

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

BOSTON SCIENTIFIC CORP. AND
BOSTON SCIENTIFIC NEUROMODULATION
CORP.,

Plaintiffs and Counter-Defendants,

v.

NEVRO CORP.,

Defendant and Counterclaimant.

C.A. No. 16-1163-CFC-CJB
CONSOLIDATED

FILED UNDER SEAL

THIRD AMENDED 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 and theft of trade secrets. 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 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. 7,496,404 (the "'404 patent"); U.S. Patent 8,682,447 (the "'447 patent"); U.S. Patent No. 6,993,384 (the "'384 patent"); U.S. Patent No. 7,853,330 (the "'330 patent"); U.S. Patent No. 7,822,480 (the "'480 patent"); U.S. Patent No. 6,381,496 (the "'496 patent"); U.S. Patent No. 7,177,690 (the "'690 patent"); and U.S. Patent No. 9,162,071 (the "'071 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" or "Senza"), the Senza II™ Spinal Cord Stimulation System (the "Senza II System" or "Senza II") and the Senza® Omnia™ Spinal Cord Stimulation System (the "Senza Omnia" or "Omnia") (collectively, the "Nevro Senza Systems" or "Senza Systems").

3. 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

4. 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

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

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 and state claims alleged by Boston Scientific 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 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™ SCS System, the first rechargeable SCS platform with unique current steering technology, wireless remote, and a wireless charger. In 2007, Boston Scientific launched its improved Precision™ Plus SCS System, the first system 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 provides 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 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 system 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 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.¹

17. The Senza II System, like the Senza I system, is a neuromodulation system 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.² The Senza II System received CE Mark approval in Europe in

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

² 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>.

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 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. On November 5, 2019, Nevro announced it received FDA approval for the Senza Omnia. International approvals for Omnia are expected in Europe during the first half of 2020 with Australia sometime during the latter part of 2020.³ Senza Omnia, like the Senza I and II systems, is a neuromodulation system 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, the Senza Omnia incorporates all of the functionalities of the Senza I and II Systems, in addition to other features that are new to Nevro's products.

19. 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.⁴ Upon information and belief, CCC's manufacturing facility is located in Montevideo, Uruguay.

³ <https://www.nevro.com/English/Newsroom/Press-Releases/press-release-details/2019/Nevro-Announces-US-Launch-of-Senza-Omnia-Spinal-Cord-Stimulation-System-to-Treat-Chronic-Pain/default.aspx>

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

20. 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.

21. 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.⁵ 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.

22. Upon information and belief, EaglePicher Medical Power LLC (“EaglePicher”) is Nevro’s single-source supplier of its IPG’s battery and related products.⁶ Upon information and belief, EaglePicher is headquartered in Joplin, Missouri.

23. 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.⁷ Upon information and belief, Pro-Tech has two manufacturing facilities: one in Arlington, Texas and one in Santa Fe Springs, California.⁸ Upon information and belief, Pro-Tech delivers the Senza Systems to Nevro FCA (Incoterms 2000) Pro-Tech’s Santa Fe Springs, California manufacturing facility.⁹

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

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

⁷ Source: <https://www.sec.gov/Archives/edgar/data/1444380/000119312516485541/d102615d10k.htm>.

⁸ Source: <http://www.protechdesign.com/SitePages/Protech.aspx>.

⁹ Source: https://www.sec.gov/Archives/edgar/data/1444380/000104746914008300/a2221785zex-10_3.htm.

NEVRO'S KNOWLEDGE OF THE ASSERTED PATENTS

24. 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 First Amended Complaint.

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 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 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.¹⁰

26. Moreover, Nevro participated in an FDA-monitored randomized controlled trial in a head-to-head comparison against Boston Scientific's Precision™ SCS System. As evidenced by Nevro's statement above, it is standard practice in the SCS industry to monitor competitors'

¹⁰ Source: <https://www.sec.gov/Archives/edgar/data/1444380/000119312516485541/d102615d10k.htm>.

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.

27. 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 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.

28. 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 Senior 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. Mr. Bradley was an inventor or co-inventor on numerous neuromodulation patents. Mr. Bradley is a co-inventor of the '447, '384, and '330 patents.

29. Upon information and belief, Jim Thacker was Nevro's Director of Field Clinical Engineering from 2009 until April 2019. Mr. Thacker worked for Boston Scientific (and its predecessors) from 2000 to 2006 as Manager of Field Clinical Engineering. During his time at Boston 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, '447, '384, and '330 patents.

30. 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.

31. 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.

32. Upon information and belief, at least 48 past employees of Boston Scientific are or were 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-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.

33. 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.

34. 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.

35. 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. 7,496,404

36. Boston Scientific realleges paragraphs 1-35 above as if fully set forth herein.

37. The '404 patent, entitled "Rechargeable Spinal Cord Stimulator System," is a valid, enforceable patent that was duly issued by the USPTO on February 24, 2009 in full compliance with Title 35 of the United States Code. A true and correct copy of the '404 patent is attached as **Exhibit 2**.

38. BSN is the assignee of the '404 patent with ownership of all substantial rights in the '404 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 '404 patent.

39. The claims of the '404 patent cover SCS systems and methods for initiating and controlling power consumption and charging in an IPG with a rechargeable battery. Claim 7 is illustrative of the claims of the '404 patent and is directed to a spinal cord stimulation system that utilizes circuitry to monitor the voltage of the rechargeable battery and control the electrical

connection and disconnection between the rechargeable battery and an integrated circuit within the IPG housing.

40. Nevro has directly infringed, and continues to directly infringe, at least claim 7 of the '404 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 Senza Systems that include an (IPG) with an integrated circuit that is coupled to the rechargeable power source, a processor that is electrically coupled to the integrated circuit and controls stimulation based on the voltage of the rechargeable battery. The IPG further includes a power source protection circuitry that controls the electrical connection and disconnection between the rechargeable power source and the integrated circuit. The protection circuitry disconnects the rechargeable battery from the integrated circuit if the voltage of the rechargeable power source falls below a power disconnect level, and reconnects the rechargeable battery if the voltage of the rechargeable battery rises above a power reconnect level.

41. Boston Scientific, through its investigation of the Senza I System via publicly available information and an examination of the Senza IPG,¹¹ has determined that the Senza I System meets every element of at least claim 7 of the '404 patent, either literally or under the doctrine of equivalents. On information and belief, the Senza II System and Senza Omnia are

¹¹ Exemplary materials:

https://www.accessdata.fda.gov/cdrh_docs/pdf13/P130022a.pdf

http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130022b.pdf

http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130022c.pdf

http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130022d.pdf

Testing of a publicly available Senza I system, including IPG, leads, clinical programmer, and patient remote.

insubstantially different from the Senza I System and, like the Senza I System, meet all limitations of claim 7 of the '404 patent.

42. Claim 7 of the '404 patent recites “A spinal cord stimulation system.” As explained in the Claim Chart attached hereto as **Exhibit 1**, the Nevro Senza Systems are spinal cord stimulation systems. (Ex. 1 at 1.)

43. Claim 7 of the '404 patent also recites “an implantable pulse generator (IPG), the IPG having a housing.” As explained in the Claim Chart, the Nevro Senza Systems include an implantable pulse generator (IPG) with a hermetically sealed housing. (Ex. 1 at 1.)

44. Claim 7 of the '404 patent also recites “an implantable electrode array detachably connected to the IPG, the electrode array having at least two electrodes thereon.” As explained in the Claim Chart, the Nevro Senza Systems include at least one lead detachably connected to the IPG and the lead has at least two electrodes. (Ex. 1 at 2-4.)

45. Claim 7 of the '404 patent also recites “a rechargeable power source contained within the IPG housing.” As explained in the Claim Chart, the Nevro Senza Systems include a rechargeable battery contained within the IPG housing. (Ex. 1 at 4-5.)

46. Claim 7 of the '404 patent also recites “monitoring circuitry contained in the IPG housing that monitors the voltage of the rechargeable power source and any charging current flowing to the rechargeable power source.” As explained in the Claim Chart, the Nevro Senza Systems monitor the battery level of the IPG's rechargeable battery. (Ex. 1 at 5-13.)

47. Claim 7 of the '404 patent also recites “at least one integrated circuit (IC) within the IPG housing and electrically couplable to the rechargeable power source, said at least one IC, when coupled to the rechargeable power source, providing essential control functions that allow the IPG to operate.” As explained in the Claim Chart, the IPGs in Nevro Senza Systems include

at least one integrated circuit (IC) within the IPG housing connected to the rechargeable battery, which provides essential control functions that allow the IPG to operate. (Ex. 1 at 13-15.)

48. Claim 7 of the '404 patent also recites “a processor electrically coupled to the at least one IC and contained within the IPG housing which issues commands to stop all stimulation if the voltage of the rechargeable power source falls below a minimum level for stimulation.” As explained in the Claim Chart, the Nevro Senza Systems stop stimulation when the battery voltage drops below a predetermined minimum level. (Ex. 1 at 15-20.)

49. Claim 7 of the '404 patent also recites “power source protection circuitry within the IPG housing that controls electrical connection and disconnection between the rechargeable power source and the at least one IC, wherein the power source protection circuitry disconnects the rechargeable power source from the at least one IC if the voltage of the rechargeable power source falls below a power disconnect level, and reconnects the rechargeable power source and the at least one IC if the voltage of the rechargeable power source rises above a power reconnect level.” As explained in the Claim Chart, the Nevro Senza Systems' IPG contains power source protection circuitry within the IPG housing that disables the IPG when the battery level is too low and restarts the IPG when the battery level is recharged to a predetermined value. (Ex. 1 at 21-23.)

50. Claim 7 of the '404 patent also recites “wherein the processor initiates a power-on-reset if the voltage of the rechargeable power source rises above a reset threshold.” As explained in the Claim Chart, the Nevro Senza Systems' processor initiates a power-on-reset and restarts the IPG if the voltage of the rechargeable battery rises above a predetermined value.” (Ex. 1 at 23-24.)

51. Claim 7 of the '404 patent also recites “wherein the processor reinitiates stimulation if the voltage of the rechargeable power source rises above the minimum level for stimulation.” As explained in the Claim Chart, the Nevro Senza Systems reinitiate stimulation if the voltage of the rechargeable battery rises above predetermined value.” (Ex. 1 at 24-26.)

52. As described in the preceding paragraphs and in the attached Claim Chart, the Nevro Senza Systems embody each limitation of Claim 7 of the '404 patent.

53. Upon information and belief, Nevro has been aware of the '404 patent, or willfully blind to its existence, and Nevro knew, should have known, or was willfully blind to the fact that it was infringing the '404 patent, and that there was a high risk of infringement of the '404 patent about which Nevro knew or should have known, particularly in view of, for example, the stark similarities between Nevro's accused products and the claims of the '404 patent, of which Nevro knew or should have known as soon as it became aware of the '404 patent as alleged herein, as well as in view the claim charts provided to Nevro on December 18, 2019. Nevro's knowledge of infringement by the Senza Systems throughout the period of infringement is based on, but not limited to: (1) Nevro's monitoring and competitive intelligence of Boston Scientific, who is a direct competitor of Nevro; (2) any pre-suit investigation related to Boston Scientific's filing of two Petitions for *Inter Partes* Review of Nevro's U.S. Patent No. 8,359,102 in May 2015; (3) Nevro's participation in an FDA-monitored randomized controlled trial in a head-to-head comparison against Boston Scientific's Precision™ SCS System; and (4) the approximately 50 Nevro employees who were formerly employed by Boston Scientific, including employees who worked on Boston Scientific SCS product development and who were responsible for its neuromodulation patent portfolio, such as Kerry Bradley and James Thacker.

