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11	Attorneys for Plaintiff NEVRO CORP.		
12	UNITED STATES DISTRICT COURT		
13	NORTHERN DISTRICT OF CALIFORNIA		
14			
15	NEVRO CORP.,	Case No. 3:16-cv-06830-VC	
16	Plaintiff,	FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT	
17	V.	AND DECLARATORY JUDGMENT	
18 19	BOSTON SCIENTIFIC CORPORATION and BOSTON SCIENTIFIC NEUROMODULATION CORPORATION,	DEMAND FOR JURY TRIAL	
	Defendants.		
20	Defendants.		
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22	[CONFIDENTIAL APPENDIX ATTACHED	AT END OF DOCUMENT CONTAINS	
23	HIGHLY CONFIDENTIAL – ATTORN	NEYS EYES ONLY MATERIAL]	
24			
25	[REDACTED VERSION OF DOCUM	MENT SOUGHT TO SEALED]	
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Plaintiff Nevro Corp. ("Nevro") complains and alleges as follows against Defendants

Boston Scientific Corporation and Boston Scientific Neuromodulation Corporation (collectively,

"Boston Scientific").

### THE NATURE OF THE ACTION

- 1. Chronic pain is a significant health problem that affects more Americans than diabetes, heart disease, and cancer combined. Nevro's pioneering spinal cord stimulation technology dramatically improves the quality of life of individuals suffering from chronic pain. Nevro brings this action to prevent Boston Scientific from infringing the patents that protect Nevro's technology.
- 2. Spinal cord stimulation ("SCS") therapy attempts to relieve pain by delivering short electrical pulses to the spinal cord through small electrodes that are implanted near the spinal cord. While SCS technology has been on the market for decades, Nevro's patented SCS technology is significantly more effective than the traditional systems supplied by the rest of the SCS industry.
- 3. Traditional SCS therapy delivers "low frequency" electrical pulse waveforms, on the order of 50 to 60 Hz, to generate a sensation known as paresthesia. Paresthesia is commonly experienced as a tingling, numbness, buzzing, or pins-and-needles sensation. The paresthesia is used to mask, or cover, the patient's area of pain. In theory, the patient feels the paresthesia and feels less pain.
- 4. Traditional, paresthesia-based low frequency SCS therapy has significant failings that reduce its efficacy and limit its applicability. It is not effective in a large portion of the population, and even when it works, the pain relief is limited. Paresthesia also narrows the applicability of SCS therapy because patients often experience uncomfortable stimulations or even jolting sensations during movement, which can impair sleep or preclude driving a car while receiving therapy.
- 5. Nevro was founded to provide a solution to chronic pain without the drawbacks of traditional low frequency SCS therapy. After years of research and development work, Nevro has brought to market an SCS therapy that differs dramatically from traditional SCS therapy. Nevro's

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27 28 SCS therapy uses a unique "high frequency" electrical waveform to provide pain relief without generating paresthesia.

- 6. With their long history of providing paresthesia-based low frequency SCS therapy, Defendant Boston Scientific and the rest of the SCS industry were highly skeptical that Nevro's paresthesia-free high frequency SCS therapy would provide clinically effective pain relief. But to the industry's surprise, Nevro's paresthesia-free high frequency SCS therapy has been scientifically proven to provide significantly superior pain relief to a significantly larger population of patients. And it does so without the failings of paresthesia-based low frequency SCS.
- 7. To obtain FDA approval, Nevro tested its paresthesia-free high frequency SCS therapy against Defendant Boston Scientific's commercial, paresthesia-based low frequency SCS system in an FDA-monitored randomized, controlled, trial. The trial showed that Nevro's paresthesia-free high frequency SCS therapy is not only clinically effective without paresthesia, but also is nearly twice as effective as Boston Scientific's paresthesia-based low frequency SCS therapy. As a result, when the FDA granted approval for Nevro's high frequency SCS therapy on May 8, 2015, it awarded Nevro's SCS therapy a rare "superiority" label—allowing Nevro to claim its high frequency SCS therapy is clinically superior to Boston Scientific's paresthesiabased low frequency SCS therapy.
- 8. What started out as skepticism has turned into copying. Witnessing Nevro's superior results and rapid success, Defendant Boston Scientific is now aggressively trying to mimic Nevro's SCS therapy. In 2014, eight years after Nevro's founding, Boston Scientific initiated a clinical trial in the United States, utilizing SCS devices that operate at the same 10,000 Hz frequency as the commercial embodiment of Nevro's SCS system. These devices infringe Nevro's patents. Boston Scientific is also manufacturing infringing SCS devices in the United States that operate at frequencies up to 10,000 Hz, and exporting these devices to Europe for commercial use in at least six countries. Nevro filed this lawsuit less than two weeks after learning that Boston Scientific has received CE Mark approval in Europe to market its SCS devices at high frequencies of up to 10,000 Hz. Additional allegations relating to Boston

#### **PARTIES**

- 11. Plaintiff Nevro is a Delaware corporation with its principal place of business at 1800 Bridge Pkwy, Redwood City, CA 94065.
- 12. Defendant Boston Scientific Corporation is a Delaware corporation with its principal place of business at 300 Boston Scientific Way, Marlborough, MA 01752, and Defendant Boston Scientific Neuromodulation Corporation is a Delaware corporation with its principal place of business at 25155 Rye Canyon Loop, Valencia, California 91355.

### JURISDICTION AND VENUE

- 13. This Court has subject matter jurisdiction under 28 U.S.C. § 1331 (federal question) and § 1338(a) (patents).
- 14. This Court has personal jurisdiction over Boston Scientific, which has multiple sales representatives and other employees in California, has filed litigation in this Court, and has

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1	facilities in Fremont, San Jose, and Valencia, California. According to its website and product
2	labeling, Boston Scientific's facility in Valencia, California develops, designs, and manufactures
3	the implantable pulse generators used in its SCS systems, which are sold and distributed in the
4	United States and worldwide.
5	15. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and 1400(b) in that

15. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and 1400(b) in that Boston Scientific is subject to personal jurisdiction in this District. In addition, venue is proper because Nevro's principal place of business is in this District, and Nevro suffered harm in this District. Moreover, the majority of the inventive activity that resulted in the patented technology occurred in this District.

### INTRADISTRICT ASSIGNMENT

16. Pursuant to Civil Local Rules 3-2(c) and 3-5(b), because this action is an intellectual property action, it is properly assigned to any of the divisions in this District.

### **BACKGROUND FACTS**

# Nevro's Pioneering Technology

- 17. Chronic pain is often treated with opioid drugs. But there is little evidence that opioids provide long term relief for patients, and they frequently cause more problems than they solve. It is well known that the use of opioid drugs, particularly over a sustained period of time, is fraught with risk and has significant side effects. SCS technology was born of the promise of providing a solution to chronic pain without the use of drugs.
- 18. Nevro was founded in 2006 to develop a novel SCS technology for the treatment of chronic pain. Nevro's SCS system, known as the Senza® system, utilizes Nevro's unique and patented HF10<sup>TM</sup> therapy. Nevro's HF10<sup>TM</sup> therapy employs a much higher frequency than traditional "low frequency" SCS systems, along with a unique waveform and treatment algorithm. In its commercial embodiment, Nevro's Senza® system provides electrical pulses to the spinal cord at a rate of 10,000 pulses per second (10,000 Hz or 10 kHz), as compared to traditional SCS systems like Boston Scientific's, which utilize low frequency stimulation, typically between 50 Hz and 60 Hz. The Senza® system, with its related subcomponents, is Nevro's only product.

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- 19. Unlike traditional low frequency SCS therapy, Nevro's Senza® system and HF10™ therapy provides pain relief *without* generating paresthesia. Nevro's advances represent a paradigm shift in SCS therapy. Before FDA approval of Nevro's Senza® system, every commercial SCS system sought to create paresthesia in the patient by using low frequency stimulation waveforms. Every commercial SCS system sought to use that paresthesia to overlap and mask pain in the patient. And virtually all of the development in the SCS industry for decades has been directed towards methods of improving paresthesia delivery and the mapping of paresthesia over a patient's area of pain. As a recent peer-reviewed publication concerning Nevro's SCS therapy stated: "Over the last 40 [years], the primary focus of innovation for SCS for chronic pain has been to improve the reliability of overlapping paresthesias with distribution of pain."¹
- 20. Like the rest of the SCS industry, Defendant Boston Scientific emphasized the importance of creating paresthesia for SCS therapy. For example, in a Boston Scientific sponsored study, one of its own co-author scientists asserted that "[p]atient-perceived concordant paresthesia overlapping the area of pain is *essential* for success of this therapy."<sup>2</sup>
- 21. Because Nevro's approach was fundamentally different from that of others in the market, the FDA put Nevro to a rigorous test. To obtain FDA approval, Nevro was required to prove that its therapy is paresthesia-free and that its therapy was clinically effective even though it is paresthesia-free. To definitely establish its results, the FDA required Nevro to test its Senza® system in an FDA-monitored randomized controlled trial in a head-to-head comparison against a commercially available low frequency SCS system (the "Controlled Trial"). Boston Scientific's Precision® SCS system was chosen as the commercially available comparator for the

<sup>&</sup>lt;sup>1</sup> Leonardo Kapural et al., "Novel 10-kHz High-frequency Therapy (HF10 Therapy) Is Superior to Traditional Low-frequency Spinal Cord Stimulation for the Treatment of Chronic Back and Leg Pain: The SENZA-RCT Randomized Controlled Trial," *Anesthesiology*, Vol. 123 No. 4 (October 2015) at 1364.

<sup>&</sup>lt;sup>2</sup> Oakley et al., "A New Spinal Cord Stimulation System Effectively Relieves Chronic, Intractable Pain: A Multicenter Prospective Clinical Study," *Neuromodulation*, Vol. 10 No. 3 (2007) at 264.

