lead fracture; 5% of the patients experienced loss of stimulation.[12] *Id.* at 7, Table 2. By comparison, in Nevro's SENZA-RCT study only 3% of patients experienced lead migration and no patients reported loss of sensation or fractured leads. D.I. 24, Ex. 2 at 856–57; D.I. 22 at ¶ 29. Given this data, it is not surprising that Stimwave does not dispute that Nevro's HF10 therapy offers clinically superior results.

The Federal Circuit has explicitly recognized that "[h]arm to reputation resulting from confusion between an inferior accused product and a patentee's superior product is a type of harm that is often not fully compensable by money

[12] At oral argument, Nevro stated that Stimwave has taken measures to address the lead migration issue, but it is unclear if the issue has been resolved. Tr. 261:8-13, 319:7-23. Even if Stimwave has adequately addressed its lead migration issue, Stimwave conceded at oral argument that Nevro's therapy is clinically superior. *See id.* at 299:4-300:6.

because the damages caused are speculative and difficult to measure." *Reebok Int'l Ltd. v. J. Baker, Inc.*, 32 F.3d 1552, 1558 (Fed. Cir. 1994); *see also Tinnus Enters.*, 846 F.3d at 1208 (affirming district court's finding of irreparable harm because consumer confusion between the patentee's product and the accused infringer's product "establishe[d] persisting harm to [the patentee's] reputation and tarnishe[d] its status as the innovator in [the] market"). Nevro has established that it would suffer this exact type of harm here absent an injunction. As Dr. Rosenberg explained, "[i]f another company were to offer high frequency paresthesia-free therapy that does not perform as well as Nevro's technology, and a skeptical physician were to try it, because, for example, it is significantly cheaper than other SCS systems, but the skeptic has a negative experience, the skeptic would find confirmation for their skepticism, and *Nevro could forever lose this physician as a potential customer*." D.I. 21 at ¶ 60 (emphasis added). Dr. Caraway similarly testified that "successful implementation of HF10 therapy ... has been the whole reason [Nevro] is around" and another company's unsuccessful implementation of HF10 therapy "could be conflated with how [Nevro's] therapy is" and also create "a negative reputation upon the therapy as a whole" Tr. 104:13-23. Although Dr. Rosenberg's statement and Dr. Caraway's testimony necessarily involve speculation as to what might happen if a physician had a negative experience with Stimwave's product, the need to speculate the extent of such harm

supports the conclusion that the harm cannot be readily quantified and is therefore irreparable. *See Reebok Int'l*, 32 F.3d at 1558.

2. Causal Nexus

Nevro must also establish that "a sufficiently strong causal nexus relates the alleged harm to the alleged infringement." *Apple II*, 695 F.3d at 1374. To do so, it must "show that the infringing feature drives consumer demand for the accused product." *Id.* at 1375. Nevro can make this showing in a variety of ways, including with "evidence that a patented feature is one of several features that cause consumers to make their purchasing decisions" or "evidence that the inclusion of a patented feature makes a product significantly more desirable." *Apple Inc. v. Samsung Elecs. Co.*, 735 F.3d 1352, 1364 (Fed. Cir. 2013) ("*Apple III*").

I find that Nevro has made the required causal nexus showing. First, Nevro's historical success at penetrating the "sticky" SCS market because of its exclusive HF10 therapy shows demand for the patented feature. Second, Nevro has offered specific evidence in the form of declarations from some of its sales representatives and testimony from Dr. Caraway detailing particular instances where physicians who were once loyal Nevro customers switched to Stimwave after Stimwave received FDA approval to treat with 10 kHz. *See* D.I. 112; 113; 115; Tr. 113:20-121:10. Third, Stimwave documents produced in discovery show

that it is using Nevro's patented therapy to target Nevro's customers, *see* D.I. 44, Ex. 82; D.I. 117, Ex. 98 at 7:2-12; and thus, Stimwave itself believes that HF10 therapy is a distinguishing feature that drives demand for SCS systems. Finally, Stimwave's irreparable harm expert admitted that the availability of 10 kHz makes Stimwave's products more desirable and increases sales. D.I. 117, Ex. 106 at 192:3-193:24. This evidence demonstrates a causal nexus between the alleged harms and Stimwave's alleged infringement.

C. Balance of Equities

The third factor a party seeking a preliminary injunction must establish is that "the balance of equities tips in [its] favor." *Winter*, 555 U.S. at 20. The district court must weigh the harm to the moving party if the injunction is not granted against the harm to the non-moving party if the injunction is granted. *Id.* at 24; *see also Hybritech*, 849 F.2d at 1457. In this case, Stimwave's CEO testified at her deposition that she "d[id] not believe" that an injunction preventing Stimwave from providing therapy at or above 3 kHz "has an impact on our bottom line." D.I. 117, Ex. 109 at 63:23-64:7. Accordingly, in light of my finding that Nevro will suffer irreparable harm absent an injunction, the balance of equities weighs strongly in Nevro's favor.

D. Public Interest

The final factor a court should consider in determining whether to issue a preliminary injunction is the impact an injunction will have on the public interest. *Winter*, 555 U.S. at 20. "[I]n a patent infringement case, although there exists a public interest in protecting rights secured by valid patents, the focus of the district court's public interest analysis should be whether there exists some critical public interest that would be injured by the grant of preliminary relief." *Hybritech*, 849 F.2d at 1457.

I agree with Stimwave that it is generally in the public's interest to allow physicians to have as wide a variety of treatment options as is possible. *See Kimberly-Clark Worldwide, Inc. v. Tyco Healthcare Grp. LP*, 635 F. Supp. 2d 870, 882 (E.D. Wis. 2009). For a small number of patients with chronic pain, it may be that they would prefer Stimwave's minimally invasive SCS system to Nevro's HF10 therapy. Nevertheless, I find that a critical public interest would not be injured by the grant of a preliminary injunction for three reasons.

First, Nevro's request for injunctive relief is narrowly tailored only to prohibit Stimwave from marketing its SCS systems at frequencies that would infringe the asserted claims. Nevro's requested relief would not entirely prohibit Stimwave from selling its SCS systems; and thus, for the small number of chronic

pain patients who cannot, or will not, be treated with IPG-based systems, Stimwave's low frequency therapy will still remain an option.

Second, Stimwave's clinical data from its SURF trial shows that its high frequency therapy is merely "noninferior" to its low frequency therapy. D.I. 24, Ex. 18 at 4, 7. Therefore, by enjoining Stimwave from selling and programming its SCS systems at high frequencies, patients using Stimwave's SCS systems will still be able to receive treatment of an equivalent quality, albeit at frequencies below 3 kHz.

Third, for those patients that desire high frequency, paresthesia-free therapy, they will have access to Nevro's products. Dr. Caraway testified that he is unaware of any patients or category of patients that cannot be treated with Nevro's SCS system but could be treated with Stimwave's SCS system. Tr. 124:7-16, 133:10-134:3.

E. Bond

A court may issue a preliminary injunction "only if the movant gives security in an amount the court considers proper to pay the costs and damages sustained by any party found to have been wrongfully enjoined or restrained." FED. R. CIV. P. 65(c). Stimwave argues that an appropriate bond amount is $5.5 million. D.I. 142 at 1. Nevro does not oppose a $5.5 million bond. D.I. 145 at 1. Accordingly, I will require Nevro to post a bond in that amount.

III. CONCLUSION

For the reasons stated above, I will grant in part and deny in part Nevro's motion for preliminary injunction (D.I. 18). I will grant the motion insofar as it seeks to enjoin Stimwave from infringing claims 24 and 28 of the #222 patent. I will otherwise deny the motion.

The Court will issue an order consistent with this Memorandum Opinion.

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

NEVRO CORP.,	:	
	:	
Plaintiff,	:	
	:	
v.	:	Civil Action No. 19-325-CFC
	:	
STIMWAVE TECHNOLOGIES, INC.,	:	
	:	
	:	
Defendant.	:	

ORDER

At Wilmington this Twenty-fourth day of July 2019:

IT IS HEREBY ORDERED, for the reasons set for in the Memorandum Opinion issued this day, that

1. Plaintiff Nevro's Motion for Preliminary Injunction (D.I. 18) is **GRANTED IN PART AND DENIED IN PART.**

2. Defendant Stimwave Technologies, Inc. ("Stimwave"), its officers, employees, agents, servants, and attorneys, and other persons and entities in active concert or participation with them, including Stimwave sales and clinical representatives, distributors and their sales and clinical representatives, and individuals receiving training or material aid from Stimwave, who receive actual notice of this Order

are preliminarily restrained and enjoined in the United States from infringing or inducing the infringement of claims 24 and 28 of U.S. Patent No. 8,874,222 by programming Stimwave's SCS systems to deliver its recently introduced high-frequency, paresthesia-free SCS therapy, or any other SCS therapy that is not more than colorably different from it. This Order does not restrain or enjoin Stimwave from providing follow-up care and programming for patients who were already programmed with such high frequency, paresthesia-free therapy before the date of this Order.

3. Stimwave is also ordered to provide copies of this Order no later than Tuesday, July 30, 2019 to its officers, employees, agents, servants, and attorneys, and other persons and entities in active concert or participation with them, including Stimwave sales and clinical representatives, distributors and their sales and clinical representatives, and individuals receiving training and material aid from Stimwave.

4. Pursuant to Federal Rule of Civil Procedure 65(c) and the parties' agreement, *see* D.I. 142, D.I. 145, Plaintiff shall post security in the amount of $5.5 million.

5. The parties shall submit a joint status report by Wednesday, July 31, 2019. That status report shall address, in addition to anything else the parties wish to raise, (a) whether the trial date should be accelerated; (b) how long the parties are likely to need for their trial presentations; and (c) whether any discovery disputes remain ripe and require judicial attention.

6. This Order shall remain in effect until further order of the Court.

COLM F. CONNOLLY,
UNITED STATES DISTRICT JUDGE

US008874222B2

(12) **United States Patent**
Alataris et al.

(10) **Patent No.: US 8,874,222 B2**
(45) **Date of Patent: *Oct. 28, 2014**

(54) **SELECTIVE HIGH FREQUENCY SPINAL CORD MODULATION FOR INHIBITING PAIN WITH REDUCED SIDE EFFECTS, AND ASSOCIATED SYSTEMS AND METHODS**

(71) Applicant: **Nevro Corporation**, Menlo Park, CA (US)

(72) Inventors: **Konstantinos Alataris**, Belmont, CA (US); **Andre B. Walker**, Monte Sereno, CA (US); **Jon Parker**, San Jose, CA (US); **Yougandh Chitre**, Santa Clara, CA (US); **Sangsoo Wesley Park**, San Jose, CA (US); **James R. Thacker**, Homer, AK (US)

(73) Assignee: **Nevro Corporation**, Menlo Park, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **14/164,100**

(22) Filed: **Jan. 24, 2014**

(65) **Prior Publication Data**

US 2014/0142659 A1 May 22, 2014

Related U.S. Application Data

(63) Continuation of application No. 12/765,747, filed on Apr. 22, 2010.

(60) Provisional application No. 61/176,868, filed on May 8, 2009, provisional application No. 61/171,790, filed on Apr. 22, 2009.

(51) **Int. Cl.**

A61N 1/18	(2006.01)
A61N 1/06	(2006.01)
A61N 1/05	(2006.01)
A61N 1/36	(2006.01)
A61N 1/372	(2006.01)

(52) **U.S. Cl.**

CPC ***A61N 1/06*** (2013.01); ***A61N 1/0553*** (2013.01); ***A61N 1/36171*** (2013.01); ***A61N 1/0551*** (2013.01); ***A61N 1/37264*** (2013.01); ***A61N 1/37247*** (2013.01); ***A61N 1/3605*** (2013.01); ***A61N 1/36021*** (2013.01); ***A61N 1/36071*** (2013.01)

USPC **607/46**; 607/117

(58) **Field of Classification Search**

CPC A61N 1/05; A61N 1/0551; A61N 1/06; A61N 1/36021; A61N 1/3605; A61N 1/36071; A61N 2001/34

USPC 607/2, 46, 115–117

See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

1,597,061 A 8/1926 Cultra
3,195,540 A 7/1965 Waller

(Continued)

FOREIGN PATENT DOCUMENTS

EP 1181947 A2 2/2002
GB 2449546 A 11/2008

(Continued)

OTHER PUBLICATIONS

U.S. Appl. No. 13/831,300, filed Mar. 14, 2013, Alataris et al.

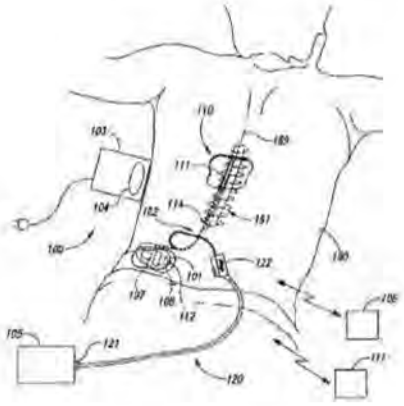
(Continued)

Primary Examiner — Carl H Layno
Assistant Examiner — Eugene Wu
(74) *Attorney, Agent, or Firm* — Perkins Coie LLP

(57) **ABSTRACT**

Selective high-frequency spinal cord modulation for inhibiting pain with reduced side effects and associated systems and methods are disclosed. In particular embodiments, high-frequency modulation in the range of from about 1.5 KHz to about 50 KHz may be applied to the patient's spinal cord region to address low back pain without creating unwanted sensory and/or motor side effects. In other embodiments, modulation in accordance with similar parameters can be applied to other spinal or peripheral locations to address other indications.

89 Claims, 15 Drawing Sheets



(56) **References Cited**

U.S. PATENT DOCUMENTS

3,817,254 A 6/1974 Maurer
3,822,708 A 7/1974 Zilber
3,893,463 A 7/1975 Williams
4,014,347 A 3/1977 Halleck et al.
4,023,574 A 5/1977 Nemec
4,055,190 A 10/1977 Tany et al.
4,414,986 A 11/1983 Dickhudt et al.
4,535,777 A 8/1985 Castel
4,541,432 A 9/1985 Molina-Negro et al.
4,608,985 A 9/1986 Crish et al.
4,649,935 A 3/1987 Charmillot et al.
4,841,973 A 6/1989 Stecker
RE33,420 E 11/1990 Sussman et al.
5,002,053 A 3/1991 Garcia-Rill
5,335,657 A 8/1994 Terry, Jr. et al.
5,354,320 A 10/1994 Schaldach et al.
5,514,175 A 5/1996 Kim et al.
5,562,717 A 10/1996 Tippey et al.
5,643,330 A 7/1997 Holsheimer et al.
5,716,377 A 2/1998 Rise et al.
5,776,170 A 7/1998 MacDonald et al.
5,830,151 A 11/1998 Hadzic et al.
5,853,373 A 12/1998 Griffith et al.
5,893,883 A 4/1999 Torgerson et al.
5,983,141 A 11/1999 Sluijter et al.
5,995,872 A 11/1999 Bourgeois
6,002,964 A 12/1999 Feler et al.
6,014,588 A 1/2000 Fitz
6,027,456 A 2/2000 Feler et al.
6,161,044 A 12/2000 Silverstone
6,167,311 A 12/2000 Rezai
6,176,242 B1 1/2001 Rise
6,233,488 B1 5/2001 Hess
6,238,423 B1 5/2001 Bardy
6,246,912 B1 6/2001 Sluijter et al.
6,341,236 B1 1/2002 Osorio et al.
6,356,786 B1 3/2002 Rezai et al.
6,405,079 B1 6/2002 Ansarinia
6,421,566 B1 7/2002 Holsheimer
6,440,090 B1 8/2002 Schallhorn
6,505,078 B1 1/2003 King et al.
6,510,347 B2 1/2003 Borkan
6,516,227 B1 2/2003 Meadows et al.
6,571,127 B1 5/2003 Ben-Haim et al.
6,584,358 B2 6/2003 Carter et al.
6,609,030 B1 8/2003 Rezai et al.
6,622,048 B1 9/2003 Mann et al.
6,721,603 B2 4/2004 Zabara et al.
6,795,737 B2 9/2004 Gielen et al.
6,871,090 B1 3/2005 He et al.
6,885,888 B2 4/2005 Rezai
6,907,295 B2 6/2005 Gross et al.
6,923,784 B2 8/2005 Stein
6,928,230 B2 8/2005 Squibbs
6,928,320 B2 8/2005 King
6,950,707 B2 9/2005 Whitehurst
6,968,237 B2 11/2005 Doan et al.
6,990,376 B2 1/2006 Tanagho et al.
7,024,246 B2 4/2006 Acosta et al.
7,047,079 B2 5/2006 Erickson
7,082,333 B1 7/2006 Bauhahn et al.
7,117,034 B2 10/2006 Kronberg
7,146,224 B2 12/2006 King
7,149,574 B2 12/2006 Yun et al.
7,167,750 B2 1/2007 Knudson et al.
7,180,760 B2 2/2007 Varrichio et al.
7,212,865 B2 5/2007 Cory
7,236,822 B2 6/2007 Dobak, III
7,239,912 B2 7/2007 Dobak, III
7,252,090 B2 8/2007 Goetz
7,260,436 B2 8/2007 Kilgore et al.
7,266,412 B2 9/2007 Stypulkowski
7,288,062 B2 10/2007 Spiegel
7,313,440 B2 12/2007 Miesel
7,324,852 B2 1/2008 Barolat et al.
7,326,181 B2 2/2008 Katims
7,333,857 B2 2/2008 Campbell
7,337,005 B2 2/2008 Kim et al.
7,346,398 B2 3/2008 Gross et al.
7,349,743 B2 3/2008 Tadlock
7,363,076 B2 4/2008 Yun et al.
7,389,145 B2 6/2008 Kilgore et al.
7,393,351 B2 7/2008 Woloszko et al.
7,493,172 B2 2/2009 Whitehurst et al.
7,502,652 B2 3/2009 Gaunt et al.
7,580,753 B2 8/2009 Kim et al.
7,599,737 B2 10/2009 Yomtov et al.
7,676,269 B2 3/2010 Yun et al.
7,689,276 B2 3/2010 Dobak
7,689,289 B2 3/2010 King
7,734,340 B2 6/2010 De Ridder
7,742,810 B2 6/2010 Moffitt et al.
7,761,170 B2 7/2010 Kaplan et al.
7,778,704 B2 8/2010 Rezai
7,813,803 B2 10/2010 Heruth et al.
7,826,901 B2 11/2010 Lee et al.
7,860,570 B2 12/2010 Whitehurst et al.
7,877,136 B1 1/2011 Moffitt et al.
7,890,176 B2 2/2011 Jaax et al.
7,933,654 B2 4/2011 Merfeld et al.
7,937,145 B2 5/2011 Dobak
8,010,198 B2 8/2011 Libbus et al.
8,027,718 B2 9/2011 Spinner et al.
8,060,208 B2 11/2011 Kilgore et al.
8,170,675 B2 5/2012 Alataris et al.
8,209,021 B2 6/2012 Alataris et al.
8,209,028 B2 6/2012 Skelton et al.
8,224,453 B2 7/2012 De Ridder
8,280,515 B2 10/2012 Greenspan
8,355,792 B2 1/2013 Alataris et al.
8,359,102 B2 1/2013 Alataris et al.
8,359,103 B2 1/2013 Alataris et al.
2,622,601 A1 3/2013 Alataris et al.
8,396,559 B2 3/2013 Alataris et al.
8,423,147 B2 4/2013 Alataris et al.
8,428,748 B2 4/2013 Alataris et al.
2002/0055779 A1 5/2002 Andrews
2002/0128700 A1 9/2002 Cross
2003/0120323 A1 6/2003 Meadows et al.
2004/0015202 A1 1/2004 Chandler et al.
2004/0034394 A1 2/2004 Woods et al.
2004/0039425 A1 2/2004 Greenwood-Van Meerveld
2004/0073273 A1 4/2004 Gluckman et al.
2004/0162590 A1 8/2004 Whitehurst et al.
2004/0167584 A1 8/2004 Carroll et al.
2004/0210270 A1 10/2004 Erickson
2005/0033381 A1 2/2005 Carter et al.
2005/0038489 A1 2/2005 Grill
2005/0060001 A1 3/2005 Singhal et al.
2005/0113882 A1 5/2005 Cameron et al.
2005/0119713 A1 6/2005 Whitehurst et al.
2005/0143789 A1 6/2005 Whitehurst et al.
2005/0153885 A1 7/2005 Yun et al.
2005/0246006 A1 11/2005 Daniels
2006/0004422 A1 1/2006 De Ridder
2006/0030895 A1 2/2006 Simon et al.
2006/0041285 A1 2/2006 Johnson
2006/0074456 A1 4/2006 Pyles et al.
2006/0095088 A1 5/2006 De Ridder
2006/0100671 A1 5/2006 Ridder
2006/0161219 A1 7/2006 Mock et al.
2006/0161235 A1 7/2006 King
2006/0190048 A1 8/2006 Gerber
2006/0229687 A1 10/2006 Goetz et al.
2006/0253182 A1 11/2006 King
2007/0021803 A1 1/2007 Deem et al.
2007/0032827 A1 2/2007 Katims
2007/0039625 A1 2/2007 Heruth et al.
2007/0049991 A1 3/2007 Klostermann et al.
2007/0060954 A1 3/2007 Cameron et al.
2007/0066997 A1 3/2007 He et al.
2007/0073353 A1 3/2007 Rooney et al.
2007/0073354 A1 3/2007 Knudson et al.
2007/0106337 A1 5/2007 Errico et al.