54. At a minimum, Nevro has been aware of the '404 patent, or willfully blind to its existence, since the service of the First Amended Complaint, and thus knew, should have known, or was willfully blind to the infringement of the '404 patent by the Nevro Senza Systems. Nevro's infringement has been ongoing. Indeed, after service of the First Amended Complaint, rather than take any steps to alter its products or cease its infringement, Nevro introduced the Senza Omnia, which, upon information and belief, is insubstantially different from the Senza I and Senza II infringing systems with respect to the subject matter of the '404 patent.

55. Nevro has, for example and without limitation, marketed, sold, and offered 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 materials¹² and videos.¹³ Nevro also instructs physicians, hospitals, other health care providers, and patients on

¹² 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>.

¹³ 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=LeLq1lvIJvs>;
<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;

how to use the Senza Systems by means of physician and patient manuals.¹⁴ 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 of or is willfully blind to the existence of the '404 patent, knows of or is willfully blind to the fact that Nevro infringes the '404 patent, at least because there was a high risk of infringement of the '404 patent about which Nevro knew or should have known, particularly in view of, for example, the stark similarities between Nevro's accused products (and/or the use of those products as instructed by Nevro as alleged above) and the claims of the '404 patent, of which Nevro knew or should have known as soon as it became aware of the '404 patent as alleged herein, as well as in view the claim charts provided to Nevro on December 18, 2019.

56. The foregoing actions by Nevro also constitute infringement of at least claim 7 of the '404 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, Nevro has exported the infringing SCS systems from the United States to at least Europe and Australia.

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

[https://www.youtube.com/watch?v=Ry8UJTzCfVw.](https://www.youtube.com/watch?v=Ry8UJTzCfVw)

¹⁴ Physician Manual: http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130022d.pdf; Patient Manual: http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130022c.pdf.

57. 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 7 of the '404 patent. Upon information and belief, Nevro, as detailed above, knows of or is willfully blind to the existence of the '404 patent, knows of or is willfully blind to the fact that it infringes the '404 patent, at least because there was a high risk of infringement of the '404 patent about which Nevro knew or should have known, particularly in view of, for example, the stark similarities between Nevro's accused products (and/or the use of those products as instructed by Nevro as alleged above) and the claims of the '404 patent, of which Nevro knew or should have known as soon as it became aware of the '404 patent as alleged herein, as well as in view the claim charts provided to Nevro on December 18, 2019. Moreover, as detailed above, Nevro's IPGs comprise a material part of the invention claimed in claim 7 of the '404 patent and, upon information and belief, Nevro knows that these components are especially made and/or especially adapted for use in infringing claim 7 of the '404 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.

58. The foregoing actions by Nevro also constitute infringement of at least claim 7 of the '404 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.

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 II: INFRINGEMENT OF U.S. PATENT NO. 8,682,447

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

61. The '447 patent, entitled "Apparatus and Method for Determining the Relative Position and Orientation of Neurostimulation Leads," is a valid, enforceable patent that was duly issued by the USPTO on March 25, 2014 in full compliance with Title 35 of the United States Code. A true and correct copy of the '447 patent is attached as **Exhibit 3**.

62. BSN is the assignee of the '447 patent with ownership of all substantial rights in the '447 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 '447 patent.

63. The claims of the '447 patent cover apparatuses and methods for determining and displaying the relative orientation of implanted leads in a user. Claim 1 is illustrative of the claims of the '447 patent and is directed to an apparatus for determining the relative position of implanted leads by conveying electrical stimulation energy from an IPG into the tissue of a patient and displaying the relative two-dimensional orientation of the leads.

64. Nevro has directly infringed, and continues to directly infringe, at least claim 1 of the '447 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 determine the relative position of implanted leads by conveying electrical

stimulation energy from the IPG into a patient's tissue and displaying the relative two-dimensional orientation of the leads.

65. Boston Scientific, through its investigation of the Senza I System via publicly available information and an examination of Nevro's IPG,¹⁵ has determined that the Senza I System meets every element of at least claim 1 of the '447 patent, either literally or under the doctrine of equivalents. On information and belief, the Senza II System and Senza Omnia are insubstantially different from the Senza I System and, like the Senza I System, meet all limitations of claim 1 of the '447 patent.

66. Claim 1 of the '447 patent recites "A method, comprising: determining, using circuitry, a relative two-dimensional orientation of first and second multiple-electrode leads implanted within a user." As explained in the attached Claim Chart, the Nevro Senza Systems determine the relative lead position of multipolar leads in a multi-lead configuration and display the relative two-dimensional orientation of the first and second multiple electrode leads. (Ex. 1 at 27-30.)

67. Claim 1 of the '447 patent also recites "conveying electrical stimulation energy from a pulse generator implanted within the user into tissue of the user via the first and second multiple-electrode leads." As explained in the attached Claim Chart, the Nevro Senza Systems

¹⁵ Exemplary materials:

https://www.accessdata.fda.gov/cdrh_docs/pdf13/P130022a.pdf

http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130022b.pdf

http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130022c.pdf

http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130022d.pdf

Testing of a publicly available Senza I system, including IPG, leads, clinical programmer, and patient remote.

determine the relative lead position by performing an “impedance check,” in which electrical stimulation energy is conveyed into the tissue of a patient. (Ex. 1 at 30-31.)

68. Claim 1 of the ’447 patent also recites “displaying the relative two-dimensional orientation of the first and second multiple-electrode leads.” As explained in the attached Claim Chart, the Nevro Senza Systems display the relative two-dimensional orientation of the first and second multiple electrode leads, as shown in the screenshot of the Senza System clinician programmer. (Ex. 1 at 31-33.)

69. As described in the preceding paragraphs and in the attached Claim Chart, each limitation of Claim 1 of the ’447 patent is performed by the Nevro Senza Systems.

70. Upon information and belief, Nevro has been aware of the ’447 patent, or willfully blind to its existence, and Nevro knew, should have known, or was willfully blind to the fact that it was infringing the ’447 patent, and that there was a high risk of infringement of the ’447 patent about which Nevro knew or should have known, particularly in view of, for example, the stark similarities between Nevro’s accused products and the claims of the ’447 patent, of which Nevro knew or should have known as soon as it became aware of the ’447 patent as alleged herein, as well as in view the claim charts provided to Nevro on December 18, 2019. Nevro’s knowledge of infringement by the Senza Systems throughout the period of infringement is based on, but not limited to: (1) Nevro’s monitoring and competitive intelligence of Boston Scientific, who is a direct competitor of Nevro; (2) any pre-suit investigation related to Boston Scientific’s filing of two Petitions for *Inter Partes* Review of Nevro’s U.S. Patent No. 8,359,102 in May 2015; (3) Nevro’s participation in an FDA-monitored randomized controlled trial in a head-to-head comparison against Boston Scientific’s Precision™ SCS System; and (4) the approximately 50 Nevro employees who were formerly employed by Boston Scientific,

including employees who worked on Boston Scientific SCS product development and who were responsible for its neuromodulation patent portfolio, such as Kerry Bradley and James Thacker, who are both named inventors of the '447 patent.

71. At a minimum, Nevro has been aware of the '447 patent, or willfully blind to its existence, since the service of the First Amended Complaint, and thus knew, should have known, or was willfully blind to the infringement of the '447 patent by the Nevro Senza Systems. Nevro's infringement has been ongoing. Indeed, after service of the First Amended Complaint, rather than take any steps to alter its products or cease its infringement, Nevro introduced the Senza Omnia, which, upon information and belief, is insubstantially different from the Senza I and Senza II infringing systems with respect to the subject matter of the '447 patent.

72. Nevro has, for example and without limitation, marketed, sold, and offered 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 materials¹⁶ and videos.¹⁷ Nevro also instructs physicians, hospitals, other health care providers, and patients on

¹⁶ 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>.

¹⁷ 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=LeLq1lvIJvs>;
<https://www.youtube.com/watch?v=-SLx9qwWXqs>;

how to use the Senza Systems by means of physician and patient manuals.¹⁸ 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 of or is willfully blind to the existence of the '447 patent, knows of or is willfully blind to the fact that it infringes the '447 patent, at least because there was a high risk of infringement of the '447 patent about which Nevro knew or should have known, particularly in view of, for example, the stark similarities between Nevro's accused products (and/or the use of those products as instructed by Nevro as alleged above) and the claims of the '447 patent, of which Nevro knew or should have known as soon as it became aware of the '447 patent as alleged herein, as well as in view the claim charts provided to Nevro on December 18, 2019.

73. The foregoing actions by Nevro also constitute infringement of at least claim 1 of the '447 patent in violation of 35 U.S.C. § 271(f)(1), wherein Nevro has supplied and/or caused

<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.](https://www.youtube.com/watch?v=Ry8UJTzCfVw)

¹⁸ Physician Manual: http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130022d.pdf; Patient Manual: http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130022c.pdf.

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

74. 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 '447 patent. Upon information and belief, Nevro, as detailed above, knows of or is willfully blind to the existence of the '447 patent, knows of or is willfully blind to the fact that it infringes the '447 patent, at least because there was a high risk of infringement of the '447 patent about which Nevro knew or should have known, particularly in view of, for example, the stark similarities between Nevro's accused products (and/or the use of those products as instructed by Nevro as alleged above) and the claims of the '447 patent, of which Nevro knew or should have known as soon as it became aware of the '447 patent as alleged herein, as well as in view the claim charts provided to Nevro on December 18, 2019. Moreover, as detailed above, Nevro's IPGs comprise a material part of the invention claimed in claim 10 of the '447 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 '447 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.

75. The foregoing actions by Nevro also constitute infringement of at least claim 1 of the '447 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.

76. 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. 6,993,384

77. Boston Scientific realleges paragraphs 1-76 above as if fully set forth herein.

78. The '384 patent, entitled "Apparatus and Method for Determining the Relative Position and Orientation of Neurostimulation Leads," is a valid, enforceable patent that was duly issued by the USPTO on January 31, 2006 in full compliance with Title 35 of the United States Code. A true and correct copy of the '384 patent is attached as **Exhibit 4**.

79. BSN is the assignee of the '384 patent with ownership of all substantial rights in the '384 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 '384 patent.

80. The claims of the '384 patent cover an apparatus and methods for determining the relative orientation of implanted leads by measuring impedance vectors between lead electrodes. Nevro infringes at least claim 1. Claim 1 is illustrative of the claims of the '384 patent and is directed to a method of determining relative position of implanted leads by conveying electrical stimulation energy from an IPG into the tissue of a patient and displaying the relative two-dimensional orientation of the leads.

81. Nevro has directly infringed, and continues to directly infringe, at least claim 1 of the '384 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 determines the relative position of implanted leads by measuring impedance vectors between electrodes and inferring the relative position of the lead by the relative minima and maxima of the impedance values.

82. Boston Scientific, through its investigation of the Senza I System via publicly available information and an examination of Nevro's IPG,¹⁹ has determined that the Senza I System meets every element of at least claim 1 of the '384 patent, either literally or under the doctrine of equivalents. On information and belief, the Senza II System and Senza Omnia are insubstantially different from the Senza I System and, like the Senza I System, meet all limitations of claim 1 of the '384 patent.

