2019-2205

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

NEVRO CORP.,

Plaintiff-Appellee,

v.

STIMWAVE TECHNOLOGIES, INC.,

Defendant-Appellant.

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

REPLY BRIEF OF APPELLANT STIMWAVE TECHNOLOGIES, INC.

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December 26, 2019

CERTIFICATE OF INTEREST

Counsel for Appellant certifies the following:

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

Stimwave Technologies, Inc.

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

Stimwave Technologies, Inc.

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

None.

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

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

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

Nevro Corp. v. Stimwave Technologies, Inc., USDC-D. DE Case 19-325-CFC.
Nevro Corp. v. Boston Scientific Corp., Fed. Cir. Case Nos. 18-2220, 18-2349.

Dated: December 26, 2019 Respectfully submitted,

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ARGUMENT

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

The district court's finding of irreparable harm rests upon clear errors of fact. ***First***, the district court misread the clinical numbers to find that Stimwave's results "pale[] in comparison" to Nevro's. Appx40. The numbers show that it is ***Stimwave's*** products that reduce more pain in more patients[1]:

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

Nevro's brief (at 21-38) strikingly fails to contest this fact. It concedes these clinical numbers, identifies no metric by which its 10kHz products outperform Stimwave's, and offers no other factual justification for concluding that Stimwave's results "pale in comparison" to Nevro's. This is clear error.

Lacking a response on the substance, Nevro obfuscates. It throws up a fog of legalistic and procedural quibbles, some irrelevant, others untrue, and all meritless. Its argument (at 22-25) that the district court would have found irreparable harm even if it had not misread the clinical studies is wrong and irrelevant anyway. The district court ***did*** make that error and ***did*** rely upon it as the core of its irreparable-

[1] *See* Blue Br. 12-14.

harm analysis; this court does not speculate as to what facts a district court might have found if it had reasoned differently. *OSRAM Sylvania, Inc. v. Am. Induction Techs., Inc.*, 701 F.3d 698, 707 (Fed. Cir. 2012). Similarly, Nevro's argument (at 27-28) that Stimwave's high-frequency results "pale in comparison" because the SENZA-RCT study calls Nevro's products "superior" whereas the SURF-RCT study only calls Stimwave's products "noninferior" is wrong. First, the district court made no such finding. Second, Nevro's substitute argument is premised on an error of logic: the studies report "superiority" and "noninferiority" compared to ***different baselines***. Finally, Nevro's argument (at 28-34) that Stimwave "conceded" the untrue assertion that its products are inferior to Nevro's is incorrect. In fact, Stimwave told the district court the same thing it says here: that its results are at least "on par with the results reported by Nevro." Appx4833-4834 (¶33).

Second, Nevro also has no serious argument that anything beyond speculation supports the additional findings that physicians would confuse the parties' products and abandon ***Nevro*** because of hypothetical bad experiences with ***Stimwave***. It still cannot identify a single physician who has ever done so and cannot answer all the evidence that goes the other way.

1. It was clear error to find that Stimwave's high-frequency results pale in comparison to Nevro's

a) Nevro does not contest the studies' clinical findings

Nevro offers no colorable argument on the substance of parties' studies. It does not dispute that Stimwave's 10kHz treatment produced more responders (92% vs. 76.4%), more remissions (84% vs. 59.6%), and more average pain reduction (77% vs. 67%) than Nevro's, *see* Blue Br. 31-33; that it produced fewer overall "adverse effects," *see id.* at 34-35; and that for lead migration—the one area where Stimwave underperformed in the studies—Stimwave has since improved its products so they now produce ten times fewer such events than Nevro's. *Id.* at 35-36. Indeed, Nevro has not identified any substantive metrics on which its 10kHz products outperform Stimwave's. Red Br. 21-38.

Nevro's response does not address these points. Instead, it argues (at 33), relying on its witness Dr. Caraway, that "[s]cientifically, you can't directly compare all of these studies." Appx7407. If true, this would be another reason why the district court erred by comparing them. But whether a scientist can "directly" compare "all" of the studies is not the question. The results of the two key studies the district judge relied on ***can*** be compared in key respects, and those results show the district court got the comparison wrong. First, both studies used the same methodology and evaluated the same metrics, defined in the same way, so that the results' values have

the same meaning. Blue Br. 31-32. Second, the SURF-RCT study expressly compares some of its numbers with SENZA-RCT's. Appx4167 (comparing serious adverse effects numbers). And third, at Nevro's counsel's urging, Dr. Caraway himself went on to compare their numbers immediately after the testimony quoted above. Appx7407-7408 at 131:21-132:1.

b) The studies do not suggest that Nevro is superior to Stimwave

Nevro's argument (at 27-28) that the clinical results can be ignored because the SENZA-RCT study calls Nevro's products "superior" whereas Stimwave's SURF-RCT study only calls its products "noninferior" is logically wrong. "Superior" and "noninferior" are comparative terms and meaningless without identifying superior ***to what*** and noninferior ***to what***? Here, the baselines were different. *See* Blue Br. 31, 33. SENZA-RCT's baseline was Boston Scientific (BSC)'s low frequency product, and the numbers show that Nevro's 10kHz product was indeed "superior" to that. *Id.* By contrast, SURF-RCT's baseline was Stimwave's (much more effective) low frequency product, and the numbers show Stimwave's 10kHz system was in the same range as that, and thus "noninferior." *Id.* Mathematically, if Nevro > BSC and Stimwave HF = Stimwave LF, that says nothing about the relationship between Nevro and Stimwave HF. Here, the undisputed numbers show that Stimwave's high-frequency system is as good as or better than Nevro's.