(56) **References Cited**

U.S. PATENT DOCUMENTS

2007/0150034	A1	6/2007	Rooney et al.
2007/0156183	A1	7/2007	Rhodes
2007/0179559	A1	8/2007	Giftakis et al.
2007/0179579	A1	8/2007	Feler et al.
2007/0239226	A1	10/2007	Overstreet
2007/0244522	A1	10/2007	Overstreet
2007/0299482	A1	12/2007	Littlewood et al.
2008/0033511	A1	2/2008	Dobak
2008/0103570	A1	5/2008	Gerber
2008/0167697	A1	7/2008	Johnson
2008/0183259	A1	7/2008	Bly et al.
2008/0234791	A1	9/2008	Arle et al.
2009/0036945	A1	2/2009	Chancellor et al.
2009/0054962	A1	2/2009	Lefler et al.
2009/0132010	A1	5/2009	Kronberg
2009/0157141	A1	6/2009	Chiao et al.
2009/0157149	A1	6/2009	Wahlgren et al.
2009/0198306	A1	8/2009	Goetz et al.
2009/0204173	A1	8/2009	Fang et al.
2009/0204192	A1	8/2009	Carlton et al.
2009/0281595	A1	11/2009	King et al.
2009/0287274	A1	11/2009	De Ridder
2009/0326611	A1	12/2009	Gillbe
2010/0016929	A1	1/2010	Prochazka
2010/0036454	A1	2/2010	Bennett et al.
2010/0094375	A1	4/2010	Donders et al.
2010/0125313	A1	5/2010	Lee et al.
2010/0137938	A1	6/2010	Kishawi et al.
2010/0191307	A1	7/2010	Fang et al.
2010/0241190	A1	9/2010	Kilgore et al.
2010/0249875	A1	9/2010	Kishawi et al.
2010/0274312	A1	10/2010	Alataris et al.
2010/0274314	A1	10/2010	Alataris et al.
2010/0274315	A1	10/2010	Alataris et al.
2010/0274316	A1	10/2010	Alataris et al.
2010/0274317	A1	10/2010	Parker et al.
2010/0274318	A1	10/2010	Walker et al.
2010/0274320	A1	10/2010	Torgerson
2010/0274326	A1	10/2010	Chitre et al.
2010/0324630	A1	12/2010	Lee et al.
2010/0331916	A1	12/2010	Parramon et al.
2011/0009919	A1	1/2011	Carbunaru et al.
2011/0009923	A1	1/2011	Lee
2011/0022114	A1	1/2011	Navarro
2011/0184486	A1	7/2011	De Ridder
2011/0201977	A1	8/2011	Tass
2011/0276107	A1	11/2011	Simon et al.
2011/0282412	A1	11/2011	Glukhovsky et al.
2012/0016437	A1	1/2012	Alataris et al.
2012/0016438	A1	1/2012	Alataris et al.
2012/0016439	A1	1/2012	Alataris et al.
2012/0089200	A1	4/2012	Ranu et al.
2012/0203304	A1	8/2012	Alataris et al.
2012/0209349	A1	8/2012	Alataris et al.
2012/0277833	A1	11/2012	Gerber et al.
2012/0283797	A1	11/2012	De Ridder
2013/0006325	A1	1/2013	Woods et al.
2013/0023951	A1	1/2013	Greenspan
2013/0041425	A1	2/2013	Fang et al.
2013/0066411	A1	3/2013	Thacker et al.
2013/0096643	A1	4/2013	Fang et al.
2013/0096644	A1	4/2013	Fang et al.
2013/0110196	A1	5/2013	Alataris et al.
2013/0123879	A1	5/2013	Alataris et al.
2013/0172955	A1	7/2013	Alataris
2013/0204173	A1	8/2013	Kelly et al.
2013/0204320	A1	8/2013	Alataris et al.
2013/0204321	A1	8/2013	Alataris et al.
2013/0204322	A1	8/2013	Alataris et al.
2013/0204323	A1	8/2013	Thacker et al.
2013/0204324	A1	8/2013	Thacker
2013/0204338	A1	8/2013	Alataris et al.
2013/0211487	A1	8/2013	Fang et al.
2013/0261696	A1	10/2013	Thacker et al.
2014/0031896	A1	1/2014	Alataris et al.

FOREIGN PATENT DOCUMENTS

JP	2007528774	A	10/2007
WO	WO-02065896	A2	8/2002
WO	WO-02092165	A1	11/2002
WO	WO-2007082382	A1	7/2007
WO	WO-2007117232	A1	10/2007
WO	WO-2008039982	A2	4/2008
WO	WO-2008045434	A2	4/2008
WO	WO-2008106174	A1	9/2008
WO	WO-2008121891	A1	10/2008
WO	WO-2008153726	A2	12/2008
WO	WO-2009018518	A1	2/2009
WO	WO-2011014570	A1	2/2011

OTHER PUBLICATIONS

U.S. Appl. No. 13/831,381, filed Mar. 14, 2013, Alataris et al.

U.S. Appl. No. 13/831,539, filed Mar. 14, 2013, Alataris et al.

Alo et al., "New Trends in Neuromodulation for the Management of Neuropathic Pain," Neurosurgery, vol. 50, No. 4, Apr. 2002, 15 pages.

Barolat et al., "Multifactorial Analysis of Epidural Spinal Cord Stimulation," Sterotactic and Functional Neurosurgery, 1991; 56: 77-103.

Bhadra et al., "High Frequency electrical conduction block of the pudendal ; nerve," Journal of Neural Engineering—Institute of Physics Publishing, 2006, 8 pages.

Bhadra MD, Niloy et al., "High-Frequency Electrical Conduction Block of Mammalian Peripheral Motor Nerve," Muscle and Nerve, Dec. 2005, 9 pages.

Boger et al., "Bladder Voiding by Combined High Frequency Electrical Pudendal Nerve Block and Sacral Root Stimulation," Neurourology and Urodynamics, 27, 2008, 5 pages.

Bowman and McNeal, Response of Single Alpha Motoneurons to High-Frequency Pulse Trains, Appl. Neurophysiol. 49, p. 121-138, 1986, 10 pages.

Burton, Charles, "Dorsal Column Stimulation: Optimization of Application,"; Surgical Neurology, vol. 4, No. 1, Jul. 1975, 10 pages.

Cuellar et al., "Effect of High Frequency Alternating Current on Spinal Afferent Nociceptive Transmission," Neuromodulation: Technology at the Neural Interface, ; 2012, 10 pages.

DeRidder et al., "Are Paresthesias necessary for pain suppression in SCS—Burst Stimulation," BRAIN, Brain Research Center Antwerp of Innovative and Interdisciplinary Neuromodulation, 2010, 27 pages.

DeRidder et al., "Burst Spinal Cord Stimulation: Toward Paresthesia-Free Pain Suppression," www.neurosurgery-online.com, vol. 66, Nos. 5, May 2010, 5 pages.

European Search Report for European Application No. 10160641.6, Applicant: Nevro Corporation, mailed Apr. 12, 2011, 7 pages.

European Search Report, European Application No. EP10160569, Applicant: Nevro Corporation, mailed Jun. 9, 2010, 7 pages.

Grill, Warren et al., "Stimulus Waveforms for Selective Neural Stimulation," IEEE Engineering in Medicine and Biology, Jul./Aug. 1995, pp. 375-385.

Holsheimer—Effectiveness of Spinal Cord Stimulation in the Management of Chronic Pain: Analysis of Technical Drawbacks and Solutions, Neurosurgery, vol. 40, No. 5, May 1997, pp. 990-999.

Hopp et al., "Effect of anodal blockade of myelinated fibers on vagal c-fiber afferents," American Journal Physiological Society, Nov. 1980; 239(5), 9 pages.

Hoppenstein, Reuben, "Electrical Stimulation of the Ventral and Dorsal Columns of the Spinal Cord for Relief of Chronic Intractable Pain: Preliminary Report," Surgical Neurology, vol. 4, No. 1, Jul. 1975, 9 pages.

Huxely et al., "Excitation and Conduction in Nerve: Quantitative Analysis," Science, Sep. 11, 1964; 145: 1154-9.

International Search Report and Written Opinion, International Application ; No. PCT/US10/32124, Applicant: Nevro Corporation, European Patent Office, mailed Jun. 16, 2010, 28 pages.

Jang et al., "Analysis of Failed Spinal Cord Stimulation Trails in the Treatment of Intractable Chronic Pain," J. Korean Neurosurg Soc 43, 2008, 5 pages.

(56) **References Cited**

OTHER PUBLICATIONS

Kilgore et al. "Nerve Conduction Block Utilizing High-Frequency Alternating Current" Medical & Biology Engineering and Computing, 2004, vol. 24, pp. 394-406.

Kilgore et al. "Reversible Nerve Conduction Block Using Kilohertz Frequency Alternating Current," Neuromodulation Technology at the Neural Interface, International Neuromodulation Society, 2013, 13 pages.

Kumar et al., "Spinal Cord Stimulation in Treatment of Chronic Benign Pain: Challenges in Treatment Planning and Present Status, a 22-Year Experience," Neurosurgery, vol. 58, No. 3, Mar. 2006, 16 pages.

Linderoth et al., "Mechanisms of Spinal Cord Stimulation in Painful Syndromes: Role of Animal Models," Pain Medicine, vol. 7, No. S1, 2006, 13 pages.

Linderoth et al., "Physiology of Spinal Cord Stimulation: Review and Update," Neuromodulation, vol. 2, No. 3, 1999, 15 pages.

Mediati, R.D "Mechanisms of Spinal Cord Stimulation," Florence, Oct. 2, 2002, 31 pages.

Melzack, Ronald et al., "Pain Mechanisms: A New Theory," Science, vol. 150, No. 3699, Nov. 19, 1965, 9 pages.

Muller and Hunsperger, "Helvetica Physiologica Acta—Reversible Blockierung der Erregungsleitung im Nerven durch Mittelfrequenz-; Daverstrom," Schwabe & Co. Basel, vol. 25, Fasc. 1, 1967, 4 pages.

North et al., "Failed Back Surgery Syndrome: 5-year Follow-Up after Spinal; Cord Stimulator Implantation," Neurosurgery, Official Journal of the; Congress of Neurological Surgeons, vol. 28, No. 5, May 1991, 9 pages.

North et al., "Spinal Cord Stimulation for Axial Low Back Pain," SPINE, vol. 30, No. 12, 2005, 7 pages.

North et al., "Spinal Cord Stimulation for Chronic, Intractable Pain: Experience over Two Decades," Neurosurgery, vol. 32, No. 2, Mar. 1993, 12 pages.

Oakley, John C., "Spinal Cord Stimulation Mechanisms of Action,"; SPINE vol. 27, No. 22, copyright 2002, 10 pages.

Partial European Search Report, European Application No. EP10160641, Applicant: Nevro Corporation, mailed Aug. 30, 2010, 3 pages.

Perruchoud et al., "Analgesic Efficacy of High-Frequency Spinal Cord Stimulation: A Randomized Double-Blind Placebo-Controlled Study," Neuromodulation: Technology at Neural Interface, International Neuromodulation Society, 2013, 7 pages.

Shealy MD, C. Norman et al., "Electrical Inhibition of Pain by Stimulation of the Dorsal Columns: Preliminary Clinical Report," Anesthesia and Analgesia Current Researches, vol. 446, No. 4, Jul.-Aug. 1967, 3 pages.

Simpson, BA, "Spinal Cord Stimulation in 60 cases of Intractable Pain." Journal of Neurology, Neurosurgery and Psychiatry, 1991; 54 pp. 196-199.

Simpson, BA, "Spinal Cord Stimulation." British Journal of Neurosurgery, Feb. 11, 1997 (1), 5-11, 7 pages.

Solomonow et al., "Control of Muscle Contractile Force through Indirect High-Frequency Stimulation," AM Journal of Physical Medicine, 1983, vol. 62, No. 3, pp. 71-82.

Tanner, J.A., "Reversible blocking of nerve conduction by alternating-current; excitation," Nature, Aug. 18, 1962; 195: 712-3.

Tiede et al., "Novel Spinal Cord Stimulation Parameters ; in Patients with Predominate Back Pain," Neuromodulation: Technology at the Neural Interface, 2013, 6 pages.

Urban et al., "Percutaneous epidural stimulation of the spinal cord for relief ; of pain—Long Term Results," Journal of Neurosurgery, vol. 48, ; Mar. 1978, 7 pages.

Van Butyen et al., "High Frequency Spinal Cord Stimulation for the Treatment of Chronic Back Pain Patients: Results of a Prospective ; Multicenter European Clinical Study," Neuromodulation Technology at the ; Neural Interface, International Neuromodulation Society, 2012, 8 pages.

Van Den Honert et al. "Generation of Unidirectionally Propagated Action Potentials Nerve by Brief Stimuli" Science, vol. 26, pp. 1311-1312.

Van Den Honert, Mortimer JT, "A Technique for Collision Block of Peripheral; Nerve: Frequency Dependence," MP-11 IEEE Trans. Biomed, Eng. 28: 379-382, 1981.

Wolter et al., "Continuous Versus Intermittent Spinal Cord Stimulation: An Analysis of Factors Influencing Clinical Efficacy," Neuromodulation: Technology at Neural Interface, www.neuromodulationjournal.com, 2011, 8 pages.

Woo MY, Campbell B. "Asynchronous Firing and Block of Peripheral Nerve Conduction by 20KC Alternating Current," Los Angeles Neuro Society, Jun. 1964; 87-94, 5 pages.

Zhang et al., "Simulation Analysis of Conduction Block in Myelinated Axons Induced by High-Frequency Biphasic Rectangular Pulses," IEEE Transactions on Biomedical Engineering, vol. 53., No. 7, Jul. 2006, 4 pages.

Bandra et al., Stimulation of High-Frequency Sinusoidal Electrical Block of Mammalian Myelinated Axons, J Comput Neurosco, 22:313-326, 2007.

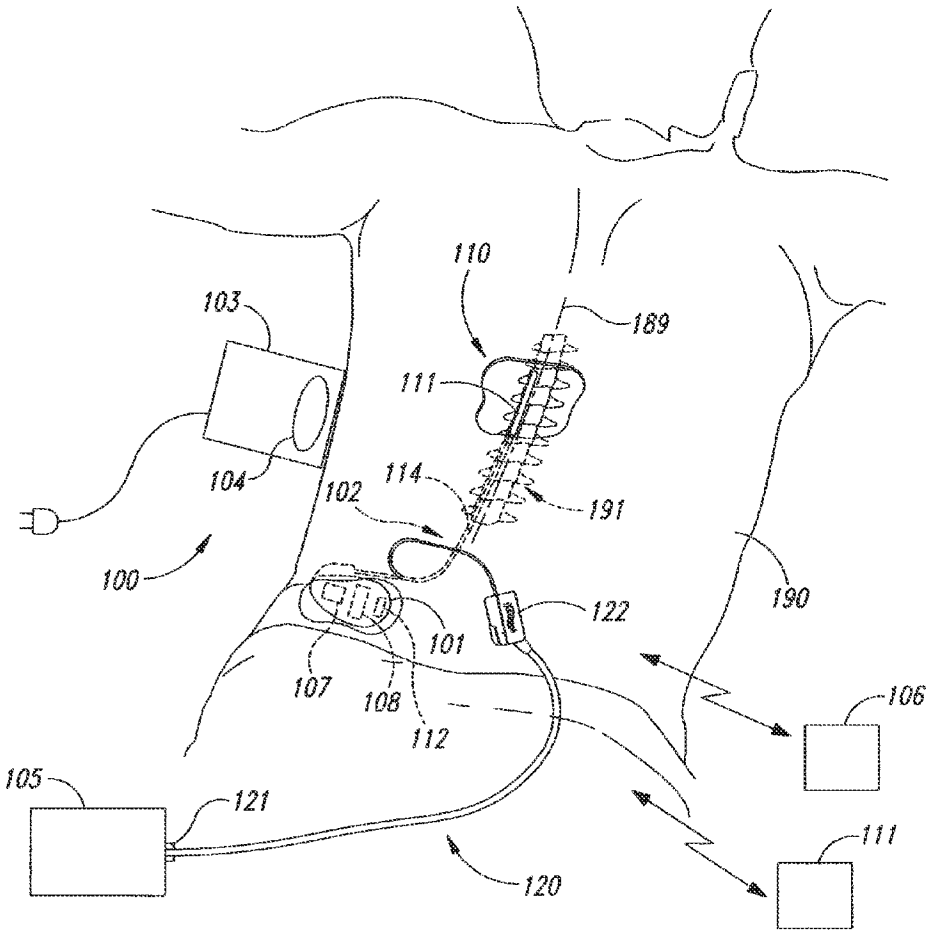

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Fig. 1A

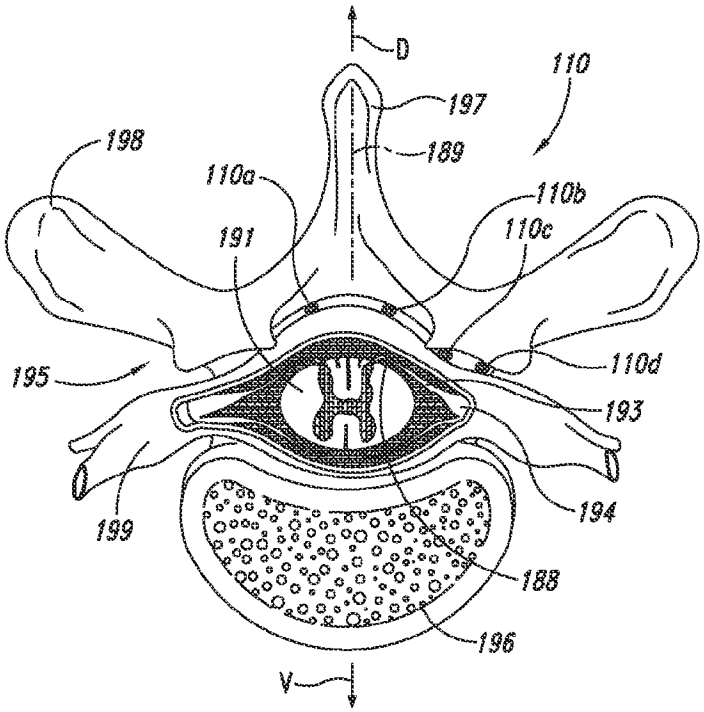
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Fig. 1B

