IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NEVRO CORP.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
STIMWAVE TECHNOLOGIES, INC.,	)	**DEMAND FOR JURY TRIAL**
	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT, DECLARATORY JUDGMENT OF PATENT INFRINGEMENT, VIOLATION OF THE LANHAM ACT, AND DECEPTIVE TRADE PRACTICES

Plaintiff Nevro Corp. ("Nevro"), for its Complaint against Defendant Stimwave Technologies, Inc. ("Stimwave"), alleges as follows:

1. This action concerns Stimwave's infringement of Nevro's United States Patent Numbers 9,333,358; 8,868,192; 9,327,127; 8,874,222; and 9,327,126 (attached as Exhibits 1-5 hereto). Nevro files this action to stop Stimwave's deliberate and willful infringement of Nevro's patents protecting its proprietary high frequency, paresthesia free technology. Nevro further files this action to stop Stimwave's false and misleading marketing, which violates the Lanham Act and 6 Del. C. Section 2532.

NATURE OF THE ACTION

2. 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.

3. 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, a groundbreaking

pivotal study established that Nevro's patented SCS technology is significantly more effective than traditional SCS therapy.

4. 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.

5. 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.

6. 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 SCS therapy uses a unique "high frequency" electrical waveform to provide pain relief without generating paresthesia. Nevro protected this breakthrough technology by securing extensive U.S. and international patent protection.

7. Stimwave is a medical device company that initially manufactured and sold low frequency, paresthesia-based SCS systems, which it marketed as the Freedom-4A and Freedom-8A SCS systems. Upon learning of the remarkable efficacy of Nevro's high frequency, paresthesia-free therapy, Stimwave launched a deliberate, years-long campaign to copy Nevro's

patented technology and divert Nevro's sales. Stimwave now manufactures at least its Freedom-8A SCS system to deliver high frequency, paresthesia-free SCS therapy, thus making deliberate use of Nevro's proprietary technology. Stimwave exports these infringing SCS systems to Europe and Australia, and markets their infringing use internationally. And Stimwave is reporting to the industry that United States FDA approval for its SCS systems for high frequency, paresthesia-free therapy is imminent, and that it intends to begin a full-scale commercial launch of its SCS systems for high frequency, paresthesia-free therapy in the United States after receiving that approval. While executing its plan to copy Nevro's patented technology, Stimwave also published a series of statements falsely and misleadingly criticizing Nevro's SCS systems and falsely and misleadingly boasting about the characteristics of its own SCS systems. Nevro brings this action to obtain redress for Stimwave's wrongful conduct and to prevent further irreparable harm to Nevro's business.

PARTIES

8. Plaintiff Nevro is a Delaware corporation with its principal place of business at 1800 Bridge Pkwy, Redwood City, CA 94065.

9. Defendant Stimwave is a privately held Delaware corporation with its principal place of business at 1310 Park Central Blvd S, Pompano Beach, FL 33064.

JURISDICTION AND VENUE

10. This Court has subject matter jurisdiction under 28 U.S.C. § 1331 (federal question) and § 1338(a) (patents).

11. This Court has personal jurisdiction over Stimwave as Delaware is Stimwave's state of incorporation.

12. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and 1400(b), as Delaware is Stimwave's state of incorporation.

BACKGROUND FACTS

Nevro's Pioneering Technology

13. Nevro was founded in 2006 to develop a novel SCS technology for the treatment of chronic pain. Nevro's SCS systems, known as the Senza® system and Senza II™ system (together, the "Senza systems"), utilize Nevro's unique and patented HF10® therapy. Amongst other distinctions, Nevro's HF10 therapy employs a much higher frequency than traditional "low frequency" SCS systems. In its commercial embodiment, Nevro's Senza systems provide 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 that utilize low frequency stimulation, typically between 50 Hz and 60 Hz. The Senza systems, with their related subcomponents, are Nevro's only products.