- Controlled Trial. In the Controlled Trial, Boston's SCS devices were programmed by Boston Scientific clinical engineers and/or sales representatives and implanted by physicians who regularly work with them. In a landmark finding, the Controlled Trial found Nevro's Senza® system and HF10<sup>TM</sup> therapy to be nearly twice as effective as Boston Scientific's paresthesia-based low frequency SCS system in providing pain relief.
- 22. The Senza® system was approved by the FDA on May 8, 2015, for sale in the United States. The FDA recognized Nevro's pioneering technology by approving Nevro's Senza® system with a "superiority" labeling—a designation that is rare in the medical device field. The superiority labeling indicates that Nevro's Senza® system and HF10<sup>TM</sup> therapy provides statistically superior efficacy when compared to Boston Scientific's paresthesia-based low frequency SCS therapy.
- 23. Nevro defied the conventional wisdom and demonstrated that effective pain relief could be achieved without paresthesia. Nevro's Senza® system provides more effective pain relief to a greater percentage of patients. Traditional, low frequency SCS therapy has limited use. For example, patients with predominant back pain are seldom seen as good candidates for traditional SCS therapy because it is anatomically difficult to cover the back with paresthesia. In contrast, Nevro's Senza® system and HF10<sup>TM</sup> therapy provide significant and sustained pain relief for *both* back and leg pain.
- 24. Nevro's Senza® system and HF10<sup>TM</sup> therapy has other significant advantages over paresthesia-based low frequency SCS systems as well. Paresthesia-based low frequency SCS has a cumbersome operating procedure that requires waking a patient during the implantation procedure so that the physician can position the paresthesia to overlap with the area of pain. In contrast, because Nevro's therapy does not require any intraoperative mapping of paresthesia, a patient does not need to be awakened for questioning during the surgical implantation procedure. This results in a much more predictable implantation procedure, and a much better patient experience, which creates the potential for greater patient and physician adoption.
- 25. Importantly, Nevro's Senza® system and HF10™ therapy also provides patients with greater freedom of movement and activity. Paresthesia-based SCS therapies can cause

unexpected jolts or shocks when a patient bends, twists, or changes posture, and must be turned off while driving or sleeping. Nevro's HF10<sup>TM</sup> SCS therapy does not have any such restriction. Traditional low frequency SCS patients who have switched to Nevro's device have found it lifechanging, as they have become truly pain and paresthesia-free for the first time in years. In the Controlled Trial, none of the patients receiving Nevro's HF10 therapy experienced induced paresthesia or reported stimulation-related discomfort. In comparison, 46.5% of patients who received Boston Scientific's low frequency paresthesia-based therapy reported uncomfortable stimulation.<sup>3</sup>

- 26. Because of the superiority of Nevro's Senza® system over traditional SCS systems, Medicare reimbursement in the United States is higher for the Senza® system than for any of Nevro's competitors. The Centers for Medicare and Medicaid ("CMS") determined that hospitals and clinics would receive this higher reimbursement after reviewing the clinical data on HF10<sup>TM</sup> therapy. The procedure that CMS followed to provide for this additional reimbursement has been employed only about a dozen times in the past ten years across the entire medical device field.
- 27. Although Nevro has only been in the U.S. market since May 2015, it has seen early success in breaking into the U.S. SCS market. The SCS market is dominated by three large competitors: Medtronic, St. Jude, and Boston Scientific. Each of these companies has an established market position, reinforced by extensive marketing and promotional infrastructure, teams of sales representatives, and longstanding connections and relationships with hospitals and doctors in the SCS field and in many other areas. Each of these companies leverages its multiple strengths to keep a tight grip on the SCS market. The sole reason Nevro has been able to break into the SCS market has been because it has unique—and demonstrably superior—SCS technology.

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<sup>26</sup> <sup>3</sup> Leonardo Kapural et al., "Novel 10-kHz High-frequency Therapy (HF10 Therapy) Is 27

Superior to Traditional Low-frequency Spinal Cord Stimulation for the Treatment of Chronic Back and Leg Pain: The SENZA-RCT Randomized Controlled Trial," Anesthesiology, Vol. 123 No. 4 (October 2015) at 1367.

28. Nevro has protected its innovative SCS technology through an extensive patent portfolio of more than 100 issued U.S. and international patents, including the patents asserted in this action. Nevro's patents cover many aspects of its pioneering technology, including implantable high frequency SCS systems and devices, methods of treating patients with paresthesia-free systems and devices, and methods of programming such systems and devices.

## Boston Scientific Begins To Pursue A High Frequency System

- 29. Boston Scientific is a supplier of paresthesia-based low frequency SCS systems. Boston Scientific is well aware of Nevro's role in pioneering paresthesia-free high frequency SCS technology. The FDA-monitored clinical study that demonstrated the superiority of Nevro's Senza® system used Boston Scientific's low frequency SCS devices as the comparator. Those devices were implanted and monitored by physicians who regularly work with Boston Scientific devices and programmed by Boston Scientific's clinical engineers and/or sales representatives.
- 30. After seeing the success of Nevro's Senza® system in the Australian and European markets, and faced with the growing evidence of the superior performance of Nevro's Senza® system in the FDA clinical study against Boston Scientific's own products, Boston Scientific aggressively began pursuing plans to copy Nevro's technology and launch a competing paresthesia-free high frequency SCS system.
- 31. Boston Scientific launched a clinical trial called "ACCELERATE" in March 2014 to evaluate the safety and effectiveness of paresthesia-free high frequency SCS therapy using Boston Scientific's Precision SCS system as part of the process of seeking FDA approval. Notably, the system that is the subject of the ACCELERATE study operates at the same 10,000 Hz frequency as Nevro's commercial paresthesia-free HF10™ therapy. The system of the ACCELERATE study is covered by many claims in Nevro's patent portfolio, including the patents in this action. The ACCELERATE study was scheduled for completion in October 2016.

## Boston Scientific Unsuccessfully Challenges Nevro's Patent Protection

32. Boston Scientific is well aware of Nevro's extensive patent portfolio protecting Nevro's innovative technology.

1	33. On May 14, 2015, just six days after the FDA approved Nevro's Senza® system		
2	for paresthesia-free high frequency SCS therapy, Boston Scientific filed two petitions with the		
3	U.S. Patent and Trademark Office ("PTO") seeking to challenge the validity of Nevro's U.S.		
4	Patent No. 8,359,102 ("the '102 patent") through <i>inter partes</i> review ("IPR") proceedings. The		
5	petitions alleged that sixteen claims of the '102 patent were invalid in light of the prior art. For		
6	example, Boston challenged the validity of claim 1 of the '102 patent, which claims:		
7	1. A method for treating a patient, comprising:		
8 9	delivering or instructing delivery of an electrical signal to the patient's spinal cord via at least one implantable signal delivery device; and		
10	wherein the electrical signal has a frequency of from about 1.5 kHz to about 50 kHz and does not create paresthesia in the		
11	patient.		
12	34. Between its two petitions, Boston Scientific raised four allegedly anticipatory		
13	grounds for invalidity, and over 25 obviousness allegations using various combinations of		
14	references. Yet both of Boston Scientific's petitions were decisively denied in their entirety. The		
15	PTO declined to institute any proceedings, finding that Boston Scientific failed to establish a		
16	reasonable likelihood of showing that even one of the sixteen challenged claims of Nevro's patent		
17	was invalid.		
18	Boston Scientific Continues To Press Forward With Its High Frequency System		
19	35. Despite the denial of its IPR petitions, Boston Scientific has continued to pursue		
20	its plans to market a paresthesia-free high frequency SCS system. Boston Scientific publicly		
21	announced that it would press forward with these plans regardless of its failed challenge against		
22	Nevro's patents.		
23	36. At the Piper Jaffray Health Care Conference in December 2015, Boston		
24	Scientific's Vice President of Investor Relations, Susan Lisa, stated the company's intentions as		
25	follows:		
26	Susan Lisa: So it was announced yesterday by the patent office that		
27	we – there are requests for an inter-party review with respect to a competitors patents and high frequency space for spinal cord		
28	stimulation. The request for that IPR review has been denied but I can say no change to our business strategy going forward in		

1	spinal cord stem		
2	Q: Okay. And you are moving forward with the 10,000 hertz trial, so, I mean, I think that's the statement maybe in and of itself.		
3 4	Susan Lisa: That's right. That's our ACCELERATE trial that is looking at the 10,000 hertz trial that we'll continue to enroll, and we'd expect to see it complete by the end of 2016.		
5	37. At the Morgan Stanley Global Healthcare Conference in September 2016, Boston		
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7	Scientific's CEO Mike Mahoney confirmed that Boston Scientific is continuing to pursue its		
8	plans for a paresthesia-free high frequency SCS system, and stated that Boston Scientific		
9	expected to release the data from the ACCELERATE study before the end of the year:		
10	Q: [A]re we going to get ACCELERATE data at NANS in January? And if the data is good are you going to launch this		
11	product in the US?		
12	Mike Mahoney: In terms of the ACCELERATE data we will disclose more of our ACCELERATE data and next steps in that area by the end of – by fourth quarter end of this year Likely		
13	you will hear more from us before NANS.		
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15	38. In its October 26, 2016 earnings call, Boston Scientific moved that date back		
16	slightly, stating that it would provide "an update on the ACCELERATE trial" and "additional		
17	insight" in its fourth quarter 2016 earnings call, which was scheduled to take place in February		
18	2017.		
19	39. In the February 2017 earnings call, contrary to its earlier announcements, Boston		
20	Scientific announced that it was extending enrollment in the ACCELERATE trial to the end of		
21	2017, with results expected in mid-2018. BSC's extension of the ACCELERATE trial, and the		
22	current status of that trial, are discussed in the Confidential Appendix.		
23	Boston Scientific Is Already Making And Selling High Frequency Capable Systems		
24	40. In the meantime, although Boston Scientific has not yet received FDA approval,		
25	Boston Scientific is already manufacturing and/or selling infringing SCS systems in the United		
26	States that are capable of operating at frequencies up to 10,000 Hz.		
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- 41. Nevro learned less than two weeks prior to filing this action that Boston Scientific has received CE Mark approval for commercial sale of paresthesia-free high frequency SCS systems in Europe.
- 42. Boston Scientific's SCS devices are manufactured in the United States, at its facility in Valencia, California.
- 43. Boston Scientific is selling these devices in at least Germany, Italy, Netherlands, Spain, Switzerland, and the United Kingdom, marketing them as Precision SCS Systems with MultiWave<sup>TM</sup> Technology. According to Boston Scientific, "[t]he Precision SCS System with MultiWave Technology can be programmed by a user to provide stimulation frequencies up to 10,000 Hz" and '[s]timulation frequencies between 2,000Hz and 10,000Hz are used with a pulse width of 20-240 µsec and an amplitude of 0-9mA."
- 44. Boston Scientific is also participating in a multi-center National Health Services ("NHS") study in the United Kingdom called VELOCITY, employing Boston Scientific's Precision SCS system. The research summary on the NHS site states that the study will be conducted "using the commercially available Boston Scientific (BSC) PRECISION Spinal Cord Stimulator System with MultiWave Technology" and that:

Up to 60 patients in up to 10 sites in Europe will be enrolled and followed up to 12 months after device activation. Eligible subjects, following written consent will receive the commercial stimulation device programmed at 10KHz [10,000 Hz] as part of their standard of care.

