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

## BOSTON SCIENTIFIC CORP. AND BOSTON SCIENTIFIC NEUROMODULATION CORP.,

Plaintiffs,

v.

NEVRO CORP.,

Defendant.

Civil Action No.

# JURY TRIAL DEMANDED

## **COMPLAINT**

Plaintiffs Boston Scientific Corp. ("BSC") and Boston Scientific Neuromodulation Corp. ("BSN") (collectively, "Boston Scientific"), by their attorneys, hereby complain against Defendant Nevro Corp. ("Nevro"), and allege as follows.

## **OVERVIEW OF THE ACTION**

1. This is an action for patent infringement, theft of trade secrets, and tortious interference with contract. In this Complaint, Boston Scientific alleges that: one or more of the dozens of former Boston Scientific employees that Nevro has recruited and hired disclosed trade secrets relating to Boston Scientific's spinal cord stimulation ("SCS") systems to Nevro, in violation of those employees' contractual obligations; those trade secrets were the product of substantial investments and treated confidentially by Boston Scientific and were of considerable value to Nevro in its effort to develop an SCS product that competed directly with Boston Scientific's SCS products; and Nevro was aware of and benefited from those disclosures. Boston Scientific further alleges that Nevro's SCS products willfully infringe Boston Scientific's patents directed to critical features of SCS systems, including features for

programming the implanted device and communicating with and recharging and monitoring the status of the battery within the implantable component of SCS systems.

2. The patent infringement claims arise from Nevro's infringement of U.S. Patent No. 8,781,596 (the "'596 patent"); U.S. Patent No. 7,177,690 (the "'690 patent"); U.S. Patent No. 6,609,032 (the "'032 patent); and U.S. Patent No. 8,918,174 (the "'174 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 I System") and the Senza II® Spinal Cord Stimulation System (the "Senza II System") (collectively, the "Senza Systems").

The trade secret claims arise from Nevro's acquisition and use of confidential
Boston Scientific documents acquired from one or more former employees of Boston Scientific.

## THE PARTIES

 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.

5. Plaintiff BSN 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. BSN is a wholly-owned subsidiary of BSC.

6. 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

The patent claims of this action arise under the Patent Laws of the United States,
Title 35 of the United States Code.

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

9. This Court has supplemental jurisdiction of the state claims asserted in this action pursuant to 28 U.S.C. § 1367. The federal claims alleged by BSC and the state claims alleged by BSC are based on a common nucleus of operative facts. Judicial economy, convenience, and fairness to the parties will result if this Court assumes and exercises jurisdiction over the state claims.

10. 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 Systems in this district. Upon information and belief, Nevro derives substantial revenues from sales in this district.

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

## **BOSTON SCIENTIFIC'S BACKGROUND**

12. 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.

13. Boston Scientific entered the SCS system market in 2004 when it launched its Precision<sup>™</sup> SCS System, the first rechargeable SCS platform with unique current steering technology, wireless remote, and a wireless charger. In 2007, Boston Scientific launched its

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improved Precision<sup>TM</sup> Plus SCS System, the first with EGL<sup>TM</sup> Scan technology, which displayed the relative position of the implanted leads to increase programming accuracy. In 2013, Boston Scientific launched the Precision<sup>TM</sup> Spectra<sup>TM</sup> 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<sup>TM</sup> Spectra<sup>TM</sup> SCS System included Illumina<sup>TM</sup> 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<sup>TM</sup> Montage<sup>TM</sup> and Precision<sup>TM</sup> Montage<sup>TM</sup> MRI SCS Systems—which allow patients to undergo a full-body MRI—in 2016. Each of these systems and their technological advances provided dramatic improvements in the care and treatment of patients with chronic pain.

14. 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, including battery charging, battery monitoring, device programming, 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 Systems.

#### THE INFRINGING NEVRO SYSTEMS

15. Nevro's Senza I System is a neuromodulation device designed to deliver electrical stimulation to spinal cord nerves for the treatment of chronic intractable pain. The Senza I System delivers stimulation using percutaneous leads and a rechargeable, implantable pulse generator ("IPG"). The percutaneous leads are implanted within the spinal column, and deliver

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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 I System include an external trial stimulator, lead extensions, adaptors, operating room ("OR") cables, and surgical accessories.

16. The Senza I System received CE Mark approval in Europe in 2010 and TGA approval in Australia in 2011. That same year, Nevro launched the Senza I System in Europe and Australia. In 2015, the Senza I System received FDA approval, and Nevro launched the product in the United States shortly thereafter. Currently, the Senza I System is sold in Europe, Australia, and the United States.<sup>1</sup>

17. The Senza II System, like the Senza I system, is a neuromodulation device designed to deliver electrical stimulation to spinal cord nerves for the treatment of chronic intractable pain and delivers stimulation using percutaneous leads and a rechargeable IPG. On information and belief, other than the IPG, the Senza II System is identical to the Senza I System. On information and belief, the Senza II System's IPG provides the same functionality as the Senza I System's IPG.<sup>2</sup> The Senza II System received CE Mark approval in Europe in 2017 and FDA approval in the United States in 2018. The Senza II System uses the same programmer wand as the Senza I IPG. On information and belief, the Senza II System also uses

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

<sup>&</sup>lt;sup>2</sup> Source: https://www.prnewswire.com/news-releases/nevro-receives-fda-approval-for-senza-ii-spinal-cord-stimulation-system-delivering-hf10-therapy-300578766.html; https://www.fiercebiotech.com/medtech/under-payer-pressure-nevro-notches-ce-mark-high-point-for-scs-therapy.

the same charger and patient remote control as the Senza I System, as Nevro has not received equipment authorization from the Federal Communications Commission for remote controls or chargers other than those already used by the Senza I System.

18. Upon information and belief, C.C.C. Del Uruguay S.A. ("CCC"), a subsidiary of Greatbatch Ltd., is one of Nevro's manufacturers of its IPGs. Upon information and belief, CCC also manufactures Nevro's external chargers, external trial stimulators, and programmer wands.<sup>3</sup> Upon information and belief, CCC's manufacturing facility is located in Montevideo, Uruguay.

Upon information and belief, Vention Medical Design and Development, Inc.
("Vention"), is one of Nevro's manufacturers of its IPGs. Upon information and belief,
Vention's manufacturing facility is located in the United States.

20. 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.<sup>4</sup> 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 Boston Scientific's leads. Stellar's manufacturing facility is located in Brooklyn Park, Minnesota.

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

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

21. Upon information and belief, EaglePicher Medical Power LLC ("EaglePicher") is Nevro's single-source supplier of its IPG's battery and related products.<sup>5</sup> Upon information and belief, EaglePicher is headquartered in Joplin, Missouri.

22. 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 Systems.<sup>6</sup> Upon information and belief, Pro-Tech has two manufacturing facilities: one in Arlington, Texas and one in Santa Fe Springs, California.<sup>7</sup> Upon information and belief, Pro-Tech delivers the Senza Systems to Nevro FCA (Incoterms 2000) Pro-Tech's Santa Fe Springs, California manufacturing facility.<sup>8</sup>

## **NEVRO'S KNOWLEDGE OF THE ASSERTED PATENTS**

23. Upon information and belief, Nevro had actual and constructive knowledge of the Asserted Patents prior to the filing of the original Complaint or willfully blinded itself to the existence of those patents. In any event, Nevro had actual knowledge of the Asserted Patents no later than the filing of the original Complaint.

24. Upon information and belief, Nevro obtained actual and constructive knowledge of the Asserted Patents or willfully blinded itself to the existence of those patents through competitive intelligence of its direct competitor, Boston Scientific. The SCS market primarily consists of only four competitors: Boston Scientific, Nevro, Medtronic, and St. Jude (acquired

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

<sup>&</sup>lt;sup>6</sup> Source: https://www.sec.gov/Archives/edgar/data/1444380/000119312516485541/ d102615d10k.htm.

<sup>&</sup>lt;sup>7</sup> Source: http://www.protechdesign.com/SitePages/Protech.aspx.

