No. 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 No. 1:19-cv-00325-CFC, Judge Colm F. Connolly.

AMICI CURIAE BRIEF OF MEDICAL DOCTORS IN SUPPORT OF APPELLANT STIMWAVE TECHNOLOGIES, INC.

Robert P. Parker
Seth E. Cockrum
ROTHWELL, FIGG, ERNST & MANBECK, P.C.
607 14th St., N.W., Suite 800
Washington, DC 20005
Telephone: 202-783-6040

Attorneys for Amici Curiae Medical Doctors

October 1, 2019

FORM 9. Certificate of Interest **Form 9**
Rev. 10/17

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

NEVRO CORP. **v.** STIMWAVE TECHNOLOGIES, INC.

Case No. 2019-2205

CERTIFICATE OF INTEREST

Counsel for the:
☐ (petitioner) ☐ (appellant) ☐ (respondent) ☐ (appellee) ■ (amicus) ☐ (name of party)

Medical Doctors

certifies the following (use "None" if applicable; use extra sheets if necessary):

1. Full Name of Party Represented by me	2. Name of Real Party in interest (Please only include any real party in interest NOT identified in Question 3) represented by me is:	3. Parent corporations and publicly held companies that own 10% or more of stock in the party
Anne Christopher, M.D.	Anne Christopher, M.D.	None
Iden Cowan, M.D.	Iden Cowan, M.D.	None
Harsh Dangaria, M.D.	Harsh Dangaria, M.D.	None
Miles Day, M.D.	Miles Day, M.D.	None
Standiford Helm II, M.D.	Standiford Helm II, M.D.	None
David Kloth, M.D.	David Kloth, M.D.	None
Jessica Jameson, M.D.	Jessica Jameson, M.D.	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 **(and who have not or will not enter an appearance in this case)** are:

Rothwell, Figg, Ernst & Manbeck, P.C. - Robert P. Parker and Seth E. Cockrum

FORM 9. Certificate of Interest **Form 9**
Rev. 10/17

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). (The parties should attach continuation pages as necessary).

Nevro Corp. v. Stimwave Technologies, Inc., Case No. 1:19-cv-00325-CFC (D. Del.)

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

10/1/2019
Date

/s/ Robert P. Parker
Signature of counsel

Please Note: All questions must be answered

Robert P. Parker
Printed name of counsel

cc: All Counsel of Record

Reset Fields

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

NEVRO CORP. v. STIMWAVE TECHNOLOGIES, INC.

Case No. 2019-2205

CERTIFICATE OF INTEREST OF AMICI CURIAE MEDICAL DOCTORS – QUESTIONS 1-3 CONT'D

1. Full Name of Party Represented by me	2. Name of Real Party in interest (Please only include any real party in interest NOT identified in Question 3) represented by me is:	3. Parent corporations and publicly held companies that own 10% or more of stock in the party
Albert Lai, M.D.	Albert Lai, M.D.	None
Suzanne Manzi, M.D.	Suzanne Manzi, M.D.	None
Ravi Panjabi, M.D.	Ravi Panjabi, M.D.	None
Ryan Pollina, M.D.	Ryan Pollina, M.D.	None
Akhtar Purvez, M.D.	Akhtar Purvez, M.D.	None
Abraham Rivera, M.D.	Abraham Rivera, M.D.	None
Louis Saeger, M.D.	Louis Saeger, M.D.	None
Chad Stephens, D.O.	Chad Stephens, D.O.	None
Baominh Vinh, M.D.	Baominh Vinh, M.D.	None

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

INTEREST OF *AMICI CURIAE*

Amici are doctors practicing in the United States in the field of chronic pain management. The *amici* have used the products of the patent owner, Nevro, and the accused infringer, Stimwave, in their treatment of patients suffering from chronic pain. A list of the *amici* is set forth in Appendix A.

Amici submit this brief because they believe it is important that patients suffering from chronic pain have unencumbered access to the best possible treatment tailored to their individual needs and preferences. Three of the sixteen *amicus* physicians have invested in Stimwave. No other *amicus* physician has a personal or financial interest in either party.[1]

Stimwave consented to the filing of this brief. Nevro did not consent. A motion for leave to file accompanies this brief.

SUMMARY OF ARGUMENT

The public interest is an important factor to consider in deciding whether to grant a preliminary injunction. This is particularly true when the needs of patients would be put at risk by blocking access to unique medical technology, such as that provided by Stimwave.

[1] No party's counsel authored this brief in part or in whole, and, except as disclosed in the text, no party or individual with an interest in a party contributed money intended to fund the preparation and submission of this brief.

