IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NEVRO CORP.,	)	
	)	
Plaintiff,	)	C.A. No. 19-325 (CFC)
	)	
v.	)	REDACTED - PUBLIC VERSION
	)	
STIMWAVE TECHNOLOGIES, INC.,	)	
	)	
Defendant.	)	

NEVRO'S OPENING BRIEF IN SUPPORT OF
ITS MOTION FOR PRELIMINARY INJUNCTION

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I. INTRODUCTION

Nevro brings this preliminary injunction motion to protect its position as the sole provider of an innovative treatment for chronic pain against defendant Stimwave, which is flagrantly infringing Nevro's patents. Infringement here is clear and readily demonstrated. And Nevro has a history of surviving validity challenges to patent claims like those asserted here.

The patent claims at issue go to the very heart of Nevro's innovative technology, which has been the key to Nevro penetrating the competitive spinal cord stimulation market. Since announcing FDA approval two weeks ago, Stimwave is specifically and aggressively targeting Nevro's market position, threatening irreparable harm. Granting Nevro's motion will protect the status quo while the case proceeds to trial on the merits and allow Nevro to defend its investment in its novel therapy—precisely what the patent system is designed to do.

II. NATURE AND STAGE OF THE PROCEEDINGS

Nevro filed this action on February 14, 2019. Stimwave answered on April 8, 2019. Nevro now moves for a preliminary injunction and also seeks expedited discovery. Nevro anticipates that the requested discovery will lend even further support to this motion.

III. STATEMENT OF FACTS

A. Nevro's High Frequency, Paresthesia-Free Therapy Revolutionized Spinal Cord Stimulation Therapy

Nevro was founded in 2006 to develop a novel spinal cord stimulation ("SCS") therapy for treating chronic pain. SCS therapy treats pain by delivering short electrical pulses to the spinal cord region. (Caraway Decl. ¶ 8.) While SCS technology has been on the market for decades, Nevro's patented SCS technology is far more effective than traditional systems.

Nevro's SCS technology differs from traditional SCS technology in two ways. First, it operates at much higher frequencies. Traditional SCS systems deliver low frequency

stimulation, typically between 40 Hz and 90 Hz, while Nevro's commercial embodiment delivers high frequency stimulation at 10,000 Hz (or 10 kHz). (*Id.* ¶¶ 10, 13; Rosenberg Decl. ¶¶ 15, 18.)

Second, Nevro's therapy does not generate "paresthesia"—a tingling, pins-and-needles, or numbness sensation—in the patient. (Caraway Decl. ¶ 13.) Before Nevro, generating paresthesia over the patient's area of pain was thought to be the means for providing pain relief. (Rosenberg Decl. ¶¶ 13-15.) Thus, for decades, SCS research and development was directed toward improving paresthesia delivery. (Caraway Decl. ¶ 11; Exs[1]. 2, 3 (Kapural and Oakley).)

Because SCS therapy was based on the core principle that paresthesia was necessary to treat pain, Nevro's paresthesia-free therapy initially had to overcome significant skepticism. (Rosenberg Decl. ¶ 53.) Critics also viewed Nevro's high frequency signal as unnecessary and potentially unsafe. (Ex. 4; Pless Decl. ¶¶ 33-37.)

The FDA put Nevro to a rigorous test to confirm its safety and efficacy. It required Nevro to conduct a randomized controlled trial, testing its system in a head-to-head comparison against a commercial low frequency SCS system. In a landmark finding the trial, known as the Senza RCT, found Nevro's therapy to be nearly twice as effective as the traditional low frequency, paresthesia-based system in providing pain relief. (Caraway Decl. ¶ 15; Ex. 2.) Based on these findings, the FDA provided Nevro with a rare "superiority" labeling—the first ever in the SCS field. (Caraway Decl. ¶ 15.) Investors took notice. A May 2015 J.P. Morgan analysis proclaimed: "Friday's FDA approval sets the stage for the most compelling new product launch in the field of neurostimulation to treat chronic pain in more than a decade." (Ex. 5.)

Nevro's therapy has other significant advantages. Unlike traditional SCS therapy, it does not impose movement restrictions, and requires few adjustments—once a *week* compared to

[1] All references to "Ex." are to the Appendix in Support of Nevro's Opening Brief in Support of Its Motion for Preliminary Injunction, filed herewith.

dozens of times a day. (Rosenberg Decl. ¶ 74.) Paresthesia-based therapy requires that a patient remain awake during part of the procedure so that the physician can "map" the paresthesia to the area of pain. Nevro's therapy does not. (*Id.* ¶ 20.) And Nevro's therapy is effective in treating lower back pain, which has been difficult to treat with traditional therapy. (*Id.* ¶ 24.)

Nevro has invested well over [redacted] in research and development and clinical costs to develop its proprietary high frequency paresthesia-free technology, and [redacted] to bring a commercial product to the market. (Caraway Decl. ¶ 13.) On receiving FDA approval in May 2015, Nevro launched its Senza® SCS system in the United States and promoted its patented HF10® therapy. The Senza system is Nevro's only product. (*Id.*)

Nevro's HF10 therapy has been a commercial success, as industry observers have noted. In November 2016, Morgan Stanley proclaimed that "Nevro's clinical data is compelling and of a quality rarely seen in medical devices today," and that "Nevro's entry into the $1.5 billion market for spinal cord stimulation (SCS) is a potentially disruptive event." (Ex. 6.) A February 2017 J.P. Morgan analysis recognized that "Senza is driving SCS market acceleration and expansion into the underserved back pain segment." (Ex. 7.)