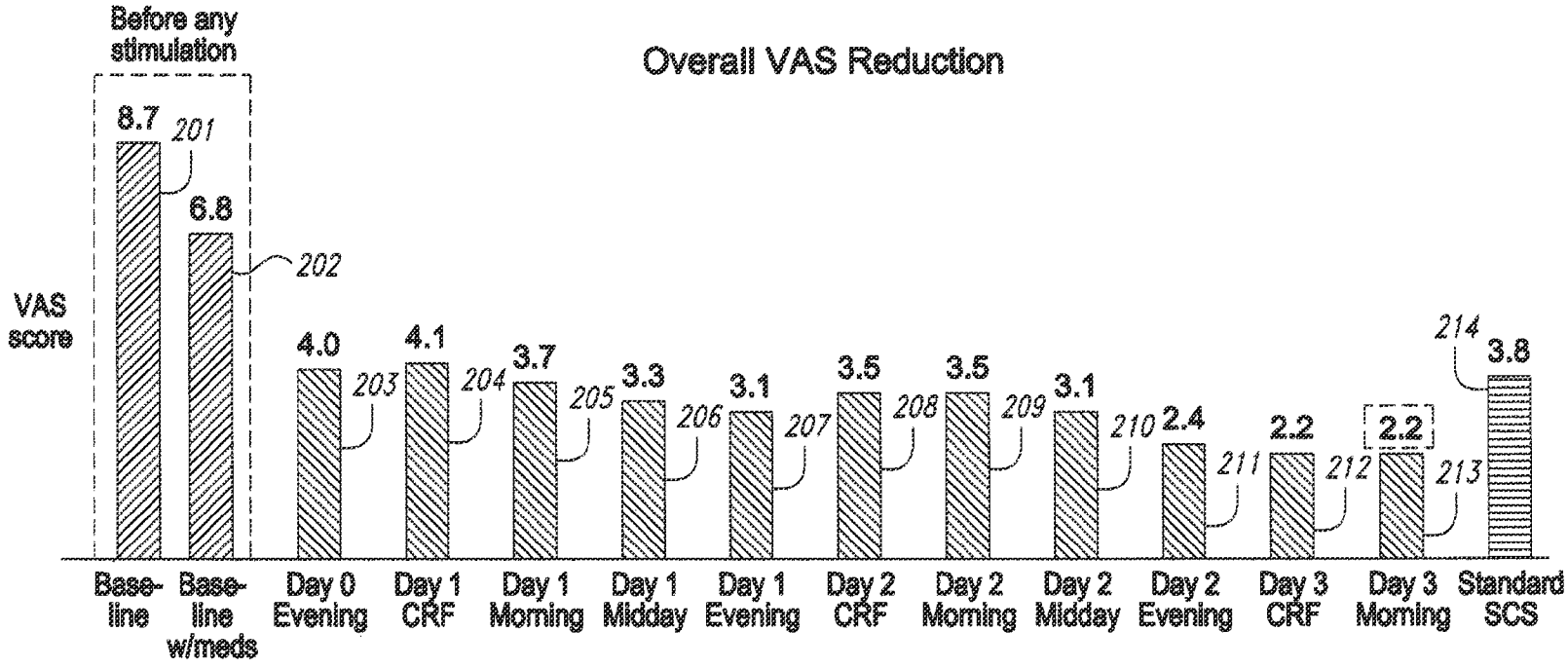
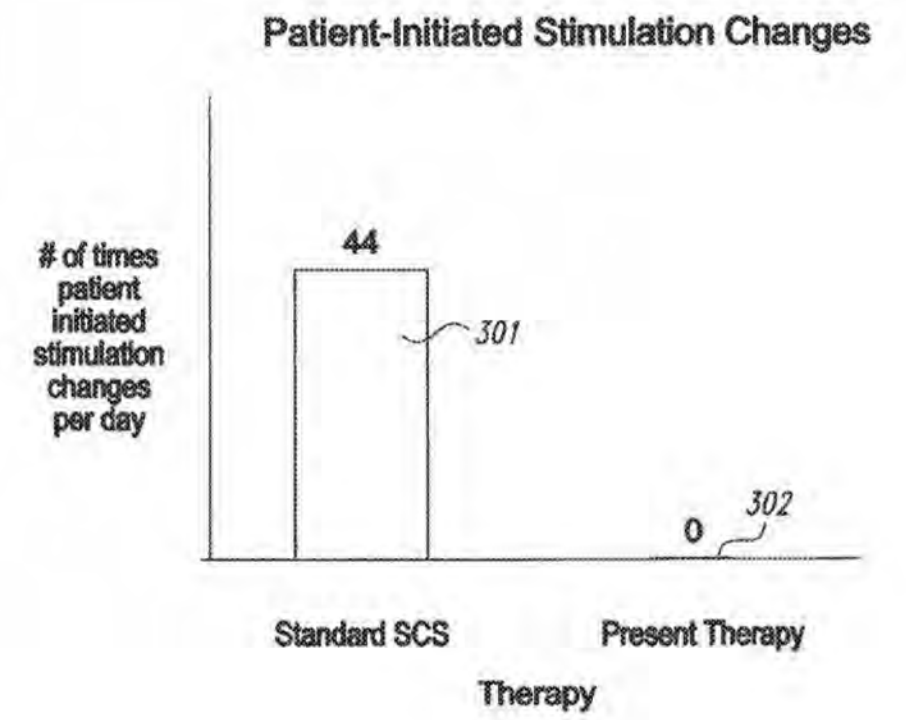

Before any stimulation
Overall VAS Reduction
VAS score
8.7
201
6.8
202
4.0
203
4.1
204
3.7
205
3.3
206
3.1
207
3.5
208
3.5
209
3.1
210
2.4
211
2.2
212
2.2
213
214
3.8
Base-line
Base-line w/meds
Day 0 Evening
Day 1 CRF
Day 1 Morning
Day 1 Midday
Day 1 Evening
Day 2 CRF
Day 2 Morning
Day 2 Midday
Day 2 Evening
Day 3 CRF
Day 3 Morning
Standard SCS

Fig. 2


Patient-Initiated Stimulation Changes
# of times patient initiated stimulation changes per day
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301
0
302
Standard SCS
Present Therapy
Therapy

Fig. 3

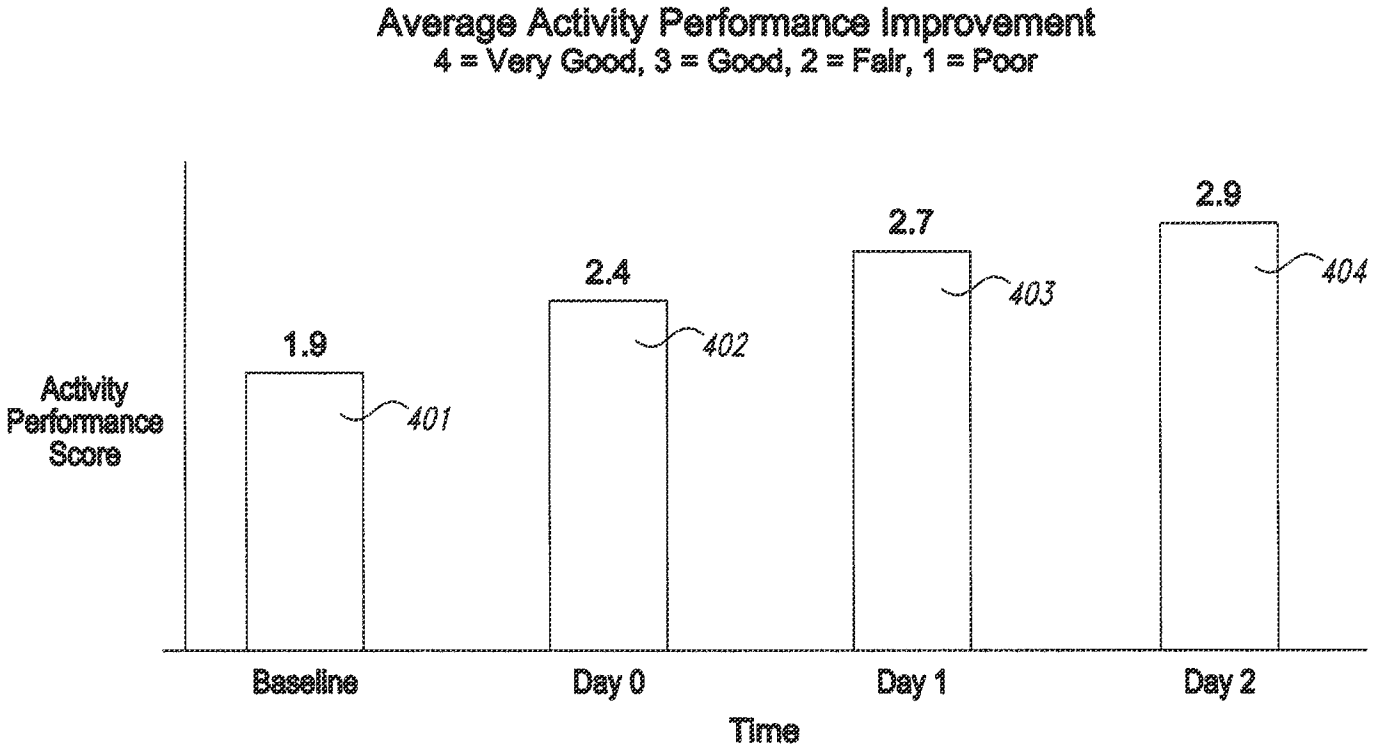
Average Activity Performance Improvement
4 = Very Good, 3 = Good, 2 = Fair, 1 = Poor
Activity Performance Score
1.9
401
2.4
402
2.7
403
2.9
404
Baseline
Day 0
Day 1
Day 2
Time

Fig. 4

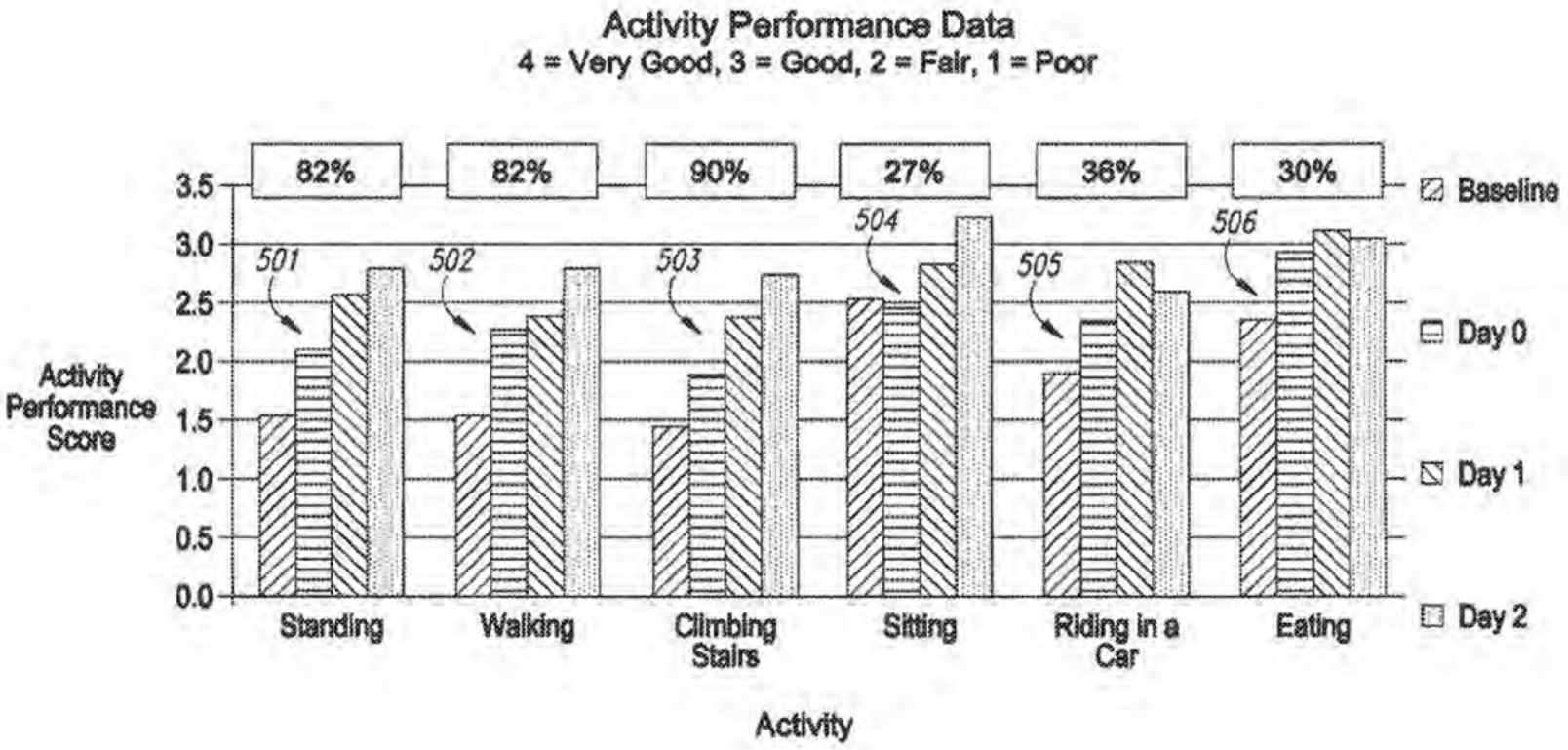
Activity Performance Data
4 = Very Good, 3 = Good, 2 = Fair, 1 = Poor
82%
82%
90%
27%
36%
30%
501
502
503
504
505
506
Baseline
Day 0
Day 1
Day 2
Activity Performance Score
3.5
3.0
2.5
2.0
1.5
1.0
0.5
0.0
Standing
Walking
Climbing Stairs
Sitting
Riding in a Car
Eating
Activity

Fig. 5A

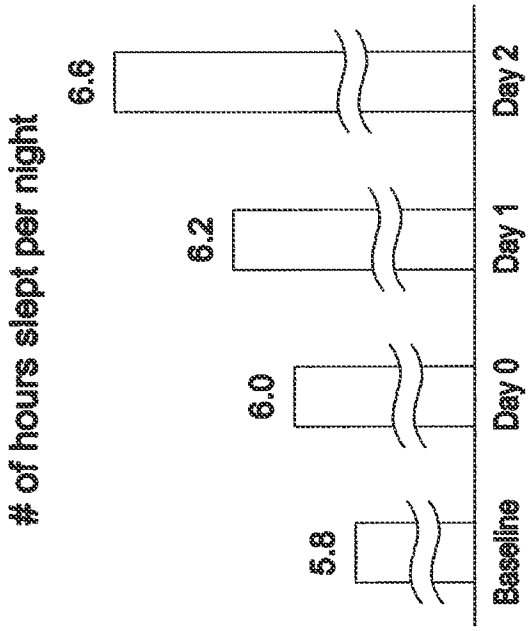
# of hours slept per night
5.8
6.0
6.2
6.6
Baseline
Day 0
Day 1
Day 2

Fig. 5C

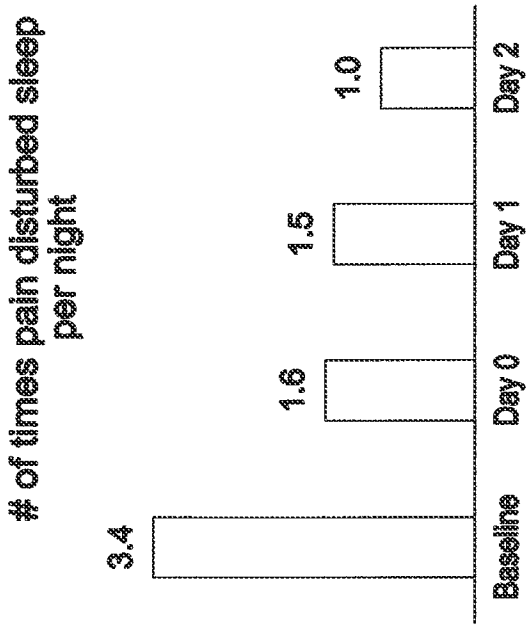
# of times pain disturbed sleep per night
3.4
1.6
1.5
1.0
Baseline
Day 0
Day 1
Day 2

Fig. 5B

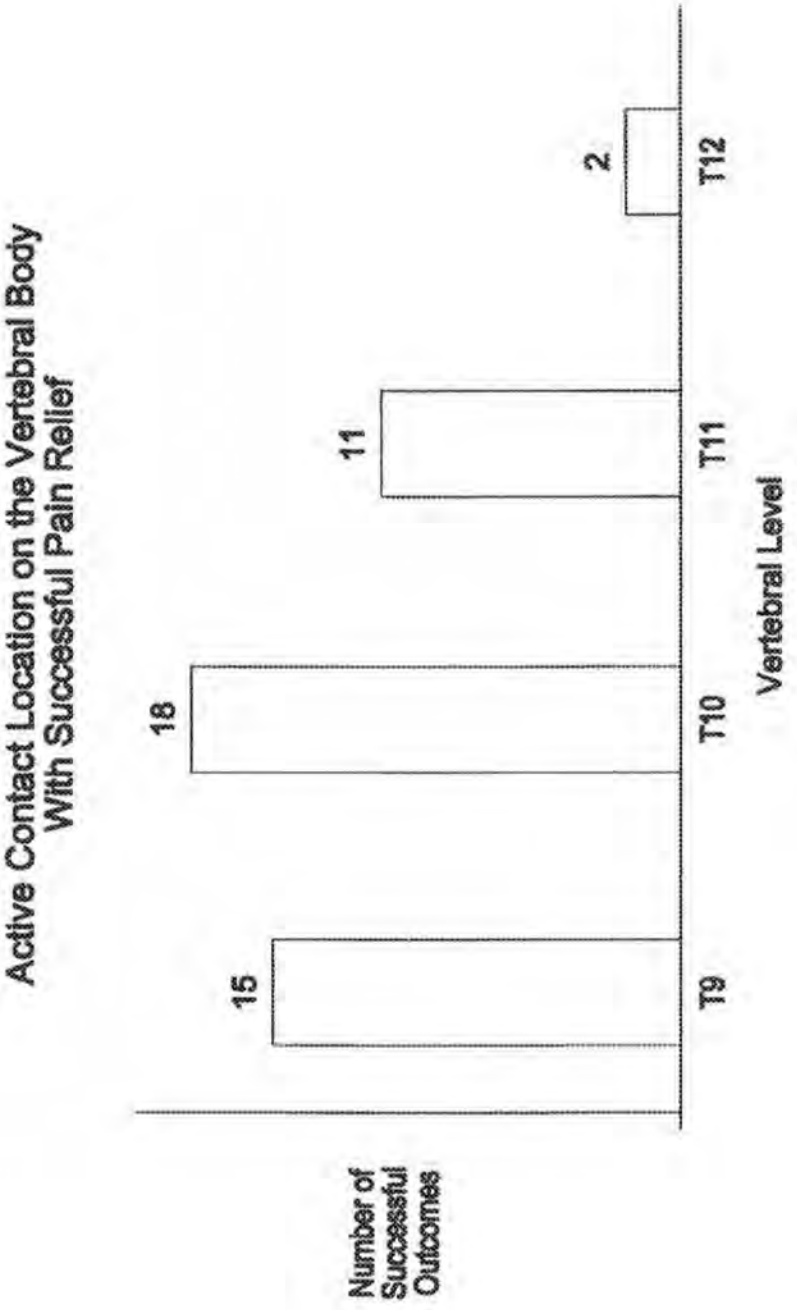
Active Contact Location on the Vertebral Body
With Successful Pain Relief
Number of Successful Outcomes
15
18
11
2
T9
T10
T11
T12
Vertebral Level

Fig. 6A

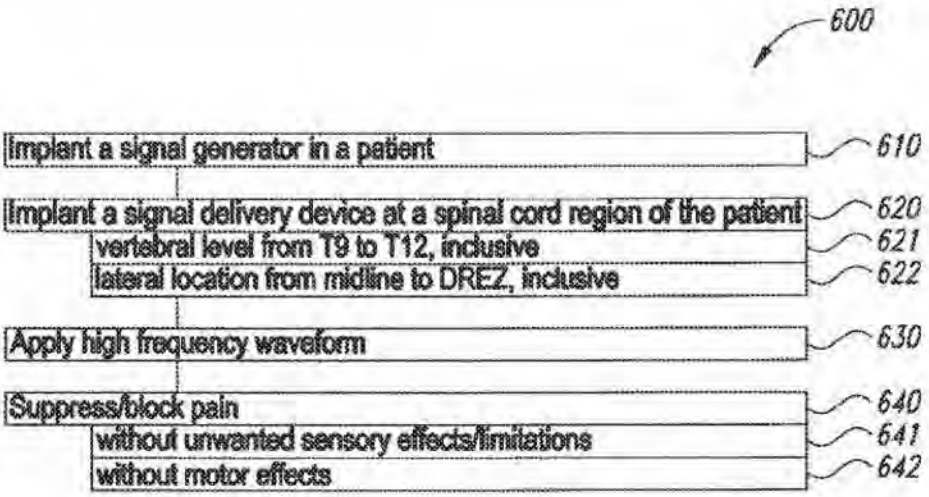
600
Implant a signal generator in a patient
610
Implant a signal delivery device at a spinal cord region of the patient
620
vertebral level from T9 to T12, inclusive
621
lateral location from midline to DREZ, inclusive
622
Apply high frequency waveform
630
Suppress/block pain
640
without unwanted sensory effects/limitations
641
without motor effects
642

Fig. 6B

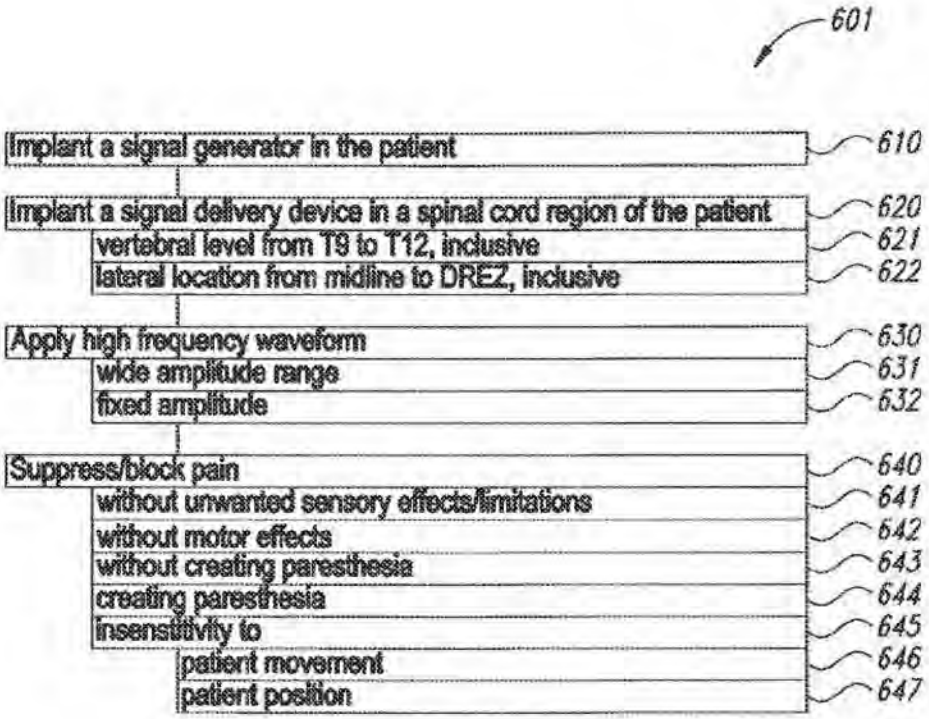
601
Implant a signal generator in the patient
610
Implant a signal delivery device in a spinal cord region of the patient
620
vertebral level from T9 to T12, inclusive
621
lateral location from midline to DREZ, inclusive
622
Apply high frequency waveform
630
wide amplitude range
631
fixed amplitude
632
Suppress/block pain
640
without unwanted sensory effects/limitations
641
without motor effects
642
without creating paresthesia
643
creating paresthesia
644
insensitivity to
645
patient movement
646
patient position
647