The Stimwave and Nevro devices are not interchangeable. Some patients suffering from chronic pain are simply unable to benefit from the Nevro device, or are unwilling to undergo the surgical procedures necessary to use it. Physicians should be able to offer those patients an alternative, effective therapy, but the preliminary injunction prevents them from doing so. Consequently, the preliminary injunction leads to suboptimal care in those patients that are not candidates for the Nevro device.

If the Stimwave device is ultimately found to infringe the Nevro patents, patent law provides a mechanism to compensate Nevro. There is no need for an injunction that would interfere with medical decisions and patient care.

For these reasons, it is not in the public's interest to deny physicians and patients access to the Stimwave device for whatever use they may determine is appropriate for a particular patient. Instead, the choice should be left to the treating doctor and patient to select the pain management therapy best suited to the patient's individual needs. The courts should not make that choice for them.

ARGUMENT

I. PUBLIC INTEREST IN ACCESS TO HEALTHCARE IS A STRONG REASON TO DENY A PRELIMINARY INJUNCTION

The public interest is one of the four factors a court must consider in deciding whether to grant injunctive relief to a patentee. *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006). "[T]he standards of the public

interest not the requirements of private litigation measure the propriety and need for injunctive relief in these cases." *Hecht Co. v. Bowles*, 321 U.S. 321, 331 (1944). While the public interest will often favor the enforcement of patents, an exception exists when public health and safety is at risk. This Court has previously upheld the denial of injunctive relief where the effect of an injunction would be to deny the public access to needed therapy. *See, e.g., Hybritech Inc. v. Abbott Labs.,* 849 F.2d 1446 (Fed. Cir. 1998) (affirming denial of preliminary injunction of sales of cancer test kits and HIV test kits for public health reasons).

II. THE INJUNCTION ISSUED BY THE DISTRICT COURT PLACES PATIENT HEALTH AT RISK BY LIMITING PHYSICIAN'S OPTIONS

A. The Stimwave and Nevro Devices Are Different, Non-Interchangeable Products

The Stimwave and Nevro devices are both utilized for spinal cord stimulation ("SCS"), which is a method of treating chronic pain by delivering short electrical pulses to the spinal cord through electrical leads implanted in the body. Appx2. But that is where the similarity between the two devices ends. The Nevro device requires surgical implantation of a significant amount of hardware, including a pulse generator and battery. The Stimwave device does not. Thus, as the district court found, the Stimwave and Nevro devices are different. Appx6.

Critically, the differences between the products are not trivial design choices; they have a real impact on a physician's ability to treat a patient for

chronic pain appropriately, and for the patient to benefit from that treatment. The failure to provide the treatment of chronic pain that is best suited to the patient's needs can be debilitating and seriously impact the quality of his or her life.

First, the Nevro product – like products from other major market players, including Abbott, Boston Scientific, and Medtronic – requires an implantable pulse generator ("IPG") that includes a battery powering the system. Appx4813-4814.[2] Implantation of the Nevro product necessarily requires an invasive surgical procedure.[3] Many patients are unwilling or unable to undergo this surgical procedure. For example, patients with a low body mass index may not have room in their body cavity for the Nevro device. Appx4814. In addition, the surgical risk for patients on certain medications, such as blood thinners or chemotherapeutic agents, may be too great for the Nevro device to be safely implanted. *Id.* Other patients may have conditions, such as a compromised immune system or diabetes, that preclude them from using the Nevro device (or any other implantable device) because of the surgery requirement. For those patients, the Stimwave product is the only SCS device that offers hope of relief from their chronic pain.

---

[2] Amici have reviewed the cited portions of the Perryman declaration, and agree those portions are an accurate representation of their own knowledge, opinions, and experience in treating patients with the Nevro and Stimwave devices.

[3] Although the Stimwave system also requires implantation, the total implant volume for Stimwave is less than 5% of the volume required for the Nevro system. Appx4812. Thus, patients that are not candidates for the Nevro product may be candidates for the Stimwave product.