Nevro's market strategy is based on its differentiating technology and the clinically superior results it provides. (Caraway Decl. ¶ 16.) It has never licensed that technology. (*Id.* ¶ 39.) Before Nevro's entry, the U.S. and global SCS markets were dominated by three of the world's largest medical device companies—Boston Scientific, Medtronic, and St. Jude (now Abbott). (*Id.* ¶ 11.) Without a differentiating technology, physicians and health care providers would have no compelling reason to choose Nevro. (*Id.* ¶ 16; Rosenberg Decl. ¶ 59.) Even today, notwithstanding the evidence of Nevro's superior therapy, many physicians with ties to these companies are reluctant to switch. (Rosenberg Decl. ¶¶ 57-61.) Nevro is still in an early

adoption phase, having captured only about 15% of the market. (Schoettelkotte Decl. ¶ 27.)

Nevro has protected its SCS technology through an extensive patent portfolio. For this motion, Nevro focuses on five claims from two of the five asserted patents—claims 22 and 23 of U.S. Patent No. 9,327,127, and claims 24, 28, and 48 of U.S. Patent No. 8,874,222. All five claims protect methods of treating patients with high frequency, paresthesia-free SCS therapy, the core of Nevro's differentiation. (*See* Ex. 1 for recitation of claims.)

B. Stimwave's Launch of a High Frequency System That Competes Directly with Nevro's Breakthrough Therapy

Stimwave is a medical device company that markets the Freedom-4A and Freedom-8A SCS systems. (D.I. 8 ¶ 7.) Stimwave's claimed differentiating feature is that its systems have an external battery instead of a battery implanted in the patient. (Caraway Decl. ¶ 22.) The concept of an external battery is not new. (Pless Decl. ¶¶ 29, 49.) Before the current wave of implantable SCS devices, stimulators were powered by external power sources. (*Id.*; Caraway Decl. ¶¶ 9, 22.) But because patients disliked wearing an external battery over the long term, most SCS manufacturers abandoned this approach in favor of implantable batteries. (*Id.* ¶ 9.)

Until recently, Stimwave had FDA approval only up to 1,500 Hz. (Ex. 8.) On April 1, 2019, however, Stimwave issued a press release announcing its "FDA cleared waveforms to 10,000 Hz available commercially in USA." (Ex. 9, April 1, 2019 Press Release.) Stimwave immediately published marketing materials touting its high frequency therapy and targeting Nevro. The timing surprised Nevro, which had been conferring for weeks with Stimwave over expedited discovery, including whether and how Stimwave would launch an infringing product. (Lanham Declaration in Support of Nevro's Motion to Expedite Discovery ("Lanham Decl.") ¶ 5.) Stimwave represented throughout these discussions that it had no documents concerning plans to launch high frequency therapy. (*Id.*) Those representations were evidently untrue.

Stimwave is squarely targeting Nevro's distinctive market position. Since its U.S. launch in 2015, Nevro has been the exclusive provider of high frequency, paresthesia-free therapy in the United States. But Stimwave is now marketing 10 kHz therapy to physicians through social media postings and direct communications. (Exs. 10-15.) Stimwave's recent invitation to physicians at a major upcoming conference is emblematic: Stimwave is promoting the event with a picture of a surfer titled "Hang 10k at the Stimwave Lunch Presentation." (Ex. 16.)

IV. ARGUMENT

A preliminary injunction should be entered if Nevro shows: (1) a reasonable likelihood of success on the merits of its claims; (2) irreparable harm if an injunction is not granted; (3) a balance of hardships tipping in its favor; and (4) the injunction's favorable impact on the public interest. *Tinnus Enters., LLC v. Telebrands Corp.*, 846 F.3d 1190, 1202 (Fed. Cir. 2017). Although the patent owner bears the burden of proof, it may initially rely on statutory or other presumptions. *Polymer Techs., Inc. v. Bridwell*, 103 F.3d 970, 973 (Fed. Cir. 1996). Nevro strongly establishes each factor here.

A. Nevro Is Likely to Succeed on the Merits

1. Stimwave Infringes the Claims of the '127 and '222 Patents

The evidence amply demonstrates Stimwave's infringement of the '127 and '222 patent claims. The declaration of Ben Pless, a medical device expert with over 30 years of neuromodulation and electrical stimulation experience, sets forth an element-by-element analysis of Stimwave's infringement. (Pless Decl. ¶ 2.) The evidence and analysis is summarized below.

a. Stimwave's Direct Infringement

The five claims Nevro asserts are directed to methods of treatment using high frequency paresthesia-free therapy—the core of Nevro's intellectual property. Claims 22 and 23 of the '127 patent cover such methods of treating patients by "delivering an electrical signal" within

certain parameters via a "signal delivery device" to the patient's spinal cord. Relatedly, claims 24, 28, and 48 of the '222 patent cover methods of configuring SCS systems by "programming" them to generate and deliver high frequency, paresthesia-free therapy within certain parameters. Stimwave directly infringes these claims by programming its SCS systems to provide high frequency, paresthesia-free therapy. Stimwave's infringement can be broken down into the following five aspects covered by the patent claims. Not every claim requires all five aspects.