- 45. The Dutch Central Committee on Research Involving Human Subjects (CCMO) recently approved the VELOCITY study in the Netherlands. The research summary on the CCMO website similarly states that the study is using Boston Scientific's Precision SCS System with MultiWave Technology and that this system "is capable of providing stimulation at rates up to 10 kHz [10,000 Hz]." The summary also states: "This is a post CE mark study, within the indications for use." (emphasis added).
- 46. Boston Scientific is also participating in a separate clinical trial in the United Kingdom called "PROCO" using its Precision SCS system to evaluate stimulation pulse rate on

clinical outcomes in patients whose back pain is controlled by 10,000 Hz frequency. The PROCO study began in June 2015 and is scheduled for completion in August 2017.

- 47. It also appears that Boston Scientific is already manufacturing SCS systems that are capable of operating at high frequencies (up to 10,000 Hz) for sale within the United States. Boston Scientific submitted product specifications to the National Institutes of Health ("NIH") in September 2015 listing the Boston Scientific products available for the NIH BRAIN Initiative. The list of products included Boston Scientific's Precision MultiWave<sup>TM</sup> SCS system, which the specifications described as similar to the Precision SCS system "but capable of stimulation frequencies up to 10kHz [10,000 Hz]." Boston Scientific describes its MultiWave technology as enabling the delivery of "higher rates," and provides a chart indicating that the Precision SCS System with MultiWave has the frequency, amplitude, and pulse width parameters described in paragraph 43 above. Additional relevant facts are set forth in the Confidential Appendix.
- 48. Boston Scientific markets its Precision Spectra, Precision Montage, and Precision Novi SCS systems commercially as containing MultiWave technology. For example, in a June 4, 2015 Press Release, Boston Scientific proclaimed that "Precision Novi is a MultiWave<sup>TM</sup> Platform capable of delivering a variety of field shapes and waveforms with or without paresthesia, including burst and higher rate frequencies." The press release indicates on its face that it was issued from Boston Scientific's headquarters in Marlborough, Massachusetts.
- 49. Boston Scientific has admitted that the system being used in the ACCELERATE study is the Precision™ SCS System with MultiWave technology, the same system that is commercially sold and used in Europe. These devices are being programmed by Boston Scientific representatives.

<sup>&</sup>lt;sup>4</sup> In this action, Boston Scientific has asserted that there are two different forms of MultiWave technology, one of which operates at frequencies of between 2,000 and 10,000 Hz, as described above, and one of which operates at frequencies below 1,200 Hz. Boston Scientific's nomenclature is unclear and inconsistent. Even if they do not currently have the capability to operate at frequencies above 2,000 Hz, Nevro believes that these SCS systems will be modified to do so.

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- 50. Boston Scientific has allowed patients who had completed their participation in the ACCELERATE Study to continue to receive high frequency therapy using the Precision SCS System with MultiWave Technology and estimates that approximately 50% to 70% of patients chose to do so. Boston Scientific states that it has provided programming support to these patients on an as-requested basis.
- 51. Additional allegations relating to Boston Scientific's U.S. activities are set forth in the Confidential Appendix.
- 52. In addition, multiple Boston Scientific sales representatives across the country have been promoting Boston Scientific's upcoming high frequency device to discourage physicians and health care providers from using Nevro's Senza SCS device by telling them that Boston Scientific imminently will be launching its own high frequency device. Just since this lawsuit was filed, Nevro has learned that such representations were made to physicians and/or health care providers by at least Boston Scientific sales representatives Mitch D'Agastino, John Taylor, Sean Dugan, Michael Canning, and Wes Layton.
- 53. Boston Scientific has been conducting its infringing activities in knowing violation of Nevro's patents that cover these systems.
- 54. Nevro will be irreparably harmed if Boston Scientific is permitted to manufacture, use, offer to sell, and sell a competing, infringing device. Nevro will be forced to compete against the very technology that it spent years researching, developing and bringing to market. Nevro does not license its technology to anyone else. This differentiating technology, developed in the face of the skepticism of Boston Scientific and the SCS industry, has been the key to Nevro's ability to break into a market that has been dominated for decades by three of the largest medical device companies in the world. Nevro's marketing strategy has been built around educating physicians, health care providers and consumers about the superior performance of its Senza® system and paresthesia-free high frequency SCS, in comparison with traditional paresthesia-based low frequency SCS therapy. If Boston Scientific is permitted to sell an infringing paresthesia-free device, Nevro will lose its key distinguishing feature, and other companies will feel free to launch their own competing, infringing devices.

- 55. Nevro believes that, when it does engage in the full commercial launch of its high frequency paresthesia-free SCS systems in the United States, Boston Scientific will be able to immediately launch on a widescale basis.
- 56. Nevro will accordingly seek an order from this Court preliminarily and permanently enjoining Boston Scientific from infringing Nevro's patents.

### FIRST CAUSE OF ACTION

(Infringement of U.S. Patent No. 8,712,533)

- 57. Nevro incorporates by reference the allegations contained in paragraphs 1-56 above, and the Confidential Appendix.
- 58. Nevro is the owner of all right, title, and interest in and to U.S. Patent No. 8,712,533 (the '533 patent). The '533 patent issued on April 29, 2014 and is entitled "Selective High Frequency Spinal Cord Modulation for Inhibiting Pain with Reduced Side Effects, and Associated Systems and Methods." A copy of the '533 patent is attached to the original Complaint as Exhibit A.
- 59. The claims of the '533 patent cover implantable SCS systems and devices capable of providing high frequency SCS therapy without creating paresthesia. For example, claim 1 of the '533 patent is directed to an SCS system that has a signal generator capable of generating high frequency therapy signals in a range from 1.5 kHz to 100 kHz without creating paresthesia, and an implantable signal delivery device electrically coupleable to the signal generator and capable of delivering the therapy signal to the patient's spinal cord region.
- 60. Boston Scientific has infringed, and will continue to infringe, the '533 patent by manufacturing, using, selling and/or offering to sell in the United States SCS systems that have a signal generator capable of generating high frequency therapy signals in a range from 1.5 kHz to 100 kHz without creating paresthesia, and an implantable signal delivery device electrically coupleable to the signal generator and capable of delivering the therapy signal to the patient's spinal cord region. Boston Scientific's manufacture, use, offer to sell and/or sale of these systems infringes one or more claims of the '533 patent, including at least claim 1, literally or under the doctrine of equivalents, and violate 35 U.S.C. § 271.

- 61. Boston Scientific has engaged in substantial preparation and taken concrete steps with the intent to conduct these infringing activities. As discussed in more detail above, Boston Scientific is already manufacturing SCS systems designed to perform at frequencies of up to 10,000 Hz in the United States for commercial use and sale in Europe. Additional information is set forth in the Confidential Appendix. Boston Scientific sales representatives are already promoting Boston Scientific's upcoming high frequency device to U.S. physicians, representing that Boston Scientific will be imminently launching its own high frequency device. As such, Nevro believes that Boston Scientific will immediately begin to further directly infringe the '533 patent on a wider scale upon receiving FDA approval.
- 62. Boston Scientific knows of or has been willfully blind to the existence of the '533 patent. The '533 patent is the parent of the '102 patent. Boston Scientific has already unsuccessfully challenged the validity of sixteen claims of Nevro's '102 patent covering Nevro's high frequency paresthesia-free SCS system by filing two IPR petitions with the PTO. Although both petitions were denied by the PTO, Boston Scientific publicly announced at the December 2015 Piper Jaffray Health Conference that it intended to press forward nonetheless, and has continued with the ACCELERATE study and with manufacturing and/or selling infringing 10,000 Hz-capable devices. Boston Scientific is also formally opposing Nevro's European patents in Europe.
- 63. Boston Scientific has intentionally instructed, and will intentionally instruct, others, including doctors and health care providers, to use its high frequency SCS in a manner that infringes the '533 patent, literally or under the doctrine of equivalents. In the SCS industry, the clinical engineers and/or sales representatives of the device manufacturer normally are present in the operating room and will program the SCS device for the operation, including by setting the parameters for the frequency, amplitude and pulse width of the electronic signal to be delivered by the device. Boston Scientific knows or has been willfully blind to the fact that such actions are inducing, and will induce, infringement. The foregoing actions by Boston Scientific constitute, and will constitute, induced infringement of one or more claims of the '533 patent in violation of 35 U.S.C. § 271(b).

- 64. Moreover, Boston Scientific is continuing to program patients who have completed their participation in the ACCELERATE study to provide paresthesia-free high frequency SCS therapy, and will further induce infringement of the '533 patent by its actions.
- 65. Boston Scientific has supplied from the United States all or a substantial portion of the components of its infringing SCS systems and induced the combination of such components outside of the United States in a manner that would infringe the '533 patent if it occurred within the United States. The foregoing actions by Boston Scientific constitute infringement of one or more claims of the '533 patent in violation of 35 U.S.C. § 271(f).
- 66. Additional allegations relating to Boston Scientific's United States activities which support this claim for infringement are set forth in the Confidential Appendix.
- 67. Boston Scientific's infringement is without the consent or other authority of Nevro. Boston Scientific is not licensed under the '533 patent.
- 68. An actual and justiciable controversy exists between Nevro and Boston Scientific regarding infringement of the '533 patent. Nevro is entitled to a declaration that Boston Scientific's current and future commercial manufacture, use, offer for sale, sale, and/or importation of high frequency SCS systems does and will infringe the '533 patent, directly and indirectly.
- 69. Boston Scientific has actual and constructive notice of the '533 patent. Boston Scientific's actions are willful and deliberate, and render this an exceptional case under 35 U.S.C. § 285.
- 70. Nevro has been and will be damaged by Boston Scientific's acts in an amount as yet unknown. Nevro has no adequate legal remedy. Unless enjoined by this Court, Boston Scientific's continued acts of infringement will cause Nevro substantial and irreparable harm. Under 35 U.S.C. § 283, Nevro is entitled to an injunction barring Boston Scientific from further infringement of the '533 patent.

