No. 19-2205

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

NEVRO CORP.,

Plaintiff-Appellee,

v.

STIMWAVE TECHNOLOGIES, INC.,

Defendant-Appellant.

Appeal from the United States District Court for the District of Delaware, Case No. 1:19-cv-00325-CFC, Hon. Colm F. Connolly

NON-CONFIDENTIAL BRIEF FOR PLAINTIFF-APPELLEE NEVRO CORP.

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December 4, 2019

CERTIFICATE OF INTEREST

Counsel for plaintiff-appellee Nevro Corp. certify the following:

1. The full name of every party or amicus represented by me is:

Nevro Corp.

2. The name of the Real Party in interest (Please only include any real party in interest NOT identified in Question 3) represented by me is:

N/A

3. All parent corporations and any publicly held companies that own 10% or more of the stock of the party or amicus curiae represented by me are:

Nevro Corp. has no parent corporation and no publicly held company owns 10% or more of Nevro Corp.'s stock based on currently available ownership reports filed with the Securities and Exchange Commission.

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court (and who have not or will not enter an appearance in this case) are the following (some of whom are no longer with their respective firms):

MORRISON & FOERSTER LLP: John R. Lanham; Nicholas R. Fung.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP: Rodger Dallery Smith, II; Lucinda Cole Cucuzzella.

5. The title and number of any case known to counsel to be pending in this or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal:

N/A

Dated: December 4, 2019 /s/ Deanne E. Maynard

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CONFIDENTIAL MATERIAL

Confidential material has been redacted from pages 61, 62, and 65 of the non-confidential version of this brief and has been identified with yellow highlighting in the confidential version of this brief. Redacted materials include highly confidential business information that was filed under seal in the district court under a protective order.

TABLE OF AUTHORITIES

Cases

Statutes

Other Authorities

STATEMENT OF RELATED CASES

No appeal from this proceeding has previously been before this Court or any other court. Counsel for plaintiff-appellee Nevro Corp. ("Nevro") know of no other cases pending in this Court or any other court that will directly affect or be affected by this Court's decision in this appeal.

INTRODUCTION

After reviewing thousands of pages of evidence and holding a full-day evidentiary hearing with live testimony, the district court found that each preliminary injunction factor favored Nevro. In a 45-page opinion, it made extensive factual findings, determined witness credibility, identified evidence it found persuasive, and explained its reasoning.

Stimwave appeals that injunction without challenging numerous findings supporting it. Stimwave challenges none of the following facts, all found by the district court: Nevro built its company on its unique high-frequency, paresthesia-free therapy. Nevro's therapy went against conventional wisdom, which for decades held that effective spinal cord stimulation required masking pain with low-frequency stimulation that produced paresthesia, a sensation usually described as tingling, pins and needles, or numbness. Nevro invested hundreds of millions of dollars to develop its novel therapy and convince skeptical physicians its technology is not only effective, but more effective than traditional, low-frequency, paresthesia-based therapy. Nevro succeeded by producing clinically superior results in an FDA-monitored study. Nevro leveraged that success to create a reputation as the exclusive provider for high-frequency, paresthesia-free therapy. Losing exclusivity would devastate Nevro because it is Nevro's "reason for being." Appx38. Stimwave's infringement interfered with Nevro's exclusivity, and Stimwave was

using Nevro's patented therapy to target Nevro's customers. Stimwave's own CEO admitted that a preliminary injunction will have no effect on Stimwave's bottom line. In finding all these facts, the district court credited testimony from Nevro's chief medical officer, while finding that Stimwave's CEO lacked credibility given her "patently false deposition testimony" and her "combative and dismissive demeanor during her deposition." Appx16-17.

Unable to contest these findings, Stimwave sets up a straw man about a superiority "finding" the district court never made, adding words to the district court's decision and then contending those words were clear error. But contrary to Stimwave's faulty premise, the district court did not base its superiority finding on comparing efficacy data from Nevro's and Stimwave's studies. Stimwave never asked for such a comparison in the district court nor argued (as it does here for the first time) that Stimwave's therapy is superior to Nevro's. Quite the opposite: Stimwave repeatedly acknowledged that it had no claim to superiority, and it affirmatively embraced Nevro's clinical results showing superiority to argue that Nevro would not be irreparably harmed by Stimwave's infringement. It is far too late for Stimwave to take back its concessions and make arguments it never raised to try to challenge well-supported factual findings—especially with nothing but attorney argument based on discredited testimony.

None of Stimwave's other arguments show clear error. The district court correctly determined Stimwave showed no substantial question of invalidity for Nevro's presumptively valid patent. And the court acted well within its discretion in entering a narrow preliminary injunction that merely preserves the status quo before March 2019, when Stimwave began infringing Nevro's patent.

The Court should affirm.

STATEMENT OF THE ISSUE

Whether the district court acted within its discretion in preliminarily enjoining Stimwave from infringing claims 24 and 28 of U.S. Patent No. 8,874,222 ("'222 patent").

STATEMENT OF THE CASE

A. Spinal Cord Stimulation Therapy

Spinal cord stimulation attempts to relieve pain by delivering electrical pulses to the spinal cord through implanted electrodes. Appx2; Appx1470; Appx1519; Appx1466-1516; Appx1517-1531. Historically, spinal cord stimulation systems consisted of electrodes, or leads, implanted near a patient's spinal cord, a receiver implanted beneath the skin and electrically connected to the leads, and an external battery connected to the receiver. Appx2-3, Appx7 n.1; Appx1519, Appx1524. But patients disliked constantly lugging around an external battery, and disliked how the external battery required them to interrupt therapy for activities like showering and

sleeping. Appx1519. Beginning in the 1980s, spinal cord stimulation suppliers abandoned external batteries for implanted pulse generators, which combine the battery and receiver into a single implanted device. Appx7 n.1; Appx1519, Appx1524.

Spinal cord stimulation systems typically include a device known as a "programmer" that allows clinical representatives or physicians to select the therapy signal parameters, such as the amplitude, frequency, and pulse width. Appx2-4; Appx1418, Appx1414-1447; Appx1479; Appx1519-1520. In this industry, the process of selecting signal parameters is called "programming." Appx3-4; Appx1418. Before Nevro's inventions, traditional spinal cord stimulation relied on pulse generators programmed to deliver signals at frequencies between 40 to 90 Hz (pulses per second). Appx3; Appx1470-1471; Appx1519. Traditional systems work by producing paresthesia—"a sensation usually described as tingling, pins and needles, or numbness." Appx3; Appx1519. Paresthesia is not a "side effect" that is "sometimes" produced. *Contra* Stimwave Br. 7-8. Instead, the district court found that, for decades, masking pain with paresthesia "was generally deemed 'an absolute requirement.'" Appx3-4, Appx14. Paresthesia is "the means by which the therapy works." Appx1470-1471; Appx1519. As stated in a paper co-authored by Boston Scientific Corporation ("BSC"), a major spinal cord stimulation system supplier, "Patient-perceived concordant paresthesia overlapping the area of pain is *essential*

for success of this therapy." Appx1471 (citing Appx1577, Appx1575-1592; emphasis in original).

B. Nevro's Technology

1. Nevro's patented technology revolutionized spinal cord stimulation therapy

Nevro was founded in 2006 to provide a solution to chronic pain without the drawbacks of traditional spinal cord stimulation. Appx1520-1523. As the district court found, Nevro's inventions are significantly more effective than traditional spinal cord stimulation systems and differ in two fundamental ways. Appx4-6; Appx1472-1479; Appx1520.

First, Nevro's therapy focuses on high-frequency stimulation; the current commercial embodiment uses signals at 10,000 Hz (10 kHz). Appx4; Appx1472. Before Nevro's inventions, applying such high frequencies to the spinal cord was considered unnecessary and potentially unsafe. Appx4; Appx1421-1422; Appx1595 ("there is no physiological evidence that increasing the pulse rate beyond physiological limits (~300 pps [Hz]) will provide therapeutic benefit"); *see* Appx1414-1445; Appx1593-1607. Yet as detailed below (*infra* pp. 7-9), Nevro's novel therapy produces much better pain control, and for a far greater percentage of patients. Appx1474-1484.

Second, Nevro's inventions provide effective pain relief using signals with parameters that generate no paresthesia. Appx4; Appx1472. Paresthesia-free

therapy offers many advantages: it eliminates the need to endure paresthesia; it allows patients to return to a wider range of activities while still relieving pain; and it avoids the need to adjust therapy signal parameters constantly—patients adjust parameters on average less than once per week, compared to an average 210 times per week reported by one study for low-frequency, paresthesia-based therapy. Appx1474-1479.

Nevro achieved these advances with its patented technology. Nevro's '222 patent claims 24 and 28 recite methods for programming a signal generator to generate and deliver a high-frequency, "non-paresthesia-producing therapy signal" via implanted leads. Appx114-115. FIG. 1A of the '222 patent shows an exemplary system for performing the claimed methods:

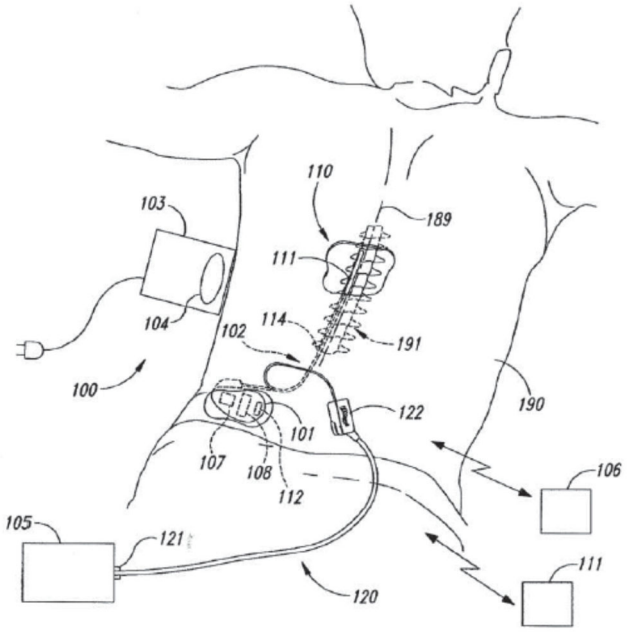

Fig. 1A

Appx87; Appx102-111. The system includes a signal generator (or pulse generator **101**), which may be implanted in the patient. Appx103 (col.3:31-34). The pulse generator **101** is coupled to an implanted signal delivery device (e.g., leads). Appx103 (col.3:34-45). After implantation, users (such as company sales representatives or physicians) can select the signal parameters—such as frequency, amplitude, or pulse width—via an external programmer. Appx103-104 (col.4:46-50, col.5:25-31, 35-41).

Unlike traditional low-frequency, paresthesia-based therapy, the claimed methods provide electrical stimulation at frequencies from 3 kHz to 10 kHz. The patent discloses signal parameters, like amplitude and pulse width, for delivering non-paresthesia-producing therapy signals at these frequencies. Appx111 (col.19:25-39, 48-50). It explains how to set the amplitude below the threshold at which a patient experiences paresthesia. Appx106 (col.10:18-53). The specification also discloses the parameters Nevro used in clinical studies: the patients "received therapeutic signals" at "8 kHz, 9 kHz or 10 kHz," with pulse widths of "about 30-35 μs" and amplitudes "from about 1 mA to about 4 mA (nominally about 2.5 mA)." Appx104-105 (col.6:58-62, col.7:4-7).