Signal delivery devices. The asserted claims of both patents recite that the SCS therapy is delivered via a "signal delivery device." In SCS systems, these signal delivery devices commonly include "leads"—insulated wires with electrodes that deliver the electrical pulses to the spinal cord. (Pless Decl. ¶¶ 23, 60, 87, 97.) Stimwave's Freedom-4A and Freedom-8A systems each use such leads: "The stimulator has small metal electrodes near the tip that create an electrical field of energy when power is applied." (Ex. 17, Stimwave Freedom Stimulators website.) Claims 24, 28, and 48 of the '222 patent refer to leads that are implantable or implanted in the patient's "epidural space." That is where Stimwave's leads are implanted: "All subjects were immediately implanted with a permanent wireless system using a Tuohy needle, placing the stimulator electrodes in the epidural space." (Ex. 18 at 2.)

Programming. The asserted claims of the '222 patent are directed to "programming the signal generator" of an SCS system to provide therapy within certain parameters. Stimwave uses its WaveCrest Programmer to perform such programming. (Ex. 19, WaveCrest Programmer User Manual.) In the SCS industry, company representatives are present in the operating room and during follow-up, and they program the devices. (Rosenberg Decl. ¶¶ 62-69.) Stimwave's programming manual states that only its trained clinical representatives may use the WaveCrest Programmer. (Ex. 19 at 3.)

High frequency. The asserted claims are directed to high frequency SCS within certain frequency ranges. Claim 23 of the '127 patent and claim 24 of the '222 patent specify a frequency of 10 kHz; the other three claims specify frequency ranges that include 10 kHz. Stimwave's infringing high frequency SCS therapy is at 10 kHz or frequency ranges up to 10 kHz. Stimwave's CEO recently stated: "With the FDA clearance of 10,000 Hz, Stimwave U.S. patients now have an additional waveform to ensure maximum amount of ability to modify their programming to fit their individual pain management needs and decrease the effects of plasticity." (Ex. 9 at 3.) Public statements confirm that Stimwave patients are already receiving treatment with its 10 kHz SCS therapy. (Exs. 11-15, LinkedIn posts.)

Paresthesia-free. All of the asserted patent claims are directed to high frequency SCS at amplitudes that are therapeutic but do not generate paresthesia—sensations such as tingling, numbness, or pins-and-needles that are associated with traditional SCS therapy. (Pless Decl. ¶¶ 25, 67, 80, 117.) Stimwave also provides high frequency SCS therapy at amplitudes that do not generate paresthesia. As explained in Stimwave's 10 kHz study, "tonic stimulation generates paresthesia whereas HF [high frequency] stimulation does not." (Ex. 18 at 2.)

Pulse width and amplitude. Claim 48 of the '222 patent specifies that the electrical signal has a pulse width range between about 25 microseconds and about 166 microseconds, and an amplitude range from about 0.1 mA to about 6 mA. Stimwave's 10 kHz study states that it used a pulse width of 30 microseconds, which falls within the claimed range. (Ex. 18 at 2.) Stimwave has not publicly disclosed the amplitudes it uses. But as explained in the declaration of Dr. William Rosenberg, a physician with substantial experience treating patients with high frequency SCS, given the other parameters of Stimwave's high frequency therapy, the typical amplitudes are below 6 mA. (Rosenberg Decl. ¶ 79.)

b. Stimwave's Indirect Infringement

Stimwave is also inducing infringement of Nevro's patents under 35 U.S.C. §271(b). Induced infringement requires that: 1) a third party's actions directly infringed one or more patent claims; (2) the accused infringer induced those infringing acts; and (3) the accused infringer knew or should have known the acts it induced constituted infringement. *Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 843 F.3d 1315, 1332 (Fed. Cir. 2016).

To the extent Stimwave seeks to avoid direct infringement by arguing that it is physicians that actually provide the therapy, Stimwave induces that infringement through its encouragement of the physicians to directly infringe. *Barry v. Medtronic, Inc*., 914 F.3d 1310, 1334 (Fed. Cir. 2019) ("[I]nducement can be found where there is [e]vidence of active steps taken to encourage direct infringement, which can in turn be found in advertising an infringing use or instructing how to engage in an infringing use.") (citation omitted); *LG Display Co. v. AU Optronics Corp.*, C.A. Nos. 06-726-JJF, 07-357-JJF, 2010 WL 545921, at *32 (D. Del. Feb. 16, 2010) (finding accused infringer induced infringement by providing product information and marketing materials touting patented features to encourage U.S. sales).