**SECOND CAUSE OF ACTION** 

(Infringement of U.S. Patent No. 9,327,125)

71. Nevro incorporates by reference the allegations contained in paragraphs 1-70 above, and the Confidential Appendix.

- 72. Nevro is the owner of all right, title, and interest in and to U.S. Patent No. 9,327,125 (the '125 patent). The '125 patent issued on May 3, 2016, and is entitled "Selective High Frequency Spinal Cord Modulation for Inhibiting Pain with Reduced Side Effects, and Associated Systems and Methods." A copy of the '125 patent is attached to the original Complaint as Exhibit B.
- 73. The claims of the '125 patent cover implantable SCS systems that include means for providing high frequency SCS therapy without creating paresthesia. For example, claim 12 of the '125 patent is directed to an SCS system that includes means of generating a paresthesia-free therapy signal in a range from 1.5 kHz to 100 kHz and implantable means of delivering the therapy signal to the patient's spinal cord.
- 74. Boston Scientific has infringed, and will continue to infringe, the '125 patent by manufacturing, selling and/or offering to sell in the United States SCS systems that include means of generating a paresthesia-free therapy signal in a range from 1.5 kHz to 100 kHz and implantable means of delivering the therapy signal to the patient's spinal cord. Boston Scientific's manufacture and/or sale of these systems infringes one or more claims of the '125 patent, including at least claim 12, literally or under the doctrine of equivalents, and violate 35 U.S.C. § 271.
- 75. Boston Scientific has engaged in substantial preparation and taken concrete steps with the intent to conduct these infringing activities. As discussed in more detail above, Boston Scientific is already manufacturing SCS systems designed to perform at frequencies of up to 10,000 Hz in the United States for commercial use and sale in Europe. Additional information is set forth in the Confidential Appendix. Boston Scientific sales representatives are already promoting Boston Scientific's upcoming high frequency device to U.S. physicians, representing that Boston Scientific will be imminently launching its own high frequency device. As such,

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27 28 Nevro believes that Boston Scientific will immediately begin to further directly infringe the '125 patent on a wider scale upon receiving FDA approval.

- 76. Boston Scientific knows of or has been willfully blind to the existence of the '125 patent. The '125 patent is in the same patent family as the '102 patent. Boston Scientific has already unsuccessfully challenged the validity of sixteen claims of Nevro's '102 patent covering Nevro's high frequency paresthesia-free SCS system by filing two IPR petitions with the PTO. Although both petitions were denied by the PTO, Boston Scientific publicly announced at the December 2015 Piper Jaffray Health Conference that it intended to press forward nonetheless, and has continued with the ACCELERATE study and with manufacturing and/or selling infringing 10,000 Hz-capable devices. Boston Scientific is also formally opposing Nevro's European patents in Europe.
- 77. Boston Scientific has intentionally instructed, and will intentionally instruct, others, including doctors and health care providers, to use its high frequency SCS in a manner that infringes the '125 patent, literally or under the doctrine of equivalents. In the SCS industry, the clinical engineers and/or sales representatives of the device manufacturer normally are present in the operating room and will program the SCS device for the operation, including by setting the parameters for the frequency, amplitude and pulse width of the electronic signal to be delivered by the device. Boston Scientific knows or has been willfully blind to the fact that such actions are inducing, and will induce, infringement. The foregoing actions by Boston Scientific constitute, and will constitute, induced infringement of one or more claims of the '125 patent in violation of 35 U.S.C. § 271(b).
- 78. Moreover, Boston Scientific is continuing to program patients who have completed their participation in the ACCELERATE study to provide paresthesia-free high frequency SCS therapy, and will further induce infringement of the '125 patent by its actions.
- 79. Boston Scientific has supplied from the United States all or a substantial portion of the components of its infringing SCS systems and induced the combination of such components outside of the United States in a manner that would infringe the '125 patent if it occurred within

1	the United States. The foregoing actions by Boston Scientific constitute infringement of one or	
2	more claims of the '125 patent in violation of 35 U.S.C. § 271(f).	
3	80. Additional allegations relating to Boston Scientific's United States activities which	
4	support this claim for infringement are set forth in the Confidential Appendix.	
5	81. Boston Scientific's infringement is without the consent or other authority of	
6	Nevro. Boston Scientific is not licensed under the '125 patent.	
7	82. An actual and justiciable controversy exists between Nevro and Boston Scientific	
8	regarding infringement of the '125 patent. Nevro is entitled to a declaration that Boston	
9	Scientific's current and future commercial manufacture, use, offer for sale, sale, and/or	
10	importation of high frequency SCS systems does and will infringe the '125 patent, directly and	
11	indirectly.	
12	83. Boston Scientific has actual and constructive notice of the '125 patent. Boston	
13	Scientific's actions are willful and deliberate, and render this an exceptional case under 35 U.S.C.	
14	§ 285.	
15	84. Nevro has been and will be damaged by Boston Scientific's acts in an amount as	
16	yet unknown. Nevro has no adequate legal remedy. Unless enjoined by this Court, Boston	
17	Scientific's continued acts of infringement will cause Nevro substantial and irreparable harm.	
18	Under 35 U.S.C. § 283, Nevro is entitled to an injunction barring Boston Scientific from further	
19	infringement of the '125 patent.	
20	THIRD CAUSE OF ACTION	
21	(Infringement of U.S. Patent No. 8,359,102)	
22	85. Nevro incorporates by reference the allegations contained in paragraphs 1-84	
23	above, and the Confidential Appendix.	
24	86. Nevro is the owner of all right, title, and interest in and to the '102 patent. The	
25	'102 patent issued on January 22, 2013, and is entitled "Selective High Frequency Spinal Cord	
26	Modulation for Inhibiting Pain with Reduced Side Effects, and Associated Systems and	
27	Methods." A copy of the '102 patent is attached to the original Complaint as Exhibit C.	

- 87. The claims of the '102 patent cover methods of treating patients with high frequency SCS without creating paresthesia. For example, claim 1 of the '102 patent is directed to a method for treating a patient with an implantable electrode and high frequency electrical signals (from about 1,500 Hz to about 50,000 Hz) without creating paresthesia in the patient.
- 88. Boston Scientific has infringed and continues to infringe the '102 patent by using, offering to sell, and/or selling in the United States SCS systems and methods for treating a patient that have an implantable electrode high frequency electrical signals above 1,500 Hz and up to 10,000 Hz without creating paresthesia in the patient. Boston Scientific's use, offer to sell, and/or sale of these systems and methods infringes one or more claims of the '102 patent, literally or under the doctrine of equivalents, in violation of 35 U.S.C. § 271.
- 89. Boston Scientific knows of the existence of the '102 patent. Nevro believes that Boston Scientific has intentionally instructed others, including doctors and health care providers, to use its high frequency SCS in a manner that infringes the '102 patent. In the SCS industry, the clinical engineers and/or sales representatives of the device manufacturer normally are present in the operating room and will program the SCS device for the operation, including by setting the parameters for the frequency, amplitude and pulse width of the electronic signal to be delivered by the device. Boston Scientific knows or has been willfully blind to the fact that such actions are induced infringement. The foregoing actions by Boston Scientific constitute induced infringement of one or more claims of the '102 patent in violation of 35 U.S.C. § 271(b) and (f)(1).
- 90. Boston Scientific has supplied from the United States all or a substantial portion of the components of its infringing SCS systems and induced the combination of such components outside of the United States in a manner that would infringe the '102 patent if it occurred within the United States. The foregoing actions by Boston Scientific constitute infringement of one or more claims of the '102 patent in violation of 35 U.S.C. § 271(f).
- 91. Additional allegations relating to Boston Scientific's United States activities which support this claim for infringement are set forth in the Confidential Appendix.

- 92. Boston Scientific's infringement is without the consent or other authority of Nevro. Boston Scientific is not licensed under the '102 patent.
- 93. Boston Scientific has actual notice of the '102 patent. Boston Scientific's actions are willful and deliberate, and render this an exceptional case under 35 U.S.C. § 285.
- 94. Nevro has been damaged by Boston Scientific's acts in an amount as yet unknown. Nevro has no adequate legal remedy. Unless enjoined by this Court, Boston Scientific's imminent infringement will cause Nevro substantial and irreparable harm. Under 35 U.S.C. § 283, Nevro is entitled to an injunction barring Boston Scientific from infringement of the '102 patent.

### FOURTH CAUSE OF ACTION

(Declaratory Judgment of Infringement of U.S. Patent No. 8,359,102)

- 95. Nevro incorporates by reference the allegations contained in paragraphs 1-94 above, and the Confidential Appendix.
- 96. Boston Scientific does engage, and will engage, in the commercial manufacture, use, offer for sale, sale, and/or importation of SCS systems that have an implantable electrode and are capable of delivering high frequency electrical signals above 1,500 Hz and up to at least 10,000 Hz without creating paresthesia in the patient. Boston Scientific's use of such systems to provide high frequency SCS without creating paresthesia will constitute direct infringement of one or more claims of the '102 patent, literally or under the doctrine of equivalents, in violation of 35 U.S.C. § 271.
- 97. Boston Scientific has engaged in substantial preparation and taken concrete steps with the intent to conduct these infringing activities. As discussed in more detail above, Boston Scientific is already manufacturing SCS systems designed to perform at frequencies of up to 10,000 Hz in the United States for commercial sale in Europe. Additional information relating to imminence is set forth in the Confidential Appendix. Boston Scientific sales representatives are already promoting Boston Scientific's upcoming high frequency device to U.S. physicians, representing that Boston Scientific will be imminently launching its own high frequency device.

As such, Nevro believes that Boston Scientific will immediately begin to further directly infringe the '102 patent on a wider scale upon receiving FDA approval.