Fig. 6C

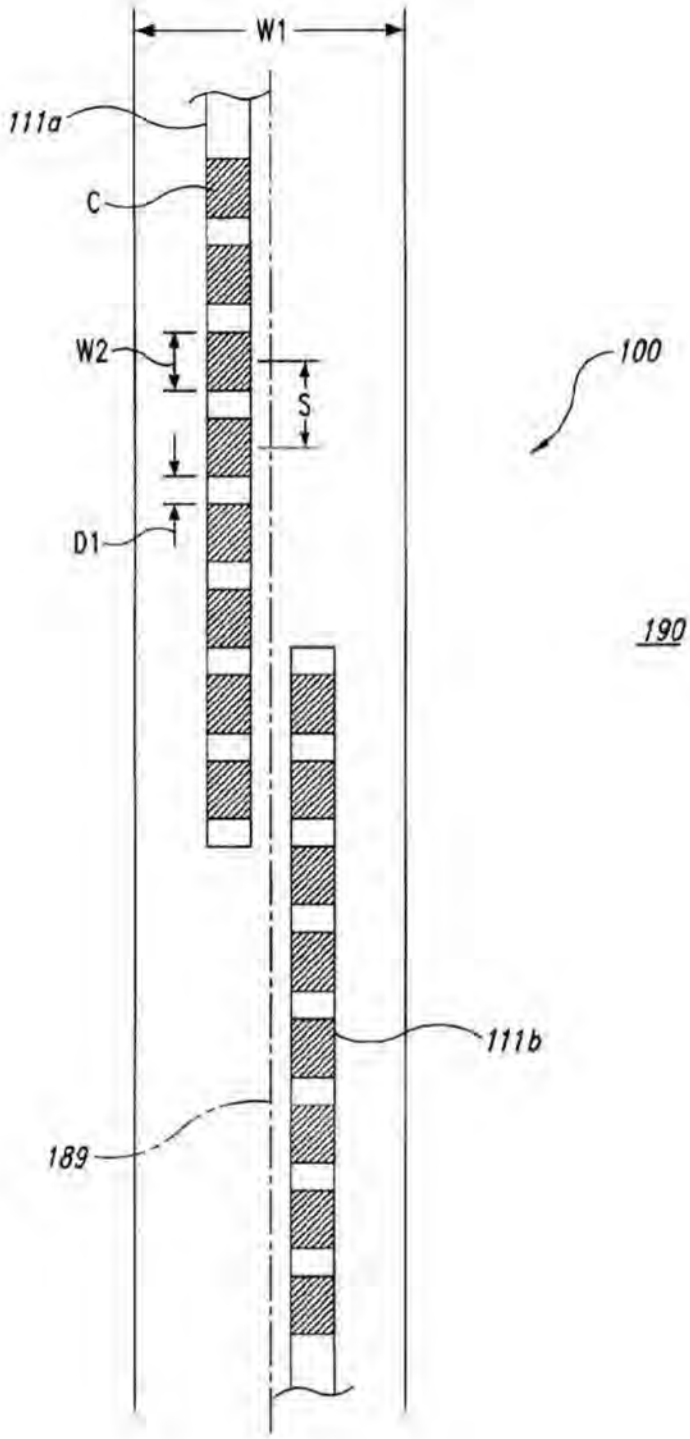

Fig. 7A

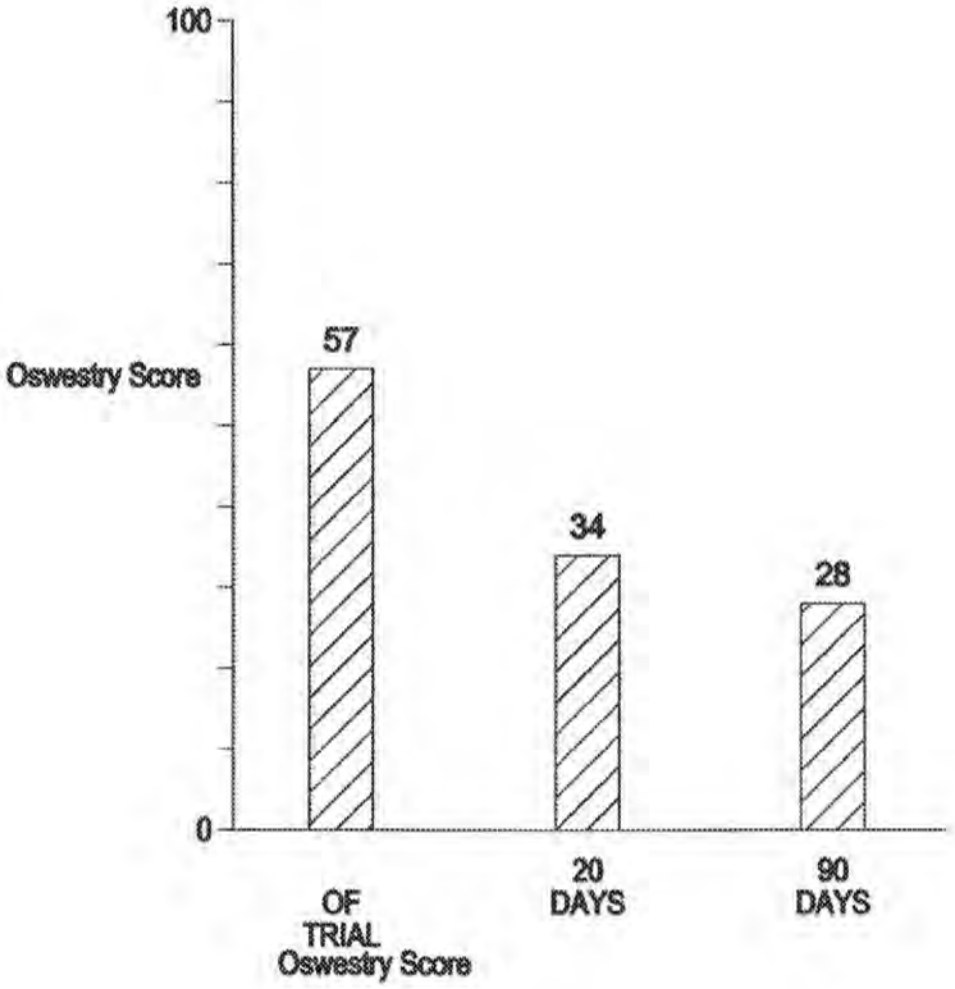
100
0
Oswestry Score
57
34
28
OF TRIAL
20 DAYS
90 DAYS
Oswestry Score

Fig. 7B

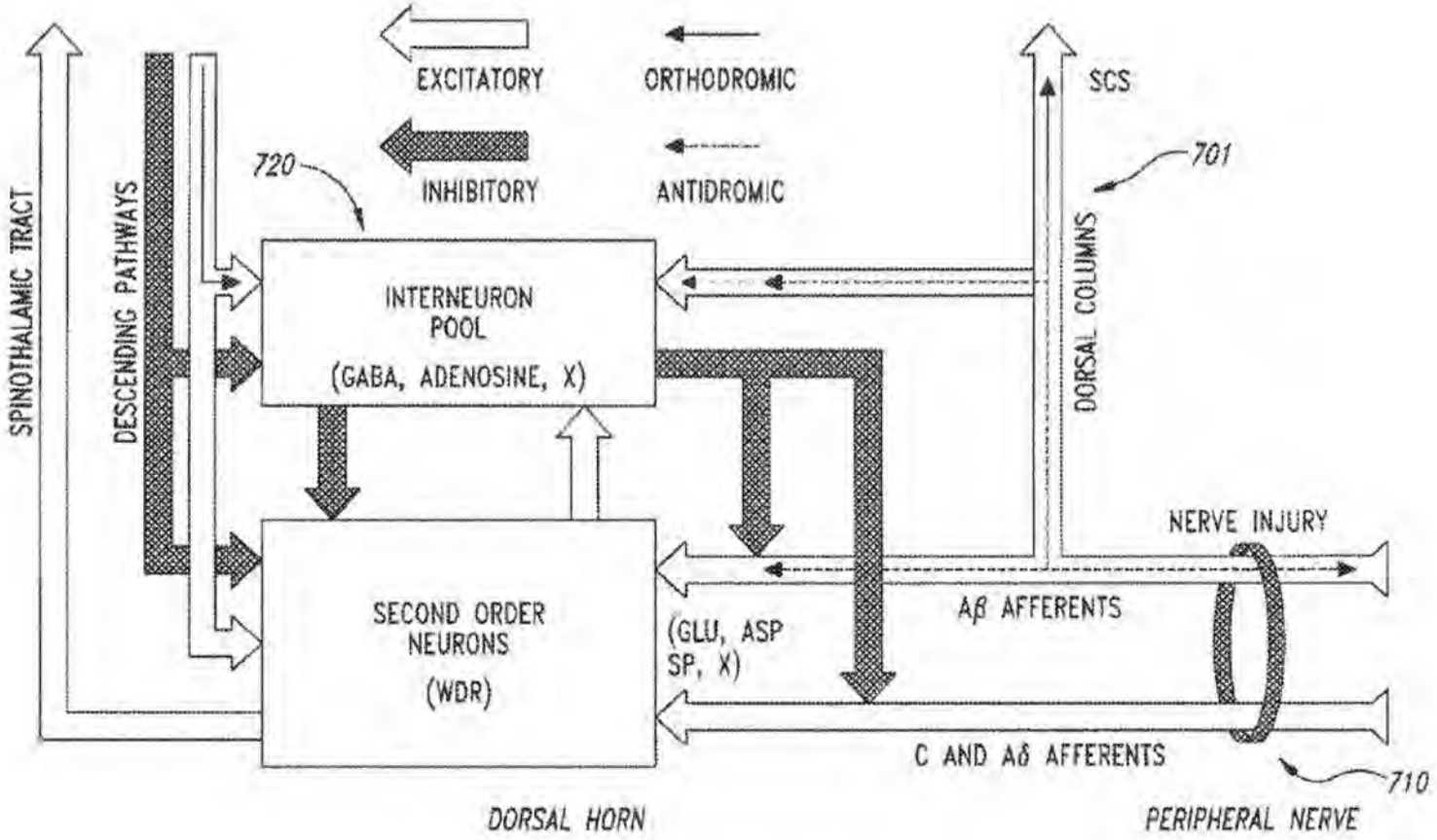
EXCITATORY
ORTHODROMIC
SCS
720
INHIBITORY
ANTIDROMIC
701
SPINOTHALAMIC TRACT
DESCENDING PATHWAYS
INTERNEURON POOL
(GABA, ADENOSINE, X)
DORSAL COLUMNS
NERVE INJURY
SECOND ORDER NEURONS
(WDR)
(GLU, ASP SP, X)
Aβ AFFERENTS
C AND Aδ AFFERENTS
710
DORSAL HORN
PERIPHERAL NERVE

Fig. 8

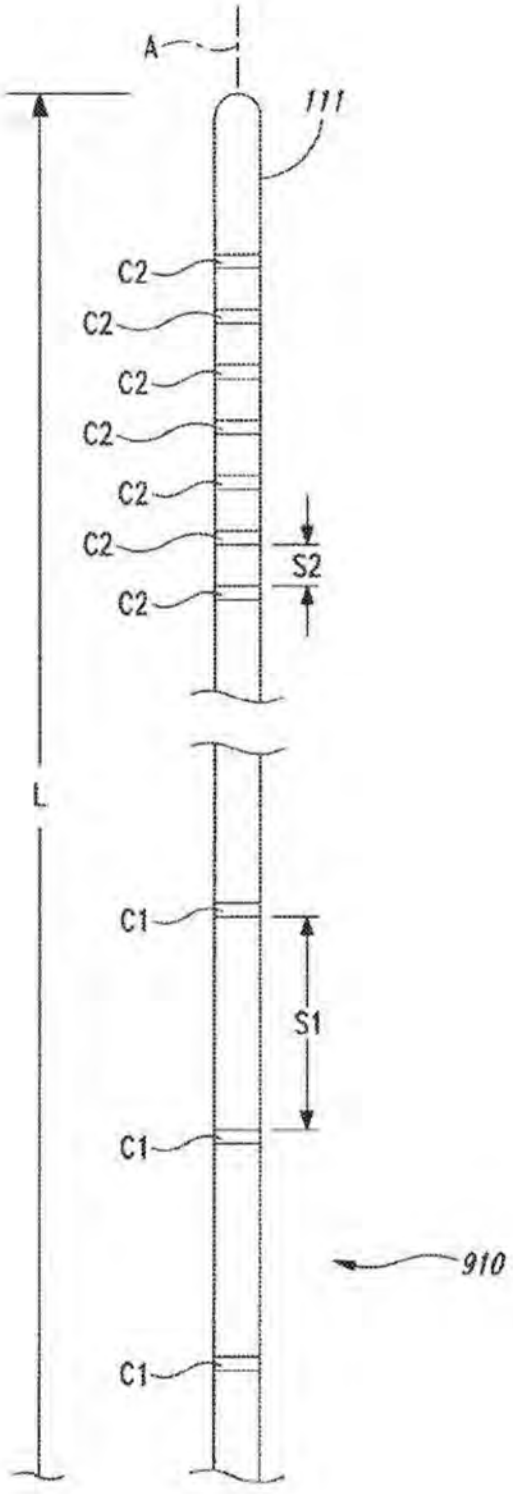

Fig. 9

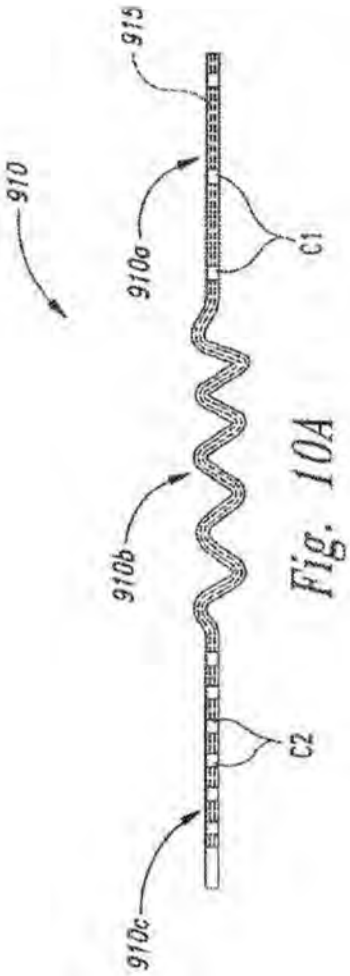

Fig. 10A

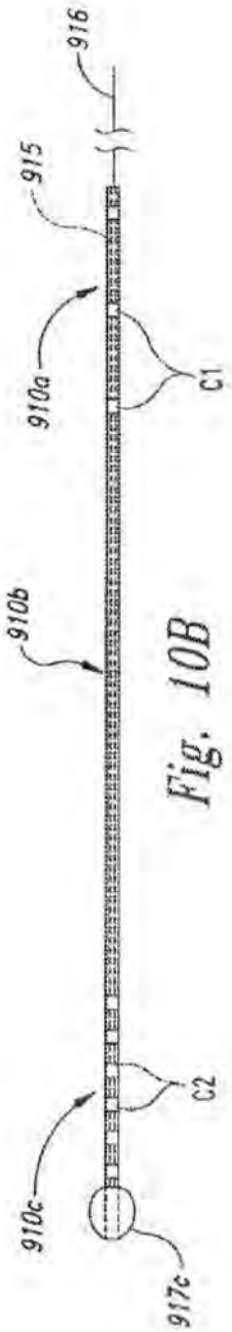

Fig. 10B

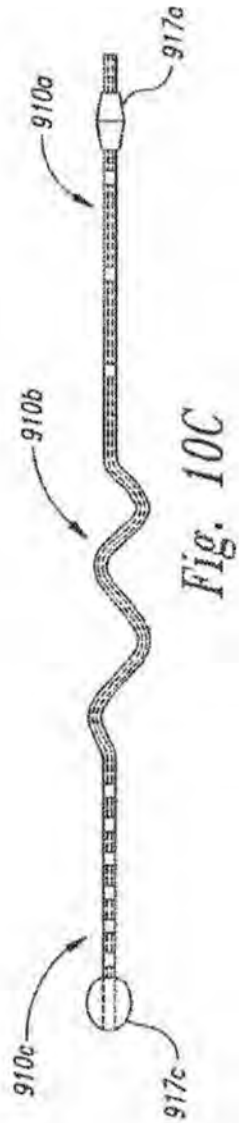

Fig. 10C

Fig. 11A

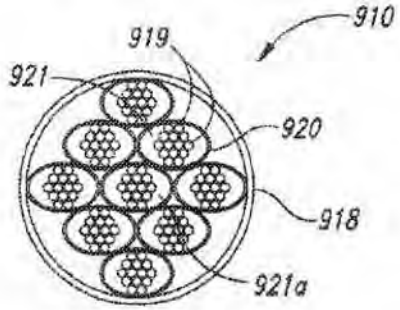

Fig. 11B

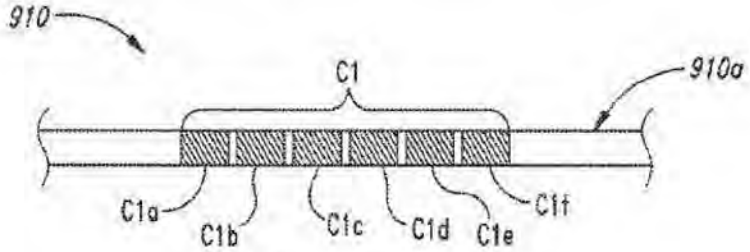

Fig. 11C

SELECTIVE HIGH FREQUENCY SPINAL CORD MODULATION FOR INHIBITING PAIN WITH REDUCED SIDE EFFECTS, AND ASSOCIATED SYSTEMS AND METHODS

CROSS-REFERENCE TO RELATED APPLICATIONS

The present application is a continuation of U.S. patent application Ser. No. 12/765,747, now U.S. Pat. No. 8,712,533, filed Apr. 22, 2010. U.S. patent application Ser. No 12/765,747 claims priority to U.S. Provisional Application No. 61/176,868, filed May 8, 2009 and incorporated herein by reference, and claims priority to U.S. Provisional Application No. 61/171,790, filed Apr. 22,2009, and incorporated herein by reference.

TECHNICAL FIELD

The present disclosure is directed generally to selective high frequency spinal cord modulation for inhibiting pain with reduced side effects, and associated systems and methods.

BACKGROUND

Neurological stimulators have been developed to treat pain, movement disorders, functional disorders, spasticity, cancer, cardiac disorders, and various other medical conditions. Implantable neurological stimulation systems generally have an implantable pulse generator and one or more leads that deliver electrical pulses to neurological tissue or muscle tissue. For example, several neurological stimulation systems for spinal cord stimulation (SCS) have cylindrical leads that include a lead body with a circular cross-sectional shape and one or more conductive rings spaced apart from each other at the distal end of the lead body. The conductive rings operate as individual electrodes and, in many cases, the SCS leads are implanted percutaneously through a large needle inserted into the epidural space, with or without the assistance of a stylet.

Once implanted, the pulse generator applies electrical pulses to the electrodes, which in turn modify the function of the patient's nervous system, such as by altering the patient's responsiveness to sensory stimuli and/or altering the patient's motor-circuit output. In pain treatment, the pulse generator applies electrical pulses to the electrodes, which in turn can generate sensations that mask or otherwise alter the patient's sensation of pain. 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. While this may be the case for many patients, many other patients may report less beneficial effects and/or results. Accordingly, there remains a need for improved techniques and systems for addressing patient pain.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1**A is a partially schematic illustration of an implantable spinal cord modulation system positioned at the spine to deliver therapeutic signals in accordance with several embodiments of the present disclosure.

FIG. **1**B is a partially schematic, cross-sectional illustration of a patient's spine, illustrating representative locations for implanted lead bodies in accordance with embodiments of the disclosure.