The district court's irreparable harm finding also ***requires*** evidence of an actual difference in performance. Based on its "pale in comparison" finding, the court found irreparable harm from "confusion between an ***inferior*** accused product and a patentee's ***superior*** product," because if Stimwave's "paresthesia-free therapy [] ***does not perform as well*** as Nevro's technology, and a skeptical physician were to try it … but the skeptic has a negative experience, … Nevro could forever lose this physician as a potential customer." Appx39-40. This reasoning requires that Stimwave's products are in fact "inferior" or "do not perform as well." Since they actually work as well or better, this line of reasoning is clear error.

c) Nevro's criticisms of the SURF-RCT study are meritless.

Finally, Nevro's criticisms of the SURF-RCT study are either misleading or irrelevant. In the misleading category is Nevro's attorney argument (at 11-12 and 32 (citing Appx4162-4163)) that SURF-RCT is less reliable than SENZA-RCT because it "cherry pick[ed]" data by "exclud[ing] data from [certain patients] who 'were considered nonresponders' to the therapy" after a preliminary trial phase. Not so. In fact, ***both*** studies included a trial phase, both excluded "nonresponders" at the end of that phase, and both excluded the same percentage of subjects on this basis. This is not "cherry picking" but ethical human experimentation: when an initial trial phase shows that a patient is not responding to SCS therapy, experimenters cannot

put them through months of fruitless treatment but must release them, Appx4162 (SURF-RCT), as both studies did:

	SENZA-RCT	SURF-RCT
Trial phase was performed	"97 subjects … completed a ***trial*** of HF10 therapy" Appx1568.	An "an ***initial trial period*** of 30 days" was performed. Appx4162.
Trial-phase "nonresponders" were excluded	"Subjects who did not have a successful trial phase ***were considered nonresponders*** for the intention-to-treat and per protocol analyses." Appx1567	"Subjects who did not have a successful trial phase ***were considered nonresponders*** for the PP analyses." Appx4162.
~92% of subjects remained[2] afterwards	"Of the 97 subjects who completed a trial of HF10 therapy, 90 ***(92.8%)*** [were successfully trialed]. In comparison, 81 of 92 subjects (88.0%) were successfully trialed with traditional SCS …." Appx1568.	"The trial success rate … was ***92%*** (46/50) for the HF arm and 84% (41/49) for the LF arm." Appx4163.

Nevro's other quibbles (at 32-33) about sample size (both studies were indisputably statistically large enough) and average pain length (10-11 years vs. 13-14

[2] In both studies, a handful of subjects were also excluded for other reasons, such as their decision to "withdr[a]w consent," (SENZA), "medical contraindications," (SENZA) and not having completed the full six-month course of treatment at the time the study was published (SURF). Appx1568 Fig. 1 (SENZA-RCT); Appx4162 (SURF-RCT).

years) are plainly irrelevant; Nevro does not even try to argue that its quibbles affected any study result.

2. The district court's clearly erroneous findings are relevant to its finding of irreparable harm

Lacking a substantive response, Nevro argues (at 22-25) that the district court would have found irreparable harm even if it had not misunderstood the clinical studies. Nevro asks this court to string together unconnected sentences from multiple sections of the district court's opinion to make a new irreparable-harm finding that is not based on clinical superiority. Red. Br. 22-25. That fails. The Federal Rules require the district court issuing a preliminary injunction to specifically "state the findings and conclusions that support its action" FED. R. CIV. P. 52(a)(2), and "[i]t is not [this court's] role to scour the record and search for something to justify a lower court's conclusions …." *OSRAM*, 701 F.3d at 707.

Here, the clearly erroneous findings were the heart of the district court's analysis. The district court found irreparable harm solely based on damage to Nevro's "goodwill and reputation," Appx38, and declined to adopt Nevro's lost-sales or price-erosion arguments. And it explained that "confusion between an inferior accused product and a patentee's superior product" was the ***mechanism*** by which this purported "harm to reputation" would arise, saying:

> "The Federal Circuit has explicitly recognized that ***harm to reputation resulting from confusion between an inferior accused product and a patentee's superior product*** is a type of harm that is often not fully compensable by money …. [citation to *Reebok,* 32 F.3d at 1558]; *see also Tinnus Enters.*, 846 F.3d at 1208 (affirming district court's finding of irreparable harm because ***consumer confusion*** between the patentee's product and the accused infringer's product ***established persisting harm to the patentee's reputation*** and tarnished its status as the innovator in the market."