- 98. In addition to directly infringing, Nevro believes that upon FDA approval and commercial launch of Boston Scientific's infringing paresthesia-free high frequency SCS systems, Boston Scientific will further induce infringement of the '102 patent by inducing others to directly infringe the '102 patent, literally or under the doctrine of equivalents.
- 99. Moreover, Boston Scientific is continuing to program patients who have completed their participation in the ACCELERATE study to provide paresthesia-free high frequency SCS therapy, and will further directly infringe and induce infringement of the '102 patent by its actions.
- Boston Scientific knows of the existence of the '102 patent. Nevro believes that Boston Scientific has intentionally made substantial preparation to and will instruct others, including doctors and health care providers, to use its high frequency SCS in a manner that infringes the '102 patent. In the SCS industry, the clinical engineers and/or sales representatives of the device manufacturer normally are present in the operating room and will program the SCS device for the operation, including by setting the parameters for the frequency, amplitude and pulse width of the electronic signal to be delivered by the device. Boston Scientific knows or is willfully blind to the fact that such actions will induce infringement. The foregoing actions by Boston Scientific will constitute induced infringement of one or more claims of the '102 patent in violation of 35 U.S.C. § 271(b) and (f)(1).
- 101. An actual and justiciable controversy exists between Nevro and Boston Scientific regarding infringement of the '102 patent. Boston Scientific has already unsuccessfully challenged the validity of sixteen claims of Nevro's '102 patent covering Nevro's high frequency paresthesia-free SCS system by filing two IPR petitions with the Patent and Trademark Office. Although both petitions were denied by the PTO, Boston Scientific announced at the December 2015 Piper Jaffray Health conference that it intended to press forward nonetheless, and has continued with the ACCELERATE study and with manufacturing and/or selling infringing

1	10,000 Hz-capable devices nonetheless. Boston Scientific is also formally opposing Nevro's
2	European patents in Europe.
3	102. Additional allegations relating to Boston Scientific's United States activities which
4	support this claim for declaratory relief are set forth in the Confidential Appendix.
5	103. Boston Scientific's imminent infringement will be without the consent or other
6	authority of Nevro. Boston Scientific is not licensed under the '102 patent.
7	104. Nevro is entitled to a declaratory judgment that Boston Scientific's future
8	commercial manufacture, use, offer for sale, sale, and/or importation of high frequency SCS
9	systems does and will infringe the '102 patent, directly and indirectly.
10	105. Boston Scientific has actual notice of the '102 patent. Boston Scientific's actions
11	are willful and deliberate, and render this an exceptional case under 35 U.S.C. § 285.
12	106. Nevro has been and will be damaged by Boston Scientific's acts in an amount as
13	yet unknown. Nevro has no adequate legal remedy. Unless enjoined by this Court, Boston
14	Scientific's imminent infringement will cause Nevro substantial and irreparable harm. Under 35
15	U.S.C. § 283, Nevro is entitled to an injunction barring Boston Scientific from further
16	infringement of the '102 patent.
17	FIFTH CAUSE OF ACTION
18	(Infringement of U.S. Patent No. 9,480,842)
19	107. Nevro incorporates by reference the allegations contained in paragraphs 1-106
20	above, and the Confidential Appendix.
21	108. Nevro is the owner of all right, title, and interest in and to U.S. Patent No.
22	9,480,842 (the '842 patent). The '842 patent issued on November 1, 2016 and is entitled
23	"Selective High Frequency Spinal Cord Modulation for Inhibiting Pain with Reduced Side
24	Effects, and Associated Systems and Methods." A copy of the '842 patent is attached to the
25	original Complaint as Exhibit D.
26	109. The claims of the '842 patent cover implantable SCS systems and devices capable
27	of providing high frequency SCS therapy with certain ranges of amplitudes and pulse widths. For
28	example, claim 1 of the '842 patent is directed to an SCS system that has a signal generator
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capable of generating therapy signals with a frequency of 10 kHz, an amplitude up to 6 mA, and pulses with a pulse width between 30 and 35 microseconds, and an implantable signal delivery device electrically coupleable to the signal generator and capable of being implanted within a patient's epidural space to deliver the therapy signal to the patient's spinal cord.

- 110. Boston Scientific has infringed, and will continue to infringe, the '842 patent by manufacturing, and/or selling or offering to sell in the United States SCS systems that have a signal generator capable of generating therapy signals with a frequency of 10 kHz, an amplitude up to 6 mA, and pulses with a pulse width between 30 and 35 microseconds, and an implantable signal delivery device electrically coupleable to the signal generator and capable of being implanted within a patient's epidural space to deliver the therapy signal to the patient's spinal cord. Boston Scientific's manufacture and/or sale of these systems infringes one or more claims of the '842 patent, including at least claim 1, literally or under the doctrine of equivalents, and violate 35 U.S.C. § 271.
- 111. Boston Scientific has engaged in substantial preparation and taken concrete steps with the intent to conduct these infringing activities. As discussed in more detail above, Boston Scientific is already manufacturing SCS systems designed to perform at frequencies of up to 10,000 Hz in the United States for commercial use and sale in Europe. Additional information is set forth in the Confidential Appendix. Boston Scientific sales representatives are already promoting Boston Scientific's upcoming high frequency device to U.S. physicians, representing that Boston Scientific will be imminently launching its own high frequency device. As such, Nevro believes that Boston Scientific will immediately begin to further directly infringe the '842 patent on a wider scale upon receiving FDA approval.
- patent. The '842 patent is in the same patent family as the '102 patent. Boston Scientific has already unsuccessfully challenged the validity of sixteen claims of Nevro's '102 patent covering Nevro's high frequency paresthesia-free SCS system by filing two IPR petitions with the PTO. Although both petitions were denied by the PTO, Boston Scientific publicly announced at the December 2015 Piper Jaffray Health Conference that it intended to press forward nonetheless,

and has continued with the ACCELERATE study and with manufacturing and/or selling infringing 10,000 Hz-capable devices. Boston Scientific is also formally opposing Nevro's European patents in Europe.

- 113. Boston Scientific has intentionally instructed, and will intentionally instruct, others, including doctors and health care providers, to use its high frequency SCS in a manner that infringes the '842 patent, literally or under the doctrine of equivalents. In the SCS industry, the clinical engineers and/or sales representatives of the device manufacturer normally are present in the operating room and will program the SCS device for the operation, including by setting the parameters for the frequency, amplitude and pulse width of the electronic signal to be delivered by the device. Boston Scientific knows or has been willfully blind to the fact that such actions are inducing, and will induce, infringement. The foregoing actions by Boston Scientific constitute, and will constitute, induced infringement of one or more claims of the '842 patent in violation of 35 U.S.C. § 271(b).
- 114. Moreover, Boston Scientific is continuing to program patients who have completed their participation in the ACCELERATE study to provide paresthesia-free high frequency SCS therapy, and will further induce infringement of the '842 patent by its actions.
- 115. Boston Scientific has supplied from the United States all or a substantial portion of the components of its infringing SCS systems and induced the combination of such components outside of the United States in a manner that would infringe the '842 patent if it occurred within the United States. The foregoing actions by Boston Scientific constitute infringement of one or more claims of the '842 patent in violation of 35 U.S.C. § 271(f).
- 116. Additional allegations relating to Boston Scientific's United States activities which support this claim for infringement are set forth in the Confidential Appendix.
- 117. Boston Scientific's infringement is without the consent or other authority of Nevro. Boston Scientific is not licensed under the '842 patent.
- 118. An actual and justiciable controversy exists between Nevro and Boston Scientific regarding infringement of the '842 patent. Nevro is entitled to a declaration that Boston Scientific's current and future commercial manufacture, use, offer for sale, sale, and/or

1	importation of high frequency SCS systems does and will infringe the '842 patent, directly and	
2	indirectly.	
3	119. Boston Scientific has actual and constructive notice of the '842 patent. Boston	
4	Scientific's actions are willful and deliberate, and render this an exceptional case under 35 U.S.C.	
5	§ 285.	
6	120. Nevro has been and will be damaged by Boston Scientific's acts in an amount as	
7	yet unknown. Nevro has no adequate legal remedy. Unless enjoined by this Court, Boston	
8	Scientific's continued acts of infringement will cause Nevro substantial and irreparable harm.	
9	Under 35 U.S.C. § 283, Nevro is entitled to an injunction barring Boston Scientific from further	
10	infringement of the '842 patent.	
11	SIXTH CAUSE OF ACTION	
12	(Infringement of U.S. Patent No. 9,333,357)	
13	121. Nevro incorporates by reference the allegations contained in paragraphs 1-120	
14	above, and the Confidential Appendix.	
15	122. Nevro is the owner of all right, title, and interest in and to U.S. Patent No.	
16	9,333,357 (the '357 patent). The '357 patent issued on May 10, 2016 and is entitled "Selective	
17	High Frequency Spinal Cord Modulation for Inhibiting Pain with Reduced Side Effects, and	
18	Associated Systems and Methods." A copy of the '357 patent is attached to the original	
19	Complaint as Exhibit E.	
20	123. The claims of the '357 patent cover implantable SCS systems and devices capable	
21	of providing SCS therapy within certain ranges of pulse widths and amplitudes without	
22	generating paresthesia. For example, claim 1 of the '357 patent is directed to an SCS system that	
23	has a signal generator that can be programmed to generate and deliver electrical therapy signals to	
24	a patient's spinal cord from an epidural location via a coupleable implantable signal delivery	
25	device, wherein the signal has a plurality of sequential bi-phasic pulses with a pulse width	
26	between 10 and 333 microseconds and an amplitude between 0.5 mA and 10 mA, and at least	
27	partially reduces the patient's sensation of pain without generating paresthesia.	

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124. Boston Scientific has infringed, and will continue to infringe, the '357 patent by manufacturing, and/or selling or offering to sell in the United States SCS systems that have a signal generator that can be programmed to generate and deliver electrical therapy signals to a patient's spinal cord from an epidural location via a coupleable implantable signal delivery device, wherein the signal has a plurality of sequential bi-phasic pulses with a pulse width between 10 and 333 microseconds and an amplitude between 0.5 mA and 10 mA, and at least partially reduces the patient's sensation of pain without generating paresthesia. Boston Scientific's manufacture and/or sale of these systems infringes one or more claims of the '357 patent, including at least claim 1, literally or under the doctrine of equivalents, and violate 35 U.S.C. § 271.