FIG. **2** is a bar chart illustrating pain reduction levels for patients over a four day period of a clinical study, during which the patients received therapy in accordance with an embodiment of the disclosure, as compared with baseline levels and levels achieved with conventional spinal cord stimulation devices.

FIG. **3** is a bar chart comparing the number of times patients receiving therapy in accordance with an embodiment of the present disclosure during a clinical study initiated modulation changes, as compared with similar data for patients receiving conventional spinal cord stimulation.

FIG. **4** is a bar chart illustrating activity performance improvements for patients receiving therapy in accordance with an embodiment of the disclosure, obtained during a clinical study.

FIG. **5**A is a bar chart comparing activity performance levels for patients performing a variety of activities, obtained during a clinical study.

FIGS. **5**B and **5**C are bar charts illustrating sleep improvement for patients receiving therapy in accordance with embodiments of the disclosure, obtained during a clinical study.

FIG. **6**A is a bar chart illustrating successful therapy outcomes as a function of modulation location for patients receiving therapy in accordance with an embodiment of the disclosure, obtained during a clinical study.

FIGS. **6**B and **6**C are flow diagrams illustrating methods conducted in accordance with embodiments of the disclosure.

FIG. **7**A illustrates an arrangement of leads used during a follow-on clinical study in accordance with an embodiment of the disclosure.

FIG. **7**B illustrates results obtained from a follow-on clinical study of patients receiving therapy in accordance with an embodiment of the disclosure.

FIG. **8** is a schematic illustration identifying possible mechanisms of action for therapies in accordance with the present disclosure, as compared with an expected mechanism of action for conventional spinal cord stimulation.

FIG. **9** is a partially schematic illustration of a lead body configured in accordance with an embodiment of the disclosure.

FIGS. **10**A-**10**C are partially schematic illustrations of extendible leads configured in accordance with several embodiments of the disclosure.

FIGS. **11**A-**11**C are partially schematic illustrations of multifilar leads configured in accordance with several embodiments of the disclosure.

DETAILED DESCRIPTION

1.0 Introduction

The present technology is directed generally to spinal cord modulation and associated systems and methods for inhibiting pain via waveforms with high frequency elements or components (e.g., portions having high fundamental frequencies), generally with reduced or eliminated side effects. Such side effects can include unwanted motor stimulation or blocking, and/or interference with sensory functions other than the targeted pain. Several embodiments also provide simplified spinal cord modulation systems and components, and simplified procedures for the practitioner and/or the patient. Specific details of certain embodiments of the disclosure are described below with reference to methods for modulating one or more target neural populations (e.g., nerves) or sites of a patient, and associated implantable structures for providing the modulation. Although selected embodiments are described below with reference to modulating the dorsal col-

umn, dorsal horn, dorsal root, dorsal root entry zone, and/or other particular regions of the spinal column to control pain, the modulation may in some instances be directed to other neurological structures and/or target neural populations of the spinal cord and/or other neurological tissues. Some embodiments can have configurations, components or procedures different than those described in this section, and other embodiments may eliminate particular components or procedures. A person of ordinary skill in the relevant art, therefore, will understand that the disclosure may include other embodiments with additional elements, and/or may include other embodiments without several of the features shown and described below with reference to FIGS. **1A-11C**.

In general terms, aspects of many of the following embodiments are directed to producing a therapeutic effect that includes pain reduction in the patient. The therapeutic effect can be produced by inhibiting, suppressing, downregulating, blocking, preventing, or otherwise modulating the activity of the affected neural population. In many embodiments of the presently disclosed techniques, therapy-induced paresthesia is not a prerequisite to achieving pain reduction, unlike standard SCS techniques. It is expected that the techniques described below with reference to FIGS. **1A-11C** can produce more effective, more robust, less complicated and/or otherwise more desirable results than can existing spinal cord stimulation therapies.

FIG. **1A** schematically illustrates a representative treatment system **100** for providing relief from chronic pain and/or other conditions, arranged relative to the general anatomy of a patient's spinal cord **191**. The system **100** can include a pulse generator **101**, which may be implanted subcutaneously within a patient **190** and coupled to a signal delivery element **110**. In a representative example, the signal delivery element **110** includes a lead or lead body **111** that carries features for delivering therapy to the patient **190** after implantation. The pulse generator **101** can be connected directly to the lead **111**, or it can be coupled to the lead **111** via a communication link **102** (e.g., an extension). Accordingly, the lead **111** can include a terminal section that is releasably connected to an extension at a break **114** (shown schematically in FIG. **1A**). This allows a single type of terminal section to be used with patients of different body types (e.g., different heights). As used herein, the terms lead and lead body include any of a number of suitable substrates and/or support members that carry devices for providing therapy signals to the patient **190**. For example, the lead **111** can include one or more electrodes or electrical contacts that direct electrical signals into the patient's tissue, such as to provide for patient relief. In other embodiments, the signal delivery element **110** can include devices other than a lead body (e.g., a paddle) that also direct electrical signals and/or other types of signals to the patient **190**.

The pulse generator **101** can transmit signals (e.g., electrical signals) to the signal delivery element **110** that up-regulate (e.g., stimulate or excite) and/or down-regulate (e.g., block or suppress) target nerves. As used herein, and unless otherwise noted, the terms "modulate" and "modulation" refer generally to signals that have either type of the foregoing effects on the target nerves. The pulse generator **101** can include a machine-readable (e.g., computer-readable) medium containing instructions for generating and transmitting suitable therapy signals. The pulse generator **101** and/or other elements of the system **100** can include one or more processors **107**, memories **108** and/or input/output devices. Accordingly, the process of providing modulation signals and executing other associated functions can be performed by computer-executable instructions contained on computer-readable media, e.g., at the processor(s) **107** and/or memory(s) **108**. The pulse generator **101** can include multiple portions, elements, and/or subsystems (e.g., for directing signals in accordance with multiple signal delivery parameters), housed in a single housing, as shown in FIG. **1A**, or in multiple housings.

The pulse generator **101** can also receive and respond to an input signal received from one or more sources. The input signals can direct or influence the manner in which the therapy instructions are selected, executed, updated and/or otherwise performed. The input signal can be received from one or more sensors **112** (one is shown schematically in FIG. **1** for purposes of illustration) that are carried by the pulse generator **101** and/or distributed outside the pulse generator **101** (e.g., at other patient locations) while still communicating with the pulse generator **101**. The sensors **112** can provide inputs that depend on or reflect patient state (e.g., patient position, patient posture and/or patient activity level), and/or inputs that are patient-independent (e.g., time). In other embodiments, inputs can be provided by the patient and/or the practitioner, as described in further detail later. Still further details are included in co-pending U.S. application Ser. No. 12/703,683, filed on Feb. 10, 2010 and incorporated herein by reference.

In some embodiments, the pulse generator **101** can obtain power to generate the therapy signals from an external power source **103**. The external power source **103** can transmit power to the implanted pulse generator **101** using electromagnetic induction (e.g., RF signals). For example, the external power source **103** can include an external coil **104** that communicates with a corresponding internal coil (not shown) within the implantable pulse generator **101**. The external power source **103** can be portable for ease of use.

In another embodiment, the pulse generator **101** can obtain the power to generate therapy signals from an internal power source, in addition to or in lieu of the external power source **103**. For example, the implanted pulse generator **101** can include a non-rechargeable battery or a rechargeable battery to provide such power. When the internal power source includes a rechargeable battery, the external power source **103** can be used to recharge the battery. The external power source **103** can in turn be recharged from a suitable power source (e.g., conventional wall power).

In some cases, an external programmer **105** (e.g., a trial modulator) can be coupled to the signal delivery element **110** during an initial implant procedure, prior to implanting the pulse generator **101**. For example, a practitioner (e.g., a physician and/or a company representative) can use the external programmer **105** to vary the modulation parameters provided to the signal delivery element **110** in real time, and select optimal or particularly efficacious parameters. These parameters can include the position of the signal delivery element **110**, as well as the characteristics of the electrical signals provided to the signal delivery element **110**. In a typical process, the practitioner uses a cable assembly **120** to temporarily connect the external programmer **105** to the signal delivery device **110**. The cable assembly **120** can accordingly include a first connector **121** that is releasably connected to the external programmer **105**, and a second connector **122** that is releasably connected to the signal delivery element **110**. Accordingly, the signal delivery element **110** can include a connection element that allows it to be connected to a signal generator either directly (if it is long enough) or indirectly (if it is not). The 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**. Optionally, the practitioner may move the partially implanted signal delivery element **110** without disconnecting the cable assembly **120**. Further details of suitable cable assembly methods and associated techniques are described in co-pending U.S. application Ser. No. 12/562,892, filed on Sep. 18, 2009, and incorporated herein by reference. As will be discussed in further detail later, particular aspects of the present disclosure can advantageously reduce or eliminate the foregoing iterative process.

After the position of the signal delivery element **110** and appropriate signal delivery parameters are established using the external programmer **105**, the patient **190** can receive therapy via signals generated by the external programmer **105**, generally for a limited period of time. In a representative application, the patient **190** receives such therapy for one week. During this time, the patient wears the cable assembly **120** and the external programmer **105** outside the body. Assuming the trial therapy is effective or shows the promise of being effective, the practitioner then replaces the external programmer **105** with the implanted pulse generator **101**, and programs the pulse generator **101** with parameters selected based on the experience gained during the trial period. Optionally, the practitioner can also replace the signal delivery element **110**. Once the implantable pulse generator **101** has been positioned within the patient **190**, the signal delivery parameters provided by the pulse generator **101** can still be updated remotely via a wireless physician's programmer (e.g., a physician's remote) **111** and/or a wireless patient programmer **106** (e.g., a patient remote). Generally, the patient **190** has control over fewer parameters than does the practitioner. For example, the capability of the patient programmer **106** may be limited to starting and/or stopping the pulse generator **101**, and/or adjusting the signal amplitude.

In any of the foregoing embodiments, the parameters in accordance with which the pulse generator **101** provides signals can be modulated during portions of the therapy regimen. For example, the frequency, amplitude, pulse width and/or signal delivery location can be modulated in accordance with a preset program, patient and/or physician inputs, and/or in a random or pseudorandom manner. Such parameter variations can be used to address a number of potential clinical situations, including changes in the patient's perception of pain, changes in the preferred target neural population, and/or patient accommodation or habituation.

Certain aspects of the foregoing systems and methods may be simplified or eliminated in particular embodiments of the present disclosure. For example, in at least some instances, the therapeutic signals delivered by the system can produce an effect that is much less sensitive to lead location and signal delivery parameters (e.g., amplitude) than are conventional stimulation systems. Accordingly, as noted above, the trial and error process (or parts of this process) for identifying a suitable lead location and associated signal delivery parameters during the lead implant procedure can be eliminated. In addition to or in lieu of this simplification, the post-lead implant trial period can be eliminated. In addition to or in lieu of the foregoing simplifications, the process of selecting signal delivery parameters and administering the signals on a long-term basis can be significantly simplified. Further aspects of these and other expected beneficial results are discussed in greater detail below.

2.0 Representative Therapy Parameters

Nevro Corporation, the assignee of the present application, has conducted a multi-site clinical study during which multiple patients were first treated with conventional spinal cord stimulation (SCS) techniques, and then with newly developed techniques that are disclosed further below. This study was followed up by a further clinical study focusing on the newly developed techniques, which confirmed and expanded on results obtained during the initial study. Multiple embodiments of the newly developed techniques, therapies and/or systems are referred to as presently disclosed techniques, therapies, and/or systems, or more generally as presently disclosed technologies.

2.1. Initial Comparison Study

Prior to the initial clinical study, selected patients were identified as suffering from primary chronic low back pain (e.g., neuropathic pain, and/or nociceptive pain, and/or other types of pain, depending upon the patient), either alone or in combination with pain affecting other areas, typically the patient's leg(s). In all cases, the low back pain was dominant. During the study, the patients were outfitted with two leads, each implanted in the spinal region in a manner generally similar to that shown in FIG. **1**A. One lead was implanted on one side of the spinal cord midline **189**, and the other lead was implanted on the other side of the spinal cord midline **189**. FIG. **1**B is a cross-sectional illustration of the spinal cord **191** and an adjacent vertebra **195** (based generally on information from Crossman and Neary, "Neuroanatomy," 1995 (published by Churchill Livingstone)), along with the locations at which leads **110** were implanted in a representative patient. The spinal cord **191** is situated between a ventrally located ventral body **196** and the dorsally located transverse process **198** and spinous process **197**. Arrows V and D identify the ventral and dorsal directions, respectively. The spinal cord **191** itself is located within the dura mater **199**, which also surrounds portions of the nerves exiting the spinal cord **191**, including the dorsal roots **193** and dorsal root ganglia **194**. The leads **110** were positioned just off the spinal cord midline **189** (e.g., about 1 mm. offset) in opposing lateral directions so that the two leads **110** were spaced apart from each other by about 2 mm.

Patients with the leads **110** located as shown in FIG. **1**B initially had the leads positioned at vertebral levels T7-T8. This location is typical for standard SCS treatment of low back pain because it has generally been the case that at lower (inferior) vertebral levels, standard SCS treatment produces undesirable side effects, and/or is less efficacious. Such side effects include unwanted muscle activation and/or pain. Once the leads **110** were implanted, the patients received standard SCS treatment for a period of five days. This treatment included stimulation at a frequency of less than 1500 Hz (e.g., 60-80 Hz), a pulse width of 100-200 μsec, and a duty cycle of 100%. The amplitude of the signal (e.g., the current amplitude) was varied from about 3 mA to about 10 mA. The amplitude was initially established during the implant procedure. The amplitude was then changed by the patient on an as-desired basis during the course of the study, as is typical for standard SCS therapies.

After the patient completed the standard SCS portion of the study, the patient then received modulation in accordance with the presently disclosed techniques. One aspect of these techniques included moving the leads **110** inferiorly, so as to be located at vertebral levels T9, T10, T11, and/or T12. After the leads **110** were repositioned, the patient received therapeutic signals at a frequency of from about 3 kHz to about 10 kHz. In particular cases, the therapy was applied at 8 kHz, 9 kHz or 10 kHz. These frequencies are significantly higher than the frequencies associated with standard SCS, and accordingly, modulation at these and other representative frequencies (e.g., from about 1.5 kHz to about 100 kHz) is occasionally referred to herein as high frequency modulation. The modulation was applied generally at a duty cycle of from

about 50% to about 100%, with the modulation signal on for a period of from about 1 msec. to about 2 seconds, and off for a period of from about 1 msec. to about 1.5 seconds. The width of the applied pulses was about 30-35 μsec., and the amplitude generally varied from about 1 mA to about 4 mA (nominally about 2.5 mA). Modulation in accordance with the foregoing parameters was typically applied to the patients for a period of about four days during the initial clinical study.

FIGS. **2**-**6**A graphically illustrate summaries of the clinical results obtained by testing patients in accordance with the foregoing parameters. FIG. **2** is a bar chart illustrating the patients' Visual Analog Scale (VAS) pain score for a variety of conditions. The scores indicated in FIG. **2** are for overall pain. As noted above, these patients suffered primarily from low back pain and accordingly, the pain scores for low back pain alone were approximately the same as those shown in FIG. **2**. Each of the bars represents an average of the values reported by the multiple patients involved in this portion of the study. Bars **201** and **202** illustrate a baseline pain level of 8.7 for the patients without the benefit of medication, and a baseline level of 6.8 with medication, respectively. After receiving a lead implant on day zero of the study, and initiating high frequency modulation in accordance with the foregoing parameters, patients reported an average pain score of about 4.0, as represented by bar **203**. Over the course of the next three days, (represented by bars **204**-**213**) the patients recorded pain levels in a diary every morning, midday and evening, as indicated by the correspondingly labeled bars in FIG. **2**. In addition, pain levels were recorded daily by the local center research coordinator on case report forms (CRFs) as indicated by the correspondingly labeled bars in FIG. **2**. During this time period, the patients' average pain score gradually decreased to a reported minimum level of about 2.2 (represented by bars **212** and **213**).

For purposes of comparison, bar **214** illustrates the pain score for the same patients receiving standard SCS therapy earlier in the study. Bar **214** indicates that the average pain value for standard SCS therapy was 3.8. Unlike the results of the presently disclosed therapy, standard SCS therapy tended to produce relatively flat patient pain results over the course of several days. Comparing bars **213** and **214**, the clinical results indicate that the presently disclosed therapy reduced pain by 42% when compared with standard SCS therapy.

Other pain indices indicated generally consistent results. On the Oswestry Disability Index, average scores dropped from a baseline value of 54 to a value of 33,which is equivalent to a change from "severe disability" to "moderate disability". Patients' global improvement scores ranked 1.9 on a scale of 1 ("very much improved") to 7 ("very much worse").

In addition to obtaining greater pain relief with the presently disclosed therapy than with standard SCS therapy, patients experienced other benefits as well, described further below with reference to FIGS. **3**-**5**C. FIG. **3** is a bar chart illustrating the number of times per day that the patients initiated modulation changes. Results are illustrated for standard SCS therapy (bar **301**) and the presently disclosed therapy (bar **302**). The patient-initiated modulation changes were generally changes in the amplitude of the applied signal, and were initiated by the patient via an external modulator or remote, such as was described above with reference to FIG. **1**A. Patients receiving standard SCS therapy initiated changes to the signal delivery parameters an average of 44 times per day. The initiated changes were typically triggered when the patient changed position, activity level, and/or activity type, and then experienced a reduction in pain relief and/or an unpleasant, uncomfortable, painful, unwanted or unexpected sensation from the therapeutic signal. Patients receiving the presently disclosed therapy did not change the signal delivery parameters at all, except at the practitioners' request. In particular, the patients did not change signal amplitude to avoid painful stimulation. Accordingly, FIG. **3** indicates that the presently disclosed therapy is significantly less sensitive to lead movement, patient position, activity level and activity type than is standard SCS therapy.

FIG. **4** is a bar graph illustrating activity scores for patients receiving the presently disclosed therapy. The activity score is a quality of life score indicating generally the patients' level of satisfaction with the amount of activity that they are able to undertake. As indicated in FIG. **4**, bar **401** identifies patients having a score of 1.9 (e.g., poor to fair) before beginning therapy. The score improved over time (bars **402**-**404**) so that at the end of the second day of therapy, patients reported a score of nearly 3 (corresponding to a score of "good"). It is expected that in longer studies, the patients' score may well improve beyond the results shown in FIG. **4**. Even the results shown in FIG. **4**, however, indicate a 53% improvement (compared to baseline) in the activity score for patients receiving the presently disclosed therapy over a three day period. Anecdotally, patients also indicated that they were more active when receiving the presently disclosed therapy than they were when receiving standard SCS therapy. Based on anecdotal reports, it is expected that patients receiving standard SCS therapy would experience only a 10-15% improvement in activity score over the same period of time.

FIG. **5**A is a bar chart illustrating changes in activity score for patients receiving the presently disclosed therapy and performing six activities: standing, walking, climbing, sitting, riding in a car, and eating. For each of these activities, groups of bars (with individual groups identified by reference numbers **501**, **502**, **503** . . . **506**) indicate that the patients' activity score generally improved over the course of time. These results further indicate that the improvement in activity was broad-based and not limited to a particular activity. Still further, these results indicate a significant level of improvement in each activity, ranging from 30% for eating to 80%-90% for standing, walking and climbing stairs. Anecdotally, it is expected that patients receiving standard SCS treatment would experience only about 10%-20% improvement in patient activity. Also anecdotally, the improvement in activity level was directly observed in at least some patients who were hunched over when receiving standard SCS treatment, and were unable to stand up straight. By contrast, these patients were able to stand up straight and engage in other normal activities when receiving the presently disclosed therapy.

The improvement experienced by the patients is not limited to improvements in activity but also extends to relative inactivity, including sleep. For example, patients receiving standard SCS therapy may establish a signal delivery parameter at a particular level when lying prone. When the patient rolls over while sleeping, the patient may experience a significant enough change in the pain reduction provided by standard SCS treatments to cause the patient to wake. In many cases, the patient may additionally experience pain generated by the SCS signal itself, on top of the pain the SCS signal is intended to reduce. With the presently disclosed techniques, by contrast, this undesirable effect can be avoided. FIGS. **5**B and **5**C illustrate the average effect on sleep for clinical patients receiving the presently disclosed therapy. FIG. **5**B illustrates the reduction in patient disturbances, and FIG. **5**C illustrates the increase in number of hours slept. In other embodiments, the patient may be able to perform other tasks with reduced pain. For example, patients may drive without having to adjust the therapy level provided by the implanted device. Accordingly, the presently disclosed therapy may be more

readily used by patients in such situations and/or other situations that improve the patients' quality of life.

