

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

Boston Scientific Corp. and
Boston Scientific Neuromodulation Corp.,

Plaintiffs,

v.

Nevro Corp.,

Defendant.

C.A. No. 16-1163-GMS

JURY TRIAL DEMANDED

FIRST AMENDED COMPLAINT

Plaintiffs Boston Scientific Corp. (“BSC”) and Boston Scientific Neuromodulation Corp. (“BSNC”) (collectively, “Boston Scientific”), by their attorneys, hereby complain against Defendant Nevro Corp. (“Nevro”) and allege as follows:

OVERVIEW OF THE ACTION

1. This is a patent infringement action arising from Nevro’s infringement of Boston Scientific’s U.S. Patent No. 6,895,280 (the “‘280 patent”), U.S. Patent No. 7,428,438 (the “‘438 patent”), U.S. Patent No. 7,437,193 (the “‘193 patent”), U.S. Patent No. 7,587,241 (the “‘241 patent”), U.S. Patent No. 7,891,085 (the “‘085 patent”), U.S. Patent No. 8,019,439 (the “‘439 patent”), U.S. Patent No. 8,644,933 (the “‘933 patent”), U.S. Patent No. 8,646,172 (the “‘172 patent”), U.S. Patent No. 8,650,747 (the “‘747 patent”), and U.S. Patent No. 9,370,664 (the “‘664 patent”) (collectively, the “Asserted Patents”) via the manufacture, use, sale, offer to sell, exportation, and/or importation, in whole or in part, of Nevro’s Senza® Spinal Cord Stimulation System (the “Senza System”).

THE PARTIES

2. Plaintiff BSC is a corporation organized and existing under the laws of the State of Delaware and having a principal place of business at 300 Boston Scientific Way, Marlborough, Massachusetts 01752.

3. Plaintiff BSNC is a corporation organized and existing under the laws of the State of Delaware and having a principal place of business at 25155 Rye Canyon Loop, Valencia, California 91355. BSNC is a wholly-owned subsidiary of BSC.

4. Upon information and belief, Defendant Nevro is a corporation organized and existing under the laws of the State of Delaware and having a principal place of business at 1800 Bridge Pkwy, Redwood City, California, 94065.

JURISDICTION AND VENUE

5. This action arises under the Patent Laws of the United States, Title 35 of the United States Code.

6. This Court has subject matter jurisdiction over the causes of action asserted herein pursuant to 28 U.S.C. §§ 1331, 1338(a), and 2201 *et seq.*

7. This Court has personal jurisdiction over Nevro. Upon information and belief, Nevro is a resident of this judicial district, has systematic and continuous contacts in this judicial district, regularly transacts business within this district, and regularly avails itself of the benefits of this district. Upon information and belief, Nevro also sells and distributes the Senza System in this district. Upon information and belief, Nevro derives substantial revenues from sales in this district.

8. Venue is proper in this District under 28 U.S.C. §§ 1391(a), 1391(c), and 1400(b).

BOSTON SCIENTIFIC'S BACKGROUND

9. Boston Scientific is a leading medical device manufacturer across a range of medical specialties, including interventional cardiology, radiology, peripheral interventions, neuromodulation, neurovascular intervention, electrophysiology, cardiac surgery, vascular surgery, endoscopy, oncology, urology, and gynecology. Boston Scientific is a pioneer and innovator in the Spinal Cord Stimulation (“SCS”) industry, and has been developing and selling SCS systems for the treatment of chronic pain for over a decade.

10. Boston Scientific entered the SCS system market in 2004 when it launched its Precision™ SCS System, the first rechargeable SCS platform with unique current steering technology, wireless remote, and wireless charger. In 2007, Boston Scientific launched its improved Precision™ Plus SCS System, the first with EGL™ Scan technology, which displayed the relative position of the implanted leads to increase programming accuracy. In 2013, Boston Scientific launched the Precision™ Spectra™ SCS System, the world’s first and only SCS platform with 32 contacts, to offer unprecedented coverage and a new level of flexibility intended to provide therapy to a broader spectrum of patients. The Precision™ Spectra™ SCS System included Illumina™ 3D Programming Technology, which provided advanced controls including the ability to account for the environment of the lead placed in the epidural space of the spine, with the design objective to optimize stimulation and pain relief. Boston Scientific next introduced the Precision™ Montage™ and Precision™ Montage™ MRI SCS System—which allows patients to undergo a full-body MRI—in 2016. Each of these systems and their technological advances provided drastic improvements in the care and treatment of patients with chronic pain.