83. Claim 1 of the '384 patent recites "A method for determining the relative lead position of multipolar leads in a multi-lead configuration comprising measuring impedance vectors between electrodes, and inferring the relative position of the lead by the relative minima and maxima of the impedance values." As explained in the Claim Chart, the Nevro Senza Systems determine the relative lead position of multipolar leads in a multi-lead configuration by measuring impedance vectors between electrodes and inferring the relative position of the lead by the relative minima and maxima of the impedance. (Ex. 1 at 34-40.)

¹⁹ Exemplary materials:

https://www.accessdata.fda.gov/cdrh_docs/pdf13/P130022a.pdf

http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130022b.pdf

http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130022c.pdf

http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130022d.pdf

Testing of a publicly available Senza I system, including IPG, leads, clinical programmer, and patient remote.

84. As described in the preceding paragraphs and in the attached Claim Chart, each limitation of Claim 1 of the '384 patent is performed by the Nevro Senza Systems.

85. Upon information and belief, Nevro has been aware of the '384 patent, or willfully blind to its existence, and Nevro knew, should have known, or was willfully blind to the fact that it was infringing the '384 patent, and that there was a high risk of infringement of the '384 patent about which Nevro knew or should have known, particularly in view of, for example, the stark similarities between Nevro's accused products and the claims of the '384 patent, of which Nevro knew or should have known as soon as it became aware of the '384 patent as alleged herein, as well as in view the claim charts provided to Nevro on December 18, 2019. Nevro's knowledge of infringement by the Senza Systems throughout the period of infringement is based on, but not limited to: (1) Nevro's monitoring and competitive intelligence of Boston Scientific, who is a direct competitor of Nevro; (2) any pre-suit investigation related to Boston Scientific's filing of two Petitions for *Inter Partes* Review of Nevro's U.S. Patent No. 8,359,102 in May 2015; (3) Nevro's participation in an FDA-monitored randomized controlled trial in a head-to-head comparison against Boston Scientific's Precision™ SCS System; and (4) the approximately 50 Nevro employees who were formerly employed by Boston Scientific, including employees who worked on Boston Scientific SCS product development and who were responsible for its neuromodulation patent portfolio, such as James Thacker, who is a listed inventor of the '384 patent, and Kerry Bradley.

86. At a minimum, Nevro has been aware of the '384 patent, or willfully blind to its existence, since the service of the First Amended Complaint, and thus knew, should have known, or was willfully blind to the infringement of the '384 patent by the Nevro Senza Systems. Nevro's infringement has been ongoing. Indeed, after service of the First Amended Complaint,

rather than take any steps to alter its products or cease its infringement, Nevro introduced the Senza Omnia, which, upon information and belief, is insubstantially different from the Senza I and Senza II infringing systems with respect to the subject matter of the '384 patent.

87. Nevro has, for example and without limitation, marketed, sold, and offered 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 materials²⁰ and videos.²¹ 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.²² Upon information and belief, Nevro also has a clinical engineer, sales representative, therapy consultant, therapy

²⁰ 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>.

²¹ 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=LeLq1lv1Jvs>;
<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>.

²² Physician Manual: http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130022d.pdf; Patient Manual: http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130022c.pdf.

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 of or is willfully blind to the existence of the '384 patent, knows of or is willfully blind to the fact that it infringes the '384 patent, at least because there was a high risk of infringement of the '384 patent about which Nevro knew or should have known, particularly in view of, for example, the stark similarities between Nevro's accused products (and/or the use of those products as instructed by Nevro as alleged above) and the claims of the '384 patent, of which Nevro knew or should have known as soon as it became aware of the '384 patent as alleged herein, as well as in view the claim charts provided to Nevro on December 18, 2019.

88. The foregoing actions by Nevro also constitute infringement of at least claim 1 of the '384 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, Nevro has exported the infringing SCS systems from the United States to at least Europe and Australia.

89. 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 '384 patent. Upon information and belief, Nevro, as detailed above, knows of or is willfully

blind to the existence of the '384 patent, knows of or is willfully blind to the fact that it infringes the '384 patent, at least because there was a high risk of infringement of the '384 patent about which Nevro knew or should have known, particularly in view of, for example, the stark similarities between Nevro's accused products (and/or the use of those products as instructed by Nevro as alleged above) and the claims of the '384 patent, of which Nevro knew or should have known as soon as it became aware of the '384 patent as alleged herein, as well as in view the claim charts provided to Nevro on December 18, 2019. Moreover, as detailed above, Nevro's IPGs comprise a material part of the invention claimed in claim 1 of the '384 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 '384 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.

90. The foregoing actions by Nevro also constitute infringement of at least claim 1 of the '384 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.

91. 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. 7,853,330

92. Boston Scientific realleges paragraphs 1-91 above as if fully set forth herein.

93. The '330 patent, entitled "Apparatus and Method for Determining the Relative Position and Orientation of Neurostimulation Leads," is a valid, enforceable patent that was duly issued by the USPTO on December 14, 2010 in full compliance with Title 35 of the United States Code. A true and correct copy of the '330 patent is attached as **Exhibit 5**.

94. BSN is the assignee of the '330 patent with ownership of all substantial rights in the '330 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 '330 patent.

95. The claims of the '330 patent cover methods for determining the relative orientation of implanted leads by measuring impedances and field potentials of lead electrodes. Claim 1 is illustrative of the claims of the '330 patent and is directed to a method of determining relative position of implanted leads by measuring a monopolar and bipolar electrical impedance to determine amplitude of a field potential and using the measured field potential to determine the relative positions of implanted leads.

96. Nevro has directly infringed, and continues to directly infringe, at least claim 1 of the '330 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 determines the relative position of implanted leads by measuring impedance vectors between electrodes and inferring the relative position of the lead by the relative minima and maxima of the impedance values.

97. Boston Scientific, through its investigation of the Senza I System via publicly available information and an examination of Nevro's IPG,²³ has determined that the Senza I System meets every element of at least claim 1 of the '330 patent, either literally or under the doctrine of equivalents. On information and belief, the Senza II System and Senza Omnia are insubstantially different from the Senza I system and, like the Senza I System, meet all limitations of claim 1 of the '330 patent.

98. Claim 1 of the '330 patent recites "A method of performing a medical procedure using a plurality of electrodes implanted within a patient, comprising." As explained in the Claim Chart, the Nevro Senza Systems practice a method of performing a medical procedure using a plurality of electrodes implanted within a patient. The Nevro Senza Systems include an implantable pulse generator (IPG) that delivers stimulation to a patient using implantable leads. (Ex. 1 at 41-42.)

99. Claim 1 of the '330 patent also recites "measuring a first monopolar electrical impedance between a first one of the electrodes and a return or reference electrode; measuring a second monopolar electrical impedance between each of at least one of the electrodes and the return or reference electrode measuring a bipolar electrical impedance between the first one of the electrodes and each of the at least one electrode." As explained in the Claim Chart, the

²³ Exemplary materials:

https://www.accessdata.fda.gov/cdrh_docs/pdf13/P130022a.pdf

http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130022b.pdf

http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130022c.pdf

http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130022d.pdf

Testing of a publicly available Senza I system, including IPG, leads, clinical programmer, and patient remote.

Nevro Senza Systems measure impedance to determine relative positions of implanted leads. (Ex. 1 at 42-46.)

100. Claim 1 of the '330 patent also recites “determining the amplitude of a field potential at each of at least one of the electrodes based on the measured first monopolar electrical impedance, each of the second monopolar electrical impedances, and each of the measured bipolar electrical impedances; and determining the relative positions of the electrodes based on each of the determined field potential amplitudes.” As explained in the Claim Chart, the Nevro Senza Systems determine the amplitude of a field potential at each of at least one of the electrodes based on the measured first monopolar electrical impedance, each of the second monopolar electrical impedances, and each of the measured bipolar electrical impedances. The Nevro Senza Systems also determine the relative positions of the electrodes based on each of the determined field potential amplitudes. (Ex. 1 at 46-50.)

101. As described in the preceding paragraphs and in the attached Claim Chart, each limitation of Claim 1 of the '330 patent is performed by the Nevro Senza Systems.

102. Upon information and belief, Nevro has been aware of the '330 patent, or willfully blind to its existence, and Nevro knew, should have known, or was willfully blind to the fact that it was infringing the '330 patent, and that there was a high risk of infringement of the '330 patent about which Nevro knew or should have known, particularly in view of, for example, the stark similarities between Nevro's accused products and the claims of the '330 patent, of which Nevro knew or should have known as soon as it became aware of the '330 patent as alleged herein, as well as in view the claim charts provided to Nevro on December 18, 2019. Nevro's knowledge of infringement by the Senza Systems throughout the period of infringement is based on, but not limited to: (1) Nevro's monitoring and competitive intelligence of Boston

Scientific, who is a direct competitor of Nevro; (2) any pre-suit investigation related to Boston Scientific's filing of two Petitions for *Inter Partes* Review of Nevro's U.S. Patent No. 8,359,102 in May 2015; (3) Nevro's participation in an FDA-monitored randomized controlled trial in a head-to-head comparison against Boston Scientific's Precision™ SCS System; and (4) the approximately 50 Nevro employees who were formerly employed by Boston Scientific, including employees who worked on Boston Scientific SCS product development and who were responsible for its neuromodulation patent portfolio, such as Kerry Bradley and James Thacker.

103. At a minimum, Nevro has been aware of the '330 patent, or willfully blind to its existence, since the service of the First Amended Complaint, and thus knew, should have known, or was willfully blind to the infringement of the '330 patent by the Nevro Senza Systems. Nevro's infringement has been ongoing. Indeed, after service of the First Amended Complaint, rather than take any steps to alter its products or cease its infringement, Nevro introduced the Senza Omnia, which, upon information and belief, is insubstantially different from the Senza I and Senza II infringing systems with respect to the subject matter of the '330 patent.

104. Nevro has, for example and without limitation, marketed, sold, and offered 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 materials²⁴ and

²⁴ 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>.

videos.²⁵ 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.²⁶ 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 of or is willfully blind to the existence of the '330 patent, knows of or is willfully blind to the fact that it infringes the '330 patent, at least because there was a high risk of infringement of the '330 patent about which Nevro knew or should have known, particularly in view of, for example, the stark similarities between Nevro's accused products (and/or the use of those products as instructed by Nevro as alleged above) and the

²⁵ 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=LeLq1lv1Jvs>;
<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>.

²⁶ Physician Manual: http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130022d.pdf; Patient Manual: http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130022c.pdf.

claims of the '330 patent, of which Nevro knew or should have known as soon as it became aware of the '330 patent as alleged herein, as well as in view the claim charts provided to Nevro on December 18, 2019.

105. 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 '330 patent. Upon information and belief, Nevro, as detailed above, knows of or is willfully blind to the existence of the '330 patent, knows of or is willfully blind to the fact that it infringes the '330 patent, at least because there was a high risk of infringement of the '330 patent about which Nevro knew or should have known, particularly in view of, for example, the stark similarities between Nevro's accused products (and/or the use of those products as instructed by Nevro as alleged above) and the claims of the '330 patent, of which Nevro knew or should have known as soon as it became aware of the '330 patent as alleged herein, as well as in view the claim charts provided to Nevro on December 18, 2019. Moreover, as detailed above, Nevro's IPGs comprise a material part of the invention claimed in claim 1 of the '330 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 '330 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.