Second, even those patients that are medically able to receive an implanted Nevro device may not wish to have it implanted because of potential complications. A significant number of patients that have received an IPG complain of implantation site pain. Appx4822-4823. Other patients have or can develop an allergy to the metals and other materials in the implant, resulting in serious complications. There is also the ever-present risk of post-surgical infection, a risk that is elevated by the volume of the Nevro device relative to the Stimwave system. Many patients (and physicians) do not consider these risks trivial, and forego the implantation of large devices like the Nevro system, despite the potential for life-changing treatment for their chronic pain.[4]

Third, once the IPG has been implanted in those patients willing to accept the risks, there are still restrictions and complications that are unacceptable for some patients. Many patients suffering from chronic pain also suffer from other conditions, such as cancer or anatomical anomalies, that require frequent medical procedures. Appx4814, Appx4830-4832. Many of these procedures, such as MRI scans, ultrasounds, and radiotherapy, cannot be performed on patients with IPGs.

[4] Patients also often find IPGs inconvenient because the battery powering the IPG must be recharged up to several times a week with an external device. Appx4818-4819. During the recharging process, patients are quite literally tethered to the external device and are unable to move freely. Not only do some patients find this frustrating, but it can make the Nevro device inappropriate for patients that have certain lifestyes, careers, or obligations (*e.g.,* single or stay-at-home parents).

For those patients, the Stimwave device is the only one capable of alleviating their chronic pain without compromising treatment options for other, often life-threatening conditions.

Members of the patient groups discussed above, although not candidates to receive the Nevro device, could be candidates for the Stimwave device. Given its much smaller implantation volume and its wireless system, patients who might not tolerate or choose the Nevro device would benefit from the Stimwave device. Each of the *amici* physicians has had patients who fall into this category.

In sum, the two devices are not interchangeable, and Nevro is not superior to Stimwave – it is different. Contrary to the district court's conclusion, physicians ***do*** see and treat patients that cannot be treated with Nevro's device, but can be treated with Stimwave's. Appx45. A district court should not stand in the way of these patients receiving the medical treatment they require.

B. Doctors Should Have the Power to Choose the Best Medical Care for Their Patients

The choice of treatment should rest with the treating physician based on his or her medical knowledge and experience. In particular, the choice of treatment for chronic pain should be a determination made on a case-by-case evaluation of the individual patient's medical and personal needs. The court agreed with Stimwave that "it is generally in the public's interest to allow physicians to have as wide a variety of treatment options as is possible." Appx44. Yet, by granting the

preliminary injunction, the district court has taken away one of those treatment options. This Court has previously rejected injunctive relief under similar circumstances. *Datascope Corp. v. Kontron Inc.*, 786 F.2d 398, 401 (Fed. Cir. 1986) (affirming denial of preliminary injunction and recognizing "the public will be harmed by an injunction in that some physicians prefer defendant's [device]" over the patentee's device.). The Court should reverse the district court's preliminary injunction and permit doctors to choose the best pain management device for each patient's needs.

C. The Limited Injunction Is Still Too Restrictive

The injunction entered by the district court prohibits Stimwave from marketing and programming its device with the high-frequency range encompassed by the Nevro patents. The district court reasoned that the injunction "would not entirely prohibit Stimwave from selling its [device]; and thus, for the small number of chronic pain patients who cannot, or will not, be treated with IPG-based systems, Stimwave's low frequency therapy will still remain an option." Appx44-45. *Amici* disagree. Even this limited injunction is too restrictive and imposes a significant burden on too many doctors and patients.

First, the number of patients who cannot or will not be treated with IPG-based systems is not "small." Indeed, the number of such patients is significant

enough that Stimwave based its entire business model on serving the needs of those patients.

Second, as the district court noted, the Nevro technology is based on the idea that a high-frequency range may be twice as effective as traditional low frequency treatment. Appx5. Patients who are not candidates for the Nevro device should not be forced to choose between a less effective option for their chronic pain and a potentially dangerous otherwise contra-indicated IPG implantation. The preliminary injunction would force those patients into making that choice.

The limited injunction 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.

III. DENYING A PRELIMINARY INJUNCTION WOULD NOT DENY NEVRO A REMEDY

Innovative medical technology is critically important to patient treatment and care. *Amici* understand and appreciate that patent protection helps drive that innovation. For this reason, if the Stimwave device is ultimately found to infringe a valid Nevro patent, Stimwave should be required to provide compensation or other redress to Nevro. Indeed, United States patent law provides for an appropriate remedy. 35 U.S.C. § 284 ("Upon finding for the claimant the court shall award the claimant damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the

infringer...”). There is no need to provide an additional remedy to Nevro that prohibits patient access to Stimwave’s technology.