Appx40-41 (alterations omitted). "Nevro," the district court said, "has established that it would suffer ***this exact type of harm*** here absent an injunction." *Id.*

The district court's legal citations also confirm that it based its analysis on finding superiority and confusion. Under Rule 52, the court "must carefully enunciate and explain [its] resolution of questions of law …." 9 MOORE'S FEDERAL PRACTICE § 52.15 (2019). Here, the court's only legal grounds for finding irreparable harm were citations *Reebok* and *Tinnus* (reproduced above), quoted for the proposition that irreparable harm could arise because of "customer confusion" between a patentee's superior product and an infringer's inferior one. Appx40-41.

The findings that Nevro identifies (at 23)—namely that high-frequency therapy "has been the whole reason Nevro is around" and that Nevro has obtained exclusivity in this area—were also made to support the customer-confusion rationale. The court reasoned that these supported the idea that, if doctors "conflate" Stimwave's allegedly inferior offerings with Nevro's, that could "create a negative reputation" for high-frequency therapy:

> Dr. Caraway similarly testified that "successful implementation of HF 10 therapy ... has been the ***whole reason [Nevro] is around***" and another company's ***unsuccessful implementation*** of HF 10 therapy "***could be conflated with how [Nevro's] therapy is***" and also create "a negative reputation upon the therapy as a whole.

Appx40. In sum, the district court's customer-confusion theory is the basis for its irreparable-harm finding and cannot be disentangled from it. It is for the district court, not this court, to decide if there were irreparable harm on some other basis.

3. Stimwave has not forfeited the right to argue that its results do not "pale in comparison" to Nevro's

a) Waiver does not apply

Nevro never expressly argues waiver—for reasons we discuss shortly—and its hints (at 26, 28) that this Court should not consider whether the studies support the district court's conclusions are mistaken.

First, as Nevro concedes, the district court (at Appx39) made its "pale in comparison" finding *sua sponte* in its preliminary-injunction order, and this is Stimwave's first chance to contest it. "A party cannot … waive an argument that did not exist when he submitted his brief," *Spiegla v. Hull*, 481 F.3d 961, 964 (7th Cir. 2007), and so when "the District Court considered [a] defense *sua sponte*, appellate review of the issue is appropriate." *Albrecht v. Horn*, 485 F.3d 103, 120 (3d Cir. 2007).

Here, Nevro admits that it never argued its own clinical superiority to Stimwave as a basis for irreparable harm—it couldn't, as that would have been false—and so Stimwave had no reason to refute the point until the district court raised it in its order. Nevro admits (at 18) that "[n]either Nevro [nor] Stimwave [sic] ... raised any such data-comparison issue" and (at 26) that "[t]here was no debate about this efficacy data in the district court." Nevro's briefs below confirm this. Appx1387 at 1402-1408.

Second, Stimwave did nevertheless present evidence that Nevro's products were not superior. Dr. Perryman testified that "both Stimwave's Low Frequency and High Frequency results were on par with the results reported by Nevro in their published data set (64% pain relief)," Appx4833 (Perryman) ¶33, and presented a graph of the studies' results to prove this. Appx4834. Nevro's hints of waiver fail.

b) Stimwave did not concede that Nevro was better

Nevro's argument (at 29-30) that Stimwave "conceded" the untrue assertion that its products are inferior to Nevro's is wrong. Legally, Nevro identifies no doctrine or case that supports such estoppel. And factually, Stimwave's position below was not inconsistent: Dr. Perryman told the court that its products were ***not*** inferior to Nevro's and provided a graph of study results to prove it.

And Stimwave did not contradict its witness's sworn testimony. Nevro is conflating product-labelling approvals with actual clinical performance. Nevro had sought FDA clearance to use the word "superior" on its 10kHz marketing materials, and—after jumping through the necessary regulatory hoops—obtained it. Red Br. 8-9; Appx5. Stimwave never sought such approval. Appx4832-4833. So Nevro had authorization to ***say*** that it was superior to its low-frequency baseline, which Stimwave lacked. Stimwave pointed this out, explaining that Nevro was using this "club of clinical superiority" in its marketing to distinguish itself. Appx7577 at 301:4-7; Appx5120 ¶69. The "club of clinical superiority" referred to what Nevro could legally ***say*** based on its study, not how Nevro's products compared to Stimwave's:

> … [T]hey have the club of clinical superiority. ***They <u>can say</u>***, our 10k product gives you clinically superior result. Your 10k product does not.

Appx7577 at 301:4-7. And of course, Stimwave also agreed below, as it does here, that the SENZA-RCT study reported "superiority" (over its baseline) while the SURF-RCT study reported only "noninferiority" (over its different baseline), which Nevro likewise touted in its advertising. Appx7577 at 301:21-22; Appx5120 ¶69.

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

Separately, the district court erred (at Appx40-41) because there is no evidence that physicians would "confuse[]" Nevro's products with Stimwave's and

abandon ***Nevro*** because of hypothetical bad experiences with ***Stimwave***. As we explained (Blue Br. 36-41), there is no evidence that any physician has ever done so and many undisputed facts show otherwise. Nevro's response (at 34-37) offers no additional evidence other than arguments that "Nevro faces significant skepticism in the market …." Red. Br. 35. This has nothing to do with customer confusion and is not evidence that anyone ever had a bad experience with Stimwave; it is irrelevant. Accordingly, this is an independent reason why the injunction should be vacated.