Stimwave is actively encouraging use of Nevro's patented methods. Its April 1, 2019 press release states, "[t]he Freedom SCS system is currently available in the U.S. and worldwide, with frequencies up to 10,000 Hz." (Ex. 9 at 3-4.) On LinkedIn, Stimwave announced to its more than 4,000 followers that it is "pleased to announce that the Freedom #SCS system is now FDA cleared up to 10 kHz to provide chronic pain relief therapy." (Ex. 15.) In response to the CEO of Stimwave promoting 10 kHz, a territory manager for Stimwave stated, "We have a great product that just got better. We have every available waveform that is available in the United States in one system." (Ex. 11, *see* Rickey Johnson LinkedIn comment.)

U.S. Physicians have already begun implanting Stimwave's infringing 10 kHz therapy

and are offering it to patients. Stimwave is encouraging this: it congratulated a physician "on his first Stimwave SCS implant utilizing 10 kHz!" (Exs. 11, 14.) Stimwave will be presenting at the American Society of Interventional Pain Physicians (ASIPP) Annual Meeting in Las Vegas (May 3-5, 2019) to promote its infringing therapy. The invitations, sent directly to physicians, feature a surfer photo and ask attendees to "Hang 10k with Stimwave." (Ex. 16 at 3.)

Stimwave intends to induce infringement—and it has made a deliberate decision to target Nevro's technology without permission. It has been aware of Nevro's patents for years. In June 2014, Stimwave's CEO, Laura Tyler Perryman, told Nevro's Chief Medical Officer that it would not activate the high frequency programming on its systems in the United States because that would violate Nevro's patents. (Caraway Decl. ¶ 23.) But Ms. Perryman's promise did not last long. In 2016, Stimwave began a study overseas, using Nevro's HF10 parameters to observe the efficacy of high frequency stimulation. (Ex. 20.) In December 2017, Stimwave's CEO, Laura Tyler Perryman, published an article recognizing high frequency therapy's ability to "produce[] better pain relief without the accompanying paresthesia" and cited to clinical data showing the high efficacy of Nevro's Senza systems. (Ex. 21, Open Journal of Surgery at 021.)

In a February 2019 presentation, Stimwave misleadingly claimed that it "can have a high frequency product on the market" because of a patent infringement suit between Nevro and Boston Scientific Corporation. (Ex. 22 at 23; Complaint, *Nevro Corp. v. Boston Scientific Corp.*, No. 3:16-cv-06830-VC (N.D. Cal. Nov. 28, 2019), D.I. 1.) Stimwave omitted key material to support its claim.[2] But as Stimwave knows, that litigation did not clear the way for Stimwave's

[2] Stimwave's presentation excerpted a portion of Nevro's press release focusing on system claims, but omitted that the court found in Nevro's favor with regard to six method claims, including claims similar to those asserted here, "finding them patent eligible and rejecting Boston Scientific's arguments that the claims were invalid as indefinite." (Ex. 23 at 1.) Stimwave also omitted: "Nevro believes that the six method claims that were upheld would

launch. Rather, the district court in that action upheld the validity of Nevro's method claims against challenges based on theories of unpatentable subject matter and invalidity. (Ex. 34.) And critically, unlike Stimwave, as a result of Nevro's enforcement, Boston Scientific chose not to launch high frequency, paresthesia-free SCS therapy in the United States. (Ex. 22 at 23.)

2. Nevro's Method Claims Are Valid

"Every patent is presumed valid, so if [the accused infringer] fails to identify any persuasive evidence of invalidity, the very existence of the patent satisfies [the patentee's] burden on validity." *Purdue Pharma L.P. v. Boehringer Ingelheim GmbH*, 237 F.3d 1359, 1365 (Fed. Cir. 2001) (affirming preliminary injunction). This presumption of validity is constant throughout all stages of litigation, including preliminary injunction proceedings. *Titan Tire Corp. v. Case New Holland, Inc.*, 566 F.3d 1372, 1376-77 (Fed. Cir. 2009). To overcome it, the accused infringer must establish a "substantial question" regarding validity by presenting an invalidity defense that the patentee cannot show "lacks substantial merit." *Id.* at 1377.

But the validity of Nevro's method claims does not hang solely on the presumption of validity. The claimed innovations have been confirmed and upheld by the Patent and Trademark Office, the Patent Trial and Appeal Board, and in federal district court. And rightly so. Nevro's patents claim genuine innovations. Nevro's pioneering high frequency, paresthesia-free therapy had to overcome widespread skepticism in an industry that had been dominated for decades by traditional low frequency, paresthesia-based SCS therapy. (Caraway Decl. ¶ 14.) The proven success and superiority of Nevro's therapy changed the paradigm. (*Id.* ¶¶ 13, 19.)

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effectively preclude Boston Scientific from commercially providing high frequency SCS therapy between 1.5 kHz and 100 kHz in the United States." (*See id*. at 2.) As a result, Boston Scientific announced that it now had "no plans" to launch a system that would infringe Nevro's upheld patents. Stimwave also presented an excerpt of a legal article, but omitted that six method claims survived challenges in the lawsuit, which could "complicate a U.S. commercial launch" for Boston Scientific. (Ex. 23-26.) The *Boston Scientific* matter is currently on appeal.