106. 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 V: INFRINGEMENT OF U.S. PATENT NO. 7,822,480

107. Boston Scientific realleges paragraphs 1-106 above as if fully set forth herein.

108. The '480 patent, entitled "Apparatus and Method for Determining the Relative Position and Orientation of Neurostimulation Leads," is a valid, enforceable patent that was duly issued by the USPTO on October 26, 2010 in full compliance with Title 35 of the United States Code. A true and correct copy of the '480 patent is attached as **Exhibit 6**.

109. BSN is the assignee of the '480 patent with ownership of all substantial rights in the '480 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 '480 patent.

110. The claims of the '480 patent cover a system that transmits a uniquely modulated signal with On-Off Keying (OOK) from an external device to an implantable medical device. Claim 2 is directed to a system including an external device with circuitry configured to send a signal modulated with a unique OOK modulation technique for transmission of control data to an implanted device using a coil. The system also includes an implantable device to receive the OOK signal. The modulated signal comprises logic '0' bits of a first pulse width and logic '1' bits of a second pulse width different from the first pulse width, where each bit further comprises either an ON state with a signal that varies with a first frequency or an OFF state and the transition between adjacent bits in the first signal is marked by a change in the first modulated signal between the ON and OFF states. The external device of Claim 2 includes a second modulation circuitry for producing from second data a second signal modulated with frequency

modulation. The system of Claim 2 also has second receiver in the implanted device to receive the frequency modulated signal.

111. Nevro has directly infringed, and continues to directly infringe, at least claim 2 of the '480 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 transmit control data using the unique modulate signal of claim 2 of the '480 patent.

112. Boston Scientific, through its investigation of the Senza I System via publicly available information and an examination of Nevro's IPG,²⁷ has determined that the Senza I System meets every element of at least claim 2 of the '480 patent, either literally or under the doctrine of equivalents. On information and belief, the Senza II System and Senza Omnia are insubstantially different from the Senza I System and, like the Senza I System, meet all limitations of claim 1 of the '480 patent.

113. Claim 1 of the '480 patent recites "A system, comprising: an external device, comprising." As explained in the Claim Chart, the Nevro Senza Systems include an external charger. (Ex. 1 at 51-53.)

114. Claim 1 of the '480 patent also recites "first modulation circuitry for producing from first data a first signal modulated with on-off keying (OOK) modulation, wherein the first

²⁷ Exemplary materials:

https://www.accessdata.fda.gov/cdrh_docs/pdf13/P130022a.pdf

http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130022b.pdf

http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130022c.pdf

http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130022d.pdf

Testing of a publicly available Senza I system, including IPG, leads, clinical programmer, and patient remote.

modulated signal comprises logic ‘0’ bits of a first pulse width and logic ‘1’ bits of a second pulse width different from the first pulse width.” As explained in the Claim Chart, the Nevro Senza Systems’ external charger uses OOK modulation with a logic “0” having a pulse width different than a logic “1.” (Ex. 1 at 53-55.)

115. Claim 1 of the ’480 patent also recites “wherein each bit further comprises either an ON state with a signal that varies with a first frequency or an OFF state, wherein a transition between adjacent bits in the first signal is marked by a change in the first modulated signal between the ON and OFF states.” As explained in the Claim Chart, the logic bits transmitted by OOK from Nevro Senza Systems’ external charger have ON and OFF states, where a transition between adjacent bits is marked by a change in the ON and OFF states. (Ex. 1 at 55-57.)

116. Claim 1 of the ’480 patent also recites “a coil configured to wirelessly transmit the first modulated signal to the implantable medical device.” As explained in the Claim Chart, Nevro Senza Systems’ external charger includes a coil. (Ex. 1 at 57-61.)

117. Claim 1 of the ’480 patent also recites “an implantable medical device, comprising a first telemetry receiver in the implantable medical device for demodulating the first modulated signal to recover the first data.” As explained in the Claim Chart, Nevro Senza Systems include an implantable pulse generator (IPG) that contains a telemetry receiver for demodulating the first modulated signal (OOK modulated signal). (Ex. 1 at 61-62.)

118. Claim 2 of the ’480 patent recites “The system of claim 1, further comprising: second modulation circuitry in the external device for producing from second data a second signal modulated with frequency modulation.” As explained in the Claim Chart, the Nevro Senza Systems include an external patient remote and/or an external clinician programmer with

programmer wand (*i.e.*, coil), each with a second modulation circuitry that modulates telemetry using FSK frequency modulation. (Ex. 1 at 62-64.)

119. Claim 2 of the '480 patent also recites “wherein the coil is further configured to wirelessly transmit the second modulated signal to the implantable medical device.” As explained in the Claim Chart, the Nevro Senza Systems include an external patient remote with an internal coil and/or an external clinician programmer with programmer wand (*i.e.*, coil) that transmit the FSK frequency modulation signal to the IPG. (Ex. 1 at 64.)

120. Claim 2 of the '480 patent also recites “a second telemetry receiver in the implantable medical device for demodulating the second modulated signal to recover the second data.” As explained in the Claim Chart, the Nevro Senza Systems include an IPG, which is an implantable medical device that contains a telemetry receiver for demodulating the second modulated signal (FSK frequency modulation) to recover the second data. (Ex. 1 at 64-65.)

121. As described in the preceding paragraphs and in the attached Claim Chart, each limitation of Claim 2 of the '480 patent is performed by the Nevro Senza Systems.

122. Upon information and belief, Nevro has been aware of the '480 patent, or willfully blind to its existence, and Nevro knew, should have known, or was willfully blind to the fact that it was infringing the '480 patent, and that there was a high risk of infringement of the '480 patent about which Nevro knew or should have known, particularly in view of, for example, the stark similarities between Nevro's accused products and the claims of the '480 patent, of which Nevro knew or should have known as soon as it became aware of the '480 patent as alleged herein, as well as in view the claim charts provided to Nevro on December 18, 2019. Nevro's knowledge of infringement by the Senza Systems throughout the period of infringement is based on, but not limited to: (1) Nevro's monitoring and competitive intelligence of Boston

Scientific, who is a direct competitor of Nevro; (2) any pre-suit investigation related to Boston Scientific's filing of two Petitions for *Inter Partes* Review of Nevro's U.S. Patent No. 8,359,102 in May 2015; (3) Nevro's participation in an FDA-monitored randomized controlled trial in a head-to-head comparison against Boston Scientific's Precision™ SCS System; and (4) the approximately 50 Nevro employees who were formerly employed by Boston Scientific, including employees who worked on Boston Scientific SCS product development and who were responsible for its neuromodulation patent portfolio, such as Kerry Bradley and James Thacker.

123. At a minimum, Nevro has been aware of the '480 patent, or willfully blind to its existence, since the service of the First Amended Complaint, and thus knew, should have known, or was willfully blind to the infringement of the '480 patent by the Nevro Senza Systems. Nevro's infringement has been ongoing. Indeed, after service of the First Amended Complaint, rather than take any steps to alter its products or cease its infringement, Nevro introduced the Senza Omnia, which, upon information and belief, is insubstantially different from the Senza I and Senza II infringing systems with respect to the subject matter of the '480 patent.

124. Nevro has, for example and without limitation, marketed, sold, and offered 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 materials²⁸ and

²⁸ 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>.

videos.²⁹ 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.³⁰ 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 of or is willfully blind to the existence of the '480 patent, knows of or is willfully blind to the fact that it infringes the '480 patent, at least because there was a high risk of infringement of the '480 patent about which Nevro knew or should have known, particularly in view of, for example, the stark similarities between Nevro's accused products (and/or the use of those products as instructed by Nevro as alleged above) and the claims of the '480 patent, of which Nevro knew or should have known as soon as it became

²⁹ 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=LeLq1lvIJvs;>
<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.](https://www.youtube.com/watch?v=Ry8UJTzCfVw)

³⁰ Physician Manual: http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130022d.pdf; Patient Manual: http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130022c.pdf.

aware of the '480 patent as alleged herein, as well as in view the claim charts provided to Nevro on December 18, 2019.

125. The foregoing actions by Nevro also constitute infringement of at least claim 2 of the '480 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, Nevro has exported the infringing SCS systems from the United States to at least Europe and Australia.

126. 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 2 of the '480 patent. Upon information and belief, Nevro, as detailed above, knows of or is willfully blind to the existence of the '480 patent, knows of or is willfully blind to the fact that it infringes the '480 patent, at least because there was a high risk of infringement of the '480 patent about which Nevro knew or should have known, particularly in view of, for example, the stark similarities between Nevro's accused products (and/or the use of those products as instructed by Nevro as alleged above) and the claims of the '480 patent, of which Nevro knew or should have known as soon as it became aware of the '480 patent as alleged herein, as well as in view the claim charts provided to Nevro on December 18, 2019. Moreover, as detailed above, Nevro's IPGs comprise a material part of the invention claimed in claim 2 of the '480 patent and, upon information and belief, Nevro knows that these components are especially made and/or especially adapted for use in infringing claim 2 of the '480 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.

127. The foregoing actions by Nevro also constitute infringement of at least claim 2 of the '480 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.

128. 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 VI: INFRINGEMENT OF U.S. PATENT NO. 6,381,496

129. Boston Scientific realleges paragraphs 1-128 above as if fully set forth herein.

130. The '496 patent, entitled "Parameter Context Switching for an Implanted Device," is a valid, enforceable patent that was duly issued by the USPTO on April 30, 2002 in full compliance with Title 35 of the United States Code. A true and correct copy of the '496 patent is attached as **Exhibit 7**.

131. BSN is the assignee of the '496 patent with ownership of all substantial rights in the '496 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 '496 patent.

132. The claims of the '496 patent cover systems, methods, and devices that provides context switching that allows a user to change operational parameters with another set of operational parameters. Claim 1 is illustrative of the claims of the '496 patent and is directed to

an implantable device with electronic circuitry that includes a control register for storing a control set of operational parameters that can be changed through the selection of a different set of operational parameters.

133. Nevro has directly infringed, and continues to directly infringe, at least claim 1 of the '496 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 provides context switching as disclosed in claim 1 of the '496 patent.

134. Boston Scientific, through its investigation of the Senza I System via publicly available information and an examination of Nevro's IPG,³¹ has determined that the Senza I System meets every element of at least claim 1 of the '496 patent, either literally or under the doctrine of equivalents. On information and belief, the Senza II System and Senza Omnia are insubstantially different from the Senza I System and, like the Senza I System, meet all limitations of claim 1 of the '496 patent.

135. Claim 1 of the '496 patent recites "An implant device comprising: an implantable case." As explained in the Claim Chart, the Nevro Senza Systems include implantable medical devices having a hermetically sealed housing, which is implanted case. (Ex. 1 at 66.)

136. Claim 1 of the '496 patent also recites "electronic circuitry housed within said implantable case for performing a prescribed function, the electronic circuitry including: a

³¹ Exemplary materials:

https://www.accessdata.fda.gov/cdrh_docs/pdf13/P130022a.pdf

http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130022b.pdf

http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130022c.pdf

http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130022d.pdf

Testing of a publicly available Senza I system, including IPG, leads, clinical programmer, and patient remote.

control register wherein a control set of operational parameters is stored, a controller that controls the operation of the implant device as a function of the control set of operational parameters stored in the control register.” As explained in the Claim Chart, the Nevro Senza Systems include implantable medical devices, which contain electronic circuitry housed within their implantable cases for performing prescribed functions, including controlling the operation of the IPG as a function of a control register storing a set of operational parameters. (Ex. 1 at 66-67).