<sup>&</sup>lt;sup>8</sup> Source: https://www.sec.gov/Archives/edgar/data/1444380/000104746914008300/ a2221785zex-10\_3.htm.

by Abbott in 2017). Nevro itself routinely identifies Boston Scientific as a direct competitor, and the companies compete for the same business from physicians, hospitals, and other health care providers. For instance, Nevro stated the following in its February 29, 2016 Form 10-K filing:

Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit, or otherwise interfere with our ability to make, use, sell, and/or export our products. For example, our major competitors, Medtronic plc, Boston Scientific Corporation and St. Jude Medical, Inc., each have significant patent portfolios covering systems, sub-systems, methods, and manufacturing processes. These competitors may have one or more patents for which they can threaten and/or initiate patent infringement actions against us and/or any of our third-party suppliers.<sup>9</sup>

Moreover, Nevro participated in an FDA-monitored randomized controlled trial in a head-to-

head comparison against Boston Scientific's Precision<sup>™</sup> SCS System. As evidenced by Nevro's

statement above, it is standard practice in the SCS industry to monitor competitors' patent

portfolios. Upon information and belief, Nevro monitored the patent portfolio of Boston

Scientific, whereby Nevro obtained actual and constructive knowledge of the Asserted Patents.

25. Upon information and belief, Nevro obtained actual and constructive knowledge

of the Asserted Patents or willfully blinded itself to the existence of those patents through a pre-

suit investigation of Boston Scientific. In May 2015, Boston Scientific filed two Petitions for

Inter Partes Review of Nevro's U.S. Patent No. 8,359,102. In November 2016, Nevro filed a

Complaint for Patent Infringement and Declaratory Judgment against certain of Boston

<sup>&</sup>lt;sup>9</sup> Source: https://www.sec.gov/Archives/edgar/data/1444380/000119312516485541/ d102615d10k.htm.

Scientific's SCS Systems in the United States District Court for the Northern District of California (*Nevro Corp. v. Boston Scientific Corp. and Boston Scientific Neuromodulation Corp.*, Case No. 3:16-cv-06830-VC (N.D. Cal.)). It is standard practice to conduct competitive intelligence when sued and to conduct a pre-suit investigation prior to initiating a lawsuit. Upon information and belief, Nevro investigated Boston Scientific's patent portfolio no later than after Boston Scientific filed its Petitions for *Inter Partes* Review and before filing its Complaint in the Northern District of California, whereby Nevro obtained actual and constructive knowledge of the Asserted Patents.

26. Upon information and belief, Nevro obtained actual and constructive knowledge of the Asserted Patents or willfully blinded itself to the existence of those patents through the knowledge of current Nevro employees that previously worked for Boston Scientific, including employees that staffed critical Boston Scientific SCS product development and management positions and who were responsible for its neuromodulation patent portfolio. For example, upon information and belief, Kerry Bradley is currently the Director of Clinical Science & Research at Nevro. Mr. Bradley worked for Boston Scientific (and its predecessors) from 2000 to 2012 as a Principal Biomedical Systems Engineer, Senior Principal Biomedical Systems Engineer, Fellow in Research & Development, and Manager II. During his time at Boston Scientific, Mr. Bradley was an inventor or co-inventor on numerous neuromodulation patents and was a subject matter expert reviewer of neuromodulation patents.

27. Upon information and belief, Jim Thacker is currently the Director of Field Clinical Engineering at Nevro. Mr. Thacker worked for Boston Scientific (and its predecessors) from 2000 to 2006 as Manager of Field Clinical Engineering. During his time at Boston

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Scientific, Mr. Thacker led Boston Scientific's field clinical engineering group, which helped to develop, administer, and analyze clinical studies, de-bugged SCS systems, and worked in conjunction with Boston Scientific's research & development group to develop, test, and commercialize its core SCS technologies. Mr. Thacker was an inventor or co-inventor on numerous neuromodulation patents. Mr. Thacker is a co-inventor of the '690 and '174 patents.

28. Upon information and belief, Dongchul Lee is currently the Director of Theoretical Research at Nevro. Mr. Lee worked for Boston Scientific from 2006 to 2013 as a Senior Biomedical System Engineer and Principal Research Scientist. During his time at Boston Scientific, Mr. Lee developed numerous core SCS technologies, including stimulation algorithms and sub-perception stimulation. Mr. Lee was an inventor or co-inventor on numerous neuromodulation patents.

29. Upon information and belief, Messrs. Bradley, Thacker, and Lee had extensive knowledge of Boston Scientific's neuromodulation patent portfolio, including many of the Asserted Patents, their applications, and/or their patent families. Upon information and belief, Nevro institutionalized this knowledge, whereby Nevro obtained actual and constructive knowledge of the Asserted Patents.

30. Upon information and belief, at least 48 past employees of Boston Scientific are currently employed by Nevro, including: Lisa Earnhardt, Member Board of Directors; Doug Alleavitch, Vice President, Quality; Reynaldo Nossa, Director of Technical Services; Andreas Koenig, Sr. Clinical Affairs Manager; David Marco, Sr. Field Clinical Engineer; Tamara Baynham, Sr. Field Clinical Engineer; Dan Hestera, Regional Sales Director; Jeff Orr, Regional Sales Director; Jim Sackleh, Regional Sales Director; Richard James, Regional Sales Director; Angela Holley, District Sales Manager; Laurie Cigan, District Sales Manager; Heather Moss-

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Gad, District Sales Manager; Anthony Puglisi, District Sales Manager; Cable Hawkins, District Sales Manager; Matt Goldstone, District Sales Manager; Phil Almeida, District Sales Manager; Ryan Livingston, District Sales Manager; Chris White, District Sales Manager; Lindsay Molden, District Sales Manager; Christine Biello, District Sales Manager; Chad Sellers, District Sales Manager; Brian Warriner, District Sales Manager; Scott Shoultz, District Sales Manager; Croix Paquin, District Sales Manager; Ashley Bailey, Therapy Consultant; Danielle Pronesti, Therapy Consultant; Mandy Cash, Therapy Consultant; Gretchen Thomas, Therapy Consultant; Will Windauer, Therapy Consultant; Kate Ginter, Therapy Optimization Specialist; and Kelly Engle, Therapy Support Specialist. (Source: linkedin.com.) Many of these Nevro employees are intimately familiar with Boston Scientific's SCS systems and core SCS technologies, which Boston Scientific has been developing for decades. Upon information and belief, Nevro strived to acquire information regarding Boston Scientific's SCS systems and core SCS technologies, and its institutional knowledge of the SCS market and SCS business practices from these former Boston Scientific employees.

31. Upon information and belief, Nevro obtained actual and constructive knowledge of the Asserted Patents or willfully blinded itself to the existence of those patents through the prosecution of its own patent portfolio.

32. To the extent that Nevro lacked actual and constructive knowledge of the Asserted Patents prior to the filing of the original Complaint, then Nevro willfully blinded itself to the existence of those patents. Upon information and belief, Nevro monitored and investigated Boston Scientific's patent portfolio, and institutionalized the extensive knowledge of Boston Scientific's patent portfolio from past employees of Boston Scientific.

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33. Despite Nevro's actual and constructive knowledge of the Asserted Patents, it continues its infringing conduct to this day.

## COUNT I: INFRINGEMENT OF U.S. PATENT NO. 8,781,596

34. Boston Scientific realleges paragraphs 1-33 above as if fully set forth herein.

35. The '596 patent, entitled "Implantable Medical Device with Single Coil for Charging and Communicating," is a valid, enforceable patent that was duly issued by the USPTO on July 15, 2014 in full compliance with Title 35 of the United States Code. A true and correct copy of the '596 patent is attached as **Exhibit 1**.

36. BSN is the assignee of the '596 patent with ownership of all substantial rights in the '596 patent, including the right to exclude others and to enforce, sue, and recover damages for past and future infringements. BSC is an exclusive licensee of the '596 patent.

37. The claims of the '596 patent cover a combined charging and telemetry circuit for use within an IPG, wherein a single coil is used for both charging and telemetry. Claim 1 is illustrative of the claims of the '596 patent and is directed to an IPG with a single coil for charging and communicating. The IPG comprises a single coil which is configured to wirelessly receive power for charging a battery in the IPG at one frequency and to wirelessly receive and transmit data at another frequency.