B. "NON-PARESTHESIA-PRODUCING … SIGNAL" IS INDEFINITE

Stimwave raised at least a substantial question that "non-paresthesia-producing … signal" in the claims at issue is indefinite. The ***same*** signal could cause paresthesia in one patient and not cause paresthesia in another. "[A]n artisan would not know from one [patient] to the next whether a certain [signal] was within the scope of the claims." *Halliburton Energy Servs., Inc. v. M-I LLC*, 514 F.3d 1244, 1254-55 (Fed. Cir. 2008). This renders the claims indefinite. *Id.*

1. The parameters of a "non-paresthesia … producing" signal vary from patient to patient

The established facts for purposes of this appeal are: (1) that a separate determination of paresthesia-producing has to be made for each signal applied to each patient; and (2) determining whether a given signal will induce paresthesia requires

applying the signal to the patient and asking what they feel. Nevro's contrary assertion (at 41-42) that the patent "discloses specific signal parameters … to deliver … paresthesia-free signals" contradicts the district court's findings, contradicts its own witnesses' testimony, and misrepresents the '222 patent.

First, the district court found as a fact that no such abstract non-paresthesia-producing signal parameters exist. These "subsidiary factual [findings] made in the course of its construction" are entitled to deference and reviewed for clear error. *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S.Ct. 831, 836 (2015). Here, the court found that "paresthesia is a subjective assessment that can vary from patient to patient," Appx25, and that "it is ***impossible to know*** whether paresthesia will be induced until after the signal is applied" to the patient. Appx27. Accordingly, it found that "patient interactions"—i.e. applying the signal and asking the patient what they feel—are used to determine "whether a signal produces paresthesia for any given patient." *Id*.

Second, Nevro's witnesses said the same thing. Dr. Caraway testified that it is impossible to identify parameters beforehand that will cause a given patient to feel paresthesia:

> **Q. For a given frequency [and] pulse width, there isn't any way to tell before you start the process of adjusting the amplitude setting in the therapy when a given patient is going to feel something, is there?**
>
> A. That's true for all forms of spinal cord stimulation in every frequency.

Appx7417 at 141:14-19. Similarly, Nevro's expert testified that he "didn't know" whether specific signal parameters would be paresthesia-free and that the '222 patent only provides the "starting point" for an "iterative process" with the patient that would be needed to actually "identify a paresthesia-free signal":

> **Q. Would those [signal parameters] be paresthesia-free for the vast majority of patients?**
>
> A. I don't know.
>
> **Q. … [T]he disclosure in the patents that you discussed, that wouldn't help you?**
>
> A. The disclosure tells me the ***starting point*** at which we can use an iterative process, which is not simply a declaration in a deposition. ***An iterative process*** to identify a [patient's] sensory threshold and ***thereby identify a paresthesia-free signal.***

Appx5927 at 238:2-11.

Third, as this testimony confirms, the parts of the specification that Nevro cites (at 41-42) do not purport to identify signal parameters that are "non-paresthesia-producing." Rather, they disclose broad parameter ranges for pain treatment while saying nothing about which ones will produce paresthesia in which patients.

Appx104-107 (6:54-7:8, 9:3-17, 12:23-32). An "iterative process" must be conducted with each patient to determine which parameters in these ranges would be "non-paresthesia-producing" for them. Appx5927 at 238:2-11.

2. The claims are indefinite under *Halliburton* and related cases

These facts render the claims indefinite under *Halliburton*, 514 F.3d 1244, and *Geneva Pharmaceuticals v. GlaxoSmithKline*, 349 F.3d 1373 (Fed. Cir. 2003). *See* Blue Br. 42-43. Both cases hold that a term is "the epitome of indefiniteness" when—as here—it requires a skilled artisan to "make a separate infringement determination for every set of circumstances in which the composition may be used, and when such determinations are likely to result in differing outcomes (sometimes infringing and sometimes not)." 514 F.3d at 1254-55; 349 F.3d at 1384.

Contrary to Nevro's argument (at 48), indefiniteness in those cases did not turn on whether the terms at issue were labelled "terms of degree." Instead, both cases confronted the problem we have here: that one cannot tell what meets the claim in general. Here, no signal parameters can distinguish a "non-paresthesia-producing … signal" from a paresthesia-producing one without reference to a specific patient. Similarly, in *Halliburton*, there were no parameters—"quantity, weight, size and/or volume of cuttings [that] must be suspended"—that could distinguish the claimed "fragile gel" from a non-"fragile" one without reference to the oil well where it was

used. *Id*. at 1254. And in *Geneva*, the patentee conceded that the dosage parameters of a "synergistically effective amount" of an antibiotic could not be distinguished without reference to the particular bacterium against which it was applied. 349 F.3d at 1384.

Further, the patentees in both cases sought to escape indefiniteness as Nevro does here: by arguing that the terms should be evaluated on a case-by-case basis. Just as Nevro argues that the signal parameters that produce a "non paresthesia producing … signal" can be evaluated separately for each patient, Halliburton argued that the suspension parameters of its "fragile gel" were those "adequate for the circumstances" of the particular well, 514 F.3d at 1254, and the *Geneva* plaintiff argued that the "dosage range depend[s] on the particular antibiotic and bacteria." 349 F.3d at 1384.