137. Claim 1 of the ’496 patent also recites “a plurality of sets of operational parameters.” As explained in the Claim Chart, the Nevro Senza Systems include implantable medical devices that contain a plurality of sets of operational parameters called “stimulation programs.” (Ex. 1 at 67-69.)

138. Claim 1 of the ’496 patent also recites “selection means for selecting one of the plurality of sets of operational parameters as the control set of operational parameters that is stored in the control register; whereby the operation of the implant device may be changed through selection of a different set of operational parameters.” As explained in the Claim Chart, the Nevro Senza Systems contain a program button that is used to transmit commands to change programs, or operational parameters. Selection of different set of operational parameters changes the operation of the implanted device. (Ex. 1 at 69-73.)

139. As described in the preceding paragraphs and in the attached Claim Chart, each limitation of Claim 1 of the ’496 patent is performed by the Nevro Senza Systems.

140. Upon information and belief, Nevro has been aware of the ’496 patent, or willfully blind to its existence, and Nevro knew, should have known, or was willfully blind to the fact that it was infringing the ’496 patent, and that there was a high risk of infringement of the

'496 patent about which Nevro knew or should have known, particularly in view of, for example, the stark similarities between Nevro's accused products and the claims of the '496 patent, of which Nevro knew or should have known as soon as it became aware of the '496 patent as alleged herein, as well as in view the claim charts provided to Nevro on December 18, 2019. Nevro's knowledge of infringement by the Senza Systems throughout the period of infringement is based on, but not limited to: (1) Nevro's monitoring and competitive intelligence of Boston Scientific, who is a direct competitor of Nevro; (2) any pre-suit investigation related to Boston Scientific's filing of two Petitions for *Inter Partes* Review of Nevro's U.S. Patent No. 8,359,102 in May 2015; (3) Nevro's participation in an FDA-monitored randomized controlled trial in a head-to-head comparison against Boston Scientific's Precision™ SCS System; and (4) the approximately 50 Nevro employees who were formerly employed by Boston Scientific, including employees who worked on Boston Scientific SCS product development and who were responsible for its neuromodulation patent portfolio, such as Kerry Bradley and James Thacker.

141. At a minimum, Nevro has been aware of the '496 patent, or willfully blind to its existence, since the service of the First Amended Complaint, and thus knew, should have known, or was willfully blind to the infringement of the '496 patent by the Nevro Senza Systems. Nevro's infringement has been ongoing. Indeed, after service of the First Amended Complaint, rather than take any steps to alter its products or cease its infringement, Nevro introduced the Senza Omnia, which, upon information and belief, is insubstantially different from the Senza I and Senza II infringing systems with respect to the subject matter of the '496 patent.

142. Nevro has, for example and without limitation, marketed, sold, and offered 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 materials³² and videos.³³ 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.³⁴ 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 of or is willfully blind to the existence of the '496 patent,

³² 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>.

³³ 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=LeLq1lv1Jvs>;
<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=kQHf1fS0ik>;
https://www.youtube.com/watch?v=V4RX_2W4OMk;
<https://www.youtube.com/watch?v=fr08-nZy-cY>;
<https://www.youtube.com/watch?v=Ry8UJTzCfVw>.

³⁴ Physician Manual: http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130022d.pdf; Patient Manual: http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130022c.pdf.

knows of or is willfully blind to the fact that it infringes the '496 patent, at least because there was a high risk of infringement of the '496 patent about which Nevro knew or should have known, particularly in view of, for example, the stark similarities between Nevro's accused products (and/or the use of those products as instructed by Nevro as alleged above) and the claims of the '496 patent, of which Nevro knew or should have known as soon as it became aware of the '496 patent as alleged herein, as well as in view the claim charts provided to Nevro on December 18, 2019.

143. The foregoing actions by Nevro also constitute infringement of at least claim 1 of the '496 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, Nevro has exported the infringing SCS systems from the United States to at least Europe and Australia.

144. 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 '496 patent. Upon information and belief, Nevro, as detailed above, knows of or is willfully blind to the existence of the '496 patent, knows of or is willfully blind to the fact that it infringes the '496 patent, at least because there was a high risk of infringement of the '496 patent about which Nevro knew or should have known, particularly in view of, for example, the stark similarities between Nevro's accused products (and/or the use of those products as instructed by Nevro as alleged above) and the claims of the '496 patent, of which Nevro knew or should have known as soon as it became aware of the '496 patent as alleged herein, as well as in view the

claim charts provided to Nevro on December 18, 2019. Moreover, as detailed above, Nevro's IPGs comprise a material part of the invention claimed in claim 1 of the '496 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 '496 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.

145. The foregoing actions by Nevro also constitute infringement of at least claim 1 of the '496 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.

146. 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 VII: INFRINGEMENT OF U.S. PATENT NO. 7,177,690

147. Boston Scientific realleges paragraphs 1-146 above as if fully set forth herein.

148. 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 8**.

149. 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.

150. 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 indicator for indicating the status of the replenishable power source.

151. 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.

152. 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 investigation of the Senza Systems via publicly available information and an examination of Nevro's Senza I

System,³⁵ 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 and Senza Omnia are insubstantially different from the Senza I System and, like the Senza I System, meet all limitations of claim 1 of the '690 patent.

153. Claim 1 of the '690 patent recites “An implantable medical device system having a replenishable power source comprising.” As explained in the Claim Chart, the Nevro Senza Systems include implantable medical devices with rechargeable batteries. (Ex. 1 at 74.)

154. Claim 1 of the '690 patent also recites “an implantable medical device, the device having a housing which contains processing circuitry.” As explained in the Claim Chart, the Nevro Senza Systems' IPGs have a hermetically sealed housing which contains processing circuitry. (Ex. 1 at 74-75.)

155. Claim 1 of the '690 patent also recites “an external programmer that may be placed in telecommunicative contact with the implantable medical device.” As explained in the Claim Chart, the Nevro Senza Systems include external programmers in the form of a Clinician Programmer and Patient Remote, both of which may be placed in telecommunicative contact, *i.e.*, communicate by telemetry, with the IPG. (Ex. 1 at 75-76.)

156. Claim 1 of the '690 patent also recites “means for recording battery charging information, which may be recalled later.” As explained in the Claim Chart, the Nevro Senza Systems' IPGs contain processing circuitry which contains a means for recording battery

³⁵ Exemplary materials:

https://www.accessdata.fda.gov/cdrh_docs/pdf13/P130022a.pdf

http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130022b.pdf

http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130022c.pdf

http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130022d.pdf

Testing of a publicly available Senza I system, including IPG, leads, clinical programmer, and patient remote.

charging information which may be recalled later. Nevro Senza Systems' external programmers receive the recorded battery charging information and display it, at least in a device history report. (Ex. 1 at 76-80.)

157. Claim 1 of the '690 patent also recites "wherein the external programmer includes a status indicator for indicating the status of the replenishable power source within the implantable medical device." As explained in the Claim Chart, the Nevro Senza Systems includes an external programmer with a status indicator for indicating the status of the replenishable power source within the implantable medical device. (Ex. 1 at 81-84.)

158. As described in the preceding paragraphs and in the attached Claim Chart, each limitation of Claim 1 of the '690 patent is performed by the Nevro Senza Systems.

159. Upon information and belief, Nevro has been aware of the '690 patent, or willfully blind to its existence, and Nevro knew, should have known, or was willfully blind to the fact that it was infringing the '690 patent, and that there was a high risk of infringement of the '690 patent about which Nevro knew or should have known, particularly in view of, for example, the stark similarities between Nevro's accused products and the claims of the '690 patent, of which Nevro knew or should have known as soon as it became aware of the '690 patent as alleged herein, as well as in view the claim charts provided to Nevro on December 18, 2019. Nevro's knowledge of infringement by the Senza Systems throughout the period of infringement is based on, but not limited to: (1) Nevro's monitoring and competitive intelligence of Boston Scientific, who is a direct competitor of Nevro; (2) any pre-suit investigation related to Boston Scientific's filing of two Petitions for *Inter Partes* Review of Nevro's U.S. Patent No. 8,359,102 in May 2015; (3) Nevro's participation in an FDA-monitored randomized controlled trial in a head-to-head comparison against Boston Scientific's Precision™ SCS System; and (4) the

approximately 50 Nevro employees who were formerly employed by Boston Scientific, including employees who worked on Boston Scientific SCS product development and who were responsible for its neuromodulation patent portfolio, such as James Thacker, who is a listed inventor on the '690 patent, and Kerry Bradley.

160. At a minimum, Nevro has been aware of the '690 patent, or willfully blind to its existence, since the service of the First Amended Complaint, and thus knew, should have known, or was willfully blind to the infringement of the '690 patent by the Nevro Senza Systems. Nevro's infringement has been ongoing. Indeed, after service of the First Amended Complaint, rather than take any steps to alter its products or cease its infringement, Nevro introduced the Senza Omnia, which, upon information and belief, is insubstantially different from the Senza I and Senza II infringing systems with respect to the subject matter of the '690 patent.

161. Nevro has, for example and without limitation, marketed, sold, and offered 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 materials³⁶ and videos.³⁷ Nevro also instructs physicians, hospitals, other health care providers, and patients on

³⁶ 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>.

³⁷ 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>;

how to use the Senza Systems by means of physician and patient manuals.³⁸ 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 of or is willfully blind to the existence of the '690 patent, knows of or is willfully blind to the fact that it infringes the '690 patent, at least because there was a high risk of infringement of the '690 patent about which Nevro knew or should have known, particularly in view of, for example, the stark similarities between Nevro's accused products (and/or the use of those products as instructed by Nevro as alleged above) and the claims of the '690 patent, of which Nevro knew or should have known as soon as it became aware of the '690 patent as alleged herein, as well as in view the claim charts provided to Nevro on December 18, 2019.

<https://www.youtube.com/watch?v=LeLq1lv1Jvs>;
<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>.

³⁸ Physician Manual: http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130022d.pdf; Patient Manual: http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130022c.pdf.

162. 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.

163. 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 of or is willfully blind to the existence of the '690 patent, knows of or is willfully blind to the fact that it infringes the '690 patent, at least because there was a high risk of infringement of the '690 patent about which Nevro knew or should have known, particularly in view of, for example, the stark similarities between Nevro's accused products (and/or the use of those products as instructed by Nevro as alleged above) and the claims of the '690 patent, of which Nevro knew or should have known as soon as it became aware of the '690 patent as alleged herein, as well as in view the claim charts provided to Nevro on December 18, 2019. 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. 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.

164. 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.

165. 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 VIII: INFRINGEMENT OF U.S. PATENT NO. 9,162,071

166. Boston Scientific realleges paragraphs 1-165 above as if fully set forth herein.

167. The '071 patent, entitled "Method for controlling telemetry in an implantable medical device based on power source capacity," is a valid, enforceable patent that was duly issued by the USPTO on October 20, 2015 in full compliance with Title 35 of the United States Code. A true and correct copy of the '071 patent is attached as **Exhibit 9**.

168. BSN is the assignee of the '071 patent with ownership of all substantial rights in the '071 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 '071 patent.