38. Nevro has directly infringed, and continues to directly infringe, at least claim 1 of the '596 patent in violation of 35 U.S.C. § 271(a) by, for example and without limitation, making, using, offering to sell, selling, and/or importing in and into the United States infringing SCS systems that includes an implantable medical device (IPG) comprising a single coil charging system that is used to wirelessly receive power from an external charger and charge the internal IPG battery subcutaneously at a first frequency. That same coil can be used to transmit and receive data.

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39. For example, Boston Scientific, through its investigation of the Senza I System via publicly available information and an examination of Nevro's IPG, has determined that the Senza I System meets every element of at least claim 1 of the '596 patent, either literally or under the doctrine of equivalents. On information and belief, the Senza II System IPG, like that of the Senza I System, includes a single coil charging system that is used to wireless receive power from an external charger at a first frequency and to transmit and receive data at another frequency.

40. Nevro has actively induced others to infringe at least claim 1 of the '596 patent in violation of 35 U.S.C. § 271(b) by causing, instructing, urging, encouraging, and/or aiding others, including physicians, hospitals, other health care providers, and patients, to directly infringe at least claim 1 of the '596 patent by making, using, offering to sell, selling, and/or importing in and into the United States infringing SCS systems, as detailed above. Nevro's active inducement includes, for example and without limitation, marketing, selling, and offering to sell the Senza Systems, providing instructions on how to use the Senza Systems, and promoting the use of the Senza Systems. For example, Nevro encourages physicians, hospitals, other health care providers, and patients to use the Senza Systems by means of marketing materials<sup>10</sup> and videos.<sup>11</sup> Nevro also instructs physicians, hospitals, other health care providers,

http://www.nevro.com/English/Physicians/Clinical-Evidence/default.aspx;

http://www.nevro.com/English/Physicians/SENZA-RCT-Design/default.aspx;

http://www.nevro.com/English/Physicians/HF10-Therapy-Superiority/default.aspx;

http://www.nevro.com/English/Physicians/HF10-Therapy-Benefits/default.aspx;

http://www.nevro.com/English/Physicians/Senza-System/default.aspx.

<sup>&</sup>lt;sup>10</sup> Exemplary marketing materials:

<sup>&</sup>lt;sup>11</sup> Exemplary marketing videos:

https://www.youtube.com/watch?v=s2LtOcCiMVg;

https://www.youtube.com/watch?v=Ua7rJ97S2Bk;

https://www.youtube.com/watch?v=I0RJaWyFeCQ;

https://www.youtube.com/watch?v=6773eKbZQis;

and patients on how to use the Senza Systems by means of physician and patient manuals.<sup>12</sup> Upon information and belief, Nevro also has a clinical engineer, sales representative, therapy consultant, therapy optimization specialist, and/or therapy support specialist present in the operating room, as is customary in the SCS industry. These Nevro employees will provide guidance and instruction to the physicians during and after surgery, including by advising on lead placement, setting the stimulation parameters of the external trial stimulator or IPG, and otherwise programming the external trial stimulator or IPG and familiarizing the patient with the Senza Systems. Upon information and belief, Nevro knows or is willfully blind to the existence of the '596 patent, knows or is willfully blind to the fact that Nevro's actions will induce infringement thereof, and has induced such infringement with the intent that one or more claims of the '596 patent be infringed.

41. The foregoing actions by Nevro also constitute infringement of at least claim 1 of the '596 patent in violation of 35 U.S.C. § 271(f)(1), wherein Nevro has supplied and/or caused to be supplied in or from the United States, and it continues to supply and/or cause to be supplied in or from the United States, infringing SCS systems. Upon information and belief,

https://www.youtube.com/watch?v=W1Q3p7YYgPs;

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https://www.youtube.com/watch?v=-t82yCBSjE0;

https://www.youtube.com/watch?v=LeLq1lvlJvs;

https://www.youtube.com/watch?v=-SLx9qwWXqs;

https://www.youtube.com/watch?v=YuuwSTRq2ls;

https://www.youtube.com/watch?v=-FXhOFNKHgU;

https://www.youtube.com/watch?v=kQHTF1fS0ik;

https://www.youtube.com/watch?v=V4RX\_2W4OMk;

https://www.youtube.com/watch?v=fr08-nZy-cY;

https://www.youtube.com/watch?v=Ry8UJTzCfVw.

<sup>&</sup>lt;sup>12</sup> Physician Manual: http://www.accessdata.fda.gov/cdrh\_docs/pdf13/P130022d.pdf; Patient Manual: http://www.accessdata.fda.gov/cdrh\_docs/pdf13/P130022c.pdf.

Nevro has exported the infringing SCS systems from the United States to at least Europe and Australia.

42. Nevro has contributed to infringement by others of at least claim 1 of the '596 patent in violation of 35 U.S.C. § 271(c) by offering to sell, selling, and/or importing the infringing SCS systems and/or one or more components of the infringing SCS systems to physicians, hospitals, and other health care providers, which, as detailed above, are components of a patented combination and which constitute a material part of the inventions claimed in the '596 patent, including without limitation the invention in at least claim 1 of the '596 patent. Nevro has offered to sell, sold, and/or imported infringing SCS systems and/or one or more components of infringing SCS systems knowing the same to be especially made or especially adapted for use in an infringement of at least claim 1 of the '596 patent, and that the infringing SCS systems and/or one or more components of the infringing SCS systems are not staple articles or commodities of commerce suitable for substantial noninfringing use.

43. For example, Nevro has offered to sell, sold, and/or imported its IPGs (which, as detailed above, practices the patented invention) to others, including physicians, hospitals, and other health care providers. The physicians, hospitals, and other health care providers then make, use, sell, or offer to sell systems that incorporate Nevro's IPGs to directly infringe at least claim 1 of the '596 patent. Upon information and belief, Nevro, as detailed above, knows or is willfully blind to the existence of the '596 patent, knows or is willfully blind to the fact that Nevro's actions will contribute to the infringement thereof, and has contributed to such infringement with the intent that one or more claims of the '596 patent be infringed. Moreover, as detailed above, Nevro's IPGs comprise a material part of the invention claimed in claim 1 of the '596 patent and, upon information and belief, Nevro knows that these components are

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especially made and/or especially adapted for use in infringing claim 1 of the '596 patent. Upon information and belief, these components are not staple articles or commodities of commerce suitable for substantial non-infringing use at least because Nevro's IPGs have no use apart from, and is a component of a medical device that is not approved for any purpose other than, making the infringing SCS system.

44. The foregoing actions by Nevro also constitute infringement of at least claim 1 of the '596 patent in violation of 35 U.S.C. § 271(f)(2), wherein Nevro has supplied and/or caused to be supplied in or from the United States, and it continues to supply and/or cause to be supplied in or from the United States, the infringing SCS systems. Upon information and belief, Nevro has exported the infringing SCS systems from the United States to at least Europe and Australia.

45. Upon information and belief, Nevro had actual and constructive knowledge of the '596 patent prior to the filing of the original Complaint. Nevro has continued to infringe at least claim 1 of the '596 patent. Nevro's infringement is reckless, knowing, deliberate, and willful.

46. Boston Scientific has been damaged as a result of Nevro's infringing conduct and is entitled to recover damages that adequately compensate it for Nevro's infringement, which, by law, cannot be less than a reasonable royalty, together with interest and costs as fixed by this Court under 35 U.S.C. § 284.

#### COUNT II: INFRINGEMENT OF U.S. PATENT NO. 7,177,690

47. Boston Scientific realleges paragraphs 1-46 above as if fully set forth herein.

48. The '690 patent, entitled "Implantable System Having Rechargeable Battery Indicator," is a valid, enforceable patent that was duly issued by the USPTO on February 13, 2007 in full compliance with Title 35 of the United States Code. A true and correct copy of the '690 patent is attached as **Exhibit 2**.

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49. BSN is the assignee of the '690 patent with ownership of all substantial rights in the '690 patent, including the right to exclude others and to enforce, sue, and recover damages for past and future infringements. BSC is an exclusive licensee of the '690 patent.