Based on additional patient feedback, every one of the tested patients who received the presently disclosed therapy at the target location (e.g., who received the presently disclosed therapy without the lead migrating significantly from its intended location) preferred the presently disclosed therapy to standard SCS therapy. In addition, irrespective of the level of pain relief the patients received, 88% of the patients preferred the presently disclosed therapy to standard SCS therapy because it reduced their pain without creating paresthesia. This indicates that while patients may prefer paresthesia to pain, a significant majority prefer no sensation to both pain and paresthesia. This result, obtained via the presently disclosed therapy, is not available with standard SCS therapies that are commonly understood to rely on paresthesia (i.e., masking) to produce pain relief.

Still further, anecdotal data indicate that patients receiving the presently disclosed therapy experienced less muscle capture than they experienced with standard SCS. In particular, patients reported a lack of spasms, cramps, and muscle pain, some or all of which they experienced when receiving standard SCS. Patients also reported no interference with volitional muscle action, and instead indicated that they were able to perform motor tasks unimpeded by the presently disclosed therapy. Still further, patients reported no interference with other sensations, including sense of touch (e.g., detecting vibration), temperature and proprioception. In most cases; patients reported no interference with nociceptive pain sensation. However, in some cases, patients reported an absence of incision pain (associated with the incision used to implant the signal delivery lead) or an absence of chronic peripheral pain (associated with arthritis). Accordingly, in particular embodiments, aspects of the currently disclosed techniques may be used to address nociceptive pain, including acute peripheral pain, and/or chronic peripheral pain. For example, in at least some cases, patients with low to moderate nociceptive pain received relief as a result of the foregoing therapy. Patients with more severe/chronic nociceptive pain were typically not fully responsive to the present therapy techniques. This result may be used in a diagnostic setting to distinguish the types of pain experienced by the patients, as will be discussed in greater detail later.

FIG. **6**A is a bar chart indicating the number of successful therapeutic outcomes as a function of the location (indicated by vertebral level) of the active contacts on the leads that provided the presently disclosed therapy. In some cases, patients obtained successful outcomes when modulation was provided at more than one vertebral location. As indicated in FIG. **6**A, successful outcomes were obtained over a large axial range (as measured in a superior-inferior direction along the spine) from vertebral bodies T9 to T12. This is a surprising result in that it indicates that while there may be a preferred target location (e.g., around T10), the lead can be positioned at a wide variety of locations while still producing successful results. In particular, neighboring vertebral bodies are typically spaced apart from each other by approximately 32 millimeters (depending on specific patient anatomy), and so successful results were obtained over a broad range of four vertebral bodies (about 128 mm.) and a narrower range of one to two vertebral bodies (about 32-64 mm.). By contrast, standard SCS data generally indicate that the therapy may change from effective to ineffective with a shift of as little as 1 mm. in lead location. As will be discussed in greater detail later, the flexibility and versatility associated with the presently disclosed therapy can produce significant benefits for both the patient and the practitioner.

FIGS. **6**B and **6**C are flow diagrams illustrating methods for treating patients in accordance with particular embodiments of the present disclosure. Manufacturers or other suitable entities can provide instructions to practitioners for executing these and other methods disclosed herein. Manufacturers can also program devices of the disclosed systems to carry out at least some of these methods. FIG. **6**B illustrates a method **600** that includes implanting a signal generator in a patient (block **610**). The signal generator can be implanted at the patient's lower back or other suitable location. The method **600** further includes implanting a signal delivery device (e.g., a lead, paddle or other suitable device) at the patient's spinal cord region (block **620**). This portion of the method can in turn include implanting the device (e.g., active contacts of the device) at a vertebral level ranging from about T9 to about T12 (e.g., about T9-T12, inclusive) (block **621**), and at a lateral location ranging from the spinal cord midline to the DREZ, inclusive (block **622**). At block **630**, the method includes applying a high frequency waveform, via the signal generator and the signal delivery device. In particular examples, the frequency of the signal (or at least a portion of the signal) can be from about 1.5 kHz to about 100 kHz, or from about 1.5 kHz to about 50 kHz., or from about 3 kHz to about 20 kHz, or from about 3 kHz to about 15 kHz, or from about 5 kHz to about 15 kHz, or from about 3 kHz to about 10 kHz. The method **600** further includes blocking, suppressing, inhibiting or otherwise reducing the patient's pain, e.g., chronic low back pain (block **640**). This portion of the method can in turn include reducing pain without unwanted sensory effects and/or limitations (block **641**), and/or without motor effects (block **642**). For example, block **641** can include reducing or eliminating pain without reducing patient perception of other sensations, and/or without triggering additional pain. Block **642** can include reducing or eliminating pain without triggering muscle action and/or without interfering with motor signal transmission.

FIG. **6**C illustrates a method **601** that includes features in addition to those described above with reference to FIG. **6**B. For example, the process of applying a high frequency waveform (block **630**) can include doing so over a wide amplitude range (e.g., from less than 1 mA up to about 8 mA in one embodiment, and up to about 6 mA and about 5 mA, respectively, in other embodiments) without creating unwanted side effects, such as undesirable sensations and/or motor interference (block **631**). In another embodiment, the process of applying a high frequency waveform can include applying the waveform at a fixed amplitude (block **632**). As described further later, each of these aspects can provide patient and/or practitioner benefits.

The process of blocking, suppressing or otherwise reducing patient pain (block **640**) can include doing so without creating paresthesia (block **643**), or in association with a deliberately generated paresthesia (block **644**). As noted above, clinical results indicate that most patients prefer the absence of paresthesia to the presence of paresthesia, e.g., because the sensation of paresthesia may change to an uncomfortable or painful sensation when the patient changes position and/or adjusts the signal amplitude. However, in some cases, patients may prefer the sensation of paresthesia (e.g., patients who have previously received SCS), and so can have the option of receiving it. Further details of methodologies that include combinations of paresthesia-inducing modulation and non-paresthesia-inducing modulation are included in U.S. Provisional Application No. 61/171,790, previously incorporated herein by reference. In other cases, paresthesia may be used by the practitioner for site selection (e.g., to determine the location at which active electrodes are

positioned). In addition to the above, reducing patient pain can include doing so with relative insensitivity to patient attributes that standard SCS is normally highly sensitive to (block **645**). These attributes can include patient movement (block **646**) and/or patient position (block **647**).

2.2. Follow-On Study

Nevro Corporation, the assignee of the present application, has conducted a follow-on study to evaluate particular parameters and results of the therapy described above. In the follow-on study, patients received implanted leads and simulators, and received therapy over a period of several months. This study did not include a direct comparison with conventional SCS techniques for each patient, though some of the patients received conventional SCS therapy prior to receiving modulation in accordance with the present technology. Selected results are described further below.

FIG. **7**A is a schematic illustration of a typical lead placement used during the follow-on study. In this study, two leads **111** (shown as a first lead **111***a* and a second lead **111***b*) were positioned generally end-to-end to provide a modulation capability that extends over several vertebral levels of the patients' spine. The leads **111***a*, **111***b* were positioned to overlap slightly, to account for possible shifts in lead location. During the course of the therapy, contacts C of the two leads **111***a*, **111***b* were activated on one lead at a time. In other words, the contacts C of only one lead **111** were active at any one time, and signals were not directed between the contacts C located on different leads **111**. While two leads were used during the clinical study, it is expected that in general use, a single lead can be positioned at the appropriate vertebral level. The lead can have more widely spaced contacts to achieve the same or similar effects as those described herein as will be described in greater detail below with reference to FIG. **9**.

The contacts C of each lead **111***a*, **111***b* have a width W**2** of approximately 3 mm, and are separated from each other by a distance D**1** of approximately 1 mm. Accordingly, the center-to-center spacing S between neighboring contacts C is approximately 4 mm. The leads **111***a*, **111** b were positioned at or close to the patients' spinal midline **189**. Typically, one lead was positioned on one side of the midline **189**, and the other lead was positioned on the other side of the patients' midline **189**. During the course of the study, several significant effects were observed. For example, the leads **111***a*, **111***b* could be positioned at any of a variety of locations within a relatively wide window W**1** having an overall width of ±3-5 mm from the midline **189** (e.g., an overall width of 6-10 mm), without significantly affecting the efficacy of the treatment. In addition, patients with bilateral pain (e.g., on both sides of the midline **189**) reported bilateral relief, independent of the lateral location of the leads **110***a*, **110***b*. For example, patients having a lead located within the window W**1** on one side of the midline **189** reported pain relief on the opposite side of the midline **189**. This is unlike conventional SCS therapies, for which bilateral relief, when it is obtained at all, is generally very sensitive to any departure from a strictly midline lead location. Still further, the distance between neighboring active contacts was significantly greater than is typical for standard SCS. Practitioners were able to "skip" (e.g., deactivate) several consecutive contacts so that neighboring active contacts had a center-to-center spacing of, for example, 20 mm, and an edge-to-edge spacing of, for example, 17 mm. In addition, patients were relatively insensitive to the axial location of the active contacts. For example, practitioners were able to establish the same or generally the same levels of pain relief over a wide range of contact spacings that is expected to extend up to two vertebral bodies (e.g., about 64 mm). Yet further, the practitioners obtained a similar therapeutic effect whether a given contact was identified as cathodic or anodic, as is described in greater detail in pending U.S. application Ser. No.12/765,790, filed concurrently herewith and incorporated herein by reference.

For most patients in the follow-on study, the leads were implanted at the T9-T10 vertebral locations. These patients typically experienced primarily low back pain prior to receiving the therapy, though some experienced leg pain as well. Based on the results obtained during the follow-on study and the initial study, it is expected that the overall vertebral location range for addressing low back pain is from about T9 to about T12. It is further expected that within this range, modulation at T12 or T11-T12 may more effectively treat patients with both low back and leg pain. However, in some cases, patients experienced greater leg pain relief at higher vertebral locations (e.g., T9-T10) and in still further particular cases, modulation at T9 produced more leg pain relief than modulation at T10. Accordingly, within the general ranges described above, particular patients may have physiological characteristics or other factors that produce corresponding preferred vertebral locations.

Patients receiving treatment in the follow-on study received a square-wave signal at a frequency of about 10 kHz. Patients received modulation at a 100% duty cycle, with an initial current amplitude (bi-phasic) of about 2 mA. Patients and practitioners were able to adjust the signal amplitude, typically up to about 5 mA. At any of the foregoing levels, the signal pulses are expected to be suprathreshold, meaning that they can trigger an action potential in the target neural population, independent of any intrinsic neural activity at the target neural population.

Patients in the follow-on study were evaluated periodically after the modulation system **100** was implanted and activated. The VAS scores reported by these patients after 30 days of receiving treatment averaged about 1.0, indicating that the trend discussed above with respect to FIG. **2** continued for some period of time. At least some of these patients reported an increase in the VAS score up to level of about 2.25. It is expected that this increase resulted from the patients' increased activity level. Accordingly, it is not believed that this increase indicates a reduction in the efficacy of the treatment, but rather, indicates an effective therapy that allows patients to engage in activities they otherwise would not.

FIG. **7**B illustrates overall Oswestry scores for patients engaging in a variety of activities and receiving modulation in accordance with the follow-on study protocol. A score of 100 corresponds to a completely disabled condition, and a score of 0 corresponds to no disability. These scores indicate a general improvement over time, for example, consistent with and in fact improved over results from in the initial study. In addition, several patients reported no longer needing or using canes or wheelchairs after receiving therapy in accordance with the foregoing embodiments.

Results from the follow-on study confirm a relative insensitivity of the therapeutic effectiveness of the treatment to changes in current amplitude. In particular, patients typically received modulation at a level of from about 2.0 mA to about 3.5 mA. In most cases, patients did not report significant changes in pain reduction when they changed the amplitude of the applied signal. Patients were in several cases able to increase the current amplitude up to a level of about 5 mA before reporting undesirable side effects. In addition, the side effects began to take place in a gradual, rather than a sudden, manner. Anecdotal feedback from some patients indicated that at high amplitudes (e.g., above 5 mA) the treatment efficacy began to fall off, independent of the onset of any

undesirable side effects. It is further expected that patients can receive effective therapy at current amplitudes of less than 2 mA. This expectation is based at least in part on data indicating that reducing the duty cycle (e.g., to 70%) did not reduce efficacy.

The results of the follow-on study also indicated that most patients (e.g., approximately 80% of the patients) experienced at least satisfactory pain reduction without changing any aspect of the signal delivery parameters (e.g., the number and/or location of active contacts, and/or the current amplitude), once the system was implanted and activated. A small subset of the patients (e.g., about 20%) benefited from an increased current amplitude when engaging in particular activities, and/or benefited from a lower current amplitude when sleeping. For these patients, increasing the signal amplitude while engaging in activity produced a greater degree of pain relief, and reducing the amplitude at night reduced the likelihood of over-stimulation, while at the same time saving power. In a representative example, patients selected from between two such programs: a "strong" program which provided signals at a relatively high current amplitude (e.g., from about 1 mA to about 6 mA), and a "weak" program which provided signals at a lower current amplitude (e.g., from about 0.1 mA to about 3 mA).

Another observed effect during the follow-on study was that patients voluntarily reduced their intake of opioids and/or other pain medications that they had been receiving to address pain prior to receiving modulation in accordance with the present technology. The patients' voluntary drug intake reduction is expected to be a direct result of the decreased need for the drugs, which is in turn a direct result of the modulation provided in accordance with the present technology. However, due to the addictive nature of opioids, the ease with which patients voluntarily gave up the use of opioids was surprising. Therefore, it is also expected that for at least some patients, the present technology, in addition to reducing pain, acted to reduce the chemical dependency on these drugs. Accordingly, it is further expected that in at least some embodiments, therapeutic techniques in accordance with the present disclosure may be used to reduce or eliminate patient chemical dependencies, independent of whether the patients also have and/or are treated for low back pain.

Patients entering the follow-on study typically experienced neuropathic pain, nociceptive pain, or a combination of neuropathic pain and nociceptive pain. Neuropathic pain refers generally to pain resulting from a dysfunction in the neural mechanism for reporting pain, which can produce a sensation of pain without an external neural trigger. Nociceptive pain refers generally to pain that is properly sensed by the patient as being triggered by a particular mechanical or other physical effect (e.g., a slipped disc, a damaged muscle, or a damaged bone). In general, neuropathic pain is consistent, and nociceptive pain fluctuates, e.g., with patient position or activity. In at least some embodiments, treatment in accordance with the present technology appears to more effectively address neuropathic pain than nociceptive pain. For example, patients who reported low levels of pain fluctuation before entering treatment (indicating predominantly neuropathic pain), received greater pain relief during treatment than patients whose pain fluctuated significantly. In two particular cases, the therapy did not prove to be effective, and it is believe that this resulted from a mechanical issue with the patients' back anatomy, which identified the patients as better candidates for surgery than for the present therapy. Accordingly, in addition to addressing neuropathic pain and (in at least some cases), nociceptive pain, techniques in accordance with the present technology may also act as a screening tool to identify patients who suffer primarily from nociceptive pain rather than neuropathic pain. For example, the practitioner can make such an identification based at least in part on feedback from the patient corresponding to the existence and/or amount (including amount of fluctuation) of pain reduction when receiving signals in accordance with the present technology. As a result of using this diagnostic technique, these patients can be directed to surgical or other procedures that can directly address the nociceptive pain. In particular, patients may receive signals in accordance with the present technology and, if these patients are unresponsive, may be suitable candidates for surgical intervention. Of course, if the patients are responsive, they can continue to receive signals in accordance with the present technology as therapy.

3.0 Mechanisms of Action

FIG. **8** is a schematic diagram (based on Linderoth and Foreman, "Mechanisms of Spinal Cord Stimulation in Painful Syndromes: Role of Animal Models," Pain Medicine, Vol. 51, 2006) illustrating an expected mechanism of action for standard SCS treatment, along with potential mechanisms of action for therapy provided in accordance with embodiments of the present technology. When a peripheral nerve is injured, it is believed that the Aδ and C nociceptors provide an increased level of excitatory transmitters to second order neurons at the dorsal horn of the spinal cord. Standard SCS therapy, represented by arrow **701**, is expected to have two effects. One effect is an orthodromic effect transmitted along the dorsal column to the patient's brain and perceived as paresthesia. The other is an antidromic effect that excites the interneuron pool, which in turn inhibits inputs to the second order neurons.

One potential mechanism of action for the presently disclosed therapy is represented by arrow **710**, and includes producing an incomplete conduction block (e.g., an incomplete block of afferent and/or efferent signal transmission) at the dorsal root level. This block may occur at the dorsal column, dorsal horn, and/or dorsal root entry zone, in addition to or in lieu of the dorsal root. In any of these cases, the conduction block is selective to and/or preferentially affects the smaller Aδ and/or C fibers and is expected to produce a decrease in excitatory inputs to the second order neurons, thus producing a decrease in pain signals supplied along the spinal thalamic tract.

Another potential mechanism of action (represented by arrow **720** in FIG. **8**) includes more profoundly activating the interneuron pool and thus increasing the inhibition of inputs into the second order neurons. This can, in effect, potentially desensitize the second order neurons and convert them closer to a normal state before the effects of the chronic pain associated signals have an effect on the patient.

Still another potential mechanism of action relates to the sensitivity of neurons in patients suffering from chronic pain. In such patients, it is believed that the pain-transmitting neurons may be in a different, hypersensitive state compared to the same neurons in people who do not experience chronic pain, resulting in highly sensitized cells that are on a "hair trigger" and fire more frequently and at different patterns with a lower threshold of stimulation than those cells of people who do not experience chronic pain. As a result, the brain receives a significantly increased volume of action potentials at significantly altered transmission patterns. Accordingly, a potential mechanism of action by which the presently disclosed therapies may operate is by reducing this hypersensitivity by restoring or moving the "baseline" of the neural cells in chronic pain patients toward the normal baseline and firing frequency of non-chronic pain patients. This effect can in turn

reduce the sensation of pain in this patient population without affecting other neural transmissions (for example, touch, heat, etc.).

The foregoing mechanisms of action are identified here as possible mechanisms of action that may account for the foregoing clinical results. In particular, these mechanisms of action may explain the surprising result that pain signals transmitted by the small, slow Aδ and C fibers may be inhibited without affecting signal transmission along the larger, faster Aβ fibers. This is contrary to the typical results obtained via standard SCS treatments, during which modulation signals generally affect Aβ fibers at low amplitudes, and do not affect Aδ and C fibers until the signal amplitude is so high as to create pain or other unwanted effects transmitted by the Aβ fibers. However, aspects of the present disclosure need not be directly tied to such mechanisms. In addition, aspects of both the two foregoing proposed mechanisms may in combination account for the observed results in some embodiments, and in other embodiments, other mechanisms may account for the observed results, either alone or in combination with either one of the two foregoing mechanisms. One such mechanism includes an increased ability of high frequency modulation (compared to standard SCS stimulation) to penetrate through the cerebral spinal fluid (CSF) around the spinal cord. Another such mechanism is the expected reduction in impedance presented by the patient's tissue to high frequencies, as compared to standard SCS frequencies. Still another such mechanism is the ability of high frequency signal to elicit an asynchronous neural response, as disclosed in greater detail in pending U.S. application Ser. No. 12/362,244, filed on Jan. 29, 2009 and incorporated herein by reference. Although the higher frequencies associated with the presently disclosed techniques may initially appear to require more power than conventional SCS techniques, the signal amplitude may be reduced when compared to conventional SCS values (due to improved signal penetration) and/or the duty cycle may be reduced (due to persistence effects described later). Accordingly, the presently disclosed techniques can result in a net power savings when compared with standard SCS techniques.

4.0 Expected Benefits Associated with Certain Embodiments

Certain of the foregoing embodiments can produce one or more of a variety of advantages, for the patient and/or the practitioner, when compared with standard SCS therapies. Some of these benefits were described above. For example, the patient can receive effective pain relief without patient-detectable disruptions to normal sensory and motor signals along the spinal cord. In particular embodiments, while the therapy may create some effect on normal motor and/or sensory signals, the effect is below a level that the patient can reliably detect intrinsically, e.g., without the aid of external assistance via instruments or other devices. Accordingly, the patient's levels of motor signaling and other sensory signaling (other than signaling associated with the target pain) can be maintained at pre-treatment levels. For example, as described above, the patient can experience a significant pain reduction that is largely independent of the patient's movement and position. In particular, the patient can assume a variety of positions and/or undertake a variety of movements associated with activities of daily living and/or other activities, without the need to adjust the parameters in accordance with which the therapy is applied to the patient (e.g., the signal amplitude). This result can greatly simplify the patient's life and reduce the effort required by the patient to experience pain relief while engaging in a variety of activities. This result can also provide an improved lifestyle for patients who experience pain during sleep, as discussed above with reference to FIGS. **5**B and **5**C.

Even for patients who receive a therapeutic benefit from changes in signal amplitude, the foregoing therapy can provide advantages. For example, such patients can choose from a limited number of programs (e.g., two or three) each with a different amplitude and/or other signal delivery parameter, to address some or all of the patient's pain. In one such example, the patient activates one program before sleeping and another after waking. In another such example, the patient activates one program before sleeping, a second program after waking, and a third program before engaging in particular activities that would otherwise cause pain. This reduced set of patient options can greatly simplify the patient's ability to easily manage pain, without reducing (and in fact, increasing) the circumstances under which the therapy effectively addresses pain. In any embodiments that include multiple programs, the patient's workload can be further reduced by automatically detecting a change in patient circumstance, and automatically identifying and delivering the appropriate therapy regimen. Additional details of such techniques and associated systems are disclosed in co-pending U.S. application Ser. No. 12/703,683, previously incorporated herein by reference.