14. Unlike traditional low frequency SCS therapy, Nevro's Senza systems and HF10 therapy provide pain relief without generating paresthesia. Nevro's advances represent a paradigm shift in SCS therapy. Before FDA approval of Nevro's Senza systems, every commercial SCS system sought to create paresthesia in the patient by using low frequency stimulation waveforms.[1] Paresthesia was not merely a side effect of low frequency stimulation, but was thought to be essential to providing pain relief.

15. Because Nevro's approach was fundamentally different from 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

[1] Paresthesia is a sensation usually described as tingling, pins and needles, or numbness.

paresthesia-free. To definitively 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 commercial system that was chosen was Boston Scientific's Precision Plus device—Boston Scientific's most advanced SCS system at the time. In a landmark finding, the controlled trial found Nevro's Senza system and HF10 therapy to be nearly twice as effective as Boston Scientific's paresthesia-based low frequency SCS system in providing pain relief.

16. 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 therapy provides statistically superior efficacy when compared to the commercially available paresthesia-based low frequency SCS therapy tested in the controlled trial.

17. Nevro defied the conventional wisdom and demonstrated that effective pain relief could be achieved without paresthesia. Nevro's Senza systems provide 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 systems and HF10 therapy provide significant and sustained pain relief for *both* back and leg pain.

18. Importantly, Nevro's Senza systems and HF10 therapy also provide 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 therapy does not have any such restrictions.

19. Nevro's unique—and demonstrably superior—SCS technology has been the key to Nevro breaking into the U.S. SCS market.

20. Nevro has protected its innovative SCS technology through an extensive patent portfolio of more than 170 issued U.S. and international patents, including the patents asserted in this action. Nevro's patents cover many aspects of its pioneering technology, including high frequency SCS systems and devices, methods of treating patients with paresthesia-free systems and devices, and methods of programming such systems and devices.

Stimwave's Copying of Nevro's Patented Technology

21. Not long after Nevro announced its breakthrough HF10 therapy, Stimwave embarked on a campaign to copy Nevro's patented technology.

22. Stimwave's Freedom SCS systems include an implantable device, sometimes referred to by Stimwave as a Freedom Stimulator. The implantable device contains a "stimulator" and a "micro-receiver."[2]

23. The Stimwave implant "has small metal electrodes near the tip that create an electrical field of energy when power is applied," which "aids in blocking the pain signals coming from certain nerves."[3] When used for spinal cord stimulation, the implant is placed in

[2] http://stimwave.com/mobile/products/stimulators/

[3] http://stimwave.com/mobile/products/stimulators/; Stimwave Wearable Antenna Assembly User Manual, https://fccid.io/2AHXAPDBT2/User-Manual/User-Manual-3647311.pdf

the patient's epidural space.[4] One purpose of the Stimwave implant is to deliver a signal to the patient's spinal cord region.

24. Stimwave's Freedom SCS systems also contain an external device that provides power to the implant, sometimes referred to by Stimwave as a Wearable Antenna Assembly (WAA).[5] The WAA contains a rechargeable battery and antenna and communicates with the Stimwave implant using electrical radiofrequency (RF) signals.[6] When directed by the user, including a patient or Stimwave clinical representative, the WAA will execute a program that directs the SCS system to deliver a previously stored therapy signal to the patient.

25. In a clinical setting, the Stimwave SCS system is typically programmed by a clinical representative, who is an employee or agent of Stimwave, using a programming tablet. This programming tablet is sometimes referred to by Stimwave as a WaveCrest programmer.[7] Stimwave instructs that only its trained clinical representatives may use the WaveCrest programmer.[8] The programming tablet allows the clinical representative to set programs for the patient. Using the programming tablet, a clinical representative may set a patient's stimulation parameters, including pulse rate (or frequency), pulse width, and amplitude.[9] When directed by

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[4] Stimwave 510(k) Summary for Freedom Spinal Cord Stimulator (SCS) system, https://www.accessdata.fda.gov/cdrh_docs/pdf17/K170141.pdf

[5] Stimwave Wearable Antenna Assembly User Manual

[6] Stimwave Wearable Antenna Assembly User Manual

[7] Freedom Spinal Cord Stimulation WaveCrest Programmer User Manual, http://stimwave.com/mobile/wp-content/uploads/2016/01/LA-ABRS-2-915-WaveCrest-Programmer-User-Manual.pdf

[8] Freedom Spinal Cord Stimulation WaveCrest Programmer User Manual

[9] Freedom Spinal Cord Stimulation WaveCrest Programmer User Manual

the clinical representative, the programming tablet will execute a program that directs the SCS system to deliver a therapy signal to the patient.