No prior art can defeat Nevro's claims. During prosecution of the '127 and '222 patents, the Patent Office considered more than 250 prior art references. (Exs. 27-28.) Any prior art that Stimwave may dredge up now will be cumulative at best.

The validity of Nevro's patented methods of treatment has been upheld in the face of direct challenges as well. The method claims here are similar to those of a related Nevro patent, U.S. Patent No. 8,359,102 (the '102 patent). (Ex. 29.) The '102 patent was the subject of two separate petitions seeking *inter partes review* on the basis of eight different grounds and over 15 combinations of references. (Exs. 30-31.) The PTAB declined even to institute the proceedings, finding that neither petition established "a reasonable likelihood of prevailing" that any challenged claims were unpatentable. (Ex. 32 -33, 1203 DI at 20, 1204 DI at 14; Pless Decl. 42.) As noted above, the method claims of the '102 patent were also tested in Nevro's litigation with Boston Scientific in the Northern District of California. The court held that these claims were not invalid for indefiniteness or unpatentable subject matter. (Ex. 34, MSJ Order at 7-8.)

In sum, Nevro's methods of high frequency, paresthesia-free therapy have changed the fundamental paradigm of SCS therapy in the face of widespread skepticism, and their validity has been repeatedly tested and confirmed. Stimwave will not prevail on invalidity.

B. Nevro Will Likely be Irreparably Harmed Absent an Injunction

A party seeking a preliminary injunction must establish that it is likely to suffer irreparable harm in the absence of preliminary relief. *Trebro Mfg., Inc. v. FireFly Equip., LLC*, 748 F.3d 1159, 1165 (Fed. Cir. 2014). A patentee seeking an injunction must also show a causal nexus between the infringing feature and consumer demand for the accused product. *Apple Inc. v. Samsung Elecs. Co.*, 695 F.3d 1370, 1375 (Fed. Cir. 2012).

Harm is likely to be irreparable where, as here, the patentee and infringer are direct competitors, because the patentee is forced to compete against its own invention. *Trebro*, 748

F.3d at 1171; *Douglas Dynamics, LLC v. Buyers Prods. Co*., 717 F.3d 1336, 1345 (Fed. Cir. 2013). "Indeed, the principal value of a patent is the right to exclude arch competitors from making, selling and using an infringing product." *Butamax Advanced Biofuels LLC v. Gevo, Inc.*, 868 F. Supp. 2d 359, 374 (D. Del. 2012) (citation omitted).

The irreparable harm here is clear: loss of market share, price erosion, loss of R&D investment, damage to reputation and goodwill, and inability to recover damages. These are classic examples of irreparable harm. Damages expert Todd Schoettelkotte explains in detail why Nevro could not be fully compensated for this harm. (*See* Schoettelkotte Decl. ¶¶ 20-39.)

1. Stimwave's Launch of its Infringing Therapy Will Likely Cause Nevro to Lose Market Share

Stimwave is attacking Nevro's market share by challenging Nevro's status as the exclusive provider of high frequency, paresthesia-free therapy. They are direct competitors. (Caraway Decl. ¶¶ 20, 37; *see also* Ex. 35 at 2, Morgan Stanley—It's Getting Crowded (identifying Stimwave as a "new entrant[]" to SCS market and characterizing "Stimwave's IP position vs Nevro" as a "key question[] in 2019".) Given Stimwave's ability to tout its 10 kHz therapy and its low pricing structure (*see infra*, Section IV.B.2), it is likely that Stimwave will gain traction among health care providers that would otherwise choose Nevro. (*See* Caraway Decl. ¶ 37.) Whether these providers will be permanent converts, keep some business with Nevro, or become dissatisfied with Stimwave's products and abandon 10 kHz therapy entirely cannot reasonably be ascertained—nor can Nevro's sales if it had been able to keep that provider exclusively. *See Celsis in Vitro, Inc. v. Cellzdirect, Inc.*, 664 F.3d 922, 930 (Fed. Cir. 2012).

But there is reason to worry. The SCS market is characterized by a high degree of "stickiness," where physicians tend to develop familiarity with, and loyalty to, a single provider. (Caraway Decl. ¶ 17; Rosenberg Decl. ¶¶ 57-61.) Moreover, SCS systems are implanted for

long-term use, so opportunities to convert a particular patient after implantation are rare. (Rosenberg Decl. ¶ 61.) Nevro was able to overcome this barrier to entry by virtue of its differentiating, patented therapy. (Caraway Decl. ¶ 16; Ex. 36 at 2, Sterne Agee 2015 Report (acknowledging role of Nevro's "differentiated product offering (HF10 technology)" in capturing market share).) But Nevro only entered the fiercely competetivie U.S. SCS market four years ago and and has to aggressively defend its market share against both much larger competitors, like Boston Scientific, with established relationships, and smaller, lower-priced competitors like Stimwave. (Caraway Decl. ¶ 20.) Nevro relies on its patented high frequency, paresthesia-free therapy to maintain and grow its market share. (*Id.*)

Losing market share to a head-to-head competitor is an irreparable harm. *See, e.g.*, *TEK Glob., S.R.L. v. Sealant Sys. Int'l, Inc.*, No. 2017-2507, 2019 WL 1412538, at *11 (Fed. Cir. Mar. 29, 2019); *Broadcom Corp. v. Emulex Corp*., 732 F.3d 1325, 1338 (Fed. Cir. 2013). Though economic in nature, lost market share is irreparable because "[t]here is no effective way to measure the loss of sales or potential growth—to ascertain the people who do not knock on the door or to identify the specific persons who do not reorder because of the existence of the infringer." *Celsis*, 664 F.3d at 930. (*See also* Schoettelkotte Decl. ¶¶ 23-27.)