The court rejected this argument in both cases for the same reason that "non paresthesia producing … signal" is indefinite here. *Halliburton* rejected the case-by-case approach because it "requires a skilled artisan to make a separate infringement determination for every set of circumstances." 514 F.3d at 1254-55. And *Geneva Pharms* did the same because "one of skill would not know from one bacterium to the next whether a particular composition standing alone is within the claim scope

or not. That is the epitome of indefiniteness." 349 F.3d at 1384. That holding applies with equal force here.[3]

3. The cases Nevro cites are not to the contrary

The line of cases Nevro cites (at 47-50) is not to the contrary. To begin with, Nevro's reading of these cases is simply inconsistent with *Halliburton* and *Geneva*. Nevro argues (at 46-48) that a term that requires "a separate infringement determination for every set of circumstances" is not the "epitome of indefiniteness," as *Halliburton* and *Geneva* say, but is instead fine so long as that determination is "easily ascertainable" in each circumstance. There is no fair way to read *Halliburton* and *Geneva* to say this. These cases hold that indefiniteness arises from having to determine parameters for each set of circumstances where the claim may be applied, and neither finds it relevant whether such determinations would be easy or difficult. 514 F.3d at 1254-55; 349 F.3d at 1384. Indeed, as Nevro does not contest, in *Halliburton*

[3] Nevro's discussion (at 45-47) of the indefiniteness of "purely subjective" claim terms is not responsive to our argument under *Halliburton* and in any case supports **our** position. If definiteness could be established merely by asking each subject if the limitation was met (as with the paresthesia determination here), then every subjective term would be definite, since one can always ask each individual what they feel. This conflicts with the holdings of *Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1373 (Fed. Cir. 2014) ("unobtrusive manner" indefinite because purely subjective) and *Datamize, LLC v. Plumtree Software, Inc.*, 417 F.3d 1342, 1350 (Fed. Cir. 2005) (same for "aesthetically pleasing"), and renders moot the discussion in *Sonix Tech. v. Publications, Int'l*, 844 F.3d 1370, 1378 (Fed. Cir. 2017) (finding subjective term not indefinite because it was objectively grounded).

there was no dispute that tests existed to tell if a gel could suspend drill cuttings "adequate[ly] for the circumstances" in a given well. *See* Blue Br. 44 (citing 514 F.3d 1244-55).

In fact, these lines of cases can be reconciled. Nevro's cases hold that "some experimentation … to determine the ***scope*** of the claims does not render the claims indefinite," *Biosig v. Nautilus*, 715 F.3d 891, 902 (Fed. Cir. 2013) ("*Nautilus I*"), and the *Halliburton* line clarifies that this changes where no amount of up-front experimentation can determine the claim scope, so that an "a separate ***infringement determination*** [is needed] for every set of circumstances." 514 F.3d at 1254-55. Thus, Nevro's cases would apply if a skilled artisan could, after some experimentation, establish broadly the signal parameters that would be "non-paresthesia-producing" for different classes of patients—frequency A with amplitude B and pulse-width C for children; frequency D with amplitude E and pulse-width F for adult males, etc. But because this is impossible, and a patient-by-patient infringement analysis is required to determine whether the term is met, *Halliburton* applies instead and the term is indefinite.

Nevro's cases fall into the former category. In *Orthokinetics Inc. v. Safety Travel Chairs*, an artisan could easily determine up-front what parameters would make a wheelchair "dimensioned as to be insertable" between the doorframe and

seat for various models of cars by measuring the distances between these components. 806 F.2d 1565, 1575 (Fed. Cir. 1986). Similarly, in *Warsaw Orthopedic, Inc. v. NuVasive, Inc.*, the "dimensions of the human vertebrae" within which the spinal implant were to be inserted were "well-known" and do not vary significantly between people. 778 F.3d at 1371 (Fed. Cir. 2015). The same holds for *Biosig v. Nautilus*, 783 F.3d 1374 (Fed. Cir. 2015) ("*Nautilus III*"), where simple experiments could determine the extent of the claimed "spaced relationship" between electrodes, and then "design variables" such as the "size, shape and materials of the electrodes" could be adjusted to produce a covered device. 783 F.3d at 1384; *see also Nautilus I*, 715 F.3d at 900.

Here, no amount of experimentation short of a patient-by-patient infringement analysis can determine the parameters of "non-paresthesia-producing … signal," and the term is indefinite.

4. The claims are indefinite because an artisan cannot determine infringement except by infringing

Nevro's response to Stimwave's alternative indefiniteness argument (at 49-50) also fails. As we showed (Blue Br. 44-46), even if (counterfactually) a patient-by-patient analysis could survive *Halliburton*, the claim would still be indefinite because an artisan must risk infringing to determine if infringement exists.

Nevro responds by citing cases that are no longer good law after the Supreme Court's decision in *Nautilus*. Nevro argues that *Star Scientific*, *Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357 (Fed. Cir. 2008) and *Invitrogen Corp. v. Biocrest Mfg., L.P.*, 424 F.3d 1374, 1384 (Fed. Cir. 2005) hold that "there is no rule 'that the infringement determination must be able to be made at any particular time.'" Red. Br. 49-50. This proposition does not survive *Nautilus*.