26. This programming takes place in conjunction with patient feedback about the therapy, including the degree of pain relief and whether the patient is experiencing paresthesia. The clinical representative will adjust programming parameters until the patient receives the desired therapy. The clinical representative may set multiple stimulation programs that the clinical representative or patient can later select between.[10] The Stimwave SCS systems are programmed within at least the following parameters, making use of a biphasic waveform:[11]

Technical Specifications:

Diameter	1.35 mm
Electrode/Spacing	3 mm / 4 mm
Total Length/Cut Length	45 cm / 17 cm
Total Pulse Current	0 - 24 mA
Pulse Width	10 - 1,000 µs
Pulse Rate	5 - 10,000 Hz
MR Conditionality	1.5T & 3T Full Body

27. Stimwave presently sells, uses, and supplies the components of its SCS systems for use in high frequency, paresthesia-free therapy in Europe and Australia. Stimwave is seeking FDA approval to market its SCS systems for use in high frequency, paresthesia-free therapy in the United States. That approval, and Stimwave's full commercial launch of this application in the United States, appears imminent. Stimwave is already telling United States-based physicians that its SCS systems can be used for high frequency, paresthesia-free therapy.

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[10] Freedom Spinal Cord Stimulation WaveCrest Programmer User Manual

[11] Freedom SCS System Data Sheet; Stimwave 510(k) Summary for Freedom Spinal Cord Stimulator (SCS) system

28. In late 2015, Stimwave sought and obtained European CE Mark approval for the Freedom-8A SCS system with 10,000 Hz programming. According to a January 16, 2019, Stimwave press release issued in advance of the North American Neuromodulation Society conference in Las Vegas, Nevada, high frequency stimulation using the Freedom-8A SCS system is "commercially available in the European and Australian markets." (Exhibit 6 hereto.) Stimwave has begun using international social media platforms to promote its Freedom SCS 8A SCS system in Europe and Australia. This social media promotion is clearly visible to United States customers, who comprise approximately 80% of the worldwide SCS market. Stimwave's Freedom SCS systems are manufactured in the United States.

29. In June 2016, Stimwave began a Belgian study to "observe the efficacy of stimulation on over all pain relief as reported in an initial cohort of 6 patients treated with the Freedom High Frequency Spinal Cord Stimulator (SCS) System for low back and/or leg pain." This study used the Nevro HF10 parameters of "below perception threshold with High Frequency settings (10.000 Hz, 30 μs)," with lead placement in the same area as Nevro's commercial therapy, at the T9-T10 vertebrae.

30. Stimwave likewise began a United States study in which it stated that patients would receive "a Freedom SCS system and be randomized 1:1 to receive either HF (10,000 Hz) or LF (5 Hz to 1500 Hz) stimulation parameters."