2. Nevro's patented technology achieved clinical and market success

As the district court found, Nevro's Senza® system embodies Nevro's claimed inventions. Appx42-43. It can be programmed to generate and deliver

Nevro's HF10® therapy, which provides a paresthesia-free therapy signal at a frequency of 10,000 Hz. Appx5; Appx1520.

To obtain United States regulatory clearance for its groundbreaking therapy, the FDA required Nevro to conduct an extensive, randomized clinical study. Appx4-5; Appx1520-1521. This study, called the SENZA-RCT, compared Nevro's Senza system head-to-head with BSC's then most-current system, the Precision Plus, which generates low-frequency, paresthesia-inducing therapy signals. Appx1520-1521. During the study, BSC's own representatives programmed BSC's systems. Appx1474. The SENZA-RCT involved 241 patients and is the largest prospective randomized clinical trial evaluating the comparative effectiveness of spinal cord stimulation therapies. Appx2075; *see* Appx1608-1616; Appx2072-2085.

Nevro's results were impressive. Appx1474-1475; Appx1520-1523; Appx1570. After 12 months, a much greater and statistically significant percentage of patients—79% versus 51%—experienced at least a 50% reduction in pain using Nevro's high-frequency, paresthesia-free therapy compared to BSC's low-frequency, paresthesia-based therapy. Appx1570. And Nevro's therapy provided statistically superior pain relief: after 12 months, Nevro's therapy was 1.5 times more effective than BSC's in relieving leg and back pain. Appx1474; Appx1570; Appx4-5. The study results were so strong that the FDA approved Nevro with a rare

"superiority" label, allowing Nevro to promote its system as superior to traditional therapy. Appx5; Appx1521. SENZA-RCT's strong results continued through the study's 24-month mark, leading the official journal of the Congress of Neurological Surgeons to name Nevro's 24-month study publication "Top Pain Paper of the Year." Appx1474-1475; Appx1483; Appx2451-2462; Appx2476-2479.

As the district court found, based on these strong clinical results Nevro surged from 0% U.S. market share in 2015 to over 15% market share by the end of 2017. Appx5; Appx1521; Appx1536-1537; *see* Appx1532-1550. Nevro did so despite a change-resistant, or "sticky," market dominated by three large companies: BSC, Medtronic, and St. Jude (now Abbott). Appx5, Appx1484, Appx1522. Nevro faced significant skepticism from physicians with longstanding relationships with these incumbents. Appx4; Appx1484-1485; Appx1521-1522; Appx1535-1537. The district court found that differentiating itself based on its exclusive high-frequency, paresthesia-free therapy and strong clinical results is key to Nevro's success. Appx5-6; Appx42-43. "Without differentiating technology, physicians and healthcare providers would not have a compelling reason to choose Nevro." Appx1521-1522; Appx1484-1485. Thus, as the district court found, "[a]lthough 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." Appx5 (citing Appx5958-5959); Appx5947-5986. Nevro has protected

that differentiating feature by never licensing its patented technology. Appx39 (citing Appx1530).

C. Stimwave's Lack Of Success And Copying Of Nevro

As the district court found, Stimwave directly competes against Nevro. Appx2. But unlike Nevro, Stimwave built its company on decades-old technology: low-frequency, paresthesia-based spinal cord stimulation. Appx3-4. Stimwave calls its systems the Freedom stimulators and tries to differentiate itself with even older technology—external batteries—that the industry abandoned after implanted power sources became available in the 1980s. Appx6-7 & n.1; Appx1001-1005; Appx1524. When seeking clearance to sell its systems, Stimwave told the FDA its Freedom stimulators are "substantially equivalent" to those older systems. Appx1524; Appx2581-2582, Appx2580-2599.

Despite branding its system as "micro-sized," Stimwave's system requires implanting leads spanning multiple vertebrae near the spinal cord. Appx2707-2708, Appx2700-2719; Appx3448, Appx3446-3470; Appx4938-4939, Appx4919-5034. Stimwave's systems use an implanted coiled receiver that connects to an external battery through inductive coupling. Appx3448; Appx5671, Appx5632-5690. Implanting a Stimwave system is similar to implanting other spinal cord stimulation systems and involves "the same" risks. Appx5649-5650; Appx5671-5673. Stimwave instructs physicians to create a "subcutaneous" (under-the-skin) "pocket"

to stitch the coiled receiver in place. Appx5671-5673. That implanting procedure creates a risk of "discomfort from the incision and there's a risk of infection due to the foreign body that is placed into that pocket." Appx5672.

As the district court found, despite entering the U.S. market at roughly the same time as Nevro, by the end of 2018 Stimwave had captured only 0.4% of that market. Appx6-7; Appx5107, Appx5090-5164. Having failed to gain traction with decades-old external–battery technology, Stimwave set about to copy Nevro's inventions. Appx1001-1002. Stimwave began a clinical trial, called SURF, using the same parameters as Nevro's commercial HF10 therapy. Appx40; Appx1525-1526; Appx1694-1703. The study involved 99 subjects, less than half the number from Nevro's study; even then, the study results excluded data from 27 of the 99 who "were considered nonresponders" to the therapy. Appx4162-4163, Appx4159-4168. Instead of comparing its system head-to-head against a competitor's, as Nevro did, Stimwave compared its Freedom-8A system programmed at low frequency against the same system programmed at high frequency. Appx1696-1698. Even so, as the district court found, the SURF results "pale in comparison to the results of Nevro's SENZA-RCT": the results were "not indicative of superiority" of Stimwave's high-frequency therapy compared with its low-frequency offering. Appx40; Appx1698, Appx1702. The study authors reported only the "noninferiority of HF stimulation vs LF stimulation." Appx1698

(referring to high frequency and low frequency); Appx40. And despite cherry-picking data, SURF still showed "patients experienced complications with Stimwave's systems"; 15% suffered lead migration, where electrical leads move after implantation; 2% suffered lead fracture; and 5% lost stimulation. Appx40; Appx1701. Stimwave concedes these are undesirable "complications." Br. 11, 35.

In late March 2019 and shortly after Nevro sued for infringement, Stimwave received FDA clearance and launched its high-frequency therapy in the United States using the same 10,000 Hz frequency as Nevro's HF10 therapy. Appx1280-1281, Appx1279-1283; Appx1654-1656; Appx1658-1688. As the district court found, Stimwave immediately began "using Nevro's patented therapy to target Nevro's customers," including with a surf-themed marketing campaign called "hang 10k." Appx43 (citing Appx2961-2962; Appx5469); Appx1686-1688. Stimwave identified doctors who work with Nevro as "doctors we want to target" because Nevro already did the work of convincing them to "want[] to leave and go[] to something else." Appx2966-2968; Appx3018; Appx7313.

D. The Preliminary Injunction Order

To protect its status as the exclusive provider of high-frequency, paresthesia-free therapy in the United States, Nevro requested a preliminary injunction. Appx1387-1413; Appx2606-2615. At a day-long evidentiary hearing, Nevro presented live testimony from Dr. David Caraway, Nevro's chief medical officer,

and video deposition testimony from Laura Perryman, Stimwave's chief executive officer. Appx7277-7613. Stimwave presented no live or video testimony. In a 45-page decision, the district court made extensive factual findings and found that weighing the preliminary injunction factors warranted an injunction. Appx1-46; Appx47-49.

1. The district court found Nevro likely would succeed on the merits

The court found Nevro "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." Appx9.

Infringement. The court adopted the same construction of "paresthesia" as a Northern District of California court: "a sensation usually described as tingling, pins and needles, or numbness." Appx13 (citing *Nevro v. Boston Sci. Corp.*, 2018 WL 4676501, at *1 (N.D. Cal. July 24, 2018)). Applying that construction, it rejected Stimwave's noninfringement argument, which the court found based on "litigation obfuscation" about the well-understood meaning of paresthesia. Appx15-17. Although Stimwave's CEO Ms. Perryman asserted that "Stimwave's employees do not use the term 'paresthesia-free' because 'it is a made-up word,'" the court found that testimony "patently false." Appx16-17. Ms. Perryman previously wrote an article using that term and was "combative and dismissive" during deposition. Appx16-17 (citing Appx6676-6677, Appx6674-6809; Appx1751-1752, Appx1748-

1754). The court quoted a recording of Stimwave's own instructions to sales representatives "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,'" meaning below the threshold at which patients feel paresthesia. Appx15 (quoting Appx5445-5446, Appx5441-5452; alteration by district court). On appeal, Stimwave makes no challenge (Br. 3) to the district court's finding that Nevro is "very likely" to succeed in proving infringement. Appx10-11.

Indefiniteness and enablement. The court rejected Stimwave's argument that, "because whether a patient experiences paresthesia is a subjective assessment that varies from patient to patient," the term "paresthesia" renders the claims indefinite. Appx24-25. Based on the intrinsic and extrinsic evidence, the court found the term's meaning both "perfectly clear" and objective. Appx25 & n.6. The court also rejected Stimwave's argument that the claims are indefinite "because it is 'impossible to know whether paresthesia will be induced until after the signal is applied.'" Appx25 (quoting Appx6899, Appx6859-6980). That "argument misses the point." Appx25. The court found Nevro's chief medical officer Dr. Caraway "credibly testified" that determining a patient's paresthesia threshold is part of programming a signal generator, and Stimwave's 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." Appx26-27 (quoting Appx5794, Appx5780-5820).

The district court also found Nevro's "patent would enable a POSITA to practice the claimed invention with a 'reasonable' amount of 'routine experimentation.'" Appx29-30. Both parties' experts stated they "'*routinely*' (and 'always') 'determine[] the paresthesia threshold,'" which would "take seconds to minutes." Appx29-30 (quoting Appx1489-1490; Appx5794; emphasis and alteration by district court).

Anticipation and obviousness. The district court found Stimwave's prior-art invalidity "defenses lack substantial merit." Appx31-36. On the only ground Stimwave presses on appeal, the court found Royle discloses "placing the electrodes on the patient's skin rather than implanted within the patient's body" and thus fails to anticipate or render obvious Nevro's claims requiring implanted electrodes. Appx34-35 (citing Appx3616, Appx3607-3620). It held that the claims also were nonobvious because of "strong objective indicia of nonobviousness," which it noted Stimwave "fails to address." Appx36 n.11.

2. The district court found Nevro likely would suffer irreparable harm

For multiple reasons, the court found "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." Appx38-43. It credited

Dr. Caraway's testimony "because of the internal consistency and cogency of his testimony and the manner in which he handled his cross-examination." Appx38. Dr. Caraway credibly testified that "Nevro's HF10 therapy 'was the basis for founding the company' and 'the focus of the company's strategy for penetrating the market,'" as well as "'the whole reason [the] company is around.'" Appx38 (quoting Appx1530; Appx7380; alteration by district court). Were Stimwave to continue infringing, the court found Nevro "would suffer" irreparable harm to its reputation as an "innovator." Appx38-41. Nevro also would suffer because of the hit to its patented therapy's reputation. "Stimwave does not dispute that Nevro's HF10 therapy offers clinically superior results." Appx40-41. If "a skeptical physician were to try" Stimwave's therapy and "has a negative experience, the skeptic would find confirmation for the skepticism, and *Nevro could forever lose this physician as a potential customer*." Appx41 (citing Appx1485; emphasis by district court).