125. Boston Scientific has engaged in substantial preparation and taken concrete steps with the intent to conduct these infringing activities. As discussed in more detail above, Boston Scientific is already manufacturing SCS systems designed to perform at amplitudes and pulse widths within the claimed ranges in the United States for commercial use and sale in Europe. Additional information is set forth in the Confidential Appendix. Boston Scientific sales representatives are already promoting Boston Scientific's upcoming infringing paresthesia-free device to U.S. physicians, representing that Boston Scientific will be imminently launching its own device. As such, Nevro believes that Boston Scientific will immediately begin to further directly infringe the '357 patent on a wider scale upon receiving FDA approval.

patent. The '357 patent is in the same patent family as the '102 patent. Boston Scientific has already unsuccessfully challenged the validity of sixteen claims of Nevro's '102 patent covering Nevro's high frequency paresthesia-free SCS system by filing two IPR petitions with the PTO. Although both petitions were denied by the PTO, Boston Scientific publicly announced at the December 2015 Piper Jaffray Health Conference that it intended to press forward nonetheless, and has continued with the ACCELERATE study and with manufacturing and/or selling infringing paresthesia-free devices. Boston Scientific is also formally opposing Nevro's European patents in Europe.

- 127. Boston Scientific has intentionally instructed, and will intentionally instruct, others, including doctors and health care providers, to use its high frequency SCS in a manner that infringes the '357 patent, literally or under the doctrine of equivalents. In the SCS industry, the clinical engineers and/or sales representatives of the device manufacturer normally are present in the operating room and will program the SCS device for the operation, including by setting the parameters for the frequency, amplitude and pulse width of the electronic signal to be delivered by the device. Boston Scientific knows or has been willfully blind to the fact that such actions are inducing, and will induce, infringement. The foregoing actions by Boston Scientific constitute, and will constitute, induced infringement of one or more claims of the '357 patent in violation of 35 U.S.C. § 271(b).
- 128. Moreover, Boston Scientific is continuing to program patients who have completed their participation in the ACCELERATE study to provide paresthesia-free SCS therapy, and will further induce infringement of the '357 patent by its actions.
- 129. Boston Scientific has supplied from the United States all or a substantial portion of the components of its infringing SCS systems and induced the combination of such components outside of the United States in a manner that would infringe the '357 patent if it occurred within the United States. The foregoing actions by Boston Scientific constitute infringement of one or more claims of the '357 patent in violation of 35 U.S.C. § 271(f).
- 130. Additional allegations relating to Boston Scientific's United States activities which support this claim for infringement are set forth in the Confidential Appendix.
- 131. Boston Scientific's infringement is without the consent or other authority of Nevro. Boston Scientific is not licensed under the '357 patent.
- 132. An actual and justiciable controversy exists between Nevro and Boston Scientific regarding infringement of the '357 patent. Nevro is entitled to a declaration that Boston Scientific's current and future commercial manufacture, use, offer for sale, sale, and/or importation of high frequency SCS systems does and will infringe the '357 patent, directly and indirectly.

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	133.	Boston Scientific has actual and constructive notice of the '357 patent. Boston
Scient	tific's ac	ctions are willful and deliberate, and render this an exceptional case under 35 U.S.C.
§ 285		

134. Nevro has been and will be damaged by Boston Scientific's acts in an amount as yet unknown. Nevro has no adequate legal remedy. Unless enjoined by this Court, Boston Scientific's continued acts of infringement will cause Nevro substantial and irreparable harm. Under 35 U.S.C. § 283, Nevro is entitled to an injunction barring Boston Scientific from further infringement of the '357 patent.

### **SEVENTH CAUSE OF ACTION**

(Infringement of U.S. Patent No. 8,792,988)

- 135. Nevro incorporates by reference the allegations contained in paragraphs 1-134 above, and the Confidential Appendix.
- 136. Nevro is the owner of all right, title, and interest in and to U.S. Patent No. 8,792,988 (the '988 patent). The '988 patent issued on July 29, 2014, and is entitled "Selective High Frequency Spinal Cord Modulation for Inhibiting Pain with Reduced Side Effects, and Associated Systems and Methods." A copy of the '988 patent is attached to the original Complaint as Exhibit F.
- 137. The claims of the '988 patent cover methods for programming devices to treat patients with SCS without creating paresthesia. For example, claim 23 of the '988 patent is directed to a method for programming a signal generator to generate and deliver therapy signals at a frequency between 1.5 kHz and 100 kHz and at an amplitude that at least partially reduces the patient's sensation of pain without inducing paresthesia in the patient.
- 138. Boston Scientific has infringed and continues to infringe the '988 patent by using, offering to sell, and/or selling in the United States SCS systems and methods for programming a signal generator to generate and deliver therapy signals at a frequency between 1.5 kHz and 10 kHz and at an amplitude that at least partially reduces the patient's sensation of pain without inducing paresthesia in the patient. Boston Scientific's use, offer to sell, and/or sale of these

1	systems and methods infringes one or more claims of the '988 patent, including at least 23,	
2	literally or under the doctrine of equivalents, and violates 35 U.S.C. § 271.	
3	139. Boston Scientific knows of or has been willfully blind to the existence of the '988	
4	patent. Nevro believes that Boston Scientific has intentionally instructed others, including	
5	doctors and health care providers, to use its high frequency SCS in a manner that infringes the	
6	'988 patent. In the SCS industry, the clinical engineers and/or sales representatives of the device	
7	manufacturer normally are present in the operating room and will program the SCS device for the	
8	operation, including by setting the parameters for the frequency, amplitude and pulse width of the	
9	electronic signal to be delivered by the device. Boston Scientific knows or has been willfully	
10	blind to the fact that such actions are inducing infringement. The foregoing actions by Boston	
11	Scientific constitute induced infringement of one or more claims of the '988 patent in violation of	
12	35 U.S.C. § 271(b) and (f)(1).	
13	140. Additional allegations relating to Boston Scientific's United States activities which	
14	support this claim for infringement are set forth in the Confidential Appendix.	
15	141. Boston Scientific's infringement is without the consent or other authority of	
16	Nevro. Boston Scientific is not licensed under the '988 patent.	
17	142. Boston Scientific has actual notice of the '988 patent. Boston Scientific's actions	
18	are willful and deliberate, and render this an exceptional case under 35 U.S.C. § 285.	
19	143. Nevro has been damaged by Boston Scientific's acts in an amount as yet unknown.	
20	Nevro has no adequate legal remedy. Unless enjoined by this Court, Boston Scientific's	
21	imminent infringement will cause Nevro substantial and irreparable harm. Under 35 U.S.C. §	
22	283, Nevro is entitled to an injunction barring Boston Scientific from infringement of the '988	
23	patent.	
24	EIGHTH CAUSE OF ACTION	
25	(Declaratory Judgment of Infringement of U.S. Patent No. 8,792,988)	
26	144. Nevro incorporates by reference the allegations contained in paragraphs 1-143	

above, and the Confidential Appendix.

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- 145. Boston Scientific does engage, and will engage, in the commercial manufacture, use, offer for sale, sale, and/or importation of SCS systems that have a signal generator that can be programmed to generate and deliver therapy signals at a frequency between 1.5 kHz and 100 kHz and at an amplitude that at least partially reduces the patient's sensation of pain without inducing paresthesia in the patient. In the SCS industry, the clinical engineers and/or sales representatives of the device manufacturer normally are present in the operating room and will program the SCS device for the operation, including by setting the parameters for the frequency, amplitude and pulse width of the electronic signal to be delivered by the device. The foregoing actions by Boston Scientific will constitute direct infringement of one or more claims of the '988 patent, literally or under the doctrine of equivalents, in violation of 35 U.S.C. § 271.
- 146. Boston Scientific has engaged in substantial preparation and taken concrete steps with the intent to conduct these infringing activities. As discussed in more detail above, Boston Scientific is already manufacturing SCS systems designed to perform at frequencies of up to 10,000 Hz in the United States for commercial sale in Europe. Additional information relating to imminence is set forth in the Confidential Appendix. Boston Scientific sales representatives are already promoting Boston Scientific's upcoming high frequency device to U.S. physicians, representing that Boston Scientific will be imminently launching its own high frequency device. As such, Nevro believes that Boston Scientific will immediately begin to further directly infringe the '988 patent on a wider scale upon receiving FDA approval.
- 147. In addition to directly infringing, Nevro believes that upon FDA approval and commercial launch of Boston Scientific's infringing paresthesia-free high frequency SCS systems, Boston Scientific will further induce infringement of the '988 patent by inducing others to directly infringe the '988 patent, literally or under the doctrine of equivalents.
- 148. Moreover, Boston Scientific is continuing to program patients who have completed their participation in the ACCELERATE study to provide paresthesia-free high frequency SCS therapy, and will further directly infringe and induce infringement of the '988 patent by its actions.

- Nevro believes that Boston Scientific knows of or is willfully blind to the existence of the '988 patent. Nevro believes that Boston Scientific has intentionally made substantial preparation to and will instruct others, including doctors and health care providers, to use its high frequency SCS in a manner that infringes the '988 patent. In the SCS industry, the clinical engineers and/or sales representatives of the device manufacturer normally are present in the operating room and will program the SCS device for the operation, including by setting the parameters for the frequency, amplitude and pulse width of the electronic signal to be delivered by the device. Boston Scientific knows or is willfully blind to the fact that such actions will induce infringement. The foregoing actions by Boston Scientific will constitute induced infringement of one or more claims of the '988 patent in violation of 35 U.S.C. § 271(b) and (f)(1).
- 150. An actual and justiciable controversy exists between Nevro and Boston Scientific regarding infringement of the '988 patent. The '988 patent is in the same patent family as the '102 patent. Boston Scientific has already unsuccessfully challenged the validity of sixteen claims of Nevro's '102 patent covering Nevro's high frequency paresthesia-free SCS system by filing two IPR petitions with the Patent and Trademark Office. Although both petitions were denied by the PTO, Boston Scientific announced at the December 2015 Piper Jaffray Health conference that it intended to press forward nonetheless, and has continued with the ACCELERATE study and with manufacturing and/or selling infringing 10,000 Hz-capable devices nonetheless. Boston Scientific is also formally opposing Nevro's European patents in Europe.
- 151. Additional allegations relating to Boston Scientific's United States activities which support this claim for declaratory relief are set forth in the Confidential Appendix.
- 152. Boston Scientific's imminent infringement will be without the consent or other authority of Nevro. Boston Scientific is not licensed under the '988 patent.
- 153. Nevro is entitled to a declaratory judgment that Boston Scientific's future commercial manufacture, use, offer for sale, sale, and/or importation of high frequency SCS systems does and will infringe the '988 patent, directly and indirectly.

kHz and 100 kHz. Boston Scientific's use, offer to sell, and/or sale of these systems and methods infringes one or more claims of the '472 patent, including at least claim 1, literally or under the doctrine of equivalents, and violate 35 U.S.C. § 271.