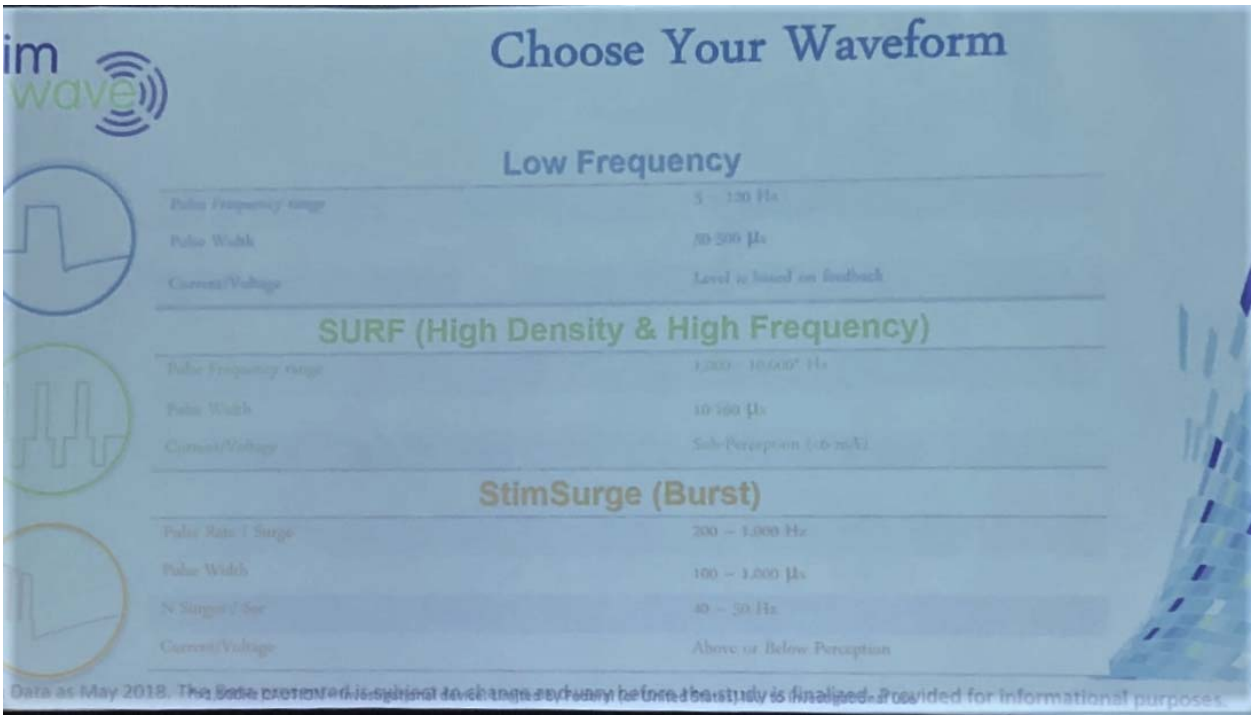
31. Stimwave has sought FDA approval to sell and market the Freedom SCS systems for high frequency, paresthesia-free therapy. In the January 16, 2019, press release discussed above, for example, Stimwave stated that "[t]he safety and effectiveness of the Freedom SCS system's high frequency stimulation parameters is in review with the FDA for market clearance."

32. Most recently, Stimwave is reporting to the industry that FDA approval is imminent and that it intends to begin commercially marketing the Freedom SCS systems for high frequency, paresthesia-free therapy in the United States after receiving that approval. According to a January 22, 2019, Morgan Stanley industry update, "Stimwave presented HF data from SURF . . . and has filed for an HF label and intends to commercialize after approval (expected by early February)."

33. Even though it has not yet received FDA approval to market high frequency, paresthesia-free therapy, Stimwave has already been informing United States-based doctors that its SCS systems can be used for such therapy, and has been promoting the use of high frequency, paresthesia-free therapy via various platforms, such as social media.

34. In December 2017, Stimwave's CEO, Laura Tyler Perryman, published an article in the Open Journal of Surgery. The Open Journal of Surgery is a publication of SciRes Literature LLC, a Middletown, Delaware-based publisher that provides "un-restricted access available open to the global audience." The article touts high frequency therapy's ability to "produce[] better pain relief without the paresthesia" and cites to clinical data showing the high efficacy of Nevro's Senza systems. Directly following this discussion of Nevro, the article represents that Stimwave's SCS systems can also operate at high frequency operation: "Stimwave technology has a wide spectrum of stimulation parameters available for clinical applications which include: Amplitude: 1 - 24 mA, pulse Width: 10 - 1000 microseconds, Frequency: 5 - 20,000 Hz." The article nowhere discloses that Stimwave's SCS systems are not approved in the United States for this use and, instead, broadly states that Stimwave's technology is "approved by FDA and CE and has been in clinical use" and "has been approved by FDA and CE for clinical use to relieve chronic back pain and leg pain via SCS."