50. The claims of the '690 patent cover systems and methods connected with medical devices having replenishable power sources. Claim 1 is illustrative of the claims of the '690 patent and is directed to an implantable medical device system having a replenishable power source with a housing which contains processing circuitry, an external programmer that may be placed in telecommunicative contact with the implantable medical device, and means for recording battery charging information, which can be recalled later, wherein the external programmer includes a status indictor for indicating the status of the replenishable power source.

51. Nevro has directly infringed, and continues to directly infringe, at least claim 1 of the '690 patent in violation of 35 U.S.C. § 271(a) by, for example and without limitation, making, using, offering to sell, selling, and/or importing in and into the United States SCS systems, that include a rechargeable IPG, and patient remotes, programmers, and chargers that can be placed in telecommunicative contact with the IPG, and that contain memory that stores battery charging information of the IPG for later recall, and a status indicator for indicating the status of the battery in the IPG.

52. For example, the Senza Systems are spinal cord stimulation systems comprising a rechargeable IPG, a patient remote, programmer, and a charger. Each of the patient remote, programmer, and charger can be placed in telecommunicative contact with the IPG, contain memory that stores battery charging information of the IPG for later recall, and a status indicator for indicating the status of the battery in the IPG. Boston Scientific, through its

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investigation of the Senza Systems via publicly available information and an examination of Nevro's Senza I System, has determined that the Senza I System meets every element of at least claim 1 of the '690 patent, either literally or under the doctrine of equivalents. On information and belief, the Senza II System also meets every element of at least claim 1 of the '690 patent. BSC does not assert direct or indirect infringement of claims 12-15 of the '690 patent.

53. Nevro has actively induced others to infringe at least claim 1 of the '690 patent in violation of 35 U.S.C. § 271(b) by causing, instructing, urging, encouraging, and/or aiding others, including physicians, hospitals, other health care providers, and patients, to directly infringe at least claim 1 of the '690 patent by making, using, offering to sell, selling, and/or importing in and into the United States the infringing SCS systems, as detailed above. Nevro's active inducement includes, for example and without limitation, marketing, selling, and offering to sell the Senza Systems, providing instructions on how to use the Senza Systems, and promoting the use of the Senza Systems. For example, Nevro encourages physicians, hospitals, other health care providers, and patients to use the Senza Systems by means of marketing materials<sup>13</sup> and videos.<sup>14</sup> Nevro also instructs physicians, hospitals, other health care providers,

https://www.youtube.com/watch?v=s2LtOcCiMVg;

Footnote continued on next page

<sup>&</sup>lt;sup>13</sup> Exemplary marketing materials:

http://www.nevro.com/English/Physicians/Clinical-Evidence/default.aspx; http://www.nevro.com/English/Physicians/SENZA-RCT-Design/default.aspx; http://www.nevro.com/English/Physicians/HF10-Therapy-Superiority/default.aspx; http://www.nevro.com/English/Physicians/HF10-Therapy-Benefits/default.aspx; http://www.nevro.com/English/Physicians/Senza-System/default.aspx.

<sup>&</sup>lt;sup>14</sup> Exemplary marketing videos:

https://www.youtube.com/watch?v=Ua7rJ97S2Bk;

https://www.youtube.com/watch?v=I0RJaWyFeCQ;

https://www.youtube.com/watch?v=6773eKbZQis;

https://www.youtube.com/watch?v=-t82yCBSjE0;

https://www.youtube.com/watch?v=LeLq1lvlJvs;

https://www.youtube.com/watch?v=-SLx9qwWXqs;

https://www.youtube.com/watch?v=YuuwSTRq2ls;

and patients on how to use the Senza Systems by means of physician and patient manuals.<sup>15</sup> Upon information and belief, Nevro also has a clinical engineer, sales representative, therapy consultant, therapy optimization specialist, and/or therapy support specialist present in the operating room, as is customary in the SCS industry. These Nevro employees will provide guidance and instruction to the physicians during and after surgery, including by advising on lead placement, setting the stimulation parameters of the external trial stimulator or IPG, and otherwise programming the external trial stimulator or IPG and familiarizing the patient with the Senza Systems. Upon information and belief, Nevro knows or is willfully blind to the existence of the '690 patent, knows or is willfully blind to the fact that Nevro's actions will induce infringement thereof, and has induced such infringement with the intent that one or more claims of the '690 patent be infringed.

54. The foregoing actions by Nevro also constitute infringement of at least claim 1 of the '690 patent in violation of 35 U.S.C. § 271(f)(1), wherein Nevro has supplied and/or caused to be supplied in or from the United States, and it continues to supply and/or cause to be supplied in or from the United States, the infringing SCS systems. Upon information and belief, Nevro has exported infringing SCS Systems from the United States to at least Europe and Australia.

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https://www.youtube.com/watch?v=-FXhOFNKHgU;

https://www.youtube.com/watch?v=W1Q3p7YYgPs;

https://www.youtube.com/watch?v=kQHTF1fS0ik;

https://www.youtube.com/watch?v=V4RX\_2W4OMk;

https://www.youtube.com/watch?v=fr08-nZy-cY;

https://www.youtube.com/watch?v=Ry8UJTzCfVw.

<sup>&</sup>lt;sup>15</sup> Physician Manual: http://www.accessdata.fda.gov/cdrh\_docs/pdf13/P130022d.pdf; Patient Manual: http://www.accessdata.fda.gov/cdrh\_docs/pdf13/P130022c.pdf.

55. Nevro has contributed to infringement by others of at least claim 1 of the '690 patent in violation of 35 U.S.C. § 271(c) by offering to sell, selling, and/or importing the infringing SCS systems and/or one or more components of the infringing SCS Systems to physicians, hospitals, and other health care providers, which, as detailed above, are components of a patented combination and which constitute a material part of the inventions claimed in the '690 patent, including without limitation the invention in at least claim 1 of the '690 patent. Nevro has offered to sell, sold, and/or imported the infringing SCS systems and/or one or more components of the infringing SCS systems knowing the same to be especially made or especially adapted for use in an infringement of at least claim 1 of the '690 patent, and that the infringing SCS systems and/or one or more components of the infringing SCS systems are not staple articles or commodities of commerce suitable for substantial noninfringing use.

56. For example, Nevro has offered to sell, sold, and/or imported its IPGs and external controllers (each of which, as detailed above, are components of a patented combination) to others, including physicians, hospitals, and other health care providers. The physicians, hospitals, and other health care providers then make, use, sell, or offer to sell systems that incorporate one or more of Nevro's components to directly infringe at least claim 1 of the '690 patent. Upon information and belief, Nevro, as detailed above, knows or is willfully blind to the existence of the '690 patent, knows or is willfully blind to the fact that Nevro's actions will contribute to the infringement thereof, and has contributed to such infringement with the intent that one or more claims of the '690 patent be infringed. Moreover, as detailed above, Nevro's IPG and external controller are a material part of the invention claimed in claim 1 of the '690 patent and, upon information and belief, Nevro knows that these components are especially made and/or especially adapted for use in infringing claim 1 of the '690 patent.

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Upon information and belief, these components are not staple articles or commodities of commerce suitable for substantial non-infringing use at least because Nevro's IPGs and external controllers have no use apart from, and are components of a medical device that is not approved for any purpose other than, making the infringing SCS system.

57. The foregoing actions by Nevro also constitute infringement of at least claim 1 of the '690 patent in violation of 35 U.S.C. § 271(f)(2), wherein Nevro has supplied and/or caused to be supplied in or from the United States, and it continues to supply and/or cause to be supplied in or from the United States, the infringing SCS systems. Upon information and belief, Nevro has exported the infringing SCS systems from the United States to at least Europe and Australia.

58. Upon information and belief, Nevro had actual and constructive knowledge of the '690 patent prior to the filing of the original Complaint. Nevro has continued to infringe at least claim 1 of the '690 patent. Nevro's infringement is reckless, knowing, deliberate, and willful.