- patent. Nevro believes that Boston Scientific has intentionally instructed others, including doctors and health care providers, to use its high frequency SCS in a manner that infringes the '472 patent. In the SCS industry, the clinical engineers and/or sales representatives of the device manufacturer normally are present in the operating room and will program the SCS device for the operation, including by setting the parameters for the frequency, amplitude and pulse width of the electronic signal to be delivered by the device. Boston Scientific knows or has been willfully blind to the fact that such actions are inducing infringement. The foregoing actions by Boston Scientific constitute induced infringement of one or more claims of the '472 patent in violation of 35 U.S.C. § 271(b).
- 161. In addition and/or in the alternative to inducing infringement, Boston Scientific also directly infringes the asserted claims of the '472 patent through joint acts with physicians, or as part of a joint enterprise with physicians, whereby the acts of one are attributable to the other such that a single entity is responsible for the infringement. Physicians implant and electrically couple the leads and signal generators for Boston Scientific's infringing SCS systems. Boston Scientific's clinical engineers and/or sales representatives program the signal generators and are present in the operating room with physicians while the implantation is performed, working jointly to carry out the procedure. Boston Scientific's Vice-President of Clinical and Regulatory Affairs, Kaoru Lee Adair, testified that Boston Scientific's clinical engineers and/or sales representatives carry out this programming under the direction of physicians.
- 162. Boston Scientific has supplied from the United States all or a substantial portion of the components of its infringing SCS systems and induced the combination of such components outside of the United States in a manner that would infringe the '472 patent if it occurred within the United States. The foregoing actions by Boston Scientific constitute infringement of one or more claims of the '472 patent in violation of 35 U.S.C. § 271(f).

- 163. Additional allegations relating to Boston Scientific's United States activities which support this claim for infringement are set forth in the Confidential Appendix.
- 164. Boston Scientific's infringement is without the consent or other authority of Nevro. Boston Scientific is not licensed under the '472 patent.
- 165. Boston Scientific has actual notice of the '472 patent. Boston Scientific's actions are willful and deliberate, and render this an exceptional case under 35 U.S.C. § 285.
- 166. Nevro has been damaged by Boston Scientific's acts in an amount as yet unknown. Nevro has no adequate legal remedy. Unless enjoined by this Court, Boston Scientific's continued acts of infringement will cause Nevro substantial and irreparable harm. Under 35 U.S.C. § 283, Nevro is entitled to an injunction barring Boston Scientific from further infringement of the '472 patent.

### TENTH CAUSE OF ACTION

(Declaratory Judgment of Infringement of U.S. Patent No. 8,768,472)

- 167. Nevro incorporates by reference the allegations contained in paragraphs 1-166 above, and the Confidential Appendix.
- 168. Boston Scientific does engage, and will engage, in the commercial manufacture, use, offer for sale, sale, and/or importation of SCS systems and methods for alleviating patient pain or discomfort that include implanting a percutaneous lead with at least one electrode in the patient's epidural space, implanting a signal generator in the patient, electrically coupling the percutaneous lead to the signal generator, and programming the signal generator to generate and deliver electrical therapy signals to the spinal cord region at a frequency between about 2.5 kHz and 100 kHz. The foregoing actions by Boston Scientific will constitute infringement of one or more claims of the '472 patent, literally or under the doctrine of equivalents, in violation of 35 U.S.C. § 271.
- 169. Boston Scientific has engaged in substantial preparation and taken concrete steps with the intent to conduct these infringing activities. As discussed in more detail above, Boston Scientific is already manufacturing SCS systems designed to perform at frequencies of up to 10,000 Hz in the United States for commercial sale in Europe. Additional information relating to

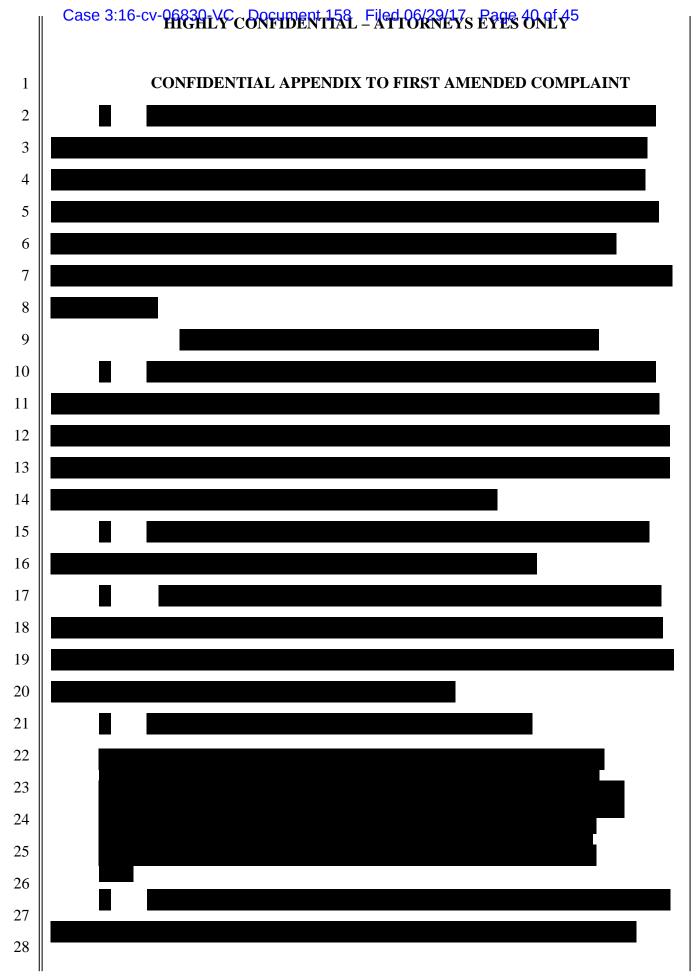
imminence is set forth in the Confidential Appendix. Boston Scientific sales representatives are already promoting Boston Scientific's upcoming high frequency device to U.S. physicians, representing that Boston Scientific will be imminently launching its own high frequency device. As such, Nevro believes that Boston Scientific will immediately begin to further directly infringe the '472 patent on a wider scale upon receiving FDA approval.

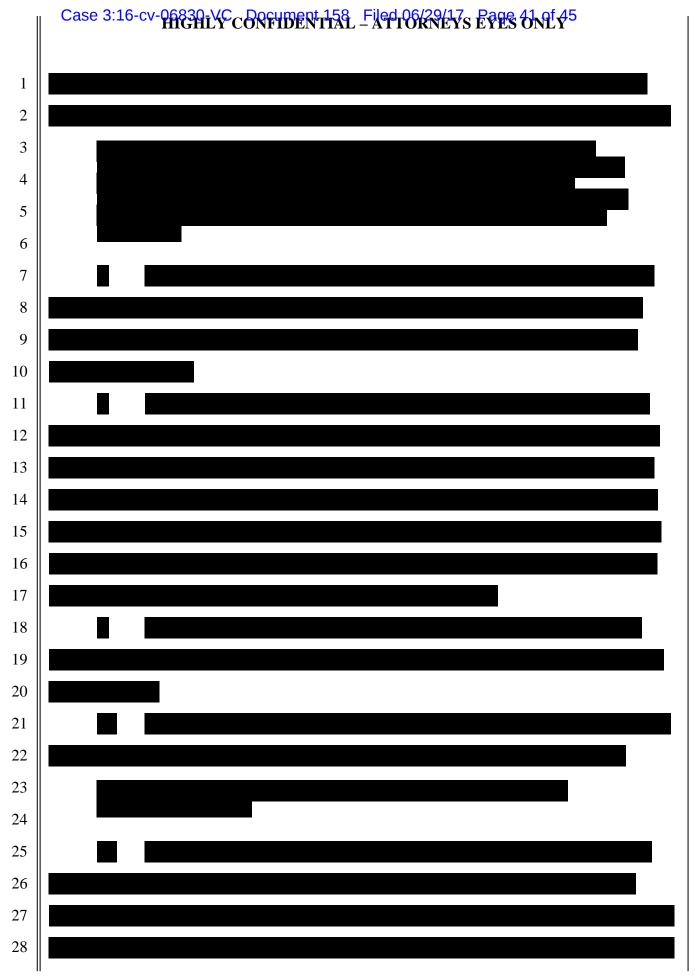
- 170. Nevro believes that upon FDA approval and commercial launch of Boston Scientific's infringing paresthesia-free high frequency SCS systems, Boston Scientific will further induce infringement of the '472 patent by inducing others to directly infringe the '472 patent, literally or under the doctrine of equivalents.
- 171. Moreover, Boston Scientific is continuing to program patients who have completed their participation in the ACCELERATE study to provide paresthesia-free high frequency SCS therapy, and will further directly infringe and induce infringement of the '472 patent by its actions.
- Nevro believes that Boston Scientific knows of or is willfully blind to the existence of the '472 patent. Nevro believes that Boston Scientific has intentionally made substantial preparation to and will instruct others, including doctors and health care providers, to use its high frequency SCS in a manner that infringes the '472 patent. In the SCS industry, the clinical engineers and/or sales representatives of the device manufacturer normally are present in the operating room and will program the SCS device for the operation, including by setting the parameters for the frequency, amplitude and pulse width of the electronic signal to be delivered by the device. Boston Scientific knows or is willfully blind to the fact that such actions will induce infringement. The foregoing actions by Boston Scientific will constitute induced infringement of one or more claims of the '472 patent in violation of 35 U.S.C. § 271(b) and (f)(1).
- 173. In addition and/or in the alternative to inducing infringement, Boston Scientific will directly infringe the asserted claims of the '472 patent through joint acts with physicians, or as part of a joint enterprise with physicians, whereby the acts of one are attributable to the other such that a single entity is responsible for the infringement. Physicians implant and electrically couple the leads and signal generators for Boston Scientific's infringing SCS systems. Boston