The court found these harms had a "causal nexus" to Nevro's claims. Appx42-43. It explained that Nevro's success "at penetrating the 'sticky' SCS market because of its exclusive HF10 therapy shows demand for the patented feature." Appx42. The court relied on Stimwave's own documents in which its sales team discussed "using Nevro's patented therapy to target Nevro's customers." Appx42-43 (citing Appx2961-2962; Appx5469, Appx5462-5478); Appx2966-2968.

Also, "Stimwave's irreparable harm expert admitted that the availability of 10 kHz makes Stimwave's products more desirable and increases sales." Appx43 (citing Appx5729-5730, Appx5691-5746).

3. The district court found the equities favored an injunction

The court found that "the balance of equities weighs strongly in Nevro's favor." Appx43. It cited Stimwave's CEO's testimony "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.'" Appx43 (quoting Appx5827-5828, Appx5821-5869; alteration by district court).

4. The district court found the public interest favored an injunction

In weighing the public interest, the court acknowledged "that it is generally in the public's interest to allow physicians to have as wide a variety of treatment options as is possible." Appx44. But it found that Nevro's "narrowly tailored" injunction would "not entirely prohibit Stimwave from selling its SCS systems." Appx44-45. Instead "Stimwave's low frequency therapy will still remain an option," one that Stimwave's own study concluded was "of an equivalent quality" to its "merely 'noninferior'" high-frequency therapy. Appx45 (citing Appx1698, Appx1701).

Based on its findings, the court entered a limited injunction barring Stimwave "from infringing or inducing the infringement of claims 24 and 28" of the

'222 patent "by programming Stimwave's SCS systems to deliver its recently introduced high-frequency, paresthesia-free SCS therapy, or any other SCS therapy that is not more than colorably different." Appx47-49. It excluded '222 patent claim 45 from the injunction and found it "unnecessary to address" the other claims. Appx9; Appx11.

SUMMARY OF ARGUMENT

A. The district court correctly found Nevro likely would suffer irreparable harm absent an injunction. Unchallenged findings alone support that determination, including: Nevro and Stimwave are direct competitors; Nevro built its reputation on its status as an innovator and exclusive provider of high-frequency, paresthesia-free therapy; and Stimwave was directly targeting Nevro's customers. Stimwave focuses on an independent basis for irreparable harm—the district court's finding that because of differences between Nevro's and Stimwave's therapy, Stimwave's infringement risked harming the reputation of high-frequency, paresthesia-free therapy as a whole. But Stimwave attacks strawmen. Contrary to Stimwave's so-called "Premise 1," the district court's irreparable-harm finding was not based on comparing efficacy data. Neither Nevro, Stimwave, nor the court raised any such data-comparison issue. Nor was the district court's finding based on confusion between Nevro's Senza and Stimwave's Freedom physical products, Stimwave's supposed "Premise 2." And Stimwave's "Premise 3," that the district court

purportedly relied on "naked speculation" (Br. 21), ignores the wealth of concrete evidence supporting the finding.

B. The district court correctly found Stimwave raised no substantial invalidity question. The term "non-paresthesia-producing" renders no claim indefinite. As the district court found and both party's clinical studies show, that term has an undisputed clear meaning that skilled artisans readily and regularly apply. Those same studies, and other intrinsic and extrinsic evidence, disprove Stimwave's theory that patient-to-patient variability in responding to spinal cord stimulation renders the claims indefinite. Based on the studies and other evidence, skilled artisans know or can readily determine the range of signal parameters that will produce paresthesia-free therapy.

Nor did Stimwave raise a substantial question of anticipation or obviousness. The district court, like the Patent Office before it, found Royle fails to anticipate because, instead of therapy via an implanted spinal cord stimulation device, Royle describes a system where high-amplitude electrical signals (up to hundreds of volts) are transmitted through electrodes placed on the skin. To avoid burning the skin, Royle proposes quickly alternating electrical pulses to lower the skin's resistance so a patient feels "no sensation" from peripheral nerves. But Royle never discloses applying high-frequency, paresthesia-free signals using electrodes implanted near the spinal cord, and so never discloses the claimed invention. The district court

rightly rejected Stimwave's identical obviousness arguments for the same reason. Even so, Stimwave never showed an ordinarily skilled artisan would have been motivated to modify Royle with a reasonable expectation of success in achieving the claimed invention. And Stimwave leaves unchallenged the district court's findings of strong objective indicia of nonobviousness.

C. The district court correctly found the public interest in fostering innovation outweighs Stimwave's unsupported public-interest assertions. The court found an injunction would still allow treatment options. Stimwave's own trial showed its high-frequency therapy was merely noninferior to its low-frequency therapy, which the injunction permits Stimwave to continue offering. And the court found Nevro's system adequate to serve patients seeking high-frequency, paresthesia-free therapy.

D. The district court properly exercised it broad discretion by issuing a narrow injunction enjoining only specific infringing conduct. The injunction identifies the patent claims and the actions it enjoins, which is all the law requires.

STANDARD OF REVIEW

This Court reviews preliminary injunctions under regional circuit law, except that the Court "gives dominant effect to Federal Circuit precedent insofar as it reflects considerations specific to patent issues." *Tinnus v. Telebrands*, 846 F.3d 1190, 1202 (Fed. Cir. 2017). The Third Circuit affirms preliminary injunction orders

"unless the court abused its discretion, committed an error of law, or seriously misjudged the evidence." *Eli Lilly & Co. v. Premo Pharm. Labs.*, 630 F.2d 120, 136 (3d Cir. 1980).

ARGUMENT

Contrary to Stimwave's mantra about "drastic" remedies and "clear" showings (e.g., Br. 4), this Court regularly affirms preliminary injunctions orders where, as here, the district court addresses each of the four factors and, acting within its discretion, finds that weighing those factors warrants maintaining the status quo. *Metalcraft v. The Toro Co.*, 848 F.3d 1358, 1368-70 (Fed. Cir. 2017); *Tinnus*, 846 F.3d at 1202; *Celsis In Vitro v. CellzDirect*, 664 F.3d 922, 930-32 (Fed. Cir. 2012).

A. The District Court Correctly Found Nevro Likely Would Suffer Irreparable Harm Absent An Injunction

Stimwave leads its appeal with an uphill battle: a clear-error challenge to the district court's well-supported findings of irreparable harm. *Eli Lilly*, 630 F.2d at 136. But Stimwave ignores findings that alone establish irreparable harm, making it unnecessary for this Court to address Stimwave's challenges. If the Court does reach them, it should reject them. Stimwave focuses on one purported finding that supposedly has three "necessary" premises. Br. 31-36. Those arguments fail for multiple, independent reasons: Stimwave did not preserve the clinical-data-comparison arguments it makes here; the district court did not base its superiority finding on comparing efficacy data across clinical studies nor on confusion between

the parties' physical "products"; and Stimwave conceded the superiority finding the district court did make.

1. Unappealed findings alone support irreparable harm

Patentees can suffer irreparable harm in multiple ways, including through "loss of goodwill, damage to reputation, and loss of business opportunities." *Celsis*, 664 F.3d at 930. "Direct competition in the same market is certainly one factor suggesting strongly the potential for irreparable harm without enforcement of the right to exclude." *Presidio Components v. Am. Technical Ceramics*, 702 F.3d 1351, 1363 (Fed. Cir. 2012). So is evidence that a party "was unwilling to license" its patent. *Id.* And so too is evidence that a party "has earned itself a reputation in the marketplace as an innovator." *Douglas Dynamics v. Buyers Prods.*, 717 F.3d 1336, 1344-45 (Fed. Cir. 2013). A company's reputation as an innovator can be irreparably harmed when "customers f[i]nd the same 'innovations' appearing in competitors'" products. *Id.* Being forced to compete against one's own patented invention can "tarnish[]" the patentee's "status as the innovator," which "is sufficient to support a finding of irreparable harm." *Tinnus*, 846 F.3d at 1208. Likewise, evidence that a party "dedicates significant amounts of time and money" to develop an invention and would, absent an injunction, be forced to compete directly with an infringer in a market that the innovator "in part created with its investment in patented technology" supports irreparable harm. *Douglas*, 717 F.3d at 1344-46.

In finding that "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," the district court found facts supporting all the above. Appx38. It found Nevro and Stimwave are "direct competitors in the field of spinal cord stimulation." Appx2. It found "Nevro has built its brand on its high-frequency, paresthesia-free therapy." Appx38. It found "Nevro has never licensed its patented technology," "publicizes in all of its marketing material and in its press releases the fact that its HF10 therapy is patented," and "losing Nevro's exclusivity over its high frequency, paresthesia-free therapy 'would be devastating' because it 'is [Nevro's] reason for being.'" Appx38-39 (quoting Appx7380, Appx7371, Appx7399; alteration by district court). It found Stimwave "is using Nevro's patented therapy to target Nevro's customers." Appx43 (citing Appx1466-1516; Appx1564-1574, Appx1608-1638; Appx4919-5089; Appx6508-6518). And before discussing irreparable harm, it found in the context of secondary considerations that Nevro "received significant industry praise" for its innovative high-frequency, paresthesia-free therapy, including from Stimwave's own witness Dr. North who (before becoming Stimwave's expert) "praised 10 kHz, paresthesia-free therapy as providing 'pain relief superior to that afforded by conventional/traditional SCS [therapy].'" Appx36-37 n.11 (quoting Appx1564-1574, Appx1608-1638;

Appx4919-5089; Appx6508-6518; alteration by district court). Stimwave's appeal brief challenges none of these findings.

The district court based many of these unappealed findings on testimony from Dr. Caraway, whom the court "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." Appx38. The district court credited Dr. Caraway's testimony that Nevro's high-frequency, paresthesia-free therapy "was the basis for founding the company" and "the focus of the company's strategy for penetrating the market." Appx38 (quoting Appx1530). 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." Appx38 (citing Appx7399); Appx5676-5677 (similar).

These findings and credited testimony alone support the district court's conclusion that Stimwave's infringement "will likely result in irreparable harm" to Nevro's "goodwill and reputation" (Appx38-39). *Tinnus*, 846 F.3d at 1208. Stimwave's sole response is that the court did not further find a "loss of market share and price-erosion." Br. 16, 20, 29. Contrary to Stimwave's suggestion, that was just one of many harms Nevro showed. And whether there is evidence of other types of irreparable harm takes nothing from the above findings showing harm to Nevro's goodwill and reputation. Because Stimwave challenges none of these findings, this

Court can sustain the irreparable-harm determination without addressing Stimwave's arguments.