169. The claims of the '071 patent cover methods for controlling an implantable medical device. Claim 1 is illustrative of the claims of the '071 patent and is directed to a method for controlling an implantable medical device having telemetry circuitry to receive both a first type of telemetry and to receive a second type of telemetry comprising listening for the

first and second telemetry types and monitoring a voltage of a power source within the implantable medical device. If the voltage falls below the first threshold, the implantable medical device discontinues listening for the first type of telemetry but continues to listen for the second type of telemetry.

170. Nevro has directly infringed, and continues to directly infringe, at least claim 1 of the '071 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 transmit control data using the unique modulate signal of claim 1 of the '071 patent.

171. Boston Scientific, through its investigation of the Senza I System via publicly available information and an examination of Nevro's IPG,³⁹ has determined that the Senza I System meets every element of at least claim 1 of the '071 patent, either literally or under the doctrine of equivalents. On information and belief, the Senza II System and Senza Omnia are insubstantially different from the Senza I System and, like the Senza I System, meet all limitations of claim 1 of the '071 patent.

172. Claim 1 of the '071 patent recites "A method for controlling an implantable medical device, the device having telemetry circuitry to receive both a first type of telemetry and to receive a second type of telemetry, the method comprising." As explained in the Claim Chart,

³⁹ Exemplary materials:

https://www.accessdata.fda.gov/cdrh_docs/pdf13/P130022a.pdf

http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130022b.pdf

http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130022c.pdf

http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130022d.pdf

Testing of a publicly available Senza I system, including IPG, leads, clinical programmer, and patient remote.

the Nevro Senza Systems include implantable pulse generators (IPGs) that include telemetry circuitry to receive both a first type of telemetry (FSK frequency modulated) and to receive a second type of telemetry (OOK modulated). (Ex. 1 at 85-89.)

173. Claim 1 of the '071 patent also recites “listening for the first and second telemetry types.” As explained in the Claim Chart, the Nevro Senza Systems include IPGs that listen for the FSK frequency modulated telemetry (*i.e.*, first telemetry type) when the battery is charged above a certain threshold. (Ex. 1 at 89.)

174. Claim 1 of the '071 patent also recites “monitoring a voltage of a power source within the implantable medical device.” As explained in the Claim Chart, the Nevro Senza Systems include IPGs that monitor the battery level of the IPG’s rechargeable battery (*i.e.*, “monitoring a voltage of a power source”). (Ex. 1 at 89-92.)

175. Claim 1 of the '071 patent also recites “if the voltage falls below a first threshold, discontinuing listening for the first telemetry type while continuing listening for the second telemetry type.” As explained in the Claim Chart, the Nevro Senza Systems include IPGs with telemetry functionality dependent upon charge level of its rechargeable battery. If the battery level falls below a voltage threshold (“first threshold”), the IPG discontinues listening for the FSK telemetry (*i.e.*, first telemetry) from the remote control. (Ex. 1 at 92-96.)

176. As described in the preceding paragraphs and in the attached Claim Chart, each limitation of Claim 1 of the '071 patent is performed by the Nevro Senza Systems.

177. Upon information and belief, Nevro has been aware of the '071 patent, or willfully blind to its existence, and Nevro knew, should have known, or was willfully blind to the fact that it was infringing the '071 patent, and that there was a high risk of infringement of the '071 patent about which Nevro knew or should have known, particularly in view of, for example,

the stark similarities between Nevro's accused products and the claims of the '071 patent, of which Nevro knew or should have known as soon as it became aware of the '071 patent as alleged herein, as well as in view the claim charts provided to Nevro on December 18, 2019. Nevro's knowledge of infringement by the Senza Systems throughout the period of infringement is based on, but not limited to: (1) Nevro's monitoring and competitive intelligence of Boston Scientific, who is a direct competitor of Nevro; (2) any pre-suit investigation related to Boston Scientific's filing of two Petitions for *Inter Partes* Review of Nevro's U.S. Patent No. 8,359,102 in May 2015; (3) Nevro's participation in an FDA-monitored randomized controlled trial in a head-to-head comparison against Boston Scientific's Precision™ SCS System; and (4) the approximately 50 Nevro employees who were formerly employed by Boston Scientific, including employees who worked on Boston Scientific SCS product development and who were responsible for its neuromodulation patent portfolio, such as Kerry Bradley and James Thacker.

178. At a minimum, Nevro has been aware of the '071 patent, or willfully blind to its existence, since the service of the First Amended Complaint, and thus knew, should have known, or was willfully blind to the infringement of the '071 patent by the Nevro Senza Systems. Nevro's infringement has been ongoing. Indeed, after service of the First Amended Complaint, rather than take any steps to alter its products or cease its infringement, Nevro introduced the Senza Omnia, which, upon information and belief, is insubstantially different from the Senza I and Senza II infringing systems with respect to the subject matter of the '071 patent.

179. Nevro has, for example and without limitation, marketed, sold, and offered 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 materials⁴⁰ and videos.⁴¹ 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.⁴² 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 of or is willfully blind to the existence of the '071 patent,

⁴⁰ 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>.

⁴¹ 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=LeLq1lvIJvs>;
<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>.

⁴² Physician Manual: http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130022d.pdf; Patient Manual: http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130022c.pdf.

knows of or is willfully blind to the fact that it infringes the '071 patent, at least because there was a high risk of infringement of the '071 patent about which Nevro knew or should have known, particularly in view of, for example, the stark similarities between Nevro's accused products (and/or the use of those products as instructed by Nevro as alleged above) and the claims of the '071 patent, of which Nevro knew or should have known as soon as it became aware of the '071 patent as alleged herein, as well as in view the claim charts provided to Nevro on December 18, 2019.

180. 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 '071 patent. Upon information and belief, Nevro, as detailed above, knows of or is willfully blind to the existence of the '071 patent, knows of or is willfully blind to the fact that it infringes the '071 patent, at least because there was a high risk of infringement of the '071 patent about which Nevro knew or should have known, particularly in view of, for example, the stark similarities between Nevro's accused products (and/or the use of those products as instructed by Nevro as alleged above) and the claims of the '071 patent, of which Nevro knew or should have known as soon as it became aware of the '071 patent as alleged herein, as well as in view the claim charts provided to Nevro on December 18, 2019. Moreover, as detailed above, Nevro's IPGs comprise a material part of the invention claimed in claim 1 of the '071 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 '071 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.

181. 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 IX: MISAPPROPRIATION OF TRADE SECRETS AND LIABILITY UNDER
THE CALIFORNIA UNIFORM TRADE SECRETS ACT, CAL. CIV. CODE §§ 3426-
3426.11**

182. Boston Scientific realleges paragraphs 1-181 above as if fully set forth herein.

183. Boston Scientific brings this trade secret claim to remedy the blatant and widespread misappropriation of its confidential and proprietary trade secret information by Nevro. Upon information and belief, Nevro engaged in a pattern of concerted effort to acquire, compile, and put to work for its own purposes vast amounts of trade secret information from Boston Scientific. This misappropriation spans many years and dates back as far as Nevro's earliest days as a company. From its very inception, with no prior experience researching, developing, navigating the regulatory pathways, commercializing, or selling any SCS products, Nevro recruited and hired existing or former Boston Scientific employees. Nevro operates a business built off of the work of others. Nevro blatantly and improperly utilized Boston Scientific confidential and proprietary trade secret information from those former employees—many times through dissemination and use of Boston Scientific trade secret documents expressly marked “Confidential”—to start and to move forward all aspects of its nascent business. Numerous detailed examples of Nevro's egregious misappropriation are set out below, but these are only examples. There are not only additional instances of misappropriation of Boston

Scientific trade secret information involving the Nevro individuals described below but, upon information and belief, there are additional employees (and former employees) of Nevro who have been involved in the extensive misappropriation of Boston Scientific's proprietary trade secret information.

184. Upon information and belief, Nevro was incorporated on March 10, 2006 as a Minnesota corporation under the name NBI Development Inc. and reincorporated in Delaware on October 4, 2006.

185. Upon information and belief, by at least November 2006, NBI Development Inc., identified current and former Boston Scientific employees as its recruiting targets to form the foundational team for the newly launched company.

186. Anthony Caparso worked at Boston Scientific as a research scientist from December 2003 to April 2007. Upon information and belief, by at least February 28, 2007 NBI Development Inc., made an offer of employment to Mr. Caparso. On April 16, 2007 Nevro hired Mr. Caparso as Principal Research Scientist.

187. Upon information and belief, Nevro changed its corporate name from NBI Development Inc., to Nevro Corporation in June, 2007.

188. James Makous worked as a field clinical engineer for Boston Scientific from 2002 to 2007. Upon information and belief, on June 28, 2007, Mr. Makous signed an NDA with NBI Development Inc., and on September 11, 2007 Nevro hired Mr. Makous as Director of Preclinical Research.

189. Huyen Duong worked at Boston Scientific from January 2005 to January 2008 in regulatory affairs. Upon information and belief, on March 1, 2008, Nevro hired Ms. Duong as

Director of Regulatory Affairs. Upon information and belief, Ms. Duong was recruited by Konstantinos Alataris.

190. Upon information and belief, as of March 2008, former Boston Scientific employees Caparso, Makous, and Duong were among the fewer than one dozen employees of Nevro.

191. David Marco worked as a field clinical engineer for Boston Scientific from January 2004 to January 2007. Upon information and belief, Nevro hired Mr. Marco as a consultant at the end of 2008, and, on February 23, 2009, Nevro hired Mr. Marco as a Field Clinical Engineer.

192. As detailed above, Nevro also hired former Boston Scientific employee James Thacker. Upon information and belief, as of December 1, 2008, at the latest, Nevro employed James Thacker as a consultant. On December 17, 2008, Nevro offered Mr. Thacker fulltime employment with Nevro. On December 29, 2008, Mr. Thacker signed an employment agreement with Nevro. On January 1, 2009 Mr. Thacker officially started at Nevro as Director of Clinical Engineering.

193. Wesley Park worked in product management, marketing and strategy for Boston Scientific from August 2005 to April 2008. On January 16, 2009, upon information and belief, Nevro offered employment to Mr. Park, and on February 23, 2009, Mr. Park signed an employment agreement with Nevro, to serve as the Director of Product Marketing.

194. Vivek Sharma worked as a senior research and development engineer for Boston Scientific from November 2008 to April 2009. Upon and information and belief, on April 1, 2009, Nevro hired Mr. Sharma as Senior Design Engineer.

195. Mike Joo worked as a product manager for Boston Scientific from 2004 to 2009. On July 22, 2009, upon information and belief, Nevro hired Mr. Joo as Director of Product Marketing.

196. Kerry Bradley worked in many roles at BSC, including Research and Development Manager and Senior Principal Biomedical Systems Engineer from 2005 to 2012. Upon information belief, on August 12, 2013, Nevro hired Mr. Bradley, as Director, Clinical Science and Research.