59. Boston Scientific has been damaged as a result of Nevro's infringing conduct and is entitled to recover damages that adequately compensate it for Nevro's infringement, which, by law, cannot be less than a reasonable royalty, together with interest and costs as fixed by this Court under 35 U.S.C. § 284.

# COUNT III: INFRINGEMENT OF U.S. PATENT NO. 6,609,032

60. Boston Scientific realleges paragraphs 1-59 above as if fully set forth herein.

61. The '032 patent, entitled "Fitting Process for a Neural Stimulation System," is a valid, enforceable patent that was duly issued by the USPTO on August 19, 2003 in full compliance with Title 35 of the United States Code. A true and correct copy of the '032 patent is attached as **Exhibit 3**.

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62. BSN is the assignee of the '032 patent with ownership of all substantial rights in the '032 patent, including the right to exclude others and to enforce, sue, and recover damages for past and future infringements. BSC is an exclusive licensee of the '032 patent.

63. The claims of the '032 patent cover a programming system and method for use with an implantable tissue stimulator. Claim 17 is illustrative of the claims of the '032 patent. Claim 17 is directed to a neural stimulation system with a multiplicity of implantable electrodes, an IPG connected to the electrodes, an external processor adapted to be coupled to the IPG that includes memory means, input/output means, and display means, and a software architecture that has a main section wherein the underlying programs that control the system reside and a navigator section that has a navigator wizard program to aid in the initial set-up of the neural stimulation device.

64. Nevro has directly infringed, and continues to directly infringe, at least claim 17 of the '032 patent in violation of 35 U.S.C. § 271(a) by, for example and without limitation, making, using, offering to sell, selling, and/or importing in and into the United States SCS systems, that include a programmer, a multiplicity of electrodes and an IPG connected to each of the multiplicity of electrodes that meets all the limitations of claim 17 of the '032 patent.

65. For example, the Senza Systems includes a programmer paired to an IPG. The programmer is a computer having input/output means (*e.g.*, a keyboard), memory, and a display. The programmer further has software including a main program for controlling the operation and parameters of the system and a programming wizard that guides a user of the neural stimulation system through each step of the initial fitting process. The Senza Systems also includes leads with a multiplicity of implantable electrodes adapted to contact body tissue that is to be stimulated, and an IPG connected to the leads and can selectively activate the

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electrodes so that a stimulus current may be applied to the body tissue through selected electrodes.

66. Boston Scientific, through its investigation of the Senza Systems via publicly available information and an examination of Nevro's Senza I System, has determined that the Senza I System meets every element of at least claim 17 of the '032 patent, either literally or under the doctrine of equivalents. On information and belief, the Senza II System also meets every element of at least claim 17 of the '032 patent.

67. Nevro has actively induced others to infringe at least claim 17 of the '032 patent in violation of 35 U.S.C. § 271(b) by causing, instructing, urging, encouraging, and/or aiding others, including physicians, hospitals, other health care providers, and patients, to directly infringe at least claim 17 of the '032 patent by making, using, offering to sell, selling, and/or importing in and into the United States the infringing SCS systems, as detailed above. Nevro's active inducement includes, for example and without limitation, marketing, selling, and offering to sell the Senza Systems, providing instructions on how to use the Senza Systems, and promoting the use of the Senza Systems. For example, Nevro encourages physicians, hospitals, other health care providers, and patients to use the Senza Systems by means of marketing materials<sup>16</sup> and videos.<sup>17</sup> Nevro also instructs physicians, hospitals, other health care providers,

http://www.nevro.com/English/Physicians/Clinical-Evidence/default.aspx;

http://www.nevro.com/English/Physicians/SENZA-RCT-Design/default.aspx;

http://www.nevro.com/English/Physicians/HF10-Therapy-Superiority/default.aspx;

http://www.nevro.com/English/Physicians/HF10-Therapy-Benefits/default.aspx;

http://www.nevro.com/English/Physicians/Senza-System/default.aspx.

<sup>17</sup> Exemplary marketing videos:

https://www.youtube.com/watch?v=s2LtOcCiMVg;

https://www.youtube.com/watch?v=Ua7rJ97S2Bk;

<sup>&</sup>lt;sup>16</sup> Exemplary marketing materials:

https://www.youtube.com/watch?v=I0RJaWyFeCQ;

https://www.youtube.com/watch?v=6773eKbZQis;

and patients on how to use the Senza Systems by means of physician and patient manuals.<sup>18</sup> Upon information and belief, Nevro also has a clinical engineer, sales representative, therapy consultant, therapy optimization specialist, and/or therapy support specialist present in the operating room, as is customary in the SCS industry. These Nevro employees will provide guidance and instruction to the physicians during and after surgery, including by advising on lead placement, setting the stimulation parameters of the external trial stimulator or IPG, and otherwise programming the external trial stimulator or IPG and familiarizing the patient with the Senza Systems. Upon information and belief, Nevro knows or is willfully blind to the existence of the '032 patent, knows or is willfully blind to the fact that Nevro's actions will induce infringement thereof, and has induced such infringement with the intent that one or more claims of the '032 patent be infringed.

68. The foregoing actions by Nevro also constitute infringement of at least claim 17 of the '032 patent in violation of 35 U.S.C. § 271(f)(1), wherein Nevro has supplied and/or caused to be supplied in or from the United States, and it continues to supply and/or cause to be supplied in or from the United States, the infringing SCS systems. Upon information and belief,

https://www.youtube.com/watch?v=-SLx9qwWXqs;

https://www.youtube.com/watch?v=W1Q3p7YYgPs;

https://www.youtube.com/watch?v=kQHTF1fS0ik;

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https://www.youtube.com/watch?v=-t82yCBSjE0;

https://www.youtube.com/watch?v=LeLq1lvlJvs;

https://www.youtube.com/watch?v=YuuwSTRq2ls;

https://www.youtube.com/watch?v=-FXhOFNKHgU;

https://www.youtube.com/watch?v=V4RX\_2W4OMk;

https://www.youtube.com/watch?v=fr08-nZy-cY;

https://www.youtube.com/watch?v=Ry8UJTzCfVw.

<sup>&</sup>lt;sup>18</sup> Physician Manual: http://www.accessdata.fda.gov/cdrh\_docs/pdf13/P130022d.pdf; Patient Manual: http://www.accessdata.fda.gov/cdrh\_docs/pdf13/P130022c.pdf.

Nevro has exported infringing SCS Systems from the United States to at least Europe and Australia.

69. Nevro has contributed to infringement by others of at least claim 17 of the '032 patent in violation of 35 U.S.C. § 271(c) by offering to sell, selling, and/or importing the infringing SCS systems and/or one or more components of the infringing SCS Systems to physicians, hospitals, and other health care providers, which, as detailed above, are components of a patented combination and which constitute a material part of the inventions claimed in the '032 patent, including without limitation the invention in at least claim 17 of the '032 patent. Nevro has offered to sell, sold, and/or imported the infringing SCS systems and/or one or more components of the infringing SCS systems and/or one or more specially adapted for use in an infringement of at least claim 17 of the '032 patent, and that the infringing SCS systems and/or one or more components of the infringing SCS systems are not staple articles or commodities of commerce suitable for substantial noninfringing use.

70. For example, Nevro has offered to sell, sold, and/or imported its IPGs and external controllers (each of which, as detailed above, are components of a patented combination) to others, including physicians, hospitals, and other health care providers. The physicians, hospitals, and other health care providers then make, use, sell, or offer to sell systems that incorporate one or more of Nevro's components to directly infringe at least claim 17 of the '032 patent. Upon information and belief, Nevro, as detailed above, knows or is willfully blind to the existence of the '032 patent, knows or is willfully blind to the fact that Nevro's actions will contribute to the infringement thereof, and has contributed to such infringement with the intent that one or more claims of the '032 patent be infringed. Moreover, as detailed above, Nevro's IPG and external controller are a material part of the invention

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claimed in claim 17 of the '032 patent and, upon information and belief, Nevro knows that these components are especially made and/or especially adapted for use in infringing claim 17 of the '032 patent. Upon information and belief, these components are not staple articles or commodities of commerce suitable for substantial non-infringing use at least because Nevro's IPGs and external controllers have no use apart from, and are components of a medical device that is not approved for any purpose other than, making the infringing SCS system.