2. Even were the Court to reach Stimwave's arguments, the district court correctly found irreparable harm based on Nevro's clinical superiority

If the Court addresses Stimwave's arguments, it should hold the district court acted well within its discretion in finding an additional, independent basis for irreparable harm: because of reported differences between Nevro's and Stimwave's high-frequency, paresthesia-free offerings, Stimwave's infringement risked harming the reputation of high-frequency therapy as a whole, hurting Nevro's ability to compete based on that reputation. Appx39-41.

a. Stimwave alleges clear error by arguing for a factual finding it never sought on an issue the district court never addressed

Stimwave challenges this irreparable-harm finding by attacking a straw man. It alleges clear error in what it calls "Premise 1"—that '"Nevro's HF10 [i.e. high-frequency 10 kHz] therapy offers clinically superior results' to Stimwave's high-frequency therapy." Br. 30 (quoting Appx40; alteration by Stimwave). It argues that "the numbers" in each party's clinical study show that Nevro's 10 kHz system "is not" "better than Stimwave's," so "Premise 1" is "wrong as a matter of arithmetic." Br. 31-33.

But this Court would search in vain Stimwave's preliminary injunction response brief, and even its expert reports, for anything like Stimwave's new charts (Br. 5, 13, 32) purportedly comparing efficacy data across Nevro's SENZA-RCT and Stimwave's SURF studies. There was no debate about this efficacy data in the district court. Stimwave never argued that the efficacy data from its SURF study showed its high-frequency therapy was superior to Nevro's. Appx3182-3222. Nor did Stimwave raise any argument or chart comparing serious adverse events across studies, as it now does. Appx3182-3222. Directly comparing Nevro's and Stimwave's efficacy data was not the basis for Nevro's showing of irreparable harm. Appx1387-1413 (Nevro opening brief); Appx2606-2615 (Nevro supplemental brief); Appx5263-5288 (Nevro reply). Had Stimwave argued at the district court, as it does now, that its therapy is superior to Nevro's, Nevro would have developed a record to show why that is wrong.[1]

To try to raise this new issue on appeal, Stimwave adds words to the finding it supposedly attacks—tacking on the words "to Stimwave's high-frequency therapy" (Br. 30) after the district court's actual finding that "Nevro's HF10 therapy

[1] In a footnote, Stimwave cites its CEO saying that Stimwave's clinical results purportedly were "on par" with Nevro's (Br. 36 n. 24; emphasis omitted), but Stimwave ignores that the district court found its CEO gave "patently false" testimony and "lacks credibility" (Appx16-17). The CEO's declaration was insufficient to preserve any challenge anyway, because the district court forbade the parties from raising issues only in declarations. Appx33 n.9.

offers clinically superior results" (Appx40). Elsewhere, Stimwave expressly acknowledges that the district court's superiority finding may not mean what Stimwave says (Br. 36 n.24 (citing Appx40)); in other words, Stimwave bases its lead argument on an admitted straw man. That alone warrants rejecting it.

The finding the district court did make on the clinical studies was different, and it was based on "the *results* Nevro obtained in the SENZA-RCT study" and "the *results* Stimwave obtained in its 10 kHz clinical trial." Appx40 (emphases added). Nevro's study showed its therapy was significantly more effective and "superior" at relieving patients' back and leg pain than a traditional low-frequency, paresthesia-based control therapy. Appx39-40 (citing Appx1570). In contrast, Stimwave's much more limited study showed that its high-frequency, paresthesia-free therapy was merely "noninferior" to a low-frequency, paresthesia-based control. Appx40 (quoting Stimwave's own paper about study results at Appx1698, Appx1701). Those results were the conclusions of the study authors themselves, not interpretations of efficacy data by the district court. Appx39-40. The district court found Nevro had staked its reputation in part on its results, on the "'superiority' label it received from the FDA based on the results of the SENZA-RCT clinical study." Appx39. Because Stimwave's study results "pale in comparison," if doctors tried Stimwave's high-frequency therapy and observed the predicted "noninferior" results, it could "'create a negative reputation upon the therapy as a whole.'"

Appx40-41 (quoting Appx7380). Nevro then "'could forever lose this physician as a potential customer.'" Appx41 (quoting Appx1485).

Stimwave thus fails to show error, both because it never raised the data-comparison issue it presses on appeal and because such data-comparison was not a basis for any district court finding anyway. "It is the general rule ... that a federal appellate court does not consider an issue not passed upon below." *Singleton v. Wulff*, 428 U.S. 106, 120 (1976). That is especially true here, where Stimwave asks this Court to compare in the first instance scientific data from randomized clinical trials performed under very different circumstances. Br. 32-34. "[A]s an appellate court, it is beyond [this Court's] role to reweigh the evidence or consider what the record might have supported, or investigate potential arguments that were not meaningfully raised." *Apple v. Samsung Elecs.*, 839 F.3d 1034, 1062 (Fed. Cir. 2016) (en banc). Also, having failed to raise the issue earlier, Stimwave now has only attorney argument (Br. 31-36) to support its reading of the study data. But "[u]nsubstantiated attorney argument regarding the meaning of technical evidence is no substitute for competent, substantiated expert testimony." *Invitrogen v. Clontech Labs.*, 429 F.3d 1052, 1068 (Fed. Cir. 2005).

b. Stimwave conceded the superiority finding the district court made, which the record amply supports

For three independent reasons, Stimwave cannot show clear error in the superiority finding the district court made—that Stimwave's study results "pale in

comparison" to Nevro's because Nevro's study showed its high-frequency therapy is clinically superior to the low-frequency therapy in its study while Stimwave's study did not. Appx40.

First, Stimwave conceded this point, as the district court twice found: "Stimwave does not dispute that Nevro's HF10 therapy offers clinically superior results" (Appx40); "Stimwave conceded at oral argument that Nevro's therapy is clinically superior" (Appx40 n.12).

Stimwave's statements at the preliminary injunction hearing, in its brief opposing a preliminary injunction, and in its expert report all support that concession finding. At the hearing, Stimwave insisted Nevro would not be irreparably harmed by Stimwave's infringement *because* "[i]t's the clinical result, the clinical superiority" that Nevro could use to differentiate itself from Stimwave (Appx7575): "they [Nevro] have the club of clinical superiority. They can say, our 10k product gives you clinically superior results. Your [Stimwave's] 10k product does not.... That's, and I assume that's what they are telling people, because that's what they are telling the Court. And so we're not disputing that. We're not saying that our clinical results show superiority." Appx7577.

Stimwave's preliminary injunction briefing followed that same approach. It embraced Nevro's claim that Nevro's products "provide superior outcomes" and Stimwave's "do not." Appx3209. Stimwave argued there would be no irreparable

harm because "Stimwave's alleged use of the patented technology … does not offer the key sales driving benefits exclusive to Nevro's products." Appx3209. Stimwave made similar statements throughout its brief, never disputing that Nevro had shown clinically superior outcomes over low-frequency, paresthesia-based therapy, and Stimwave had not. Appx3212, Appx3214.

Stimwave's expert followed the same script: "The evidence that Nevro's products provide superior outcomes is primarily based on a clinical study of Nevro's HF10 Therapy. Stimwave does not get to free ride on Nevro's clinical data supporting HF10." Appx5120. "It does not get to claim that its implementation is the same as Nevro's" or "that it has any superiority claim." Appx5120.

Because Stimwave conceded that Nevro has "the club of superiority" and Stimwave "does not," Stimwave cannot now challenge the district court's finding of superiority in this Court. When a party "chose not to properly raise" a challenge on a factual issue before the district court, or affirmatively conceded the issue as Stimwave did here, this Court "does not consider" such challenges. *Celsis*, 664 F.3d at 931. Even now, Stimwave fails to challenge the district court's finding of a concession, acknowledging it only in a footnote. Br. 36 n.24. But "arguments not raised in the opening brief," "arguments raised in footnotes," and "mere statements of disagreement with the district court" "are waived." *SmithKline Beecham v. Apotex*, 439 F.3d 1312, 1320 (Fed. Cir. 2006).

Second, even without Stimwave's concession, the clinical studies confirm the district court's finding that the "results" of Stimwave's study "pale in comparison" to Nevro's. Appx39-40. Nevro's randomized, controlled trial, which compared a competitor's low-frequency, paresthesia-based therapy to Nevro's high-frequency, paresthesia-free therapy, showed Nevro's therapy was "statistically superior," a defined term with a specific meaning. Appx1567-1568, Appx1571. By contrast, Stimwave's subsequent study showed no statistical superiority. Appx4159-4168. In its authors' words, "[a]nalysis of the current data is consistent with noninferiority of HF when compared with LF treatment," but "the HF arm results" are "not indicative of superiority." Appx4163, Appx4166 (referring to high-frequency and low-frequency treatment).

Stimwave thus is wrong (Br. 31-36) that the district court "missed the fact" that the control group, or "baseline," in each study was different or made an "arithmetic" error. Rather, the court's superiority finding does not depend on "baseline[s]" or "arithmetic": Nevro's study authors reported statistically superior results and Stimwave's did not. Appx39-40

In any event, Stimwave chose the baseline for its study, after seeing Nevro's study results and the market success Nevro achieved based on those results. Having elected to perform a different study that produced different results, Stimwave cannot now "free ride" on Nevro's results to assert how its high-frequency therapy might

have compared against a competitor's. Appx5120 (Stimwave's expert conceding this).

Third, even if the district court had found that "Nevro's 10 kHz system was better than Stimwave's," as Stimwave asserts (Br. 33), the record would support such a finding. Given Stimwave's repeated invitations to the district court to treat Nevro as having an advantage over Stimwave because only Nevro had "the club of clinical superiority" (Appx7577), the district court could reasonably infer Stimwave was conceding the superiority of Nevro's therapy *over Stimwave's*. *Rolls-Royce v. GTE Valeron*, 800 F.2d 1101, 1110 (Fed. Cir. 1986) (inferences are for the factfinder and subject to clear-error review). After all, that was the reason Stimwave contended that Nevro would not suffer irreparable harm from Stimwave marketing high-frequency therapy, because Nevro could tell market participants that Nevro's therapy was superior. Appx3209, Appx7575, Appx7577.