197. Upon information and belief, at least 60 past employees of Boston Scientific are or were employed by Nevro, including:

- James Makous, Director Preclinical Research
- Wesley Park, Head of Global Clinical Research Programs
- James Thacker, Director of Field Clinical Engineering
- Huyen Duong, Senior Director, Clinical & Regulatory Affairs
- Dongchul Lee, Principal Research Scientist
- Kerry Bradley, Sr. Director, Research
- Anthony Caparso, Sr. Principle Research Scientist
- Michael Joo, Director of Product Marketing
- Anita Yip, Manager, Systems Engineering
- Hamid Idrissi, Senior Manager, Regulatory Affairs
- Veerle Minne, Sr. Field Clinical Engineer
- Corinne Lee, Sr. Clinical Research Associate
- Vivek Sharma, Director R&D
- 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-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
- Kelly Engle, Therapy Support Specialist

198. Many of these Nevro employees are intimately familiar with Boston Scientific's SCS systems, core SCS technologies, and related technologies, which Boston Scientific has been developing for decades. Upon information and belief, Nevro employed a systematic strategy to hire former Boston Scientific employees to acquire information regarding Boston Scientific's SCS systems, core SCS technologies, and related technologies, and its institutional knowledge of the SCS market and SCS business practices.

199. During the course and scope of their duties at Boston Scientific, these employees who Nevro sought out and hired had access to, used, contributed to the development of, and were responsible for safeguarding, Boston Scientific's trade secrets and confidential and proprietary information.

200. Boston Scientific is the owner of trade secrets, including but not limited to, confidential and proprietary: customer lists, strategies for obtaining regulatory approval, quality assurance plans, software testing methods, testing methods and capabilities for functional qualification and verification, future product plans, hazard and risk analysis assessments, product designs, product development processes, marketing requirements, specifications and strategies,

functional specifications including drawings and schematics, employee training methods, 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 created these trade secrets and considerable proprietary technical information as a result of the research, development, clinical work, sales and marketing of its SCS products, as well as related technologies. In the hands of a competitor, such confidential, trade secret, and proprietary information would be of great value and could be used to compete unlawfully 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 and related technologies.

201. Boston Scientific's trade secrets include 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.

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

203. The confidential, trade secret, and proprietary information developed and maintained 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 to protect the confidentiality of its proprietary information, including, but not limited to, requiring its employees to certify that they have completed annual training concerning the Boston Scientific "code of conduct," which addresses the use and protection of confidential and proprietary information and then to sign

acknowledgments that such information should only be used for the benefit of Boston Scientific. In addition, employees were provided with an Employee Handbook, which includes additional guidance on the use and protection of confidential information, and specifies that no confidential or proprietary information should be taken or accessed by anyone outside of Boston Scientific without authorization.

204. Though additional discovery is needed to uncover the full scope of Nevro's misconduct, upon information and belief, Nevro obtained confidential and proprietary Boston Scientific information from sources that include at least several former Boston Scientific employees hired by Nevro. Those former Boston Scientific employees were obligated to return Boston Scientific company property and to maintain the secrecy of Boston Scientific's confidential, proprietary and trade secret information both during and after being employed by Boston Scientific. Nevro received this confidential and proprietary information from former Boston Scientific employees and used that information for its own purposes. Such former Boston Scientific employees disclosed and used Boston Scientific's confidential, proprietary and trade secret information within the scope of their employment at Nevro and such disclosures and uses of Boston Scientific's trade secrets were in furtherance of their employment duties to Nevro.

205. Upon information and belief, the misappropriation of Boston Scientific's trade secrets by Nevro extended beyond the possession, sharing, and use of confidential documents. Upon information and belief, and as a non-limiting example, former employees verbally conveyed trade secrets during the course of their employment in meetings and other communications with Nevro employees and executives.

206. As noted above, Jim Thacker, formerly 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 10**. 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.

207. 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.

208. Mr. Thacker signed the EICIA on August 28, 2000.

209. 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.

210. 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.

211. 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™ SCS system. Mr. Thacker also took Boston Scientific-owned thumb drives, actual Precision™ demonstration devices, Physician lead manuals, Physician implant manuals, and Precision™ 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.

212. 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.

213. 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.

214. 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™ 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.

215. 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.”

216. The Stimulus Confirmatory Study was Boston Scientific’s protocol to run the clinical investigation for its Precision™ 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.”

217. Upon information and belief, Nevro’s possession of Boston Scientific’s internal clinical investigation protocol for its Precision™ 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.

218. 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. As described above, 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™ SCS product, helped with all phases of equipment troubleshooting, and contributed many ideas for new equipment. Mr. Marco also taught salesmen and physicians.

219. 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.

220. 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

221. 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.

222. Receipt, possession and use of Boston Scientific’s confidential and proprietary 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 received from 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.

223. Nevro acquired and used Boston Scientific’s trade secrets through improper means when Nevro employees disclosed and used Boston Scientific’s confidential, proprietary and trade secret information to benefit Nevro’s business. Nevro acquired Boston Scientific’s trade secrets through, at least, former employees who improperly retained Boston Scientific confidential documents after employment and distributed them via email and other means to other Nevro employees and executives and uploaded them to Nevro internal systems and property, evidenced by Nevro’s production of many such documents to Boston Scientific in the course of discovery. Nevro did not request or obtain Boston Scientific’s consent to acquire or use Boston Scientific’s trade secrets, company property, confidential and proprietary information. The full scope of Nevro’s acquisition and use is unknown and additional discovery

is needed to uncover that information and the complete host of individuals involved. Upon information and belief, Nevro's coordinated misappropriation scheme includes at least, but is not limited to, the following sources of Boston Scientific information and exemplary instances of conduct:

224. **David Marco** retained at least 1,991 Boston Scientific internal, confidential and propriety documents, including emails, containing Boston Scientific's trade secrets. Upon information and belief, Mr. Marco accessed and used these documents during the time of his employment at Nevro and Nevro therefore acquired these trade secrets through improper means because Nevro and Mr. Marco knew or had reason to know that it was not in rightful possession of the information since it knew or had reason to know that Mr. Marco owed a duty to maintain their secrecy and limit their use. Upon information and belief, Boston Scientific documents in Mr. Marco's possession were uploaded onto Nevro servers during his employment. Discovery is needed to understand the full scope of Nevro's conduct based on information provided by Mr. Marco.

225. For example, on July 19, 2011, David Marco emailed Geraldine Linares attaching a document titled "Protocol RevC_locked.pdf." The attached "Stimulus™ Confirmatory Study" belonged to Boston Scientific's predecessor Advanced Bionics. This is a draft of the same document detailed above at ¶¶ 212-215, which included on the front page: "Proprietary Information of Advanced Bionics. Subject to terms of Non-Disclosure Agreement." Mr. Marco did not receive Boston Scientific's permission to retain this document or disclose this document to Nevro. Nevro did not obtain Boston Scientific's permission to use this document or the information disclosed therein. Nevro knew or had reason to know that it was not in rightful possession of the information since it knew or had reason to know that Mr. Marco owed a duty to

maintain its secrecy and limit its use. Upon information and belief, this example represents just one of many instances whereby Nevro acquired, possessed and used confidential Boston Scientific information from Mr. Marco as the source.

226. **James Makous** retained and disclosed to Nevro at least 1,922 Boston Scientific internal, confidential and proprietary documents, including emails, containing Boston Scientific's trade secrets. Upon information and belief, Mr. Makous accessed and used these documents during the time of his employment at Nevro and Nevro therefore acquired these trade secrets through improper means because Nevro and Mr. Makous knew or had reason to know that it was not in rightful possession of the information since it knew or had reason to know that the documents were confidential and that Mr. Makous owed a duty to maintain their secrecy and limit their use. Upon information and belief, the documents retained by Mr. Makous were saved to Nevro's internal network systems and available for Nevro employees to access and use for an unknown period of time.

227. For example, on October 11, 2007, James Makous emailed Konstantinos Alataris, Andre Walker, Anthony Caparso, Lance Boling, and Zi-Ping Fang and attached a document with the file name "InvestigatorBrochure_4Jun02C.doc." The attachment was the confidential and proprietary draft of Advanced Bionics' Investigator's Brochure for the bion® Clinical Investigation. In his email, Mr. Makous stated: "Enclosed is a draft of the investigator's brochure that AB submitted to the EU for the bion clinical trial." The front page included "CONFIDENTIALITY: This document contains confidential and proprietary information concerning Advanced Bionics bion® product. By review of this document, none of the information contained herein shall be disclosed to other parties without the express consent from Advanced Bionics." This document includes detailed technical and clinical information for the

bion® system created by Advanced Bionics. Mr. Makous did not receive Boston Scientific's permission to retain or disclose this document. Nevro did not obtain Boston Scientific's permission to use this document or the information disclosed therein. Nevro knew or had reason to know that it was not in rightful possession of the information since it knew or had reason to know that Mr. Makous owed a duty to maintain its secrecy and limit its use. Upon information and belief, this example represents just one of many instances whereby Nevro acquired, possessed and used confidential Boston Scientific information from Mr. Makous as the source.

228. As another example, on October 11, 2007, James Makous emailed Konstantinos Alataris, Andre Walker, Anthony Caparso, Lance Boling, and Zi-Ping Fang and attached a document with the filename "BPB Hazard Analysis rev 00 13Jun02_Summary.doc." The attachment was the confidential and proprietary "Overview of the Hazard/Risk Analysis Assessment for Battery Powered bion® With Integrated Stimulating Electrode (BPB) System" created by Advanced Bionics. This document includes test procedures for evaluating the risk of various components of the battery powered bion® system. In his email to numerous Nevro employees, including the CEO, Mr. Alataris, and the vice president of R&D, Mr. Walker, Mr. Makous stated "Enclosed is a draft of the AB BPB hazard/risk analysis. I cannot find anything on the AB SCS device." The front page included the following: "CONFIDENTIAL: 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." Mr. Makous did not receive Boston Scientific's permission to retain or disclose this document. Nevro did not obtain Boston Scientific's permission to use this document or the information disclosed therein. Nevro knew or had reason to know that it was not in rightful possession of the information since it knew or had reason to know that Mr. Makous owed a duty

to maintain its secrecy and limit its use. Upon information and belief, the foregoing examples represent just a few of many instances whereby Nevro acquired, possessed and used confidential Boston Scientific information from Mr. Makous as the source.

229. **Huyen Duong** retained an unknown number of Boston Scientific internal, confidential and proprietary documents containing Boston Scientific's trade secrets. Upon information and belief, Ms. Duong uploaded and/or saved these documents to one or more personal, non-Boston Scientific, storage locations. Upon information and belief, Ms. Duong accessed these documents and disclosed selected documents revealing Boston Scientific trade secrets to Nevro. Upon information and belief, Nevro acquired these trade secrets through improper means because Nevro and Ms. Duong knew or had reason to know that it was not in rightful possession of the information since it knew or had reason to know that that the documents were confidential and that Ms. Duong owed a duty to maintain their secrecy and to limit their use to legitimate Boston Scientific business purposes.

230. For example, on February 20, 2008, Huyen Duong sent an email to Andre Walker and Konstantinos Alataris in response to discussions that she and Mr. Walker had the night before. Ms. Duong attached to her email a document titled "Product Development Process" that she thought would "work for us." The footer of the Product Development Process, which states that the document is "the property of Boston Scientific Corp.," was changed to state that it is "the property of the Company," and Boston Scientific's name was deleted and replaced with "Nevro Corporation." Additionally, upon information and belief, Ms. Duong copied entire sections of Advance Bionics' proprietary Standard Development Process into the document that she sent on February 20, 2008. The original footer of the document, detailed in tracked edits of the document, states the document is "the property of Boston Scientific Corp. and shall not be

reproduced, distributed, disclosed or used for manufacture or sale of apparatus without the express written consent of Boston Scientific Corp.” Ms. Duong did not receive Boston Scientific’s permission to retain or disclose Boston Scientific’s document. Nevro did not obtain Boston Scientific’s permission to receive, retain or use this document or the information disclosed therein. Nevro knew or had reason to know that it was not in rightful possession of the information since it knew or had reason to know that Ms. Duong owed a duty to maintain its secrecy and limit its use. Upon information and belief, this example represents just one of many instances whereby Nevro acquired, possessed and used confidential Boston Scientific information from Ms. Duong as the source.