Another benefit observed during the clinical studies described above is that when the patient does experience a change in the therapy level, it is a gradual change. This is unlike typical changes associated with conventional SCS therapies. With conventional SCS therapies, if a patient changes position and/or changes an amplitude setting, the patient can experience a sudden onset of pain, often described by patients as unbearable. By contrast, patients in the clinical studies described above, when treated with the presently disclosed therapy, reported a gradual onset of pain when signal amplitude was increased beyond a threshold level, and/or when the patient changed position, with the pain described as gradually becoming uncomfortable. One patient described a sensation akin to a cramp coming on, but never fully developing. This significant difference in patient response to changes in signal delivery parameters can allow the patient to more freely change signal delivery parameters and/or posture when desired, without fear of creating an immediately painful effect.

Another observation from the clinical studies described above is that the amplitude "window" between the onset of effective therapy and the onset of pain or discomfort is relatively broad, and in particular, broader than it is for standard SCS treatment. For example, during standard SCS treatment, the patient typically experiences a pain reduction at a particular amplitude, and begins experiencing pain from the therapeutic signal (which may have a sudden onset, as described above) at from about 1.2 to about 1.6 times that amplitude. This corresponds to an average dynamic range of about 1.4. In addition, patients receiving standard SCS stimulation typically wish to receive the stimulation at close to the pain onset level because the therapy is often most effective at that level. Accordingly, patient preferences may further reduce the effective dynamic range. By contrast, therapy in accordance with the presently disclosed technology resulted in patients obtaining pain relief at 1 mA or less, and not encountering pain or muscle capture until the applied signal had an amplitude of 4 mA, and in some cases up to about 5 mA, 6 mA, or 8 mA, corresponding to a much larger dynamic range (e.g., larger than 1.6 or 60% in some embodiments, or larger than 100% in other embodiments). Even at the forgoing amplitude levels, the pain experienced by the patients was significantly less than that associated with standard SCS pain onset. An expected advantage of this result is that the patient and prac-

titioner can have significantly wider latitude in selecting an appropriate therapy amplitude with the presently disclosed methodology than with standard SCS methodologies. For example, the practitioner can increase the signal amplitude in an effort to affect more (e.g., deeper) fibers at the spinal cord, without triggering unwanted side effects. The existence of a wider amplitude window may also contribute to the relative insensitivity of the presently disclosed therapy to changes in patient posture and/or activity. For example, if the relative position between the implanted lead and the target neural population changes as the patient moves, the effective strength of the signal when it reaches the target neural population may also change. When the target neural population is insensitive to a wider range of signal strengths, this effect can in turn allow greater patient range of motion without triggering undesirable side effects.

Although the presently disclosed therapies may allow the practitioner to provide modulation over a broader range of amplitudes, in at least some cases, the practitioner may not need to use the entire range. For example, as described above, the instances in which the patient may need to adjust the therapy may be significantly reduced when compared with standard SCS therapy because the presently disclosed therapy is relatively insensitive to patient position, posture and activity level. In addition to or in lieu of the foregoing effect, the amplitude of the signals applied in accordance with the presently disclosed techniques may be lower than the amplitude associated with standard SCS because the presently disclosed techniques may target neurons that are closer to the surface of the spinal cord. For example, it is believed that the nerve fibers associated with low back pain enter the spinal cord between T9 and T12 (inclusive), and are thus close to the spinal cord surface at these vertebral locations. Accordingly, the strength of the therapeutic signal (e.g., the current amplitude) can be modest because the signal need not penetrate through a significant depth of spinal cord tissue to have the intended effect. Such low amplitude signals can have a reduced (or zero) tendency for triggering side effects, such as unwanted sensory and/or motor responses. Such low amplitude signals can also reduce the power required by the implanted pulse generator, and can therefore extend the battery life and the associated time between recharging and/or replacing the battery.

Yet another expected benefit of providing therapy in accordance with the foregoing parameters is that the practitioner need not implant the lead with the same level of precision as is typically required for standard SCS lead placement. For example, while the foregoing results were identified for patients having two leads (one positioned on either side of the spinal cord midline), it is expected that patients will receive the same or generally similar pain relief with only a single lead placed at the midline. Accordingly, the practitioner may need to implant only one lead, rather than two. It is still further expected that the patient may receive pain relief on one side of the body when the lead is positioned offset from the spinal cord midline in the opposite direction. Thus, even if the patient has bilateral pain, e.g., with pain worse on one side than the other, the patient's pain can be addressed with a single implanted lead. Still further, it is expected that the lead position can vary laterally from the anatomical and/or physiological spinal cord midline to a position 3-5 mm. away from the spinal cord midline (e.g., out to the dorsal root entry zone or DREZ). The foregoing identifiers of the midline may differ, but the expectation is that the foregoing range is effective for both anatomical and physiological identifications of the midline, e.g., as a result of the robust nature of the present therapy. Yet further, it is expected that the lead (or more particularly, the active contact or contacts on the lead) can be positioned at any of a variety of axial locations in a range of about T9-T12 in one embodiment, and a range of one to two vertebral bodies within T9-T12 in another embodiment, while still providing effective treatment. Accordingly, the practitioner's selected implant site need not be identified or located as precisely as it is for standard SCS procedures (axially and/or laterally), while still producing significant patient benefits. In particular, the practitioner can locate the active contacts within the foregoing ranges without adjusting the contact positions in an effort to increase treatment efficacy and/or patient comfort. In addition, in particular embodiments, contacts at the foregoing locations can be the only active contacts delivering therapy to the patient. The foregoing features, alone or in combination, can reduce the amount of time required to implant the lead, and can give the practitioner greater flexibility when implanting the lead. For example, if the patient has scar tissue or another impediment at a preferred implant site, the practitioner can locate the lead elsewhere and still obtain beneficial results.

Still another expected benefit, which can result from the foregoing observed insensitivities to lead placement and signal amplitude, is that the need for conducting a mapping procedure at the time the lead is implanted may be significantly reduced or eliminated. This is an advantage for both the patient and the practitioner because it reduces the amount of time and effort required to establish an effective therapy regimen. In particular, standard SCS therapy typically requires that the practitioner adjust the position of the lead and the amplitude of the signals delivered by the lead, while the patient is in the operating room reporting whether or not pain reduction is achieved. Because the presently disclosed techniques are relatively insensitive to lead position and amplitude, the mapping process can be eliminated entirely. Instead, the practitioner can place the lead at a selected vertebral location (e.g., about T9-T12) and apply the signal at a preselected amplitude (e.g., 1 to 2 mA), with a significantly reduced or eliminated trial-and-error optimization process (for a contact selection and/or amplitude selection), and then release the patient. In addition to or in lieu of the foregoing effect, the practitioner can, in at least some embodiments, provide effective therapy to the patient with a simple bipole arrangement of electrodes, as opposed to a tripole or other more complex arrangement that is used in existing systems to steer or otherwise direct therapeutic signals. In light of the foregoing effect(s), it is expected that the time required to complete a patient lead implant procedure and select signal delivery parameters can be reduced by a factor of two or more, in particular embodiments. As a result, the practitioner can treat more patients per day, and the patients can more quickly engage in activities without pain.

The foregoing effect(s) can extend not only to the mapping procedure conducted at the practitioner's facility, but also to the subsequent trial period. In particular, patients receiving standard SCS treatment typically spend a week after receiving a lead implant during which they adjust the amplitude applied to the lead in an attempt to establish suitable amplitudes for any of a variety of patient positions and patient activities. Because embodiments of the presently disclosed therapy are relatively insensitive to patient position and activity level, the need for this trial and error period can be reduced or eliminated.

Still another expected benefit associated with embodiments of the presently disclosed treatment is that the treatment may be less susceptible to patient habituation. In particular, it is expected that in at least some cases, the high frequency signal applied to the patient can produce an asynchronous neural response, as is disclosed in co-pending U.S.

application Ser. No. 12/362,244, previously incorporated herein by reference. The asynchronous response may be less likely to produce habituation than a synchronous response, which can result from lower frequency modulation.

Yet another feature of embodiments of the foregoing therapy is that the therapy can be applied without distinguishing between anodic contacts and cathodic contacts. As described in greater detail in U.S. application Ser. No.12/765,790 , (previously incorporated herein by reference), this feature can simplify the process of establishing a therapy regimen for the patient. In addition, due to the high frequency of the waveform, the adjacent tissue may perceive the waveform as a pseudo steady state signal. As a result of either or both of the foregoing effects, tissue adjacent both electrodes may be beneficially affected. This is unlike standard SCS waveforms for which one electrode is consistently cathodic and another is consistently anodic.

In any of the foregoing embodiments, aspects of the therapy provided to the patient may be varied within or outside the parameters used during the clinical testing described above, while still obtaining beneficial results for patients suffering from chronic low back pain. For example, the location of the lead body (and in particular, the lead body electrodes or contacts) can be varied over the significant lateral and/or axial ranges described above. Other characteristics of the applied signal can also be varied. For example, as described above, the signal can be delivered at a frequency of from about 1.5 kHz to about 100 kHz, and in particular embodiments, from about 1.5 kHz to about 50 kHz. In more particular embodiments, the signal can be provided at frequencies of from about 3 kHz to about 20 kHz, or from about 3 kHz to about 15 kHz, or from about 5 kHz to about 15 kHz, or from about 3 kHz to about 10 kHz. The amplitude of the signal can range from about 0.1 mA to about 20 mA in a particular embodiment, and in further particular embodiments, can range from about 0.5 mA to about 10 mA, or about 0.5 mA to about 4 mA, or about 0.5 mA to about 2.5 mA. The amplitude of the applied signal can be ramped up and/or down. In particular embodiments, the amplitude can be increased or set at an initial level to establish a therapeutic effect, and then reduced to a lower level to save power without forsaking efficacy, as is disclosed in pending U.S. application Ser. No. 12/264,836, filed Nov. 4, 2008, and incorporated herein by reference. In particular embodiments, the signal amplitude refers to the electrical current level, e.g., for current-controlled systems. In other embodiments, the signal amplitude can refer to the electrical voltage level, e.g., for voltage-controlled systems. The pulse width (e.g., for just the cathodic phase of the pulses) can vary from about 10 microseconds to about 333 microseconds. In further particular embodiments, the pulse width can range from about25 microseconds to about 166 microseconds, or from about 33 microseconds to about 100 microseconds, or from about 50 microseconds to about 166 microseconds. The specific values selected for the foregoing parameters may vary from patient to patient and/or from indication to indication and/or on the basis of the selected vertebral location. In addition, the methodology may make use of other parameters, in addition to or in lieu of those described above, to monitor and/or control patient therapy. For example, in cases for which the pulse generator includes a constant voltage arrangement rather than a constant current arrangement, the current values described above may be replaced with corresponding voltage values.

In at least some embodiments, it is expected that the foregoing amplitudes will be suprathreshold. It is also expected that, in at least some embodiments, the neural response to the foregoing signals will be asynchronous, as described above. Accordingly, the frequency of the signal can be selected to be higher (e.g., between two and ten times higher) than the refractory period of the target neurons at the patient's spinal cord, which in at least some embodiments is expected to produce an asynchronous response.

Patients can receive multiple signals in accordance with still further embodiments of the disclosure. For example, patients can receive two or more signals, each with different signal delivery parameters. In one particular example, the signals are interleaved with each other. For instance, the patient can receive 5 kHz pulses interleaved with 10 kHz pulses. In other embodiments, patients can receive sequential "packets" of pulses at different frequencies, with each packet having a duration of less than one second, several seconds, several minutes, or longer depending upon the particular patient and indication.

In still further embodiments, the duty cycle may be varied from the 50%-100% range of values described above, as can the lengths of the on/off periods. For example, it has been observed that patients can have therapeutic effects (e.g., pain reduction) that persist for significant periods after the modulation has been halted. In particular examples, the beneficial effects can persist for 10-20 minutes in some cases, and up to an hour in others and up to a day or more in still further cases. Accordingly, the simulator can be programmed to halt modulation for periods of up to an hour, with appropriate allowances for the time necessary to re-start the beneficial effects. This arrangement can significantly reduce system power consumption, compared to systems with higher duty cycles, and compared to systems that have shorter on/off periods.

5.0 Representative Lead Configurations

FIG. **9** is a partially schematic illustration of a lead **910** having first and second contacts C**1**, C**2** positioned to deliver modulation signals in accordance with particular embodiments of the disclosure. The contacts are accordingly positioned to contact the patient's tissue when implanted. The lead **910** can include at least two first contacts C**1** and at least two second contacts C**2** to support bipolar modulation signals via each contact grouping. In one aspect of this embodiment, the lead **910** can be elongated along a major or lead axis A, with the contacts C**1**, C**2** spaced equally from the major axis A. In general, the term elongated refers to a lead or other signal delivery element having a length (e.g., along the spinal cord) greater than its width. The lead **910** can have an overall length L (over which active contacts are positioned) that is longer than that of typical leads. In particular, the length L can be sufficient to position first contacts C**1** at one or more vertebral locations (including associated neural populations), and position the second contacts C**2** at another vertebral location (including associated neural populations) that is spaced apart from the first and that is superior the first. For example, the first contacts C**1** may be positioned at vertebral levels T9-T12 to treat low back pain, and the second contacts C**2** may be positioned at superior vertebral locations (e.g., cervical locations) to treat arm pain. Representative lead lengths are from about 30 cm to about 150 cm, and in particular embodiments, from about 40 cm to about 50 cm. Pulses may be applied to both groups of contacts in accordance with several different arrangements. For example pulses provided to one group may be interleaved with pulses applied to the other, or the same signal may be rapidly switched from one group to the other. In other embodiments, the signals applied to individual contacts, pairs of contacts, and/or contacts in different groups may be multiplexed in other manners. In any of these embodiments, each of the contacts C**1**, C**2** can have an appropriately selected surface area, e.g., in the range of from about 3 mm^2 to about 25 mm^2, and in particular embodi-

ments, from about 8 mm^2 to about 15 mm^2. Individual contacts on a given lead can have different surface area values, within the foregoing ranges, than neighboring or other contacts of the lead, with values selected depending upon features including the vertebral location of the individual contact.

Another aspect of an embodiment of the lead **910** shown in FIG. **9** is that the first contacts C**1** can have a significantly wider spacing than is typically associated with standard SCS contacts. For example, the first contacts C**1** can be spaced apart (e.g., closest edge to closest edge) by a first distance S**1** that is greater than a corresponding second distance S**2** between immediately neighboring second contacts C**2**. In a representative embodiment, the first distance S**1** can range from about 3 mm up to a distance that corresponds to one-half of a vertebral body, one vertebral body, or two vertebral bodies (e.g., about 16 mm, 32 mm, or 64 mm, respectively). In another particular embodiment, the first distance S**1** can be from about 5 mm to about 15 mm. This increased spacing can reduce the complexity of the lead **910**, and can still provide effective treatment to the patient because, as discussed above, the effectiveness of the presently disclosed therapy is relatively insensitive to the axial location of the signal delivery contacts. The second contacts C**2** can have a similar wide spacing when used to apply high frequency modulation in accordance with the presently disclosed methodologies. However, in another embodiment, different portions of the lead **910** can have contacts that are spaced apart by different distances. For example, if the patient receives high frequency pain suppression treatment via the first contacts C**1** at a first vertebral location, the patient can optionally receive low frequency (e.g., 1500 Hz or less, or 1200 Hz or less), paresthesia-inducing signals at the second vertebral location via the second contacts C**2** that are spaced apart by a distance S**2**. The distance S**2** can be smaller than the distance S**1** and, in particular embodiments, can be typical of contact spacings for standard SCS treatment (e.g., 4 mm spacings), as these contacts may be used for providing such treatment. Accordingly, the first contacts C**1** can deliver modulation in accordance with different signal delivery parameters than those associated with the second contacts C**2**. In still further embodiments, the inferior first contacts C**1** can have the close spacing S**2**, and the superior second contacts C**2** can have the wide spacing S**1**, depending upon patient indications and/or preferences. In still further embodiments, as noted above, contacts at both the inferior and superior locations can have the wide spacing, e.g., to support high frequency modulation at multiple locations along the spinal cord. In other embodiments, the lead **910** can include other arrangements of different contact spacings, depending upon the particular patient and indication. For example, the widths of the second contacts C**2** (and/or the first contacts C**1**) can be a greater fraction of the spacing between neighboring contacts than is represented schematically in FIG. **9**. The distance S**1** between neighboring first contacts C**1** can be less than an entire vertebral body (e.g., 5 mm or 16 mm) or greater than one vertebral body while still achieving benefits associated with increased spacing, e.g., reduced complexity. The lead **910** can have all contacts spaced equally (e.g., by up to about two vertebral bodies), or the contacts can have different spacings, as described above. Two or more first contacts C**1** can apply modulation at one vertebral level (e.g., T9) while two or more additional first contacts C**1** can provide modulation at the same or a different frequency at a different vertebral level (e.g., T10).

In some cases, it may be desirable to adjust the distance between the inferior contacts C**1** and the superior contacts C**2**. For example, the lead **910** can have a coil arrangement (like a telephone cord) or other length-adjusting feature that allows the practitioner to selectively vary the distance between the sets of contacts. In a particular aspect of this arrangement, the coiled portion of the lead can be located between the first contacts C**1** and the second contacts C**2**. For example, in an embodiment shown in FIG. **10**A, the lead **910** can include a proximal portion **910***a* carrying the first contacts C**1**, a distal portion **910***c* carrying the second contacts C**2**, and an intermediate portion **910***b* having a pre-shaped, variable-length strain relief feature, for example, a sinusoidally-shaped or a helically-shaped feature. The lead **910** also includes a stylet channel or lumen **915** extending through the lead **910** from the proximal portion **910***a* to the distal portion **910***c*.

Referring next to FIG. **10**B, the practitioner inserts a stylet **916** into the stylet lumen **915**, which straightens the lead **910** for implantation. The practitioner then inserts the lead **910** into the patient, via the stylet **916**, until the distal portion **910***c* and the associated second contacts C**2** are at the desired location. The practitioner then secures the distal portion **910***c* relative to the patient with a distal lead device **917***c*. The distal lead device **917***c* can include any of a variety of suitable remotely deployable structures for securing the lead, including, but not limited to an expandable balloon.

Referring next to FIG. **10**C, the practitioner can partially or completely remove the stylet **916** and allow the properties of the lead **910** (e.g., the natural tendency of the intermediate portion **910***b* to assume its initial shape) to draw the proximal portion **910***a* toward the distal portion **910***c*. When the proximal portion **910***a* has the desired spacing relative to the distal portion **910***c*, the practitioner can secure the proximal portion **910***a* relative to the patient with a proximal lead device **917***a* (e.g., a suture or other lead anchor). In this manner, the practitioner can select an appropriate spacing between the first contacts C**1** at the proximal portion **910***a* and the second contacts C**2** at distal portion **910***c* that provides effective treatment at multiple patient locations along the spine.

FIG. **11**A is an enlarged view of the proximal portion **910***a* of the lead **910**, illustrating an internal arrangement in accordance with a particular embodiment of the disclosure. FIG. **11**B is a cross-sectional view of the lead **910** taken substantially along line **11**B-**11**B of FIG. **11**A. Referring now to FIG. **11**B, the lead **910** can include multiple conductors **921** arranged within an outer insulation element **918**, for example, a plastic sleeve. In a particular embodiment, the conductors **921** can include a central conductor **921***a*. In another embodiment, the central conductor **921***a* can be eliminated and replaced with the stylet lumen **915** described above. In any of these embodiments, each individual conductor **921** can include multiple conductor strands **919** (e.g., a multifilar arrangement) surrounded by an individual conductor insulation element **920**. During manufacture, selected portions of the outer insulation **918** and the individual conductor insulation elements **920** can be removed, thus exposing individual conductors **921** at selected positions along the length of the lead **910**. These exposed portions can themselves function as contacts, and accordingly can provide modulation to the patient. In another embodiment, ring (or cylinder) contacts are attached to the exposed portions, e.g., by crimping or welding. The manufacturer can customize the lead **910** by spacing the removed sections of the outer insulation element **918** and the conductor insulation elements **920** in a particular manner. For example, the manufacturer can use a stencil or other arrangement to guide the removal process, which can include, but is not limited to, an ablative process. This arrangement allows the same overall configuration of the lead **910** to be used for a variety of applications and patients

without major changes. In another aspect of this embodiment, each of the conductors **921** can extend parallel to the others along the major axis of the lead **910** within the outer insulation **918**, as opposed to a braided or coiled arrangement. In addition, each of the conductor strands **919** of an individual conductor element **920** can extend parallel to its neighbors, also without spiraling. It is expected that these features, alone or in combination, will increase the flexibility of the overall lead **910**, allowing it to be inserted with a greater level of versatility and/or into a greater variety of patient anatomies then conventional leads.