And Stimwave's attorney argument and invented charts (Br. 31-36) cannot show clear error, because the data comparisons Stimwave asks this Court to make ignore differences between the studies. For example, Stimwave's data excludes 27 of the 99 subjects who were surgically implanted with Stimwave's system but "were considered nonresponders" and exited the study before the six-month end point. Appx4162-4163. Nevro's data includes all subjects surgically implanted with a spinal cord stimulation system. Appx1568-1570. Stimwave ran both the test and

control arms of its study; Nevro went head-to-head against a competitor. Appx4162-4163; Appx1568-1570. Stimwave's trial involved patients with on average 10-11 years of pain, while Nevro's involved patients who on average had been diagnosed with chronic pain for 13-14 years. Appx1569, Appx4163. And Stimwave conducted its study with less than half the number of patients Nevro used. Appx1568-1570; Appx4162-4163. As Dr. Caraway explained, without accounting for these differences such as with "a meta analysis," "[s]cientifically, you can't directly compare all of these studies." Appx7407.[2]

Nor can Stimwave attack the district court's decision by claiming "superior safety" (Br. 11, 36), a claim Stimwave never attempted to establish. While it now compares data from the FDA's Manufacturer and User Facility Device Experience database, the FDA expressly warns that the data may be "incomplete, inaccurate, untimely, unverified, or biased" and so "cannot be used to … compare event rates between devices." FDA, Manufacturer and User Facility Device Experience,

[2] Although the district court noted a higher rate of some complications with Stimwave's system in "comparison" to Nevro's, the court did not itself compare study data to draw conclusions. Appx40. Rather, the court relied on testimony about such a comparison from Dr. Caraway, who acknowledged the limits of the data. Appx7404-7408. Stimwave has no such testimony. Thus although Stimwave now accuses the district court of having "cherry picked" safety data, Stimwave failed to point the district court to what it now says are "events that went the other way." Br. 34. In any event, in noting that Stimwave may have addressed its lead-migration issues, the district court expressly stated that its superiority finding independently rested on Stimwave's concession. Appx40 n.12.

https://open.fda.gov/data/maude/. And Stimwave never argued in district court any purported significance in the difference between "Class II" and "Class III" devices. *Compare* Stimwave Br. 11, 38, 39, 54, *with* Appx3182-3222. Although Stimwave now cites Nevro's manual's warning about patients who are "poor surgical candidates" (Br. 9), Stimwave's own manual includes the same warning. Stimwave, Wearable Antenna Assembly User Manual, https://fccid.io/2AHXAPDBT2/User-Manual/User-Manual-3647311. At bottom, this all just shows Stimwave should have made its arguments in the district court; this Court should not entertain Stimwave's attorney argument on the meaning of scientific information, made for the first time on appeal. *Apple*, 839 F.3d at 1062.

c. Stimwave's remaining attacks on the district court's irreparable-harm findings fail to show clear error

Stimwave's other attacks on the district court's alleged "premises" are equally flawed. Stimwave's "Premise 2"—that "there could be 'consumer confusion between [Nevro's] product and [Stimwave's] product"—is another straw man. Br. 30 (quoting Appx41; alterations by Stimwave). Stimwave has added "[Nevro's]" and "[Stimwave's]" to the district court's parenthetical description of a decision in a "*see also*" citation to suggest that the district court made a "finding" here that physicians would confuse Nevro's and Stimwave's products because of their "form and structure." Br. 30, 36-39. But nothing about the district court's irreparable-harm findings turns on such confusion. Appx40-42.

Instead, the court found that physicians would draw incorrect conclusions about high-frequency therapy after using Stimwave's implementation of that therapy. Appx40-42. It found Nevro's patented high-frequency therapy "bucked conventional wisdom" and "faced skepticism and criticism" from physicians unfamiliar with it. Appx4-5. Given physicians' general skepticism, the court did not clearly err in finding that a negative experience with Stimwave's high-frequency, paresthesia-free therapy risked tainting physicians' view of the therapy generally.

And Stimwave is wrong (Br. 30, 39-40) that the district court based its irreparable-harm findings on "pure speculation" (Stimwave's "Premise 3"). Instead, Dr. Rosenberg, who has worked in the spinal cord stimulation field for decades and implanted thousands of spinal cord stimulation systems, testified that Nevro faces significant skepticism in the market because its "paresthesia-free therapy was so different from the accepted method of SCS therapy." Appx1485. Under those conditions, "a skeptical physician" who has one "negative experience" with high-frequency therapy could cause Nevro to "forever lose the physician as a potential customer." Appx1485-1486. Dr. Caraway similarly testified that poor implementation of high-frequency, paresthesia-free therapy by another company would risk "be[ing] conflated with that's how our [Nevro's] therapy is" and "draw[ing] a negative reputation upon the therapy as a whole." Appx7380. The

district court credited both statements. Appx40. Stimwave identifies no contrary testimony.

And far from "pil[ing] speculation upon speculation," almost all of the scenarios in Stimwave's table (Br. 39-40) actually occurred. Stimwave calls it speculation that "another company" might "offer high frequency paresthesia-free therapy" and "say[] that they can do the exact same thing as Nevro" (Br. 39-40)—but the district court found Stimwave was doing just that. Appx42-43. Stimwave specifically identified Nevro doctors as "doctors that we want to target" because Nevro already did the work of convincing doctors to "want[] to leave and go[] to" high-frequency therapy and with Stimwave the doctors "are also going to be able to do that." Appx2967-2968; Appx5468-5469 (similar); Appx7313. While Stimwave calls it speculation that its technology "does not support doing the exact same thing as Nevro" (Br. 39-40), the district court found Stimwave conceded that fact. Appx40; *supra* pp. 28-34. And Stimwave calls it speculation that the market was full of "skeptical physician[s]" (Br. 39-40), but the district court found that to be true. Appx4-5, Appx41. Thus, none of those are "hypothetical events that could possibly occur someday" (Br. 39-40).

Given those realities, the district court acted well within its discretion in enjoining Stimwave. Because an injunction provides forward-looking relief, a party need not show "past wrongs" or certainty of future harm; showing "some cognizable

danger" of future harm suffices, "something more than the mere possibility" of harm. *United States v. W.T. Grant*, 345 U.S. 629, 633 (1953). For the same reason, Stimwave is wrong that the district court "turn[ed] the law upside down" (Br. 40), in observing that "[a]lthough 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." Appx41-42. Evidence that the extent of damage is "difficult to quantify" supports finding irreparable harm; easily quantifiable harm often is reparable. *Metalcraft*, 848 F.3d at 1368-69; *Celsis*, 664 F.3d at 930 (unrebutted testimony about "the difficulty in quantifying the effect on reputation and business" supports irreparable harm); *Douglas*, 717 F.3d at 1344 (similar). In describing the testimony here, the district court recognized this case presented such difficulties; it never called it "naked" or "pure speculation" (Br. 21, 30, 39-40). And because the district court drew inferences from evidence, this case is nothing like *Nutrition 21 v. United States*, where the Court rejected reliance on "no more than attorney's argument." 930 F.2d 867, 871 (Fed. Cir. 1991).

With no evidence supporting reversal, Stimwave suggests Nevro should have produced other evidence, specifically, evidence of confusion based on products sold in Europe and Australia. Br. 37. But that was never a dispute in the district court

and, even so, Nevro did produce evidence that Stimwave's foreign activity harmed Nevro: "Q. Okay. And has that HF10 or that high frequency programming [outside the United States] hurt Nevro's reputation in any way? A. In some ways, yes. I mean, we've had physicians in Europe for that matter talking to us about Stimwave and the use of 10,000 hertz, yes." Appx7419. Regardless, whether Nevro could have produced more evidence cannot show clear error on the record evidence.

In short, the district court correctly applied the law and found multiple, independent grounds for irreparable harm, all of which are well supported by the record and, at very least, not clearly erroneous.

B. The District Court Correctly Found Nevro Likely Would Succeed On Patent Validity

Given the presumption of validity, a patent owner is likely to succeed on validity unless the defendant comes forward with evidence sufficient "to show a substantial question of invalidity." *Tinnus*, 846 F.3d at 1205. Only then is the patentee required to offer evidence that any invalidity defenses "lack[] substantial merit." *Id.*

1. The district court correctly found no substantial question of invalidity for indefiniteness

The district court correctly found Nevro would likely rebuff any indefiniteness challenge based on the term "non-paresthesia-producing" therapy signal. Appx23-27. Patents must "conclude with one or more claims particularly

pointing out and distinctly claiming the subject matter which the inventor or joint inventor regards as the invention." 35 U.S.C. § 112(b). Claims need only "inform those skilled in the art about the scope of the invention with reasonable certainty." *Nautilus v. Biosig Instruments*, 572 U.S. 898, 910 (2014). "[S]ome modicum of uncertainty" is "the 'price of ensuring the appropriate incentives for innovation.'" *Id.* at 909. After all, "absolute precision is unattainable." *Id.* at 910. As with any invalidity defense, the challenger would bear the burden at trial of proving indefiniteness by clear and convincing evidence. *BASF v. Johnson Matthey*, 875 F.3d 1360, 1365 (Fed. Cir. 2017).

a. Unchallenged findings require affirmance

Undisputed findings support affirmance. The district court found—and Stimwave does not challenge—that "non-paresthesia-producing" has a "perfectly clear" meaning to persons of ordinary skill in the spinal cord stimulation field. Appx25. "It means: a therapy signal that does not produce 'a sensation usually described as tingling, pins and needles, or numbness.'" Appx25. And the court found—and Stimwave leaves unchallenged—that, "[a]lthough the wave attributes that would result in a signal that does not create paresthesia may vary among patients, a POSITA would be able to determine easily from patient interactions whether a signal produces paresthesia for any given patient." Appx27 (citing Appx1486-1490); Appx30 ("would only take seconds to minutes").

These undisputed facts show Nevro's claims meet the Supreme Court's "reasonable certainty" standard, and at the very least leave no substantial question of indefiniteness. Because non-paresthesia-producing has a "perfectly clear" meaning and skilled artisans can "determine easily" whether programmed signals produce paresthesia, skilled artisans can reasonably determine the scope of Nevro's method claims requiring non-paresthesia-producing signals. These facts are indistinguishable from *Biosig Instruments v. Nautilus* involving claims to electrodes in a "spaced relationship" that "substantially remove[s]" electromyogram signals. 783 F.3d 1374, 1376 (Fed. Cir. 2015). This Court reversed an indefiniteness ruling because that language had a clear meaning and skilled artisans could readily determine whether electrodes were spaced to achieve the result of removing electromyogram signals. *Id.* at 1383-84.

Because the district court's undisputed findings show the same circumstances here, Nevro's claims are not indefinite.

b. The district court's no-indefiniteness conclusion is well supported by the record

Even were the district court's undisputed findings not enough, intrinsic and extrinsic evidence confirms the absence of a substantial question of indefiniteness. Stimwave's failure to contest—or even mention—this evidence defeats its indefiniteness arguments.

i. Intrinsic evidence requires affirmance

The intrinsic record confirms that "non-paresthesia-producing" has a reasonably certain meaning. Nevro's patent explains that traditional spinal cord stimulation causes "a tingling or paresthesia." Appx102 (col.1:47-54). The patent describes methods for programming signal generators to deliver stimulation that "reduce[s] their pain without creating paresthesia." Appx106 (col.9:3-17).

The patent also discloses specific signal parameters for programming a signal generator to deliver these paresthesia-free signals. Appx104-106 (col.5:63-col.9:17). For example, the specification describes a comparison study between (1) low-frequency therapy that relies on paresthesia and (2) high-frequency therapy that reduces "pain without creating paresthesia." Appx104-106 (col.5:63-col.7:8, col.9:3-17). To achieve conventional paresthesia-based signals in patients, systems were programmed to generate and deliver "stimulation at a frequency of less than 1500 Hz (e.g., 60-80 Hz)" and the "amplitude of the signal (e.g., the current amplitude) was varied from about 3 mA to about 10 mA." Appx104 (col.6:37-53).