Star Scientific and *Invitrogen* both apply the pre-Nautilus "insolubly ambiguous" standard, 537 F.3d at 1371; 424 F.3d at 1383, and their reasoning contradicts the Supreme Court's more capacious view of indefiniteness. Specifically, both cases held it irrelevant whether "a potential infringer [was] ab[le] to ascertain the nature of its own accused product to determine infringement," 537 F.3d at 1372-73; 424 F.3d at 1384, because this was "really talking about the difficulty of avoiding infringement, not indefiniteness of the claim." 537 F.3d at 1372-73; 424 F.3d at 1384. The Supreme Court, however, put an infringer's ability to determine infringement at the center of the inquiry. It held that a patent must be "precise enough to afford clear notice of what is claimed, thereby apprising the public of what is still open to them in a manner that ***avoids a zone of uncertainty which enterprise and experimentation may enter only at the risk of infringement claims***." 572 U.S. at 899 (internal quotations and citations omitted).

Here, the claims are custom-designed to create a zone of uncertainty that sweeps beyond the limit of the claims by effectively preventing Stimwave from using even high-frequency signals that ***do*** produce paresthesia. Blue Br. 46. After *Nautilus*, they are indefinite.

C. ROYLE ANTICIPATES THE ASSERTED CLAIMS AND RENDERS THEM OBVIOUS

The district court found that "Royle ***discloses each element of the asserted claims***." Appx35. But it made a crucial mistake that affected both its anticipation and obviousness conclusions: It treated a statement about a "preferred" placement of Royle's disclosed electrodes on the skin as negating the plain disclosure that "if desired, the electrodes could be planted within the body." Appx35.

1. Royle anticipates the asserted claims

The district court clearly erred by finding that "Royle does not disclose the[] elements as arranged … in the same way as in the asserted claims." Appx35. Although the court found that Royle "disclose[s] paresthesia-free therapy, it does so in the context of placing the electrodes on the patent's skin ***rather than*** implanted within the patient's body." Appx34-35.

The court's "rather than" comment is incorrect. Royle teaches that, to provide therapy "so that the subject [] feels no sensation," the therapy should be delivered "without stimulating the peripheral nerves." Appx3616-3617 ¶75; Appx3618 ¶104.

As we have explained (Blue Br. 48), this technique to avoid paresthesia is applicable regardless of whether electrodes are implanted under the skin or on it. The court erred by focusing only on Royle's ¶75 (Appx3616-3617) and on-skin electrodes rather than ¶ 104 (Appx3618), where Royle's disclosure that "electrodes could be implanted within the body" immediately follows its teaching that electrodes should be applied:

> . . . ***whilst stimulating peripheral nerves*** that lie between the electrodes and the central nervous system ***to a lesser extent or not at all. If desired, the electrodes could be implanted within the body, including within the skin*** . . .

Appx3618 ¶104.[4]

Nevro's responses fail. First, it attempts (at 52-53) to backfill the district court's order with a lengthy factual analysis that the court neither made nor adopted. The district court did not even cite the portions of Royle that Nevro now relies upon. Appx34-35 (***not*** citing Royle at ¶¶1-9, 60, 64, 81, or 85). It is not for this Court to make fact-findings that formed no part of the district court's reasoning or decision, and that would have been disputed had Nevro presented its arguments below.

[4] Nevro (at 53-54) points to a footnote (at Appx35) about an IPR non-institution decision that Stimwave was not involved with. But there, "Petitioner relie[d] on paragraphs 75, 76, and 78 of Royle for meeting the limitation 'does not create paresthesia in the patent." Appx2018. Neither that IPR nor the district court considered the key disclosure at Appx3618 ¶104.

OSRAM, 701 F.3d at 707. At best, this is an argument to vacate the injunction and remand for further fact-finding.

Nevro next (at 54) misrepresents the district court as having "***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.'" The court "recognized" no such thing. The words "electrical resistance" or "electrical charge" do not appear in its opinion. Appx1-46. Rather, the district court said that "the use of a fast rise time of the pulses is preferred" but as we showed (Blue Brief 48), fast rise-time applies to either implanted or on-skin electrodes.[5] The finding below on anticipation is an error of fact and law.

2. Royle renders the asserted claims obvious

As we have shown (Blue Br. 49-51), the district court legally erred in its obviousness analysis by finding that Royle "teaches away" from implanting electrodes. The court's entire obviousness analysis is as follows:

> ***Because Roy[le] teaches away*** from implanting the electrodes, I also conclude that it does not render the asserted claims obvious. [Case quotation and citation omitted.] Here I find that Royle ***teaches away*** from implanting the electrodes because a POSITA, upon reading Royle, would choose to place the electrodes on the patient's skin rather than implant them in the patient's body.

[5] Nevro's argument (at 54-55) that Stimwave's expert did not "testify that Royle discloses the claimed invention" but only that "nothing in Royle conflicts with the claimed invention" is simply untrue. Appx4967-4968 (¶114).