2. Nevro Will Likely Suffer Irreversible Price Erosion

Stimwave's strategy from the start has been to undercut the market on price. (Caraway Decl. ¶¶ 31-32; Ex. 63.) It sells many of its SCS systems [redacted] (*Id.*) Even Stimwave's high end pricing [redacted]. (*Id.*) In addition, [redacted] if Stimwave continues to offer a discounted version of Nevro's high frequency paresthesia-free technology. (*Id.* ¶ 35.) Notably, Stimwave's reduced

pricing does not lower the cost of its SCS therapy to consumers or payors because it instructs physicians to bill at the same reimbursement codes used for other SCS systems, so the cost to Medicare and insurance companies is the same. (*Id.* ¶ 32.) But it does provide healthcare institutions with a significantly higher margin, incentivizing them to switch. (*Id.*)

Even if the health care institution ultimately does not select Stimwave, it can use Stimwave's pricing to negotiate a lower price. [redacted] (*Id.* ¶ 37.) If Stimwave's infringement is allowed to continue, Nevro will likely be forced to lower its prices, and customers may continue to expect this discounted pricing even if Stimwave's conduct is enjoined following trial. (*Id.* ¶¶ 37-39.)

Price erosion has repeatedly been held to be an irreparable harm. *See Abbott Labs. v. Sandoz, Inc*., 544 F.3d 1341, 1362 (Fed. Cir. 2008) (affirming preliminary injunction based on price erosion); *Edwards Lifesciences AG v. CoreValve, Inc*., C.A. No. 08-91 (GMS), 2014 WL 1493187, at *6 (D. Del. Apr. 15, 2014) ("likelihood of price erosion should Medtronic enter the market is sufficient to establish irreparable harm"). Price erosion is often, as here, difficult to measure and impossible to reverse. It cannot be remedied with money damages. *See Abbott Labs*, 544 F.3d at 1362 (affirming preliminary injunction, noting "added erosion of markets, customers, and prices, is rarely reversible"); *Albany Molecular Research, Inc. v. Dr. Reddy's Labs., Ltd.*, No. 09-4638, 2010 WL 2516465, at *11 (D.N.J. June 14, 2010) (rejecting argument that price erosion "boil[s] down to money"). (*See also* Schoettelkotte Decl. ¶¶ 28-30.)

3. Stimwave's Infringement Will Impair Nevro's R&D

As an innovator company, Nevro is particularly vulnerable to lost R&D opportunities. Nevro invests revenue from its Senza and HF10 products heavily into R&D, and is the only SCS manufacturer executing large scale randomized controlled trials, even at the expense of corporate

profit, and views R&D to be "vital to the success of the company moving forward." (Caraway Decl. ¶ 38; Schoettelkotte Decl. ¶¶ 31-35.) Based in part on these ongoing R&D expenditures, Nevro has still yet to turn a profit. (Caraway Decl. ¶ 13; Schoettelkotte Decl. ¶ 33.) Just some of Nevro's R&D pipeline projects have involved next generation IPGs, enhanced MRI capabilities, and pursuit of different therapeutic indications. (Schoettelkotte Decl. ¶ 34.) By taking Nevro's market share and eroding its prices, Stimwave will directly away from Nevro's R&D projects. It is impossible to fully quantify the value of this lost R&D, resulting in irreparable harm to Nevro. *See Vanda Pharm., Inc. v. Roxane Labs., Inc.*, 203 F. Supp. 3d 412, 436 (D. Del. 2016) (finding irreparable harm where patentee would lose "revenue to invest in research and development of new clinical indications for and formulations of [the patented drug] and development of other drugs"); *Janssen Prods., L.P. v. Lupin Ltd.*, 109 F. Supp. 3d 650, 704 (D.N.J. 2014) (finding irreparable harm where infringement would reduce drug-maker's R&D).

4. Nevro Will Likely Suffer Irreparable Harm to its Reputation and Goodwill

Nevro has spent years building reputation and goodwill as an innovator and the sole provider of a revolutionary therapy with excellent clinical outcomes. This hard-won recognition will suffer permanent damage if Stimwave is not enjoined. Reputational harm and loss of goodwill are grounds for finding irreparable harm. *See Tinnus Enters.*, 846 F.3d at 1208 ("persisting harm to [patentee]'s reputation and tarnishes its status as the innovator in this market" was irreparable); *Celsis*, 664 F.3d at 930. A patentee's "reputation as an innovator will certainly be damaged if customers found the same 'innovations' appearing in competitors' [products], particularly products considered less prestigious and innovative." *Douglas Dynamics, LLC v. Buyers Prods. Co.*, 717 F.3d 1336, 1344-45 (Fed. Cir. 2013).