In contrast, to achieve paresthesia-free signals in patients, systems were programmed to generate and deliver "therapeutic signals at a frequency of from about 3 kHz to about 10 kHz" and signal amplitudes ranging "from about 1 mA to about 4 mA (nominally about 2.5 mA)." Appx104-107 (col.6:54-col.7:8, col.9:3-17,

col.12:23-32) (disclosing other frequencies and amplitudes). The specification also describes the width of the applied pulses. Appx104-105 (col.6:54-col.7:8).

The study results confirmed there was no difficulty delivering paresthesia-free treatment by programming signal generators to generate and deliver signals with the specified parameters. Unlike programming for traditional, paresthesia-based therapy, programming according to the "presently disclosed therapy" "reduced [patients'] pain without creating paresthesia," that is, the therapy was paresthesia-free in all patients. Appx106 (col.9:3-17). And 88% of patients preferred the high-frequency, paresthesia-free therapy to traditional low-frequency, paresthesia-based therapy. Appx106 (col.9:3-17). The specification thus explains that "while patients may prefer paresthesia to pain, a significant majority prefer no sensation to both pain and paresthesia." Appx106 (col.9:3-17).

This intrinsic evidence, by itself, defeats indefiniteness. This Court held comparable claims not indefinite based on similar evidence in *Enzo Biochem v. Applera*, 599 F.3d 1325 (Fed. Cir. 2010). The compound and method claims there included the term "not interfering substantially" with hybridization. The challenger contended that whether substantial interference occurs depends on DNA binding strength, which varies based on each DNA strand's length and sequence. *Id.* at 1335-36. Even so, the Court held the claims not indefinite because the patent "provides a general guideline and examples sufficient to enable a person of ordinary skill in the

art to determine the scope of the claims." *Id.* at 1335 (quotation marks and brackets omitted). For "a given set of experimental conditions" a skilled artisan would be able to compare DNA binding strength with the patent's examples and readily determine, in each instance, whether substantial interference occurred. *Id.* at 1336.

Because Nevro's patent similarly gives detailed guidance and examples for how to program signal generators to generate and deliver paresthesia-free signals, there is no substantial question about their indefiniteness. *Id.* at 1335.

ii. Extrinsic evidence requires affirmance

Extrinsic evidence requires the same conclusion. As the district court found, Stimwave's "own ability to apply [the] term" non-paresthesia-producing shows an absence of indefiniteness. *Liqwd v. L'Oréal USA*, 720 F. App'x 623, 631 (Fed. Cir. 2018); Appx16-17, Appx25 n.6. Stimwave's CEO authored an article using the terms "paresthesia-free" and "paresthesia" to describe therapy signals for spinal cord stimulation. Appx1751-1752. She acknowledged that Nevro's therapy had long lasting efficacy and "was not associated with paresthesia." Appx1751. Likewise, Stimwave's study reported 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." Appx1696. Although Stimwave's CEO later asserted in litigation that "paresthesia-free" is "a made-up word," the district court found that

to be "patently false deposition testimony" given the CEO's and Stimwave's prior statements. Appx16-17, Appx25 n.6.

Nevro's and Stimwave's clinical trials reinforce that practitioners have reasonable certainty about what "generat[ing] a non-paresthesia-producing therapy signal" means and does not mean. Appx114-115. In both trials, practitioners successfully programmed systems to generate high-frequency, paresthesia-free therapy in one arm, and low-frequency, paresthesia-based therapy in the other arm. Appx1568-1570; Appx4162-4163. "None" of the patients receiving high-frequency therapy in Nevro's study "experienced paresthesia." Appx2453.

The district court further found (Appx25 n.6) that patent filings from other companies reinforce that "non-paresthesia-producing" has a well-understood meaning. *Mylan Inst. LLC v. Aurobindo Pharma Ltd.*, 857 F.3d 858, 871 (Fed. Cir. 2017) (relying on similar evidence). All three of the largest spinal cord stimulation system manufacturers have filed patent applications (after Nevro) claiming "paresthesia-free treatment." Appx6275-6319; Appx4437-4458.

Expert testimony also shows skilled artisans understand the claims' scope with reasonable certainty. Both parties' experts testified that determining the "threshold" at which patients experience paresthesia is routine and would "take seconds to minutes." Appx29-30 (quoting Appx1489-1490). Stimwave's 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 stimulation." Appx27. He stated he "always" determines "the paresthesia threshold as part of treating a patient with spinal cord stimulation." Appx5794. Nevro's expert Dr. Rosenberg testified similarly: "[d]etermining the sensory threshold at which a patient experiences paresthesia is a routine part of the procedure of implanting an SCS device." Appx1489. And Nevro's approved FDA label states, "[s]timulation at 10,000 Hz is indicated as paresthesia-free therapy and the system must be configured to deliver paresthesia-free stimulation." Appx2493-2494, Appx2485-2538. Both experts' ability to understand and apply the claim language, and industry usage of similar terms, reinforce that the claims have reasonably certain scope. *BASF*, 875 F.3d at 1368.

c. Stimwave's contrary arguments are unsupported and fail to show clear error

Stimwave's brief ignores this evidence, instead advancing flawed arguments that cannot overcome the evidence and that this Court repeatedly has rejected.

Sonix confirms that the district court rightly rejected (Appx24-25) Stimwave's argument (Br. 42) that "non-paresthesia-producing" is indefinite because "paresthesia is the subjective response of patients to whom the signals are applied." *Sonix Tech. v. Publications, Int'l*, 844 F.3d 1370, 1378 (Fed. Cir. 2017). *Sonix* rejected the view that a "visually negligible" graphical indicator was a "purely subjective" term. *Id.* at 1371-72, 1378. The Court distinguished terms that were

"subjective in the sense that they turned on a person's tastes or opinion" or "value judgment." *Id.* "[V]isually neglible" involved "what can be seen by the normal human eye." *Id.* That provided "an objective baseline through which to interpret the claims, even though what is "visually negligible" varies by individual. *Id.* at 1378-79.

The claims here provide an objective baseline for similar reasons. The undisputed clear meaning of "non-paresthesia-producing" refers to the normal human ability to perceive a sensation. Appx25. Nothing about that meaning turns on "a person's tastes or opinion" or "value judgment." *Sonix*, 844 F.3d at 1378. The claims thus provide an objective baseline and are not indefinite. *Id.* at 1379.

Nor does variability in patient responses to spinal cord stimulation raise a substantial question of invalidity. *Contra* Stimwave Br. 42-46. Both parties' experts agreed that despite any variability in patient responses, skilled artisans "routinely" determine individual patient thresholds for paresthesia. Appx5794; Appx1489. Dr. North's own article admitted that, for patients generally, stimulation at 10 kHz "is paresthesia-free at amplitudes used clinically." Appx6516; Appx17; *see* Appx6508-6518. And the '222 patent identifies signal parameters for generating and delivering paresthesia-free therapy signals to whole patient populations. *Supra*, pp. 41-43. Dr. Rosenberg testified that those parameters produce signals that "are paresthesia-free, to the best of our knowledge, in every human that it has been tried

in." Appx5878-5879, Appx5870-5934. The district court credited Dr. Rosenberg's testimony that "'the vast majority, if not all' 10 kHz patients do not experience paresthesia" at the signal parameters Stimwave uses (Appx17 (quoting Appx2621, Appx2619-2624)), a finding Stimwave does not appeal.

This Court has held that similar evidence defeats indefiniteness. For example, the patent in *Warsaw* claimed "oversized spinal implants capable of lateral insertion" with dimensions tied to the dimensions of the implant recipient. *Warsaw Orthopedic v. NuVasive*, 778 F.3d 1365, 1370-71 (Fed. Cir. 2015). Like Stimwave, the challenger argued indefiniteness because the implant size varied between patients. *Id.* This Court rejected that argument: "[t]he relative nature of the claims does not itself make it indefinite." *Id.* Because the general variability in human anatomy was known and "'easily ascertainable,'" the claims' scope was reasonably certain regardless of patient variability. *Id.*

The Court similarly rejected an indefiniteness challenge to claims to a collapsible wheelchair "so dimensioned" to fit within an automobile doorframe. *Orthokinetics v. Safety Travel Chairs*, 806 F.2d 1565, 1568 (Fed. Cir. 1986). It was "of no moment" that "a particular chair on which the claims read may fit within some automobiles and not others," because "one of ordinary skill in the art would easily have been able to determine the appropriate dimensions" by measuring "th[e]

particular automobile." *Id.* at 1576. The similar evidence here likewise shows a lack of indefiniteness.

In arguing to the contrary (Br. 42-46), Stimwave cites only one decision from this Court, *Hallibuton Energy Services v. M-I*, 514 F.3d 1244 (Fed. Cir. 2008). The patent there claimed a method for drilling using a "fragile gel," which the specification described only in unclear terms, such as a gel that is "easily disrupted" or "becomes less gel-like and more liquid-like under stress." *Id.* at 1246-47. The term was one of *degree*, but nothing in the patent or art "identif[ied] the degree of the fragility" required nor how to test for that degree. *Id.* at 1253-56. The Court thus held the claims indefinite because they were "ambiguous as to the requisite degree of the fragileness of the gel" and the degree to which the gel could "suspend drill cuttings." *Id.* at 1256.

Stimwave seizes (Br. 22, 42-46) on *Halliburton*'s discussion of *Geneva*, where *Halliburton* states that a proposed "construction is likely to be indefinite" if it "requires that an artisan make a separate infringement determination for every set of circumstances." *Halliburton*, 514 F.3d at 1254-55 (discussing *Geneva Pharmaceuticals, Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1384 (Fed. Cir. 2003)). Stimwave argues that is the situation here and that skilled artisans purportedly cannot know whether patients will experience paresthesia until after

applying a therapy signal. Br. 42-46 (citing *Halliburton* and *STX v. Brine*, 37 F. Supp. 2d 740 (D. Md. 1999)).

But Stimwave ignores *Halliburton*'s holding. "Non-paresthesia-producing" has a clear meaning and is not a term of degree. *Supra* pp. 39-40. That makes it nothing like "fragile gel." And this Court has explained that *Geneva* offers no support for arguments like Stimwave's, and so neither does *Halliburton*. *Star Scientific v. R.J. Reynolds Tobacco*, 537 F.3d 1357, 1371-73 & n.12 (Fed. Cir. 2008).

In *Star*, the claimed process required "an airflow sufficient to substantially prevent an anaerobic condition." *Id*. The meaning of "anaerobic condition" was clear, and skilled artisans knew tests to determine whether that condition had been prevented in any given circumstance, both from background knowledge and the patent specification. *Id.* But those tests could be conducted only *after* completing each individual process, so an accused infringer could not "determine if a process infringe[d] before practicing the claimed process." *Id.* at 1372. The district court held that made the claims indefinite. *Id.*

This Court reversed, calling the district court's view a "misunderstanding" of indefiniteness. *Id.* at 1371-72. The Court held there is no rule "that the infringement determination must be able to be made at any particular time." *Id.* at 1372 n.12. In reasoning otherwise, the district court "was 'really talking about the difficulty of

avoiding infringement, not indefiniteness.'" *Id.* at 1373 (citation omitted). The "term 'anaerobic condition' clearly delineates the bounds of claim scope," which is all the law requires. *Id.*; *Invitrogen Corp. v. Biocrest Mfg., L.P.*, 424 F.3d 1374, 1384 (Fed. Cir. 2005) (rejecting argument that a claim is indefinite if a potential infringer "would have had to practice the claimed process in order to determine if it was infringing"). So too here: "non-paresthesia-producing" has an undisputed clear meaning (Appx25), thus apprising skilled artisans of the bounds of the claims with reasonable certainty. *Nautilus*, 572 U.S. at 901-02.

