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.	:	

Rodger D. Smith II, Lucinda C. Cucuzzella, MORRIS, NICHOLS, ARSHT & TUNNELL LLP, Wilmington, Delaware; Bita Rahebi, MORRISON & FOERSTER LLP, Los Angeles, California; Kenneth A. Kuwayti, MORRISON & FOERSTER LLP, Palo Alto, California; John R. Lanham, MORRISON & FOERSTER LLP, San Diego, California; Michael A. Jacobs, MORRISON & FOERSTER LLP, San Francisco, California

Counsel for Plaintiff

David E. Moore, Bindu A. Palapura, Clarissa R. Chenoweth, POTTER ANDERSON & CORROON LLP, Wilmington, Delaware; Catherine Nyarady, Crystal Parker, Michael Milea, Kripa Raman, Joshua Reich, PAUL, WEISS, RIFKIND, WHARTON & GARRISON LLP, New York, New York

Counsel for Defendant

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]

---

[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

---

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.