FIG. **11**C is a partially schematic, enlarged illustration of the proximal portion **910***a* shown in FIG. **11**A. One expected advantage of the multifilar cable described above with reference to FIG. **11** B is that the impedance of each of the conductors **921** can be reduced when compared to conventional coil conductors. As a result, the diameter of the conductors **921** can be reduced and the overall diameter of the lead **910** can also be reduced. One result of advantageously reducing the lead diameter is that the contacts C**1** may have a greater length in order to provide the required surface area needed for effective modulation. If the contacts C**1** are formed from exposed portions of the conductors **921**, this is not expected to present an issue. If the contacts C**1** are ring or cylindrical contacts, then in particular embodiments, the length of the contact may become so great that it inhibits the practitioner's ability to readily maneuver the lead **910** during patient insertion. One approach to addressing this potential issue is to divide a particular contact C**1** into multiple sub-contacts, shown in FIG. **11**C as six sub-contacts C**1***a*-C**1***f*. In this embodiment, each of the individual sub-contacts C**1***a*-C**1***f* can be connected to the same conductor **921** shown in FIG. **11**B. Accordingly, the group of sub-contacts connected to a given conductor **921** can operate essentially as one long contact, without inhibiting the flexibility of the lead **910**.

As noted above, one feature of the foregoing arrangements is that they can be easy to design and manufacture. For example, the manufacturer can use different stencils to provide different contact spacings, depending upon specific patient applications. In addition to or in lieu of the foregoing effect, the foregoing arrangement can provide for greater maneuverability and facilitate the implantation process by eliminating ring electrodes and/or other rigid contacts, or dividing the contacts into subcontacts. In other embodiments, other arrangements can be used to provide contact flexibility. For example, the contacts can be formed from a conductive silicone, e.g., silicone impregnated with a suitable loading of conductive material, such as platinum, iridium or another noble metal.

Yet another feature of an embodiment of the lead shown in FIG. **9** is that a patient can receive effective therapy with just a single bipolar pair of active contacts. If more than one pair of contacts is active, each pair of contacts can receive the identical waveform, so that active contacts can be shorted to each other. In another embodiment, the implanted pulse generator (not visible in FIG. **9**) can serve as a return electrode. For example, the pulse generator can include a housing that serves as the return electrode, or the pulse generator can otherwise carry a return electrode that has a fixed position relative to the pulse generator. Accordingly, the modulation provided by the active contacts can be unipolar modulation, as opposed to the more typical bipolar stimulation associated with standard SCS treatments.

6.0 Representative Programmer Configurations

The robust characteristics of the presently disclosed therapy techniques may enable other aspects of the overall system described above with reference to FIGS. **1**A-B to be simplified. For example, the patient remote and the physician programmer can be simplified significantly because the need to change signal delivery parameters can be reduced significantly or eliminated entirely. In particular, it is expected that in certain embodiments, once the lead is implanted, the patient can receive effective therapy while assuming a wide range of positions and engaging in a wide range of activities, without having to change the signal amplitude or other signal delivery parameters. As a result, the patient remote need not include any programming functions, but can instead include a simple on/off function (e.g., an on/off button or switch), as described further in U.S. application Ser. No.12/765,790, previously incorporated herein by reference. The patient remote may also include an indicator (e.g., a light) that identifies when the pulse generator is active. This feature may be particularly useful in connection with the presently disclosed therapies because the patient will typically not feel a paresthesia, unless the system is configured and programmed to deliberately produce paresthesia in addition to the therapy signal. In particular embodiments, the physician programmer can be simplified in a similar manner, though in some cases, it may be desirable to maintain at least some level of programming ability at the physician programmer. Such a capability can allow the physician to select different contacts and/or other signal delivery parameters in the rare instances when the lead migrates or when the patient undergoes physiological changes (e.g., scarring) or lifestyle changes (e.g., new activities) that are so significant they require a change in the active contact(s) and/or other signal delivery parameters.

7.0 Representative Modulation Locations and Indications

Many of the embodiments described above were described in the context of treating chronic, neuropathic low back pain with modulation signals applied to the lower thoracic vertebrae (T9-T12). In other embodiments, modulation signals having parameters (e.g., frequency, pulse width, amplitude, and/or duty cycle) generally similar to those described above can be applied to other patient locations to address other indications. For example, while the foregoing methodologies included applying modulation at lateral locations ranging from the spinal cord midline to the DREZ, in other embodiments, the modulation may be applied to the foramen region, laterally outward from the DREZ. In other embodiments, the modulation may be applied to other spinal levels of the patient. For example, modulation may be applied to the sacral region and more particularly, the "horse tail" region at which the sacral nerves enter the sacrum. Urinary incontinence and fecal incontinence represent example indications that are expected to be treatable with modulation applied at this location. In other embodiments, the modulation may be applied to other thoracic vertebrae. For example, modulation may be applied to thoracic vertebrae above T9. In a particular embodiment, modulation may be applied to the T3-T6 region to treat angina. Modulation can be applied to high thoracic vertebrae to treat pain associated with shingles. Modulation may be applied to the cervical vertebrae to address chronic regional pain syndrome and/or total body pain, and may be used to replace neck surgery. Suitable cervical locations include vertebral levels C3-C7, inclusive. In other embodiments, modulation may be applied to the occipital nerves, for example, to address migraine headaches.

As described above, modulation in accordance with the foregoing parameters may also be applied to treat acute and/or chronic nociceptive pain. For example, modulation in accordance with these parameters can be used during surgery to supplement and/or replace anesthetics (e.g., a spinal tap). Such applications may be used for tumor removal, knee surgery, and/or other surgical techniques. Similar techniques

may be used with an implanted device to address post-operative pain, and can avoid the need for topical lidocaine. In still further embodiments, modulation in accordance with the foregoing parameters can be used to address other peripheral nerves. For example, modulation can be applied directly to peripheral nerves to address phantom limb pain.

From the foregoing, it will be appreciated that specific embodiments of the disclosure have been described herein for purposes of illustration, but that various modifications may be made without deviating from the disclosure. For example, the specific parameter ranges and indications described above may be different in further embodiments. As described above, the practitioner can avoid the use of certain procedures, (e.g., mapping, trial periods and/or current steering), but in other embodiments, such procedures may be used in particular instances. The lead described above with reference to FIGS. **9-11**C can have more than two groups of contacts, and/or can have other contact spacings in other embodiments. In some embodiments, as described above, the signal amplitude applied to the patient can be constant. In other embodiments, the amplitude can vary in a preselected manner, e.g., via ramping up/down, and/or cycling among multiple amplitudes. The signal delivery elements can have an epidural location, as discussed above with regard to FIG. **1**B, and in other embodiments, can have an extradural location. In particular embodiments described above, signals having the foregoing characteristics are expected to provide therapeutic benefits for patients having low back pain and/or leg pain, when stimulation is applied at vertebral levels from about T9 to about T12. In at least some other embodiments, it is believed that this range can extend from about T5 to about L1.

Certain aspects of the disclosure described in the context of particular embodiments may be combined or eliminated in other embodiments. For example, as described above, the trial period, operating room mapping process, and/or external modulator may be eliminated or simplified in particular embodiments. Therapies directed to particular indications may be combined in still further embodiments. Further, while advantages associated with certain embodiments have been described in the context of those embodiments, other embodiments may also exhibit such advantages, and not all embodiments need necessarily exhibit such advantages to fall within the scope of the present disclosure. Accordingly, the present disclosure and associated technology can encompass other embodiments not expressly shown or described herein.

We claim:

1. A method for configuring a signal generator to deliver a therapy signal to a patient's spinal cord via an implantable signal delivery device, wherein the implantable signal delivery device is implantable proximate to the patient's spinal cord, the method comprising:

programming the signal generator to

(1) generate a therapy signal, wherein at least a portion of the therapy signal is at a frequency in a frequency range between 5 kHz and 15 kHz, and at an amplitude that provides pain relief without generating paresthesia; and

(2) deliver the therapy signal to the patient's spinal cord via the implantable signal delivery device.

2. The method of claims **1**, wherein the amplitude is in an amplitude range from 0.5 mA to 10 mA.

3. The method of claim **2**, wherein at least a portion of the therapy signal is a bi-phasic square-wave.

4. The method of claim **3**, further comprising programming the signal generator to apply the therapy signal at a duty cycle.

5. The method of claim **3**, wherein at least a portion of the therapy signal has a pulse width between about 25 microseconds and about 166 microseconds.

6. The method of claim **3**, wherein at least a portion of the therapy signal has a pulse width between 30 microseconds and 35 microseconds, and a frequency of 10 kHz.

7. The method of claim **1** wherein the amplitude of the therapy signal is in an amplitude range from 0.5 mA to 10 mA, at least a portion of the therapy signal is a bi-phasic square-wave, and at least a portion of the therapy signal has a pulse width between about 25 microseconds and about 166 microseconds, and wherein the therapy signal is delivered to the patient's spinal cord from the patient's epidural space.

8. The method of claim **1** wherein the amplitude is in an amplitude range from 0.5 mA to 4 mA.

9. The method of claim **1** wherein the frequency is 10 kHz.

10. The method of claim **1** wherein at least a portion of the therapy signal has a pulse width between 33 microseconds to 100 microseconds.

11. The method of claim **1** wherein at least a portion of the therapy signal has a pulse width between 30 microseconds to 35 microseconds.

12. The method of claim **1**, further comprising programming the signal generator to halt delivery of the therapy signal for periods of from 1 millisecond to 2 seconds.

13. The method of claim **1** wherein the therapy signal is delivered in sequential packets of pulses.

14. The method of claim **1** wherein the signal generator is an implantable signal generator.

15. The method of claim **1** wherein the signal generator is an external signal generator.

16. The method of claim **1** wherein programming the signal generator includes programming the signal generator using an external physician's programmer.

17. The method of claim **1**, wherein the therapy signal at least partially reduces the patient's sensation of pain without affecting neural transmissions of touch or heat.

18. The method of claim **1**, further comprising conducting a placement process that includes placing the at least one implantable signal delivery device at a position in the patient's epidural space without using patient feedback during the placement process to at least assist in selecting the position.

19. The method of claim **1** wherein the therapy signal at least partially addresses patient back and leg pain.

20. The method of claim **1** wherein the therapy signal at least partially addresses patient back pain.

21. The method of claim **1** wherein the therapy signal at least partially addresses patient leg pain.

22. The method of claim **1** wherein the therapy signal at least partially addresses patient headache pain.

23. A method for configuring a signal generator to deliver a therapy signal to a patient's spinal cord, the method comprising:

programming the signal generator to

(1) generate a non-paresthesia-producing therapy signal, wherein at least a portion of the therapy signal has a frequency in a frequency range of from 1.5 kHz to 100 kHz; and

(2) deliver the therapy signal to the patient's spinal cord via a signal delivery device implanted in the patient's epidural space.

24. The method of claim **23**, wherein the frequency is 10 kHz.

25. The method of claim **24**, wherein at least a portion of the therapy signal has a pulse width between 30 microseconds and 35 microseconds.

26. The method of claim 23 wherein the amplitude of the therapy signal is in an amplitude range from 0.5 mA to 10 mA, at least a portion of the therapy signal is a bi-phasic square-wave, and at least a portion of the therapy signal has a pulse width between about 25 microseconds and about 166 microseconds, and wherein the therapy signal is delivered to the patient's spinal cord from the patient's epidural space.

27. The method of claim 23, wherein the frequency range is from 3 kHz to 20 kHz.

28. The method of claim 23 wherein the frequency range is from 3 kHz to 10 kHz.

29. The method of claim 23 wherein at least a portion of the therapy signal has a pulse width between 25 microseconds to 166 microseconds.

30. The method of claim 23 wherein at least a portion of the therapy signal has a pulse width between 33 microseconds to 100 microseconds.

31. The method of claim 23 wherein at least a portion of the therapy signal has a pulse width between 30 microseconds to 35 microseconds.

32. The method of claim 23, further comprising programming the signal generator to halt delivery of the therapy signal for periods of from 1 millisecond to 2 seconds.

33. The method of claim 23 wherein the therapy signal is delivered in sequential packets of pulses.

34. The method of claim 23 wherein the signal generator is an implantable signal generator.

35. The method of claim 23 wherein the signal generator is an external signal generator.

36. The method of claim 23 wherein programming the signal generator includes programming the signal generator using an external physician's programmer.

37. The method of claim 23, wherein the signal delivery device is implanted proximate to a vertebral level between T9 and T12, inclusively.

38. The method of claim 23, wherein the signal delivery device is implanted proximate to a thoracic vertebral level.

39. The method of claim 23, wherein the signal delivery device is implanted proximate to a vertebral level between C3 and C7, inclusively.

40. The method of claim 23, further comprising conducting a placement process that includes placing the at least one implantable signal delivery device at a position in the patient's epidural space without using patient feedback during the placement process to at least assist in selecting the position.

41. The method of claim 23 wherein the therapy signal at least partially addresses patient pain.

42. The method of claim 23 wherein the therapy signal at least partially addresses patient back pain.

43. The method of claim 23 wherein the therapy signal at least partially addresses patient leg pain.

44. The method of claim 23 wherein the therapy signal at least partially addresses patient headache pain.

45. A method for configuring a signal generator to deliver a therapy signal to a patient's spinal cord via an implantable signal delivery device, wherein the implantable signal delivery device is implantable in the patient's epidural space, the method comprising:

programming the signal generator to generate and deliver a therapy signal to the patient's spinal cord, via the implantable signal delivery device, wherein at least a portion of the therapy signal has

a frequency in a frequency range of from about 1.5 kHz to about 50 kHz,

a current amplitude in an amplitude range of from about 0.1 mA to about 6 mA,

a pulse width between about 10 microseconds and about 333 microseconds, and

at least partially reduces the patient's sensation of pain without generating paresthesia.

46. The method of claim 45, wherein the frequency is set to about 10 kHz and the pulse width is between about 30 microseconds and about 35 microseconds.

47. The method of claim 46, further comprising programming the signal generator to apply the therapy signal at a duty cycle.

48. The method of claim 45, wherein the frequency range is from about 3 kHz to about 20 kHz and the pulse width is between about 25 microseconds and about 166 microseconds.

49. The method of claim 45, wherein the frequency range is from about 5 kHz to about 15 kHz.

50. The method of claim 45 wherein the frequency range is from 3 kHz to 10 kHz.

51. The method of claim 45 wherein the frequency is 10 kHz.

52. The method of claim 45 wherein at least a portion of the therapy signal has a pulse width between 25 microseconds to 166 microseconds.

53. The method of claim 45 wherein at least a portion of the therapy signal has a pulse width between 33 microseconds to 100 microseconds.

54. The method of claim 45 wherein at least a portion of the therapy signal has a pulse width between 30 microseconds to 35 microseconds.

55. The method of claim 45, further comprising programming the signal generator to periodically halt delivery of the therapy signal for periods of from 1 millisecond to 2 seconds.

56. The method of claim 45 wherein the therapy signal is delivered in sequential packets of pulses.

57. The method of claim 45, further comprising programming the signal generator to apply the therapy signal at a duty cycle.

58. The method of claim 45 wherein the signal generator is an implantable signal generator.

59. The method of claim 45 wherein the signal generator is an external signal generator.

60. The method of claim 45 wherein programming the signal generator includes programming the signal generator using an external physician's programmer.

61. The method of claim 45, further comprising programming the signal generator to deliver the therapy signal to the patient's spinal cord at a vertebral level between T9 and T12, inclusively.

62. The method of claim 45, further comprising programming the signal generator to deliver the therapy signal to the patient's spinal cord at a thoracic vertebral level.

63. The method of claim 45, further comprising programming the signal generator to deliver the therapy signal to the patient's spinal cord at a vertebral level between C3 and C7, inclusively.

64. The method of claim 45, further comprising conducting a placement process that includes placing the at least one implantable signal delivery device at a position in the patient's epidural space without using patient feedback during the placement process to at least assist in selecting the position.

65. The method of claim 45 wherein the therapy signal at least partially addresses patient back and leg pain.

66. The method of claim 45 wherein the therapy signal at least partially addresses patient back pain.

67. The method of claim 45 wherein the therapy signal at least partially addresses patient leg pain.

68. The method of claim 45 wherein wherein the therapy signal at least partially addresses patient headache pain.

69. A method for configuring a signal generator to deliver a therapy signal to a patient's spinal cord, wherein the signal generator is in electrical communication with at least one implantable signal delivery device, and wherein the implantable signal delivery device is implantable in the patient's epidural space proximate to a vertebral level between about T9 and about T12, inclusively, the method comprising:

programming the signal generator to

(a) generate a non-paresthesia-producing therapy signal, wherein at least a portion of the therapy signal is at a frequency in a frequency range of from 3 kHz to 20 kHz, and wherein at least a portion of the therapy signal is

a bi-phasic square-wave with

a current amplitude in an amplitude range of from 0.5 mA to 10 mA, and

a pulse width between 10 microseconds and 333 microseconds; and

(b) deliver the therapy signal via the at least one implantable signal delivery device.

70. The method of claim 69, further comprising implanting the signal delivery device proximate to the vertebral level between T9 and T10.

71. The method of claim 70, wherein the frequency is 10 kHz.

72. The method of claim 71, further comprising:

programming the signal generator to apply the therapy signal at a duty cycle.

73. The method of claim 70 wherein at least a portion of the therapy signal has a pulse width between 30 microseconds to 35 microseconds.

74. The method of claim 69 wherein the frequency range is from 3 kHz to 10 kHz.

75. The method of claim 69, wherein the frequency range is between 5 kHz and 15 kHz.

76. The method of claim 69 wherein the frequency is 10 kHz.

77. The method of claim 69 wherein at least a portion of the therapy signal has a pulse width between 25 microseconds to 166 microseconds.

78. The method of claim 69 wherein at least a portion of the therapy signal has a pulse width between 33 microseconds to 100 microseconds.

79. The method of claim 69, wherein at least a portion of the therapy signal has a pulse width between 30 microseconds and 35 microseconds.

80. The method of claim 69, further comprising programming the signal generator to periodically halt delivery of the therapy signal for periods of from 1 millisecond to 2 seconds.

81. The method of claim 69 wherein the therapy signal is delivered in sequential packets of pulses.

82. The method of claim 69 wherein the signal generator is an implantable signal generator.

83. The method of claim 69 wherein the signal generator is an external signal generator.

84. The method of claim 69 wherein programming the signal generator includes programming the signal generator using an external physician's programmer.

85. The method of claim 69, wherein the therapy signal at least partially reduces the patient's sensation of pain without affecting neural transmissions of touch or heat.

86. The method of claim 69, further comprising conducting a placement process that includes placing the at least one implantable signal delivery device at a position in the patient's epidural space without using patient feedback during the placement process to at least assist in selecting the position.

87. The method of claim 69 wherein the therapy signal at least partially addresses patient pain.

88. The method of claim 69 wherein the therapy signal at least partially addresses patient back pain.

89. The method of claim 69 wherein the therapy signal at least partially addresses patient leg pain.

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UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 8,874,222 B2
APPLICATION NO. : 14/164100
DATED : October 28, 2014
INVENTOR(S) : Konstantinos Alataris et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On the Title page

On the page 3, in column 2, item (56) under "Other Publications", line 6, delete "Sterotactic" and insert -- Stereotactic --, therefor.

On the page 4, in column 2, item (56) under "Other Publications", line 44, delete "Neurosco," and insert -- Neurosci, --, therefor.

In the Drawings

On sheet 9 of 15, in Figure 6C, reference numeral 645, line 1, delete "insenstitivity" and insert -- insensitivity --, therefor.

In the Specification

In column 7, line 46, delete "33,which" and insert -- 33, which --, therefor.

In column 9, line 28, delete "cases;" and insert -- cases, --, therefor.

In column 11, line 39, delete "111 b" and insert -- 111b --, therefor.

In column 12, line 4, delete "Ser. No.12/765,790," and insert -- Ser. No. 12/765,790, --, therefor.

In column 19, lines 8-9, delete "Ser. No.12/765,790 ," and insert -- Ser. No. 12/765,790, --, therefor.

In column 19, line 51, delete "about25" and insert -- about 25 --, therefor.

Signed and Sealed this
Eighth Day of September, 2015

Michelle K. Lee

Michelle K. Lee
Director of the United States Patent and Trademark Office

CERTIFICATE OF CORRECTION (continued)
U.S. Pat. No. 8,874,222 B2

In column 23, line 15, delete "FIG. 11 B" and insert -- FIG. 11B --, therefor.

In column 24, line 12, delete "Ser. No.12/765,790," and insert -- Ser. No. 12/765,790, --, therefor.

In the Claims

In column 25, line 62, in claim 2, delete "claims" and insert -- claim --, therefor.

In column 29, line 1, in claim 68, delete "wherein wherein" and insert -- wherein --, therefor.