Stimwave fails to prove the premise of its arguments anyway. No evidence shows patients respond so differently to spinal cord stimulation that skilled artisans would not know the range of parameters likely to produce non-paresthesia-producing therapy. To the contrary, the above intrinsic and extrinsic evidence shows skilled artisans can use signals with parameters in the ranges disclosed in Nevro's patent to deliver non-paresthesia-producing therapy signals predictably and routinely in entire patient populations. *Supra* pp. 41-45. In both *Sonix* and *Warsaw*, this Court rejected arguments where the challenger failed to prove that human perception or anatomy vary so widely as to leave claims indefinite. *Sonix*, 844 F.3d at 1379; *Warsaw*, 778 F.3d at 1371; *Orthokinetics*, 806 F.2d at 1576 (similar). It similarly should reject Stimwave's argument.

At bottom, Stimwave would have the Court hold these claims present a substantial question of indefiniteness for purportedly not spelling out how to achieve paresthesia-free therapy 100% of the time, for 100% of patients, in 100% of circumstances. That rule goes beyond the Supreme Court's mandate for reasonable certainty and would threaten many patent claims, especially in the life sciences. And such a rule conflicts with Section 112's command that patents contain "clear" and "concise" disclosures, not bloated recitations of details skilled artisans already know or can readily determine. *Orthokinetics*, 806 F.2d at 1575-76 (rejecting similar argument).

2. The district court correctly found no substantial question of invalidity for anticipation or obviousness based on Royle

The district court also correctly applied the law and found Stimwave raised no substantial question of anticipation or obviousness; at the least, the court did not "seriously misjudge[]" the evidence. *Eli Lilly*, 630 F.2d at 136.

a. The record amply supports the district court's no-anticipation finding

As the district court correctly understood (Appx35), prior art that fails to disclose elements "arranged or combined in the same way as in the asserted claims" does not anticipate: "[T]he prior art reference—in order to anticipate under 35 U.S.C. § 102—must not only disclose all elements of the claim within the four

corners of the document, but must also disclose those elements 'arranged as in the claim.'" *Net MoneyIN v. VeriSign*, 545 F.3d 1359, 1369 (Fed. Cir. 2008).

Nevro's claims require delivering a high-frequency "non-paresthesia-producing therapy signal" "via a signal delivery device implanted in the patient's epidural space." Appx114 (col.26:52-62). The district court found that Royle—the sole reference Stimwave relies on here (Br. 3)—discloses something else. Instead of therapy using an implanted signal delivery device, Royle describes transcutaneous spinal electroanalgesia therapy, a therapy that involves applying high-amplitude electrical signals via electrodes placed on "the skin so as to modulate nerves electronically." Appx3614 (¶¶1-4); Appx5325-5326 (¶81), Appx5298-5377.

Because this therapy requires high-amplitude signals (up to hundreds of volts) that can burn the skin, Royle proposes rapidly alternating "positive and negative impulses" rather than using the prior art's uniform pulses. Appx3614 (¶¶3-9), Appx3615-3616 (¶¶60, 64); Appx5797 (Stimwave expert explaining the "higher intensities" required by such therapy). By quickly alternating the electrical pulses, Royle states that "higher voltages can be utilised without the electrodes burning the skin." Appx3616 (¶64). Royle further explains that alternating signals using "a fast rise time" (meaning a fast transition between voltage changes) "lower[s] the electrical resistance of the skin without stimulating the peripheral nerves, so that the subject (i.e. patient) feels no sensation" in the peripheral nerves. Appx3616-3617

(¶75). A fast rise time also allows "a relatively large quantity of electrical charge to pass through the skin and tissues." Appx3616-3617 (¶75); *see* Appx5327-5328 (¶85).

These differences support the district court's finding that Royle fails to disclose paresthesia-free therapy "in the context of an *implantable* signal delivery device" in the patient's epidural space. Appx35 (citing Appx3616-3617 (¶75)) (emphasis added). Instead of paresthesia-free therapy with implanted electrodes, Royle ties "no sensation" of peripheral nerves to electrodes placed on skin, because using a "fast rise time" can "lower the electrical resistance of the skin" and allow "a relatively large quantity of electrical charge to pass through the skin and tissues." Appx3616-3617 (¶75). Nevro's expert Dr. Pless confirmed this: "[n]othing in Royle provides evidence whether patients would actually experience pain relief without paresthesia at higher frequencies using implanted electrodes." Appx5327 (¶85).

As the district court noted (Appx35 n.10), the Patent Office reached the same conclusion in declining to institute *inter partes* review of related Nevro patent claims. The Patent Office found that "the context of these paragraphs indicates that Royle is referring to *skin electrodes*" when describing stimulation that produces "no sensation" of peripheral nerves. Appx2018 (citing Appx3616-3617 (emphasis added)), Appx2002-2022. The Patent Office thus found no reasonable likelihood

that the petitioner would prevail in showing Royle anticipates claims requiring paresthesia-free spinal cord therapy with an implantable signal delivery device. Appx2006, Appx2018.

Even so, Stimwave argues (Br. 46-48) the district court clearly erred because it failed to account for Royle's statement that "if desired, the electrodes could be implanted within the body, including within the skin, but it is more preferable that they are designed to simply be placed in contact with the skin surface." Appx3618 (¶104). Neither the district court nor the Patent Office missed this statement's import. Appx34-35; Appx2017-2018. Both acknowledged that Royle discloses the possibility of implanted electrodes. Appx34-35; Appx2017-2018. But both recognized that Royle ties its teaching of "no sensation" for peripheral nerves to electrodes on the skin because of the skin's "electrical resistance" and ability to pass "a relatively large quantity of electrical charge." Appx3616-3617 (¶75). Where Royle separately describes that "electrodes could be implanted within the body," it never discloses a "no sensation" electrical signal with electrodes "implanted in the patient's epidural space." Appx3618 (¶104). Thus, as the district court found (Appx35), Royle never discloses the claimed elements "arranged or combined in the same way as recited in the claim." *Net MoneyIN*, 545 F.3d at 1371.

Stimwave is wrong (Br. 48) that its expert suggested otherwise. Instead of testifying that Royle discloses the claimed invention, the expert testified only that

nothing in Royle conflicts with the claimed invention: "There is nothing in Royle that would lead a person of ordinary skill to believe that the peripheral nerves would be stimulated, and thus cause the patient to feel the stimulation (i.e., paresthesia), if the electrodes were implanted." Appx4967-4968 (¶114). Such "unrealized possibilities" cannot anticipate. *Perricone v. Medicis Pharm.*, 432 F.3d 1368, 1379 (Fed. Cir. 2005). Because this testimony, even if credited, would not support anticipation, Stimwave wrongly faults (Br. 48) the district court for not making findings about it.

b. The record amply supports the district court's nonobviousness determination

The district court also correctly found Stimwave failed to raise a substantial question about obviousness in view of Royle. Appx34-35. Before the district court, Stimwave made no distinct obviousness argument, asserting only that Royle "anticipates or renders obvious" by disclosing the claimed invention. Appx3204-3205. The court correctly rejected that argument for the same reasons it rejected the identical anticipation argument. *Supra* pp. 51-54.

Even aside from that, Stimwave failed to address all obviousness requirements. Appx3204-3205. "The law is clear" that "'a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.'" *Tinnus*, 846 F.3d at 1207; *KSR Int'l v. Teleflex*, 550 U.S. 398, 418 (2007). "An obviousness determination

requires finding that a person of ordinary skill in the art would have been motivated to combine or modify the teachings in the prior art and would have had a reasonable expectation of success in doing so." *OSI Pharm. v. Apotex*, 939 F.3d 1375, 1382 (Fed. Cir. 2019); *Kinetic Concepts v. Smith & Nephew*, 688 F.3d 1342, 1360 (Fed. Cir. 2012). These requirements apply regardless of whether separate elements come from a single reference or multiple references. *In re Stepan*, 868 F.3d 1342, 1345-46 & n.1 (Fed. Cir. 2017).

Stimwave never showed a skilled artisan would have been motivated to modify Royle's teachings to arrive at a therapy including paresthesia-free signals delivered "via a signal delivery device implanted in the patient's epidural space." Appx114. No expert testimony supports such a finding because Stimwave's expert testified only that "nothing in Royle" conflicts with the combination. Appx4990-4991 (¶176). And although Stimwave argued (as it does here, Br. 49-50) that Royle suggests "that electrodes of the apparatus could be implanted" (Appx3204-3205), what a skilled artisan "would have been *able* to do" is not the same as "what a skilled artisan would have been *motivated* to do." *Polaris Indus. v. Arctic Cat*, 882 F.3d 1056, 1068-69 (Fed. Cir. 2018) (emphasis in *Polaris*).

Nor did Stimwave show a skilled artisan would have reasonably expected to succeed in modifying Royle's teachings to arrive at the claimed invention. Stimwave produced no evidence that if a skilled artisan had implanted electrodes in

the epidural space it would have expected success in treating patients using non-paresthesia-producing therapy signals, particularly at the hundreds-of-volts amplitude levels Royle teaches. Given this absence of any argument or evidence, the district court correctly found, and certainly committed no clear error in finding, that the underlying facts did not show a substantial question of obviousness. *Tinnus*, 846 F.3d at 1207.

Stimwave cannot overcome these basic deficiencies, nor does it even try. Stimwave's lone obviousness argument is that the district court clearly erred in finding that Royle's preference for electrodes placed on the skin "teaches away" from the proposed combination, which Stimwave says was the district court's "sole[]" basis for finding no substantial obviousness question. Br. 49-51. Not so. Before mentioning "teaching away," the district court already rejected the only obviousness theory Stimwave argued—that Royle discloses the exact invention claimed. Appx34-35.

Stimwave's attack on the district court (Br. 49-51) for using the words "teaching away" also misses the point. Royle's preference for electrodes "placed in contact with the skin surface" rather than those implanted in the body (Appx3618 (¶104)) supports a lack of motivation to combine. A reference's "statements regarding preferences are relevant to a finding regarding whether a skilled artisan would be motivated to combine" the elements as claimed. *Polaris*, 882 F.3d at 1069.

Thus, not only did Stimwave fail to produce evidence of or even address a motivation to modify Royle's disclosures, but the district court had affirmative evidence of a motivation not to do so.