If the Nevro and Stimwave devices were identical, then a preliminary injunction might have been appropriate. *Pfizer, Inc. v. Teva Pharms., USA, Inc.*, 429 F.3d 1364, 1382 (Fed. Cir. 2005) (finding an injunction may be warranted where defendant’s device is identical to plaintiff’s). But, as explained above, the Stimwave and Nevro devices are different, and are suitable for different patient populations. This Court has previously confirmed that, when a defendant sells a device that is different from plaintiff’s and evidence shows that some doctors and patients prefer defendant’s device, a preliminary injunction is not warranted. *Cordis Corp. v. Boston Sci. Corp.*, 99 Fed. App’x 928, 935 (Fed. Cir. 2004) (unpub.) (affirming district court’s denial of preliminary injunction); *Datascope Corp.*, 786 F.2d at 401 (affirming district court’s denial of preliminary injunction because evidence showed that some doctors preferred defendant’s device over plaintiff’s). For this reason, the preliminary injunction should be vacated. Doctors and patients, not district court judges, should make the determination as to which device is appropriate for the treatment of chronic pain.

CONCLUSION

For the reasons set forth above, the public interest factor favors reversing the district court’s grant of a preliminary injunction against the Stimwave device.

Dated: October 1, 2019

Respectfully submitted,

/s/ Robert P. Parker

Robert P. Parker
Seth E. Cockrum
ROTHWELL, FIGG, ERNST & MANBECK, P.C.
607 14th St., N.W., Suite 800
Washington, DC 20005
Telephone: 202-783-6040
E-mails: rparker@rfem.com
scockrum@rfem.com

Attorneys for Amici Curiae Medical Doctors

FORM 30. Certificate of Service

Form 30
Rev. 03/16

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

CERTIFICATE OF SERVICE

I certify that I served a copy on counsel of record on October 1, 2019 by:

- ☐ U.S. Mail
- ☐ Fax
- ☐ Hand
- ☒ Electronic Means (by E-mail or CM/ECF)

Robert P. Parker	/s/ Robert P. Parker
Name of Counsel	Signature of Counsel

Law Firm	Rothwell, Figg, Ernst & Manbeck, P.C.
Address	607 14th Street, N.W., Suite 800
City, State, Zip	Washington, DC 20005
Telephone Number	202-783-6040
Fax Number	202-783-6031
E-Mail Address	rparker@rfem.com

NOTE: For attorneys filing documents electronically, the name of the filer under whose log-in and password a document is submitted must be preceded by an "/s/" and typed in the space where the signature would otherwise appear. Graphic and other electronic signatures are discouraged.

Reset Fields

CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 29(a)(5) and Federal Circuit Rule 32(a) because this brief contains 2,129 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f) and Federal Circuit Rule 32(b).

2. This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6) because this brief has been prepared in proportionally spaced typeface using Microsoft Word in 14-point Times New Roman font.

Dated: October 1, 2019

/s/ Robert P. Parker
Robert P. Parker
ROTHWELL, FIGG, ERNST & MANBECK, P.C.

Attorney for Amici Curiae
Medical Doctors

APPENDIX A: LIST OF AMICI CURIAE

Anne Christopher, M.D.
St. Louis Pain Consultants
Chesterfield, MO

Iden Cowan, M.D.
Interventional Spine
Pain Treatment Centers of America
North Little Rock, AR

Harsh Dangaria, M.D.
Pain Relief Group
Physician Partners of America
Orange Park, FL

Miles Day, M.D.
Interventional Pain Management
Grace Heath System Pain Management Center
Lubbock, TX

Standiford Helm II, M.D.
The Helm Center for Pain Management
Laguna Woods, CA

David Kloth, M.D.
Connecticut Pain Care
Danbury, CT

Jessica Jameson, M.D.
Axis Spine Center
Post Falls, ID

Albert Lai, M.D.
Centers of Rehabilitation and Pain Medicine
Orange, CA

Suzanne Manzi, M.D.
Performance Pain and Sports Medicine
Houston, TX

Ravi Panjabi, M.D.
Advanced Pain Management and Rehab Medical Group, Inc.
Castro Valley, VA

Ryan Pollina, M.D.
Blue Water Pain Specialists
Medical Director SJHMC Pain Medicine
St. Claire Shores, MI

Akhtar Purvez, M.D.
Pain & Spine Center of Charlottesville
Charlottesville, VA

Abraham Rivera, M.D.
Chief Medical Officer
Physicians Partners of America
Tampa, FL

Louis Saeger, M.D.
North American Spine
Minneapolis, MN

Chad Stephens, D.O.
Nobel Pain Management & Sports Medicine
Southlake, TX

Baominh Vinh, M.D.
Pain Management
Cy-Pain & Spine PLLC
Houston, TX