231. Upon information and belief, Nevro received, retained, disseminated and used additional confidential and proprietary Boston Scientific information, as shown by a series of documents imaged on Nevro scanners and then distributed among Nevro personnel.

232. For example, on August 11, 2008, a confidential and proprietary Advanced Bionic FDA submission was scanned and sent from Scanner@Nbidevelopment.com to Konstantinos Alataris, Andre Walker, Zi-Ping Fang, Lance Boling, and Jon Parker. The two FDA submission letters include information and images about Advanced Bionics’ Observational Mechanical Gateway “OMG” connectors and a summary of the information included in Advance Bionics’ Supplemental Application, and disclosed Boston Scientific’s trade secret information. The sender of this document was concealed because the document was sent using a scanner. Nevro did not obtain Boston Scientific’s permission to use this document or the information disclosed therein. Nevro knew or had reason to know that it was not in rightful possession of the information since it knew or had reason to know that it was confidential and protected under a duty to maintain its secrecy and limit its use.

233. On July 22, 2009, a confidential Advanced Bionics presentation for a meeting with the FDA was scanned and sent from Scanner@Nevrocorp.com to Konstantinos Alataris and Huyen Duong. On that same day Huyen Duong forwarded the Advanced Bionics confidential presentation to Andre Walker, Ric Ruedy, and James Thacker. Ms. Duong did not receive Boston Scientific's permission to retain or disclose this document. Nevro did not obtain Boston Scientific's permission to use this document or the information disclosed therein. Nevro knew or had reason to know that it was not in rightful possession of the information since it knew or had reason to know that the document was confidential and that Ms. Duong owed a duty to maintain its secrecy and limit its use. Upon information and belief, this example represents just one of many instances whereby Nevro acquired, possessed and used confidential Boston Scientific information from Ms. Duong as the source.

234. **Wesley Park** retained Boston Scientific internal, confidential and proprietary documents, containing Boston Scientific's trade secrets. Upon information and belief, Mr. Park saved these documents to his personal hard drive, then transferred these documents from his personal hard drive to a Nevro owned and issued hard drive. Upon information and belief, Mr. Park accessed these document and disclosed selected documents revealing Boston Scientific trade secrets to Nevro. Upon information and belief, Nevro acquired these trade secrets through improper means because Nevro and Mr. Park knew or had reason to know that it was not in rightful possession of the information since it knew or had reason to know that the documents were confidential and that Mr. Park owed a duty to maintain their secrecy and limit their use.

235. For example, on October 14, 2010, Wesley Park sent an email to Vivek Sharma, attaching two confidential and proprietary Boston Scientific documents. First, Mr. Park provided Mr. Sharma with Boston Scientific's slide presentation titled "M1 Precision Connector

Transfer/Acceptance Phase Review and Product Release Decision.” The presentation provides a comprehensive overview of technical and commercial aspects considered for the release of Boston Scientific’s M1 Precision connector. This document included the footer “confidential information of Boston Scientific Corporation do not copy or distribute.” Second, Mr. Park attached a Boston Scientific spreadsheet showing Advanced Bionics’ sales and financial modeling related to the marketing of the connector. Vivek Sharma replied to Mr. Park’s email that “the file does not have a good pic I can use. Can you send me some other file.” On October 15, 2010, Mr. Park emailed Vivek Sharma attaching a confidential Boston Scientific presentation “Information for Precision Connector M-1 SC-9004-35,-55,-70.” The first slide of this presentation included “Boston Scientific Confidential” and “internal use only do not distribute.” Mr. Park did not receive Boston Scientific’s permission to retain or disclose these documents. Nevro did not obtain Boston Scientific’s permission to use this document or the information disclosed therein. Nevro knew or had reason to know that it was not in rightful possession of the information since it knew or had reason to know that the document was confidential and that Mr. Park owed a duty to maintain its secrecy and limit its use. Upon information and belief, the foregoing examples represent just a few of many instances whereby Nevro acquired, possessed and used confidential Boston Scientific information from Mr. Park as the source.

236. As described above, **James Thacker** retained thousands of confidential Boston Scientific documents, some containing Boston Scientific’s trade secrets, which he saved onto six thumb drives. Upon information and belief, Mr. Thacker inserted each thumb drive, containing confidential Boston Scientific documents, containing Boston Scientific’s trade secrets, into his Nevro-issued/owned laptop at least once during the course of his employment with Nevro. Upon information and belief, Mr. Thacker saved Boston Scientific’s documents disclosing Boston

Scientific's trade secrets to Nevro computer systems, servers or other Nevro property, and then accessed them and distributed them through email. Upon information and belief, Nevro acquired these trade secrets through improper means because Nevro and Mr. Thacker knew or had reason to know that it was not in rightful possession of the information since it knew or had reason to know that the documents were confidential and that Mr. Thacker owed a duty to maintain their secrecy and limit their use.

237. On July 3, 2014, Mr. Thacker sent an email to David Caraway, Nevro's Chief Medical Officer and attached a document titled "Pacemaker to SCS Interaction Guideline." This document provides guidance and training information for Nevro's sales force concerning the use of the SCS system with pacemakers and defibrillators. This document discloses Boston Scientific's trade secrets. It is evident that Mr. Thacker copied the entire Boston Scientific "Pacemaker to SCS interaction Guideline" to create Nevro's version. In fact, in his email to Dr. Caraway, Mr. Thacker states: "I have based this document on the one I prepared for BSX when I ran their Technical Service and FCE group." Mr. Thacker did not receive Boston Scientific's permission to retain or disclose Boston Scientific's document or the information disclosed therein. Nevro did not obtain Boston Scientific's permission to use this document or the information disclosed therein. Nevro knew or had reason to know that it was not in rightful possession of the information since it knew or had reason to know that the document was confidential and that Mr. Thacker owed a duty to maintain its secrecy and limit its use. Upon information and belief, the foregoing examples represent just a few of many instances whereby Nevro acquired, possessed and used confidential Boston Scientific information from Mr. Thacker as the source.

238. Upon information and belief, Nevro's former Vice President of Research and Development, Andre Walker, was a central hub for the distribution and use of confidential Boston Scientific trade secrets. For example, on April 18, 2008, Andre Walker sent a meeting invite to Zi-Ping Fang, Anthony Caparso, Aron Stiteler, Lance Boling, Huyen Duong and Konstantinos Alataris with the Subject "CCC proposal review" and attached five documents. One of the documents attached was an internal Boston Scientific confidential competitive analysis presentation. Upon information and belief, Mr. Walker obtained this confidential presentation from one or more former Boston Scientific employees, including Mr. Caparso. Mr. Caparso did not request Boston Scientific's permission to access or use this document, and Nevro would not have had access to this document but for Nevro's improper acquisition. Nevro knew or had reason to know that it was not in rightful possession of the information since it knew or had reason to know that the document was confidential and that Mr. Caparso owed a duty to maintain its secrecy and limit its use. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] This is just one example of the extensive use and dissemination of confidential Boston Scientific information by high level Nevro executives who could not have had access to this information but for their improper acquisition of these documents from the systematic hiring and retention of former Boston Scientific employees who provided such information to Nevro by improper means.

239. Based on the foregoing examples of different sources upon which Nevro relied for its systematic scheme of misappropriation, Nevro acquired a considerable number of Boston Scientific trade secrets informing every major aspect of the business Nevro was trying to build.

Nevro not only hired these former Boston Scientific employees but also knew or at least had ample reason to know that the Boston Scientific information it was acquiring was through improper means. In addition to the obvious notations, stamps and marking on most of the documents, which would inform any reasonable recipient of the confidential nature of the materials, upon information and belief, Nevro knew that BSC's former employees had a duty to maintain the secrecy of Boston Scientific's trade secrets. Nonetheless, Nevro repeatedly encouraged and benefited from the systematic breach of those duties once those individuals were within Nevro's employ.

240. Upon information and belief, throughout the course of Nevro's early development from 2007 until its first commercial launch in the United States in 2015, thousands of Boston Scientific confidential and trade secret documents were saved on Nevro's shared network drive, Nevro's email exchange servers, Nevro-owned laptops, and external hard drives, and such documents were also emailed, scanned, and disseminated in hard copy form. All of these improper activities allowed Nevro employees to have, access and use Boston Scientific's confidential documents and trade secrets for Nevro's, not Boston Scientific's, business purposes.

241. Upon information and belief, dozens of Nevro employees, including Nevro's CEO Konstantinos Alataris and Vice President of R&D Andre Walker, through at least email and other means, acquired Boston Scientific trade secrets from documents containing Boston Scientific or Advanced Bionics' company logo and/or confidential disclaimers, which identify the documents on their face as proprietary and confidential information of Advanced Bionics/Boston Scientific that is not to be disclosed without the consent of Advanced Bionics/Boston Scientific.

242. Upon information and belief, Nevro employees emailed within Nevro, on dozens of occasions, Boston Scientific documents that contained confidential and proprietary information and trade secrets. Upon information and belief, once in receipt of Boston Scientific confidential, proprietary and trade secret information, Nevro employees, including Nevro executives such as Dr. Alataris and Mr. Walker, did not refuse such information from the sender, did not notify Boston Scientific of Nevro's acquisition, use or disclosure of such information, and made no efforts to quarantine or limit further dissemination or access of such information within Nevro.

243. Numerous Nevro internal documents show direct copying and reliance on Boston Scientific's confidential, proprietary and trade secret information, showing Nevro's use of Boston Scientific's trade secrets.

244. Nevro's improper acquisition and use of Boston Scientific's misappropriated trade secrets allowed Nevro to move its nascent business forward to launch of its first-ever SCS product, thereby bypassing the investment of time, money and effort that Boston Scientific put in to developing its trade secrets and its products.

245. 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 former Boston Scientific employees' contractual obligations to Boston Scientific.

246. 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.

247. 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.

248. Boston Scientific is informed and believes that Nevro's conduct was, and is, malicious, fraudulent, deliberate and willful, as revealed by the conduct described above. Boston Scientific is therefore entitled to recover from Nevro exemplary damages in an amount twice the total of the damages recovered as permitted by Cal. Civ. Code. § 3426.3.

249. Boston Scientific also is entitled to an award of attorneys' fees pursuant to Cal. Civ. Code. § 3426.4.

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 directly infringed 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 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 any product that infringes the Asserted Patents, including the Senza Systems, and from importing the same into the United States;

C. The entry of a judgment awarding Boston Scientific damages resulting from Nevro's infringement in an amount no less than a reasonable royalty;

D. 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;

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

F. The award of damages sufficient to compensate Boston Scientific for the misappropriation and Nevro's unjust enrichment by such misappropriation;

G. The award of punitive and exemplary damages, as well as attorneys' fees, as may be provided by law, including under the California Uniform Trade Secrets Act;

H. 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;

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

J. 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.

DATED: September 20, 2021

Respectfully submitted,

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