Neither of Stimwave's cited cases suggests the court erred, much less clearly so. *Contra* Br. 51 (citing *Galderma Labs. v. Tolmar*, 737 F.3d 731 (Fed. Cir. 2013); *Meiresonne v. Google*, 849 F.3d 1379 (Fed. Cir. 2017)). In *Galderma*, the prior art disclosed a range and the claims recited a value within that range. 737 F.3d at 737-38. In those unique circumstances, this Court presumed the claims obvious absent evidence from the patent owner of teaching away, unexpected results, or other objective indicia of nonobviousness. *Id.* Nevro bears no similar burden here. And in *Meireseonne*, the Patent Trial and Appeal Board held the challenged claims obvious, finding both a motivation to combine and an absence of any teaching away. 849 F.3d at 1382-83. On appeal the Court concluded only that, on the facts there, substantial evidence supported the Board's findings. *Id.* Here, the district court made neither of those findings.

Finally, Stimwave ignores that the district court credited Nevro's "strong objective indicia of nonobviousness." Appx36-37 n.11. "[E]vidence rising out of the so-called 'secondary considerations' must always when present be considered en route to a determination of obviousness" and "may often be the most probative and cogent evidence." *Stratoflex v. Aeorquip*, 713 F.2d 1530, 1538 (Fed. Cir. 1983).

The court here found Nevro had shown "commercial success," "significant industry praise," and "that Nevro's therapy addressed a long-felt but unsolved need." Appx36-37 n.11. Stimwave failed to rebut any of that evidence, which the district court gave "substantial weight because there is a nexus between Nevro's objective evidence of nonobviousness and the merits of the claimed invention." Appx37 n.11. Stimwave appeals none of these separate findings. That independently dooms its obviousness argument. *Apple*, 839 F.3d at 1052 n.15 (declining to consider "teaching away" because substantial evidence supported obviousness regardless).

C. The District Court Correctly Found That The Public Interest Favors An Injunction

The district court correctly found, and certainly did not clearly err in finding, that the public interest favors a preliminary injunction. The public has an "interest in the judicial protection of property rights in inventive technology." *Douglas*, 717 F.3d at 1346. Allowing direct competitors to benefit from a patentee's costly research and development, such as Nevro's investment of hundreds of millions of dollars (Appx38), has "the effect of inhibiting innovation." *Douglas*, 717 F.3d at 1346. To defeat that interest, there must be "some critical public interest that would be injured by the grant of preliminary relief." *Hybritech v. Abbott Labs.*, 849 F.2d 1446, 1458 (Fed. Cir. 1988).

The district court did not clearly err in finding that public interest in fostering innovation outweighed Stimwave's unsupported contrary public interests. The

district court acknowledged that the public "generally" has an interest in having a "wide variety of treatments options." Appx44. But on the record before it, the court found an injunction would not injure any "critical public interest" in treatment options. Appx44. It found Nevro's "narrowly tailored" injunction would allow Stimwave to sell its spinal cord stimulation systems for use in the same manner they had been used before the FDA cleared them for high-frequency therapy in March 2019. Appx44. 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." Appx44-45 (referring to implanted pulse generators). Stimwave does not dispute this finding.

The record also supports the court's finding that, even under an injunction prohibiting high-frequency therapy, "patients using Stimwave's SCS systems will still be able to receive treatment of an equivalent quality" at low frequencies. Appx45. As the court noted, Stimwave's clinical trial showed that using its systems at high frequencies "is merely 'noninferior'" to using them at low frequencies. Appx45 (quoting Appx1698, Appx1701). Stimwave's CEO said the same thing: "Significantly, as Stimwave confirmed to FDA, the study demonstrated the non-inferiority of Stimwave's low frequency programming to programming at 10,000 Hz." Appx4833, Appx4809-4842.

Despite this evidence, Stimwave argues the district court clearly erred because "some patients respond better to high frequency treatment" and its study purportedly shows that sometimes its high-frequency therapy is better than its low-frequency one. Br. 54. It is too late for that argument. Stimwave already conceded its high-frequency therapy offers no better results. Appx40 & n.12; *supra* pp. 28-34. Even if Stimwave could backtrack now, Stimwave has no evidence: its study report expressly concluded that "the HF arm results" are "not indicative of superiority." Appx4163, Appx4166. Stimwave argues otherwise (at 54) only by pointing to unsubstantiated attorney argument, which cannot show clear error. *Invitrogen*, 429 F.3d at 1068.[3]

In addition, the district court found and the record supports that the injunction permits patients access to high-frequency, paresthesia-free therapy: they "have access to Nevro's products," which are suitable for the same patients as Stimwave's. Appx45. Stimwave's CEO conceded she was [redacted] of any [redacted] finding Stimwave's system [redacted] for [redacted]. Appx5867. The district

[3] Not even *amici* Medical Doctors appear willing to support Stimwave's unsubstantiated argument. ECF No. 44. *Amici* never address the gaping hole in Stimwave's argument—whether any patient needs Stimwave's system operated at high frequency rather than low frequency. Even if they had, their unsworn brief would provide no basis to overturn the district court's finding. No such evidence was introduced in district court, not by *amici* and not by Stimwave, so *amici*'s purported personal views were never subject to any cross-examination or potential rebuttal evidence.

court credited Dr. Caraway's live testimony, "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." Appx45 (citing Appx7400, Appx7409); Appx5669-5670 (same). Contrary to Stimwave's assertion (Br. 53), Dr. Caraway did "affirmatively testify" that Nevro's system was suitable for the same patients as Stimwave's. He testified "with confidence" that there are no patients "for which [Nevro's] Senza Systems may not be appropriate as a result of their [implanted pulse generator]." Appx5649. He testified that Nevro's and Stimwave's systems involve similar risks of infection and pocket pain because they involve similar implantation procedures. Appx5649-5650; Appx5665-5666; Appx5671-5673; Appx7405-7409. This evidence disproves Stimwave's argument that its products are "safer than Nevro's." Br. 54. At the very least Stimwave fails to show the district court clearly erred.

Stimwave reargues the evidence and ignores district court findings crediting Dr. Caraway's testimony. It relies almost exclusively (Br. 51-54) on testimony from its CEO, whom the district court found gave "patently false deposition testimony" (Appx16), and from Dr. North, who gave no live testimony and whom the district court did not expressly credit. Even were the Court to reassess this testimony, all of it was disputed. Stimwave argues that Nevro cannot serve patients who need 3T (three-tesla) magnetic resonance imaging ("MRI"), but ignores that its own CEO was [redacted] of [redacted] Nevro could not serve (Appx5858). And

Dr. Rosenberg testified that an implanted system would affect at most full-body scans, and that, for full-body scans, "there is no difference" between a 3T MRI and the 1.5T MRI that Nevro's system supports. Appx5902; Appx7403-7404 (similar from Dr. Caraway). Stimwave says "Nevro's devices are not adequate substitutes for patients who are too slender" (Br. 53) but ignores testimony from Drs. Caraway and Rosenberg that Nevro's systems are suitable for "skinnier patient[s]" and that neither had encountered patients too thin for Nevro's system. Appx5653-5654; Appx5906. Stimwave fails to show the district court clearly erred in crediting this testimony.

D. The District Court Acted Well Within Its Discretion In Limiting The Injunction's Scope To Infringement Of Specific Claims By Specific Actions

Stimwave's challenge to the injunction's scope fails. District courts have broad discretion to "prevent the violation of any right secured by patent, on such terms as the court deems reasonable." 35 U.S.C. § 283. A district court appropriately exercises its discretion when it grants an injunction that identifies "the claims at issue" and the actions "which it enjoins." *Metalcraft*, 848 F.3d at 1369-70. And courts may enjoin conduct "no more than colorably different" from previously adjudged infringing conduct. *Merial Ltd. v. Cipla Ltd.*, 681 F.3d 1283, 1299 (Fed. Cir. 2012).

The district court's narrow injunction easily meets these standards. It identifies the claims and the specific infringing conduct enjoined: it prohibits Stimwave from "infringing or inducing infringement of claims 24 and 28 of U.S. Patent No. 8,874,222 by programming Stimwave's SCS systems to deliver its recently introduced high-frequency, paresthesia-free SCS therapy." Appx48. And it prohibits Stimwave from programming its systems to deliver "any other SCS therapy that is not more than colorably different" from the therapy found to infringe. Appx48; *Merial*, 681 F.3d at 1299. Even as to infringing uses, the injunction exempts "follow-up care and programming for patients who were already programmed with such high-frequency, paresthesia-free therapy before the date of this Order." Appx48. The district court thus properly limited its injunction to specific claims and specific conduct, making reasonable exclusions to protect patients.

This specificity makes the injunction nothing like the overbroad and nonspecific injunctions in *Additive* and *Allergan*, decisions on which Stimwave relies. *Additive Controls & Measurement Sys. v. Flowdata*, 986 F.2d 476 (Fed. Cir. 1993); *Allergan v. Athena Cosmetics*, 738 F.3d 1350 (Fed. Cir. 2013). In *Additive*, the district court issued a two-sentence injunction stating, "Plaintiff is forever barred from infringing Flowdata's patent." 986 F.2d at 477. Unlike here, that injunction did "not state which acts of [the enjoined party] constitute

infringement," was not limited to any "specific infringing device" or to devices "no more than colorably different." *Id.* at 479-80. The injunction in *Allergan* is even further removed from the one here. The district court there issued a nationwide injunction for violations of California law, which this Court found would violate the Commerce Clause unless limited to California. 738 F.3d at 1360.

Stimwave also wrongly argues that the injunction "effectively prevents Stimwave from a wide range of noninfringing activities." Br. 56 (emphasis omitted). Stimwave just rehashes its flawed indefiniteness argument—that "it is impossible to determine whether a given signal will cause paresthesia without first delivering it to the patient." Br. 56; *supra* pp. 38-51 (explaining why Stimwave is wrong). And Stimwave wrongly argues (Br. 56) that the injunction precludes it from providing noninfringing, paresthesia-based, high-frequency therapy. But Stimwave itself [redacted] using its systems to [redacted] at [redacted] and it did not seek FDA approval for such therapy. Appx4134, Appx4131-4158.

Stimwave asserts the injunction should be limited to 10 kHz because Nevro's evidence purportedly "relates to 10 kHz signals only." Br. 56-57. Nevro's evidence merely matched Stimwave's use, which Stimwave admits was limited to 10 kHz. Br. 57 (citing Appx21); Appx7522-7523. The injunction nevertheless properly prohibits Stimwave from programming its system to infringe at any frequency in the claimed range. Nevro showed that producing paresthesia-free therapy signals at

other claimed frequencies "would be the same as" doing so at 10 kHz. Appx7416; Appx30 (district court finding same). Given this evidence, the district court acted well within its discretion in refusing to endorse Stimwave's "Whack-a Mole" game. Appx7526. Otherwise, Nevro would prove infringement at one frequency only to have Stimwave "turn one notch down and start infringing all over again," forcing the court and the parties to repeat the process. Appx7526.

CONCLUSION

The preliminary injunction should be affirmed.

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Respectfully submitted,

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In compliance with Fed. R. App. P. 32(a)(7)(C), I certify that:

This brief complies with the type-volume limitations of Federal Circuit Rule 32(a) because it contains 13,968 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f) and Federal Circuit Rule 32(b), as determined by the word-counting feature of Microsoft Word.

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I hereby certify that I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Federal Circuit by using the CM/ECF system on December 4, 2019.

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