Nevro built its brand on high frequency, paresthesia-free therapy. (*See* Caraway Decl.

¶ 13.) This therapy is synonymous with Nevro's identity in the market, and its success is largely attributable to the goodwill it has developed as the sole provider of this breakthrough therapy and its reputation as an innovator. (*See* Caraway Decl. ¶¶ 17-18; Schoettelkotte Decl. ¶¶ 36-39.)

Industry observers corroborate this conclusion. Morgan Stanley described high frequency stimulation as Nevro's "critical innovation" and observed that "the strength of Nevro's data is a rarity in medical technology . . . *The industry needs to focus more on meaningful innovation* that can demonstrate material improvement in head-to-head randomized studies. *This is what Nevro has achieved*." (Ex. 37, Morgan Stanley 2014 Report at 5, 21 (emphasis added).) Nevro's reputation has been protected by its status as the only company that can legally market this therapy. (*See* Caraway Decl. ¶¶ 16-19.) Nevro's "Senza is the *only device on the market* to use [Nevro's] patented high frequency approach," which is "not just a small advancement but a *fundamental game changer*." (Ex. 38, JMP 2014 Report at 6 (emphasis added).)

As discussed above, just weeks after receiving FDA approval for high frequency therapy, Stimwave is already branding itself as a 10 kHz therapy company. (*See* Caraway Decl. ¶ 25.) Permitting Stimwave to continue this behavior until trial would severely harm Nevro's reputation and the goodwill that it has spent years cultivating. *See Douglas Dynamics*, 717 F.3d at 1344 (product loses "distinctiveness and market lure" if competitor can contend it has "'similar features'" without noting that those features infringe patented technologies).

Nevro will be doubly harmed if Stimwave is allowed to infringe its patents with a therapy that risks suboptimal customer experiences. Stimwave, it appears, will not reliably implement high frequency, paresthesia-free therapy. Stimwave's own clinical trial reported the following adverse events in patients using its SCS systems: 15% of patients had experienced lead migration; 5% had experienced loss of stimulation; and 2% of leads had fractured. (Ex. 18 at 7.)

In comparison, Nevro's Senza RCT showed that at the one-year point, only 3% of patients experienced lead migration, *none* reported losses of stimulation, and *none* reported lead fractures. (Caraway Decl. ¶ 29; Ex. 2, Kapural SENZA-RCT at 856.) Stimwave users may also associate the long term dissatisfaction patients previously felt with external batteries with high frequency therapy, and Nevro may lose the physician and patient as potential customers forever. (*See* Caraway Decl. ¶ 30; Rosenberg Decl. ¶ 60.) Nevro is particularly vulnerable to such harm because it is still a relatively new entrant to the U.S. market, with a fundamentally different technology that still makes up only a minority of sales, and of which some physicians remain skeptical. (*See* Rosenberg Decl. ¶ 53; Schoettelkotte Decl. ¶ 14; Caraway Decl. ¶ 20.)

5. Stimwave May Be Unable to Fully Satisfy Money Damages

SCS therapy is expensive, which will result in high per-device royalties and lost profits. And given the egregious nature of Stimwave's conduct, an award of enhanced damages or attorney fees is a possibility. But Stimwave is a comparatively small, private company and, in meet and confers to date, has claimed that its weak financial footing exposes it to heavy burdens just from discovery costs. (Lanham Decl. ¶ 5.) An accused infringer's inability to pay a judgment is evidence of irreparable harm. *Robert Bosch LLC v. Pylon Mfg. Corp.*, 659 F.3d 1142, 1150-51 (Fed. Cir. 2011) (inability to satisfy judgment combined with direct competition and lost market share constituted "overwhelming evidence" of irreparable harm). Expedited discovery is likely to shine further light on Stimwave's inability to satisfy a judgment.

6. The Irreparable Harm Flows Directly From Stimwave's Infringement of Nevro's Patents

To establish causal nexus, the patentee must show that "the infringing feature drives consumer demand for the accused product." *TEK*, 2019 WL 1412538, at *11 (quoting *Apple Inc. v. Samsung Elecs. Co.*, 695 F.3d at 1375-76). The patentee can satisfy this requirement by

showing that the patented feature is a "significant reason consumers b[uy] its device," *id.*, or that there is "some connection between the patented feature and demand for [the infringer's] products." *Apple Inc. v. Samsung Elecs. Co.*, 735 F.3d 1352, 1364 (Fed. Cir. 2013).

Nevro easily meets this standard. The innovative high frequency, paresthesia-free technology that is the subject of these claims is the means by which Nevro has broken into this highly competitive market. (Caraway Decl. ¶¶ 17, 20; Rosenberg Decl. ¶¶ 57-61.) Industry analysts have consistently observed that it forms the basis of consumer demand. (*See, e.g.*, Ex. 39, Canaccord 2017 Report at 1 (Nevro's "proprietary high frequency (HF10) technology is driving a paradigm stampede in the spinal cord stimulation field, catalyzing growth in a market that had been stagnant in recent years"); Ex. 36, Stern Agee 2015 Report at 2 (acknowledging role of Nevro's "differentiated product offering (HF10 technology)" in capturing market share).)