Appx35. This cursory analysis is legal error. Royle "expresses a general preference … but does not criticize, discredit, or otherwise discourage investigation into" implantation of electrodes into the body. *Meiresonne v. Google, Inc.*, 849 F.3d 1379, 1382 (Fed. Cir. 2017). In fact, as we explained (Blue Brief 49-51) Royle specifically teaches that electrodes could be implanted:

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

Appx3618 ¶104. Thus, Royle recognizes that such an implantation may be "desired" in some circumstances. It is error to treat this as a teaching away.

Nevro's argument (at 55-58) that there is a "lack of motivation to combine" or "modify Royle's teaching" fails for multiple reasons. ***First***, as we have discussed, these factual determinations were not the basis for the court's decision. *OSRAM*, 701 F.3d at 707. Moreover, Nevro waived this argument by not presenting it to the district court. Appx5278-5279 (Nevro's reply brief below).

Second, on the merits, Nevro is tilting at windmills. There is no need to "modify" Royle's teaching or "combine" with other art: this is single-reference obviousness from what Royle itself teaches, i.e., that "electrodes ***could*** be implanted within the body, including within the skin" and that this may be "***desired***." Appx3618 ¶104.

Nevro's secondary argument (at 56-57) as to reasonable expectation of success is waived and meritless. Nevro did not raise it below, Appx5278-5279, and it was not the basis of the court's opinion. Appx4967-4968. It also fails on the merits because Royle taught that "electrodes ***could*** be implanted within the body, including within the skin." Appx3618 ¶104.[6]

In sum, the district court erred by misapplying the concept of "teaching away" to bypass a substantive obviousness analysis.

D. THE PUBLIC INTEREST DOES NOT FAVOR AN INJUNCTION

Enjoining doctors from prescribing Stimwave's high-frequency SCS pain therapy deprives some patients of their best medical care. As laid out in our Blue Brief (at 52-53), it was clear error to hold that "for those patients that desire high frequency, paresthesia-free therapy, they will have access to Nevro's products" or that "Stimwave's low frequency therapy will still remain an option." Appx44-45.

This error was further recognized by the sixteen *amici* physicians who identify "patient groups [who] although not candidates to receive the Nevro device, could be candidates for the Stimwave device." D.I. 44 at 6. And as the amici physicians

[6] Nevro's argument about objective indicia (at 58-59) is another distraction. The court below did not base its injunction on objective indicia. *See* Appx36 (treating secondary consideration as an afterthought and "briefly examin[ing] secondary considerations . . . because I am required to do so"). It made no ultimate finding about secondary considerations.

observe, high-frequency therapy is more effective than low-frequency therapy for some patients. *Id.* at 7-8. So, for individuals "who are not candidates for the Nevro device" but who respond better to high-frequency treatment, the injunction forces doctors and these patients "to choose between a less effective option for their chronic pain and a potentially dangerous otherwise contra-indicated IPG [e.g., Nevro] implantation." *Id.* at 8.[7]

As we showed in our Blue Brief (at 53-54), there is no dispute that the preliminary injunction removes a non-drug pain treatment tool that the FDA has designated as less risky than Nevro's product. Nevro does not dispute that the FDA has classified Stimwave's ("Class II") device as less risky than Nevro's ("Class III"), *see* Blue Br. at 54; that the FDA has approved Stimwave's device but not Nevro's for patients who need 3T MRI treatment, *id.* at 53; or that Stimwave's device is 5% the size of Nevro's and does not have an implanted battery, making it an option for patients who cannot tolerate Nevro's device. *Id.* at 53-54. Nevro tries to downplay these differences but ultimately cannot dispute that the injunction takes away the best medical option for a segment of patients.

[7] Nevro ignores the amicus brief except to misleadingly state (at 61 n.3) that "Amici never address . . . whether any patient needs Stimwave's system operated at high frequency rather than low frequency." That is incorrect. Amici (at 7-8) specifically addressed this issue; "disagree[d]" with it; and explained that a "high-frequency range may be twice as effective as traditional low frequency treatment."

Nevro's responses fail. ***First***, Nevro (at 60-61) repeats the district court's finding that "Stimwave's low frequency therapy will still remain an option." Appx44-45, and that "Stimwave's clinical data from its SURF trial shows that its high frequency therapy is merely 'noninferior' to its low-frequency therapy." This conflates statistical significance with individual outcomes. *See* Section A, above. For example, 84% of patients treated with Stimave's high-frequency treatment obtained pain "remissions"—meaning their pain was nearly eliminated—as compared to 47% those treated with Stimwave's devices at low-frequencies. *See* Blue Br. 13-14. For these individuals, Stimwave's high-frequency therapy could be more effective than Stimwave's low-frequency therapy.[8]

Second, Nevro (at 61-63) repeats the district court's finding at Appx45 that "for those patients that desire high frequency, paresthesia-free therapy, they will have access to Nevro's products." But in so finding, the district court ignored objective FDA findings that the devices are different both in risk profile and approved usage. Nevro's primary response to this error (at 61-62) is to cite testimony where individual witnesses stated they were ***not aware*** if the Nevro device could be used in place of Stimwave's device. The differing FDA approvals, including the FDA's

[8] Nevro's argument (at 61) that Stimwave's argument is waived fails for the reasons we have discussed in the irreparable-harm section of this brief.

classification of Nevro's device to be a larger risk as a "Class III" device instead of Stimwave's "Class II" devices demonstrate such instances.[9]

The remainder of Nevro's reply cherry-picks evidence that the district court did not cite or rely upon, and of which Nevro admits (at 62) "all of it was disputed." The district court's injunction takes Stimwave's high-frequency SCS products out of the hands of doctors and their patients and (in the words of *amici*) "will result in suboptimal care in a significant cohort of patients with chronic pain. As a result, the injunction entered by the district court is not in the public interest." *Amici* Brief, D.I. 44 at 8.