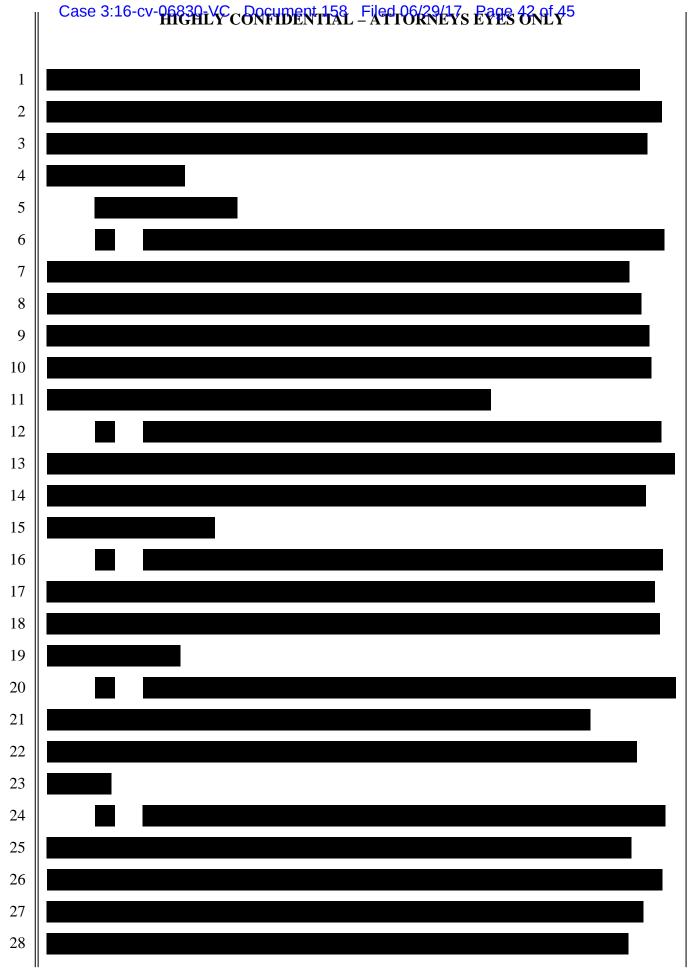
Scientific's clinical engineers and/or sales representatives program the signal generators and are present in the operating room with physicians while the implantation is performed, working jointly to carry out the procedure. Boston Scientific's Vice-President of Clinical and Regulatory Affairs, Kaoru Lee Adair, testified that Boston Scientific's clinical engineers and/or sales representatives carry out this programming under the direction of physicians.

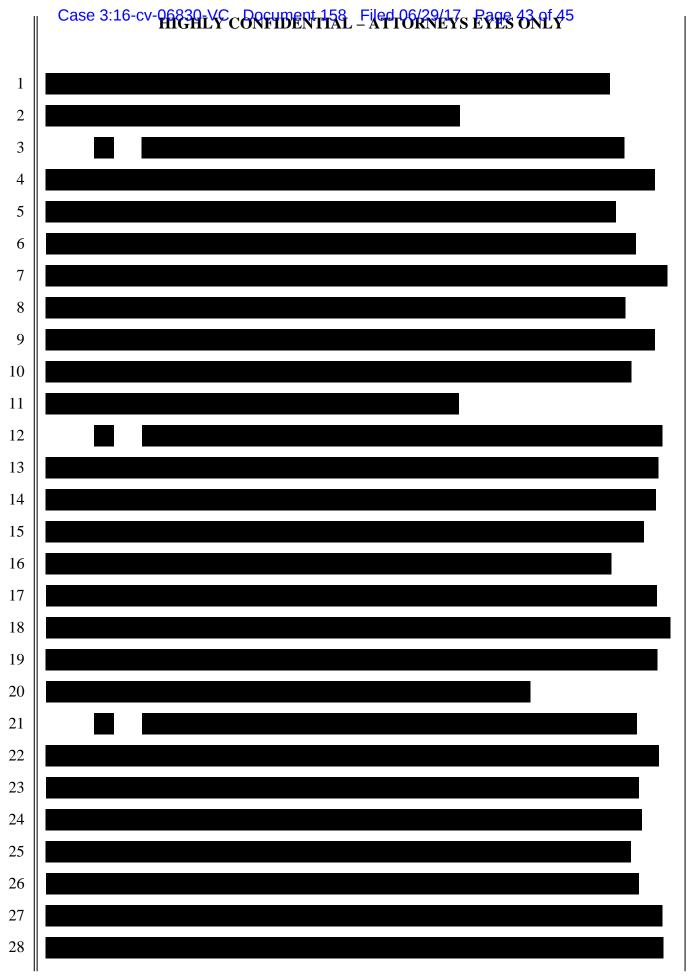
- 174. Boston Scientific supplies from the United States all or a substantial portion of the components of its infringing SCS systems and induces the combination of such components outside of the United States in a manner that would infringe the '472 patent if it occurred within the United States. The foregoing actions by Boston Scientific will constitute infringement of one or more claims of the '472 patent in violation of 35 U.S.C. § 271(f).
- 175. An actual and justiciable controversy exists between Nevro and Boston Scientific regarding infringement of the '472 patent. The '472 patent is in the same patent family as U.S. Patent Application No. 2009/0204173, which Boston Scientific has cited in its invalidity contentions in this action. Boston Scientific is formally opposing Nevro's European patents in Europe, including European counterparts to the '472 patent. Moreover, Boston Scientific has already unsuccessfully challenged the validity of sixteen claims of Nevro's '102 patent covering Nevro's high frequency paresthesia-free SCS system by filing two IPR petitions with the Patent and Trademark Office. Although both petitions were denied by the PTO, Boston Scientific announced at the December 2015 Piper Jaffray Health conference that it intended to press forward nonetheless, and has continued with the ACCELERATE study and with manufacturing and/or selling infringing 10,000 Hz-capable devices nonetheless.
- 176. Additional allegations relating to Boston Scientific's United States activities which support this claim for declaratory relief are set forth in the Confidential Appendix.
- 177. Boston Scientific's imminent infringement will be without the consent or other authority of Nevro. Boston Scientific is not licensed under the '472 patent.
- 178. Nevro is entitled to a declaratory judgment that Boston Scientific's future commercial manufacture, use, offer for sale, sale, and/or importation of high frequency SCS systems and methods does and will infringe the '472 patent, directly and indirectly.

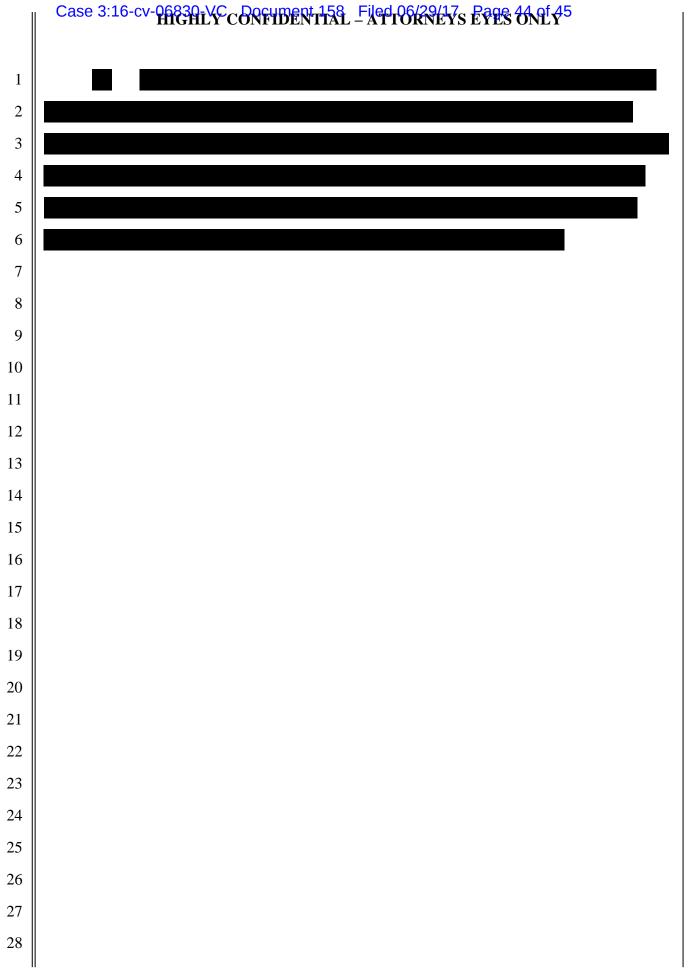
1	179. Boston Scientific has actual notice of the '472 patent. Boston Scientific's action	ons
2	are willful and deliberate, and render this an exceptional case under 35 U.S.C. § 285.	
3	180. Nevro has been and will be damaged by Boston Scientific's acts in an amount	as
4	yet unknown. Nevro has no adequate legal remedy. Unless enjoined by this Court, Boston	
5	Scientific's imminent infringement will cause Nevro substantial and irreparable harm. Under	35
6	U.S.C. § 283, Nevro is entitled to an injunction barring Boston Scientific from infringement of	f
7	the '472 patent.	
8	PRAYER FOR RELIEF	
9	WHEREFORE, Nevro prays for relief as follows:	
10	1. A judgment that Boston Scientific has infringed one or more claims of the '53'	ί,
11	'125, '102, '842, '357, '988, and '472 patents;	
12	2. A judgment and a declaration that making, using, selling, offering for sale, or	
13	importing Boston Scientific's high frequency and paresthesia-free SCS system	\$
14	and devices infringes one or more claims of the '533, '125, '102, '842, '357, '9	88,
15	and '472 patents, directly and indirectly;	
16	3. An order and judgment temporarily, preliminarily and permanently enjoining	
17	Boston Scientific and its officers, directors, agents, servants, employees, and a	1
18	others acting in privity or in concert with them, and their parents, subsidiaries,	
19	divisions, successors and assigns, from further acts of infringement of the '533	,
20	'125, '102, '842, '357, '988, and '472 patents;	
21	4. A judgment awarding Nevro all damages suffered by Nevro for Boston Scienti	fic's
22	unlawful conduct, and in no event less than a reasonable royalty for Boston	
23	Scientific's acts of infringement, including all pre-judgment and post-judgmen	Ċ
24	interest at the maximum rate permitted by law;	
25	5. A judgment trebling any damages pursuant to 35 U.S.C. § 284;	
26	6. Costs of suit and reasonable attorneys' fees; and	
27	7. Any other remedy to which Nevro may be entitled.	
28		











**DEMAND FOR JURY TRIAL** Pursuant to Federal Rule of Civil Procedure 38(b) and Civil Local Rule 3-6, Nevro demands a trial by jury on all issues so triable in this action. Dated: June 29, 2017 MORRISON & FOERSTER LLP By: \_\_/s/ Michael A. Jacobs Michael A. Jacobs Attorneys for Plaintiff NEVRÓ CORP.