71. The foregoing actions by Nevro also constitute infringement of at least claim 17 of the '032 patent in violation of 35 U.S.C. § 271(f)(2), wherein Nevro has supplied and/or caused to be supplied in or from the United States, and it continues to supply and/or cause to be supplied in or from the United States, the infringing SCS systems. Upon information and belief, Nevro has exported the infringing SCS systems from the United States to at least Europe and Australia.

72. Upon information and belief, Nevro had actual and constructive knowledge of the '032 patent prior to the filing of the original Complaint. Nevro has continued to infringe at least claim 17 of the '032 patent. Nevro's infringement is reckless, knowing, deliberate, and willful.

73. Boston Scientific has been damaged as a result of Nevro's infringing conduct and is entitled to recover damages that adequately compensate it for Nevro's infringement, which, by law, cannot be less than a reasonable royalty, together with interest and costs as fixed by this Court under 35 U.S.C. § 284.

#### COUNT IV: INFRINGEMENT OF U.S. PATENT NO. 8,918,174

74. Boston Scientific realleges paragraphs 1-73 above as if fully set forth herein.

75. The '174 patent, entitled "Patient Programmer for Implantable Devices," is a valid, enforceable patent that was duly issued by the USPTO on December 23, 2014 in full

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compliance with Title 35 of the United States Code. A true and correct copy of the '174 patent is attached as **Exhibit 4**.

76. BSN is the assignee of the '174 patent with ownership of all substantial rights in the '174 patent, including the right to exclude others and to enforce, sue, and recover damages for past and future infringements. BSC is an exclusive licensee of the '174 patent.

77. The claims of the '174 patent cover an implantable medical device system, external programmer, and method of indicating the status of a power source in a medical device implanted within a patient. Claim 1 is illustrative of the claims of the '174 patent. Claim 1 is directed to an implantable medical device configured for maintaining an actual status of the capacity of a power source contained in the implantable medical device, an external programmer configured for updating an estimated status of the power source capacity independent of the actual status of the power source, the external programmer including a status indicator configured for indicating an estimated status of the power source derived from the updated estimated status of the power source capacity, the external programmer configured for being placed in telecommunicative contact with the implantable medical device to reconcile the updated estimated status of the power source capacity with the actual status of the power source capacity.

78. Nevro has directly infringed, and continues to directly infringe, at least claim 1 of the '174 patent in violation of 35 U.S.C. § 271(a) by, for example and without limitation, making, using, offering to sell, selling, and/or importing in and into the United States SCS systems that include an IPG and a programmer that meet all the limitations of claim 1 of the '174 patent.

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79. For example, the Senza Systems are spinal cord stimulation systems comprising a programmer and IPG configured for maintaining an actual status of the capacity of a power source contained in the IPG, the programmer configured to update an estimated status of the power source capacity independent of the actual status of the power source, the programmer includes a status indicator configured for indicating an estimated status of the power source derived from the updated estimated status of the power source capacity, the programmer configured for being placed in telecommunicative contact with the IPG to reconcile the updated estimated status of the power source capacity.

80. Boston Scientific, through its investigation of the Senza Systems via publicly available information and an examination of Nevro's Senza I System IPG, has determined that the Senza I System meets every element of at least claim 1 of the '174 patent, either literally or under the doctrine of equivalents. On information and belief, the Senza II System also meets every element of at least claim 1 of the '174 patent.

81. Nevro has actively induced others to infringe at least claim 1 of the '174 patent in violation of 35 U.S.C. § 271(b) by causing, instructing, urging, encouraging, and/or aiding others, including physicians, hospitals, other health care providers, and patients, to directly infringe at least claim 1 of the '174 patent by making, using, offering to sell, selling, and/or importing in and into the United States the infringing SCS systems, as detailed above. Nevro's active inducement includes, for example and without limitation, marketing, selling, and offering to sell the Senza Systems, providing instructions on how to use the Senza Systems, and promoting the use of the Senza Systems. For example, Nevro encourages physicians, hospitals, other health care providers, and patients to use the Senza Systems by means of marketing

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materials<sup>19</sup> and videos.<sup>20</sup> Nevro also instructs physicians, hospitals, other health care providers, and patients on how to use the Senza Systems by means of physician and patient manuals.<sup>21</sup> Upon information and belief, Nevro also has a clinical engineer, sales representative, therapy consultant, therapy optimization specialist, and/or therapy support specialist present in the operating room, as is customary in the SCS industry. These Nevro employees will provide guidance and instruction to the physicians during and after surgery, including by advising on lead placement, setting the stimulation parameters of the external trial stimulator or IPG, and otherwise programming the external trial stimulator or IPG and familiarizing the patient with the Senza Systems. Upon information and belief, Nevro knows or is willfully blind to the existence of the '174 patent, knows or is willfully blind to the fact that Nevro's actions will

<sup>&</sup>lt;sup>19</sup> Exemplary marketing materials:

http://www.nevro.com/English/Physicians/Clinical-Evidence/default.aspx;

http://www.nevro.com/English/Physicians/SENZA-RCT-Design/default.aspx;

http://www.nevro.com/English/Physicians/HF10-Therapy-Superiority/default.aspx;

http://www.nevro.com/English/Physicians/HF10-Therapy-Benefits/default.aspx;

http://www.nevro.com/English/Physicians/Senza-System/default.aspx.

<sup>&</sup>lt;sup>20</sup> Exemplary marketing videos:

https://www.youtube.com/watch?v=s2LtOcCiMVg;

https://www.youtube.com/watch?v=Ua7rJ97S2Bk;

https://www.youtube.com/watch?v=I0RJaWyFeCQ;

https://www.youtube.com/watch?v=6773eKbZQis;

https://www.youtube.com/watch?v=-t82yCBSjE0;

https://www.youtube.com/watch?v=LeLq1lvlJvs;

https://www.youtube.com/watch?v=-SLx9qwWXqs;

https://www.youtube.com/watch?v=YuuwSTRq2ls;

https://www.youtube.com/watch?v=-FXhOFNKHgU;

https://www.youtube.com/watch?v=W1Q3p7YYgPs;

https://www.youtube.com/watch?v=kQHTF1fS0ik;

https://www.youtube.com/watch?v=V4RX\_2W4OMk;

https://www.youtube.com/watch?v=fr08-nZy-cY;

https://www.youtube.com/watch?v=Ry8UJTzCfVw.

<sup>&</sup>lt;sup>21</sup> Physician Manual: http://www.accessdata.fda.gov/cdrh\_docs/pdf13/P130022d.pdf; Patient Manual: http://www.accessdata.fda.gov/cdrh\_docs/pdf13/P130022c.pdf.

induce infringement thereof, and has induced such infringement with the intent that one or more claims of the '174 patent be infringed.

82. The foregoing actions by Nevro also constitute infringement of at least claim 1 of the '174 patent in violation of 35 U.S.C. § 271(f)(1), wherein Nevro has supplied and/or caused to be supplied in or from the United States, and it continues to supply and/or cause to be supplied in or from the United States, the infringing SCS systems. Upon information and belief, Nevro has exported infringing SCS Systems from the United States to at least Europe and Australia.

83. Nevro has contributed to infringement by others of at least claim 1 of the '174 patent in violation of 35 U.S.C. § 271(c) by offering to sell, selling, and/or importing the infringing SCS systems and/or one or more components of the infringing SCS Systems to physicians, hospitals, and other health care providers, which, as detailed above, are components of a patented combination and which constitute a material part of the inventions claimed in the '174 patent, including without limitation the invention in at least claim 1 of the '174 patent. Nevro has offered to sell, sold, and/or imported the infringing SCS systems and/or one or more components of the infringing SCS systems knowing the same to be especially made or especially adapted for use in an infringement of at least claim 1 of the '174 patent, and that the infringing SCS systems and/or one or more components of the infringing SCS systems are not staple articles or commodities of commerce suitable for substantial noninfringing use.