E. THE INJUNCTION IMPROPERLY PREVENTS A WIDE RANGE OF NON-INFRINGING ACTIVITY

The injunction is overbroad. ***First***, as we showed (Blue Br. 65), the injunction effectively prevents Stimwave from engaging in a wide range of noninfringing activities—in particular, high-frequency therapies that do result in paresthesia. The

[9] Nevro's claim (at 62) that "Dr. Caraway did 'affirmatively testify' that Nevro's system was suitable for the same patients as Stimwave's" is incorrect. The testimony Nevro cites (at Appx5648-5649) was not comparing Nevro to Stimwave. Moreover, Nevro omits testimony from Dr. Caraway where he admitted that doctors reported concerns with the size of the Nevro devices and its implantable battery. *See, e.g.*, Appx5652-5653 at 151:15-152:12. The FDA's differing approvals are clear objective evidence that the devices are different, and that Stimwave can be implanted in patients in situations where Nevro's devices cannot. It was error for the district court to ignore this evidence.

district court agreed that "it is ***impossible*** to know whether paresthesia will be induced until after the signal is applied," Appx27, which means that Stimwave cannot offer any high-frequency SCS therapy because it will not know if it violated the injunction by having done so. Stimwave does not learn if it has violated the injunction when providing its high-frequency SCS therapy until a patient tells Stimwave after-the-fact. Appx26-27.

Nevro's argument (at 65-66) that this overbreadth concern is a "rehash" of the indefiniteness issue is wrong. Nevro argued against indefiniteness (at 49-50) by citing *Star Scientific* for the proposition that an artisan's inability to determine if a process infringed before practicing it "was 'really talking about the ***difficulty of avoiding infringement***, not indefiniteness.'" (Red Br. 49-50.) If so, then it is directly relevant to the overbreadth of the injunction, because it effectively extends the injunction beyond the scope of the claims, and into territory (paresthesia-producing high-frequency therapy) that Nevro distinguishes for validity.[10]

[10] Nevro's one-sentence secondary argument (at 65) relies on incomplete quoting: its partial quotation of Stimwave's FDA labelling (which actually states that, for certain frequency ranges, "***amplitudes*** that produce paresthesia have not been evaluated," Appx4134) is irrelevant to whether Stimwave should have been *de facto* barred by the district court from using a ***frequency*** above 3 kHz and less than 10kHz because of the risk that doing so would violate the terms of the overbroad injunction without Stimwave knowing in advance it was doing so.

Second, there was no evidence or finding that signals at frequencies less than 10kHz would practice the "non-paresthesia-producing … signal limitation." (Blue Br. 56-57) The breadth of the injunction sweeps in frequencies from 3-10 kHz. With zero evidence of infringement below 10kHz, the injunction again effectively excludes ***all*** signals in the 3-10 kHz range—whether paresthesia-free or not—because Stimwave again cannot tell in advance if any frequency at 3-10 kHz will be a "non-parasthesia-producing … signal" or not.

Nevro's responses (at 65-66) fail. Nevro (at 65) concedes that its "evidence merely [addressed] 10 kHz." Nevro attempts to justify this by arguing that Stimwave's devices only use 10kHz, but that is not true. Stimwave's "settings are ***three***, ***seven***, and ten" kHz. Appx7522-7523 at 246:16-247:16. Patients can use all of these settings, and there is no basis to enjoin them from doing so on the present record.

Nevro's other response (at 65-66)—that "producing paraesthesia-free therapy signals at other claimed frequencies 'would be the same as' doing so at 10kHz" and that the district court found the same—is incorrect. Nevro's record cite (Appx7416), supports only that the technician's ***programming process*** at 3 or 7 kHz "would be the same as" at 10kHz, and is not evidence that the ***result*** will or will not be a "paresthesia-producing" signal. The latter is the issue here. The district court made no

such finding at these lower frequencies, nor was there evidence to do so. Blue Br. 56-57. The injunction is overbroad and should be vacated.

CONCLUSION

This Court should vacate the preliminary injunction for the reasons given in Stimwave's opening brief and above.

Dated: December 26, 2019 Respectfully submitted,

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CERTIFICATE OF SERVICE AND FILING

I hereby certify that I electronically filed the foregoing document using the Court's CM / ECF filing system on December 26, 2019. I hereby certify that all counsel of record were served via the Court's CM / ECF filing system on December 26, 2019.

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CERTIFICATE OF COMPLIANCE

The undersigned attorney certifies that the foregoing document complies with the type-volume limitation set forth in Fed. R. App. P. 27. The relevant portions of the brief, including all footnotes, contain 6,930 words, as determined by Microsoft Word.

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