The same nexus is present for Stimwave's high frequency, paresthesia-free therapy. Stimwave's belief that customers want this proprietary therapy is evident in its decision to invest in the 100-patient SURF clinical trial and to pursue FDA clearance at frequencies up to 10 kHz. *See Mylan Institutional LLC v. Aurobindo Pharma Ltd.*, 857 F.3d 858, 872-73 (Fed. Cir. 2017) (finding causal nexus where FDA applicant would infringe patent claims to make use of its regulatory approval). As discussed above, Stimwave has made 10 kHz a centerpiece of its marketing. (*See* Caraway Decl. ¶ 25; Ex. 13.) Stimwave's use and promotion of the infringing therapy makes its products "significantly more desirable." *Apple*, 735 F.3d at 1364. There is a clear causal nexus between Stimwave's infringement and the irreparable harm to Nevro.

C. The Balance of Hardships Strongly Weighs in Favor of Protecting Nevro's Technology

Without an injunction, Nevro will be forced "to compete against its own patented invention, with the resultant harms described above, [which] places a substantial hardship on

[Nevro]." *Robert Bosch*, 659 F.3d at 1156. As described in detail above, Nevro's business is based on exclusively providing high frequency, paresthesia-free therapy, and it cannot easily absorb losing the exclusivity of this technology, particularly to a competitor that is undercutting the market on price. (Caraway Decl. ¶¶ 18, 39.) *See TEK*, 2019 WL 1412538, at *12 (affirming finding of harm as patentee's "lack of diversification exposes it to a particular risk of lowered market share"). Stimwave, on the other hand, has long run a business based on low frequency SCS therapy. (Caraway Decl. ¶ 23.) And its SURF study shows no statistical difference between its infringing high frequency therapy and its non-infringing low frequency therapy. (*Id*. ¶ 28; Ex. 18 at 4.) Nevro does not seek to enjoin Stimwave from selling low frequency therapy. It seeks a preliminary injunction to maintain the status quo that has existed for years.

Moreover, to the extent Stimwave experiences any harm from a preliminary injunction, it is its own doing. As detailed above, Stimwave is willfully and flagrantly infringing Nevro's technology. Any hardship that Stimwave might encounter would be the "the result of its own calculated risk in selling a product with knowledge of [Nevro's] patent[s]." *Celsis*, 664 F.3d at 931; *see also Windsurfing Int'l, Inc. v. AMF, Inc.*, 782 F.2d 995, 1003 n.12 (Fed. Cir. 1986) ("One who elects to build a business on a product found to infringe cannot be heard to complain if an injunction against continuing infringement destroys the business so elected.").

This is not a case where the defendant did not know of the plaintiff's patents. Rather, after Stimwave's CEO promised that Stimwave would not "activate" high frequency stimulation, Stimwave changed its mind and targeted Nevro. (*See* Caraway Decl. ¶¶ 23-24.) *See M/A-COM Tech. Sols. Holdings, Inc. v. Laird Techs., Inc.,* C.A. No. 14-181-LPS, 2014 WL 2727198, at *7 *(D. Del. June 13, 2014)* (granting preliminary injunction despite lack of knowledge, but indicating willfulness might be "an important factor" in balancing harms); *Edwards Lifesciences*,

2014 WL 1493187, at *7 ("[A]ny harm to Medtronic is the result of its willful infringement and deliberate flouting of the jury verdict against it, and thus cannot be counted in its favor.").

D. The Public Interest Will Be Served by an Injunction

Courts "have long acknowledged the importance of the patent system in encouraging innovation." *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1383 (Fed. Cir. 2006). No case could better demonstrate that role than this one. To date, Nevro has spent well over [redacted] in R&D and clinical costs in developing its high frequency, paresthesia-free therapy, and [redacted] bringing that product to market. (Caraway Decl. ¶ 13.) This is what it takes for a new company to bring a pioneering medical device to the U.S. market. Nevro still carries an accumulated deficit of $306 million. (Schoettelkotte Decl. ¶ 18; Ex. 40, Nevro 2018 10-K at 26, 65.) Thus, despite creating groundbreaking technology, Nevro has yet to realize the fruits of its investment. The company has yet to turn a profit. (Caraway Decl. ¶ 13.) Nevro's investment "must be encouraged and protected by the exclusionary rights conveyed in valid patents." *Celsis*, 664 F.3d at 931. If the patent system does not protect investments like Nevro's, innovations in the high-cost-to-entry field of life sciences will cease.

The public interest will not be disserved by enjoining Stimwave's infringement. Stimwave's clinical data shows little advantage to its implementation of high frequency programming. Its SURF trial concluded that Stimwave's high frequency therapy is "noninferior" to its low frequency therapy. (*See* Caraway Decl. ¶ 28; Ex. 18 at 4.) Nevro's products will remain available to physicians and patients who want high frequency, paresthesia-free therapy.

V. CONCLUSION

Nevro requests that Stimwave be preliminarily enjoined from: (1) programming its SCS systems to deliver paresthesia-free therapy at frequencies between 3 kHz to 10 kHz; or (2) inducing third parties to do so.

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