84. For example, Nevro has offered to sell, sold, and/or imported its IPGs and external controllers (each of which, as detailed above, are components of a patented combination) to others, including physicians, hospitals, and other health care providers. The physicians, hospitals, and other health care providers then make, use, sell, or offer to sell

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systems that incorporate one or more of Nevro's components to directly infringe at least claim 1 of the '174 patent. Upon information and belief, Nevro, as detailed above, knows or is willfully blind to the existence of the '174 patent, knows or is willfully blind to the fact that Nevro's actions will contribute to the infringement thereof, and has contributed to such infringement with the intent that one or more claims of the '174 patent be infringed. Moreover, as detailed above, Nevro's IPG and external controller are a material part of the invention claimed in claim 1 of the '174 patent and, upon information and belief, Nevro knows that these components are especially made and/or especially adapted for use in infringing claim 1 of the '174 patent. Upon information and belief, these components are not staple articles or commodities of commerce suitable for substantial non-infringing use at least because Nevro's IPGs and external controllers have no use apart from, and are components of a medical device that is not approved for any purpose other than, making the infringing SCS system.

85. The foregoing actions by Nevro also constitute infringement of at least claim 1 of the '174 patent in violation of 35 U.S.C. § 271(f)(2), wherein Nevro has supplied and/or caused to be supplied in or from the United States, and it continues to supply and/or cause to be supplied in or from the United States, the infringing SCS systems. Upon information and belief, Nevro has exported the infringing SCS systems from the United States to at least Europe and Australia.

86. Upon information and belief, Nevro had actual and constructive knowledge of the '174 patent prior to the filing of the original Complaint. Nevro has continued to infringe at least claim 1 of the '174 patent. Nevro's infringement is reckless, knowing, deliberate, and willful.

87. Boston Scientific has been damaged as a result of Nevro's infringing conduct and is entitled to recover damages that adequately compensate it for Nevro's infringement, which,

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by law, cannot be less than a reasonable royalty, together with interest and costs as fixed by this Court under 35 U.S.C. § 284.

# <u>COUNT V: MISAPPROPRIATION OF TRADE SECRETS AND LIABILITY</u> <u>UNDER THE CALIFORNIA UNIFORM TRADE SECRETS ACT,</u> <u>CAL. CIV. CODE §§ 3426-3426.11</u>

88. Boston Scientific is the owner of trade secrets, including but not limited to, proprietary technical information, clinical investigation designs and protocols, internal programming manuals, manufacturing processes, manufacturing costs, product testing and analysis, software programming, pricing and other financial information. Boston Scientific has acquired these trade secrets and proprietary technical information as a result of development of its SCS products. In the hands of a competitor, such confidential, trade secret, and proprietary information would be of great value and could be used to unlawfully compete against Boston Scientific. A competitor possessing such information could utilize it to its gain without incurring the years of effort and significant expenditures that Boston Scientific incurred in developing its SCS products.

89. Boston Scientific's trade secrets constitute compilations of information that derive independent economic value, actual and potential, from not being generally known or available to the public or other persons who can obtain economic value from their disclosure or use.

90. Boston Scientific's trade secrets have significant value to Boston Scientific, resulting from significant investment of time and resources by Boston Scientific.

91. The confidential, trade secret, and proprietary information acquired by Boston Scientific is not readily available to its competitors or the general public. Boston Scientific has made, and continues to make, efforts that are reasonable under the circumstances to maintain the secrecy of its trade secrets and protect the confidentiality of its proprietary information, including, but not limited to, requiring its employees to sign acknowledgments that such

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information should only be used for the benefit of Boston Scientific, and that no confidential or proprietary information should be taken or accessed by anyone outside of Boston Scientific without authorization.

92. As noted above, Jim Thacker, Nevro's Director of Field Engineering, worked at

Boston Scientific and its predecessor Advanced Bionics from 2000 to 2006 as Manager of Field

Clinical Engineering. As a condition of his employment at Boston Scientific, Mr. Thacker

agreed to and was bound by an Employee Invention and Confidential Information Agreement

("EICIA"), attached as **Exhibit 5**. The EICIA provides:

[D]uring the course of Employee's employment, Employer expects the Employee to develop and receive from co-workers inventions and confidential information relating to Employer's business and to the Employer's actual and anticipated research and development.

93. The EICIA further provides:

Employee will, during the term of his/her employment and thereafter, keep confidential and refrain from using or disclosing to others all confidential information and trade secrets of [AB], which Employee develops or learns about during the course of his/her employment.

- 94. Mr. Thacker signed the EICIA on August 28, 2000.
- 95. As Boston Scientific's clinical manager, Mr. Thacker had access on a daily basis

to proprietary and confidential information belonging to Boston Scientific. This included

information about Boston Scientific's research and development, clinical investigation (including

testing and analysis of any patient data), business plans, product roadmaps, internal policies and

procedures, and financial/cost information. Mr. Thacker was granted access to these categories

of proprietary information during the period of his employment to facilitate the performance of

his work-related duties.

96. Mr. Thacker voluntarily left Boston Scientific in August 2006. As part of the exit process, Mr. Thacker was asked to acknowledge that he did not have in his possession any Boston Scientific-owned property, including, but not limited to, any "books, Engineering note books, periodicals, publications and company records on loan" and any "[t]ools & equipment owned by [Boston Scientific]." Mr. Thacker represented he had "none" of this Boston Scientific-owned property.

97. Unbeknownst by Boston Scientific until informed by Nevro's outside counsel on August 18, 2017, Mr. Thacker in fact took thousands of confidential Boston Scientific documents with him, including five of his own laboratory notebooks detailing the work he performed during the "Stimulus" clinical trials for Boston Scientific's Precision<sup>TM</sup> SCS system. Mr. Thacker also took Boston Scientific-owned thumb drives, actual Precision<sup>TM</sup> demonstration devices, Physician lead manuals, Physician implant manuals, and Precision<sup>TM</sup> media kits. Mr. Thacker did not have authorization from Boston Scientific to take any of these documents and materials with him upon leaving Boston Scientific.

98. In addition to the laboratory notebooks, the over 34,000 files taken by Mr. Thacker included proprietary data concerning Boston Scientific's research and development, product development plans, manufacturing plans and methods, clinical investigations, patient data, programming specifications, marketing and sales force plans, product component lists, product specifications and diagrams, and budgetary, financial, and cost data.

99. Boston Scientific is informed and believes and thereupon alleges that at least Mr. Thacker (and thereby Nevro) acquired Boston Scientific's trade secrets by improper means, including, but not limited to, taking and/or retaining these trade secrets in breach of the duties Mr. Thacker owed to Boston Scientific under the EICIA.

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100. On multiple occasions, while employed by Nevro, Mr. Thacker disclosed Boston Scientific's confidential, proprietary information to Nevro. As one example, on April 16, 2009, Mr. Thacker emailed Nevro employee Wesley Park (also a former Boston Scientific employee) and attached a 50-page document with the file name "SCS\_Protocol\_Rev.B\_3Feb03." The attachment was a draft "Stimulus<sup>TM</sup> Confirmatory Study" authored by Boston Scientific's predecessor Advanced Bionics. Upon information and belief, at the time Mr. Thacker disclosed the Confirmatory Study, Mr. Park was Nevro's Director of Clinical Marketing and responsible for, among other things, leading and managing the U.S. and European clinical trials, including designing studies, selecting study sites, analyzing and interpreting data, and managing field clinical engineers and clinical specialists.

101. On the front page—and every subsequent page—of the Confirmatory Study was the following warning typed in bold: "Proprietary Information of Advanced Bionics. Subject to terms of Non-Disclosure Agreement."

102. The Stimulus Confirmatory Study was Boston Scientific's protocol to run the clinical investigation for its Precision<sup>™</sup> product, and was a compilation of information necessary for Boston Scientific's clinical investigation, including such confidential information as subject enrollment criteria (*e.g.*, detailed inclusion and exclusion criteria), study design, methodology/testing requirements, and monitoring requirements. The Confirmatory Study would not have been disclosed to anyone not involved with the clinical investigation, and each investigator was required to sign an Investigator's Agreement in which he/she agreed, among other things, "to hold all data related to the conduct of this study as confidential and will not divulge such information to any third party (other than applicable regulatory agencies) without prior written approval from Advanced Bionics."