11. Boston Scientific’s position as a leader and innovator in the SCS industry has resulted in the development and patenting of core technologies that are essential to SCS systems,

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including battery charging, battery monitoring, zero volt recovery (“ZVR”) circuits, determining and transmitting indications of errors, telemetry systems, and percutaneous leads. These technologies form the foundation of every SCS system on the market, including Nevro’s Senza System.

NEVRO’S INFRINGING SENZA SYSTEM

12. Nevro’s Senza System is a neuromodulation device designed to deliver electrical stimulation to spinal cord nerves for the treatment of chronic intractable pain. The Senza System delivers stimulation using percutaneous leads and a rechargeable, implantable pulse generator (“IPG”). The percutaneous leads are implanted within the spinal column, and deliver stimulation to nerves through electrodes located on the distal portion of the percutaneous leads. The IPG is implanted in a subcutaneous pocket and is designed to produce current-regulated, charge-balanced, biphasic, capacitively-coupled, rectangular output pulses. The IPG is transcutaneously recharged using an external charger and is controlled by a patient remote control and/or clinician programmer. Other components of the Senza System include an external trial stimulator, lead extensions, adaptors, operating room (“OR”) cables, and surgical accessories.

13. The Senza System received CE Mark approval in Europe in 2010 and TGA approval in Australia in 2011. In that same year, Nevro launched the Senza System in Europe and Australia. In 2015, the Senza System received FDA approval and Nevro launched the product in the United States shortly thereafter. Currently, Nevro is on the market in Europe, Australia, and the United States.¹

14. Upon information and belief, C.C.C. Del Uruguay S.A. (“CCC”), a subsidiary of Greatbatch Ltd., is Nevro’s single-source manufacturer of its IPG. Upon information and belief,

¹ Source: <http://www.nevro.com/English/About-Us/Who-We-Are/default.aspx>.

CCC also manufactures Nevro's external chargers, external trial stimulators, and programmer wands.² Upon information and belief, CCC's manufacturing facility is located in Montevideo, Uruguay.

15. Upon information and belief, Stellar Technologies, Inc. ("Stellar," currently organized under the name Cirtec Medical LLC) is Nevro's single-source supplier of its percutaneous leads.³ Stellar previously manufactured Boston Scientific's percutaneous leads. Upon information and belief, Stellar manufactures Nevro's leads with the same tool that it previously used to manufacture Boston Scientific's leads. Upon information and belief, Stellar's manufacturing facility is located in Brooklyn Park, Minnesota.

16. Upon information and belief, EaglePicher Medical Power LLC ("EaglePicher") is Nevro's single-source supplier of its IPG's battery and related products.⁴ Upon information and belief, EaglePicher is headquartered in Joplin, Missouri.

17. Upon information and belief, Pro-Tech Design and Manufacturing, Inc. ("Pro-Tech") is Nevro's single-source supplier for conducting the inspection, labeling, packaging and sterilization of its Senza System.⁵ Upon information and belief, Pro-Tech has two manufacturing facilities: one in Arlington, Texas and one in Santa Fe Springs, California.⁶ Upon

² Source: <https://www.sec.gov/Archives/edgar/data/1444380/000119312516485541/d102615d10k.htm>.

³ Source: <https://www.sec.gov/Archives/edgar/data/1444380/000119312516485541/d102615d10k.htm>.

⁴ Source: <https://www.sec.gov/Archives/edgar/data/1444380/000119312516485541/d102615d10k.htm>.

⁵ Source: <https://www.sec.gov/Archives/edgar/data/1444380/000119312516485541/d102615d10k.htm>.

⁶ Source: <http://www.protechdesign.com/SitePages/Protech.aspx>.

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