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103. Upon information and belief, Nevro's possession of Boston Scientific's internal clinical investigation protocol for its Precision<sup>™</sup> SCS product would have been of value to Nevro, who during the relevant time period was developing its own SCS system, and conducting its own clinical investigations. Since Nevro had never developed an SCS product before, the Stimulus Confirmatory Study disclosed by Mr. Thacker provided Nevro with a necessary tool to develop its own clinical investigation protocol. Upon information and belief, Nevro has used the information provided by Mr. Thacker in connection with its business activities, including in its research and development, design, clinical investigation, and testing of the Senza Systems.

104. As another example, on May 4, 2009, Mr. Thacker emailed Nevro employee David Marco (also a former Boston Scientific employee) and attached a 26-page document entitled "Spinal Cord Stimulator Clinician's Programming System, Module Specification." Upon information and belief, at the time Mr. Thacker disclosed the Module Specification to Mr. Marco, Mr. Marco was a Senior Field Clinical Engineer at Nevro and responsible for, among other things, training and programming manuals. Mr. Marco worked at Boston Scientific from 2004 to 2007. During that time, Mr. Marco helped Boston Scientific complete the clinical trial for the Precision<sup>TM</sup> SCS product, helped with all phases of equipment troubleshooting, and contributed many ideas for new equipment. Mr. Marco also taught salesmen and physicians.

105. On the front page of the attachment Mr. Thacker sent to Mr. Marco, the word "CONFIDENTIAL" appears in bold. Also on the front page, directly below "CONFIDENTIAL" is the following:

This document contains confidential information and is proprietary to Advanced Bionics corporation and may not be distributed or reproduced without the prior express written consent of Advanced Bionics.

106. In the body of the email, Mr. Thacker wrote:

Hi David,

Since you and I worked at AB we can have this but we cannot share with anyone else. Please use it as an example of a requirements spec for a CP [Clinical Programmer].

Jimt

107. The attached "Module Specification" was a Boston Scientific internal document detailing the specifications necessary for the Clinician's Programmer Station, which controls the Hand-Held Programmer, which in turn controls the Implanted Pulse Generator or External Trial Stimulator. The document is a compilation of information necessary for the design and development of Boston Scientific's SCS products, and includes such confidential information as software functional requirements, including specific programming requirements.

108. Having possession of Boston Scientific's internal information would have been useful and of value to Nevro, who during the relevant time period was developing its own SCS system. Since Nevro had never developed an SCS product before, the Module Specification disclosed by Mr. Thacker provided Nevro with a necessary tool to develop its own system specification. Upon information and belief, Nevro has used the information provided by Mr. Thacker in connection with its business activities, including in its research and development, design, clinical investigation, and testing of the Senza Systems.

109. At the time Nevro acquired Boston Scientific's trade secrets, it knew or had reason to know that it had acquired them through improper means, including through derogation of Mr. Thacker's contractual obligations to Boston Scientific.

110. As a natural and proximate cause of its misappropriation, Nevro has been and will continue to be unjustly enriched, and Boston Scientific has been and will continue to suffer damages.

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111. Boston Scientific has also suffered irreparable harm as a result of Nevro's

misappropriation and will continue to suffer irreparable injury unless Nevro, and its officers,

agents, employees and all persons acting in concert with them, are permanently enjoined from

engaging in such further acts of misappropriation.

# **COUNT VI: TORTIOUS INTERFERENCE WITH CONTRACT**

112. Boston Scientific adopts and incorporates by references the allegations of

paragraphs 1 through 111 above as if fully set forth herein.

113. The Employee Invention and Confidential Information Agreement is a valid

contract between Boston Scientific and Mr. Thacker. The EICIA provides:

In exchange for the salary or wages paid to Employee by Employer, Employer and Employee agree that during the course of Employee's employment, Employer expects the Employee to develop and receive from co-workers inventions and confidential information relating to Employer's business and to the Employer's actual and anticipated research and development.

1. Employee will, during the term of his/her employment and thereafter, keep confidential and refrain from using or disclosing to others all confidential information and trade secrets of Employer, which Employee develops or learns about during the course of his/her employment.

2. As to all inventions made by Employee during the term of his/her employment, solely or jointly with others, which are made with Employer's equipment, supplies, facilities, trade secrets or time, which relate to the business of Employer or the Employer's actual or demonstrably anticipated research or development, which result from work performed by the Employee for Employer, Employee agrees that such inventions shall belong to Employer and he/she promises and agrees to assign such inventions to the Employer and to cooperate with Employer to obtain patents on the inventions for the Employer in the United States and all foreign countries. Employee also agrees that Employer shall have the right to keep such inventions as trade secrets, if Employer chooses . . . .

114. Boston Scientific has performed all of its obligations under the EICIA.

115. Mr. Thacker breached his obligations under the EICIA by, among other things,

taking information belonging to Boston Scientific without Boston Scientific's knowledge or

authorization, and for reasons unrelated to the performance of his duties for Boston Scientific;

and using and disclosing Boston Scientific's proprietary information without Boston Scientific's permission or authorization.

116. Upon information and belief, Nevro knew that Mr. Thacker was an employee of Boston Scientific, that Mr. Thacker was subject to confidentiality agreements with Boston Scientific and that Mr. Thacker was obligated not to disclose any of Boston Scientific's confidential and proprietary information. Indeed, Nevro has its own version of a Proprietary Information and Inventions Agreement that it requires employees to sign as a condition of employment.

117. Upon information and belief, Nevro intentionally, and in violation of applicable law, interfered with the contract between Mr. Thacker and Boston Scientific by encouraging Mr. Thacker to breach his contract with Boston Scientific and/or disrupt the contractual relationship between Mr. Thacker and Boston Scientific.

118. As a result of Mr. Thacker's breach substantially caused by Nevro, Boston Scientific has suffered damages and will imminently suffer further damages, in an amount to be proven at trial.

#### **PRAYER FOR RELIEF**

WHEREFORE, Boston Scientific respectfully requests the following relief:

A. The entry of a judgment in favor of Boston Scientific, and against Nevro, that Nevro has infringed, induced infringement, and contributed to infringement of one or more claims of the Asserted Patents and declaring that Nevro's importing, making, using, offering to sell, and/or selling the Senza Systems and/or components thereof in the United States are and would be acts of infringement of one or more claims of the Asserted Patents;

B. The entry of a judgment in favor of Boston Scientific, and against Nevro, that Nevro has willfully infringed one or more claims of the Asserted Patents;

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C. The entry of a judgment in favor of Boston Scientific, and against Nevro, that Nevro and its officers, employees, agents, attorneys, affiliates, successors, assigns and others acting in privity or concert with it be preliminarily and permanently enjoined from making, using, offering to sell, and selling or inducing or contributing to others to make, use, offer to sell, or sell any product that infringes the Asserted Patents, including the Senza Systems, and from importing the same into the United States;

D. The entry of a judgment awarding Boston Scientific damages resulting from Nevro's infringement in an amount no less than a reasonable royalty, and that such amount be trebled based on Nevro's willful infringement;

E. The entry of a judgment declaring that this is an exceptional case and awarding Boston Scientific its attorneys' fees in this matter pursuant to 35 U.S.C. § 285;

F. The entry of judgment that Nevro has misappropriated Boston Scientific's trade secrets within the meaning of the California Uniform Trade Secret Act;

G. The award of damages sufficient to compensate Boston Scientific for the misappropriation;

H. The award of damages sufficient to compensate Boston Scientific for Nevro's tortious interference of Boston Scientific's contract with Mr. Thacker;

I. The issuance of a permanent injunction to enjoin Nevro, its officers, agents, successors and assigns of each, from misappropriation of Boston Scientific's trade secrets;

J. The entry of a judgment in favor of Boston Scientific; and

K. That this Court order such other relief as the Court may deem just and proper.

## JURY DEMAND

Boston Scientific hereby demands trial by jury in this action on all issues so triable.

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## DATED: April 27, 2018

## Of Counsel:

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