35. At a 2018 Ohio and Kentucky Society of Interventional Pain Physicians conference, Stimwave told United States-based physicians that its SCS systems have "Choose Your Waveform" functionality that allows the selection of frequencies up to 10,000 Hz, and presented the following slide:



The slide appears to have some type of illegible disclaimer at the bottom that, when enlarged and examined closely, appears to state something pertaining to "investigational" use. This disclaimer would not be comprehensible or perceptible to a person viewing the slides, however, and also does not undercut the clearly promotional nature of the presentation.

36. Stimwave's current website explains "How Freedom Works" by telling potential patents that the therapy they receive from the Stimwave SCS systems "can feel like a tingling sensation **or no sensation at all**," i.e., paresthesia-free therapy.

37. Stimwave is well aware that Nevro's products are patent-protected. Nevro provides notice to the public that its products are patented via marking at https://www.nevro.com/English/Patents/.

38. Stimwave was also alerted to the relation between Nevro's patent portfolio and Stimwave's own products during the prosecution of one of its CEO's patent applications. Stimwave's CEO is the first named inventor on United States Patent Application Number 15/661,593, which is assigned to Micron Devices LLC, a company that, on information and belief, shares its principal place of business with Stimwave. The figures in this patent application include depictions of the Stimwave logo and Stimwave user interface. During that prosecution, the examiner informed Stimwave's CEO that United States Patent No. 8,170,675, a Nevro patent related to patents asserted in this case, is "considered pertinent to" the claimed invention of "a method to configure settings on an implanted stimulator device."

39. Further, in June 2014, Stimwave's CEO communicated to Nevro's Chief Medical Officer that Stimwave's SCS systems could do "all of the HF [high frequency] stuff too," but that Stimwave would not activate that programming in the United States because it would violate Nevro's patents. Stimwave's CEO further communicated that she believed she was free to offer high frequency programming in Europe, while avoiding Nevro's patents. Stimwave is wrong

about European sales of its SCS systems—as detailed below, Stimwave's manufacture, sale, and supply of those systems from the United States infringes Nevro's patents. Stimwave has also clearly decided to willfully infringe Nevro's patents via infringing manufacturing, sales, and use within the United States.

40. Unsurprisingly, Stimwave faces questions from physicians and Wall Street analysts about infringement of Nevro's patents. Far from its 2014 admission that providing high frequency therapy would infringe Nevro's patents, Stimwave now misleads physicians and analysts into believing that its devices are non-infringing by claiming that Nevro's patents require an implantable pulse generator (IPG) and that Stimwave's systems supposedly do not have an IPG. As demonstrated below, Stimwave is incorrect that its SCS systems avoid infringing Nevro's patents. Stimwave's conduct confirms that it is aware of Nevro's extensive patent portfolio and knows that its SCS systems do (or will) infringe or is willfully blind to infringement.

41. As Stimwave's own representations make clear, its SCS systems are presently manufactured, used, and sold in a way that infringes or could quickly be made to infringe Nevro's patents. Moreover, because Stimwave's SCS systems already can provide paresthesia-free 10,000 Hz therapy, immediately following FDA approval, Stimwave will be able to program current low frequency patients at frequencies of up to 10,000 Hz. This immediate "convertibility" is a feature that Stimwave promotes and uses to sell its Freedom SCS systems to physicians in the United States.

42. Nevro will be irreparably harmed if Stimwave is permitted to manufacture, sell, and implant 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. If Stimwave is permitted to sell an infringing paresthesia-free device, Nevro will lose its distinguishing feature, and other companies will be motivated to launch their own competing, infringing devices.

Stimwave's False and Misleading Conduct

43. Stimwave has engaged in a campaign of false and misleading statements about the Stimwave SCS systems and Nevro's Senza systems to falsely present its SCS systems as being superior to Nevro's.

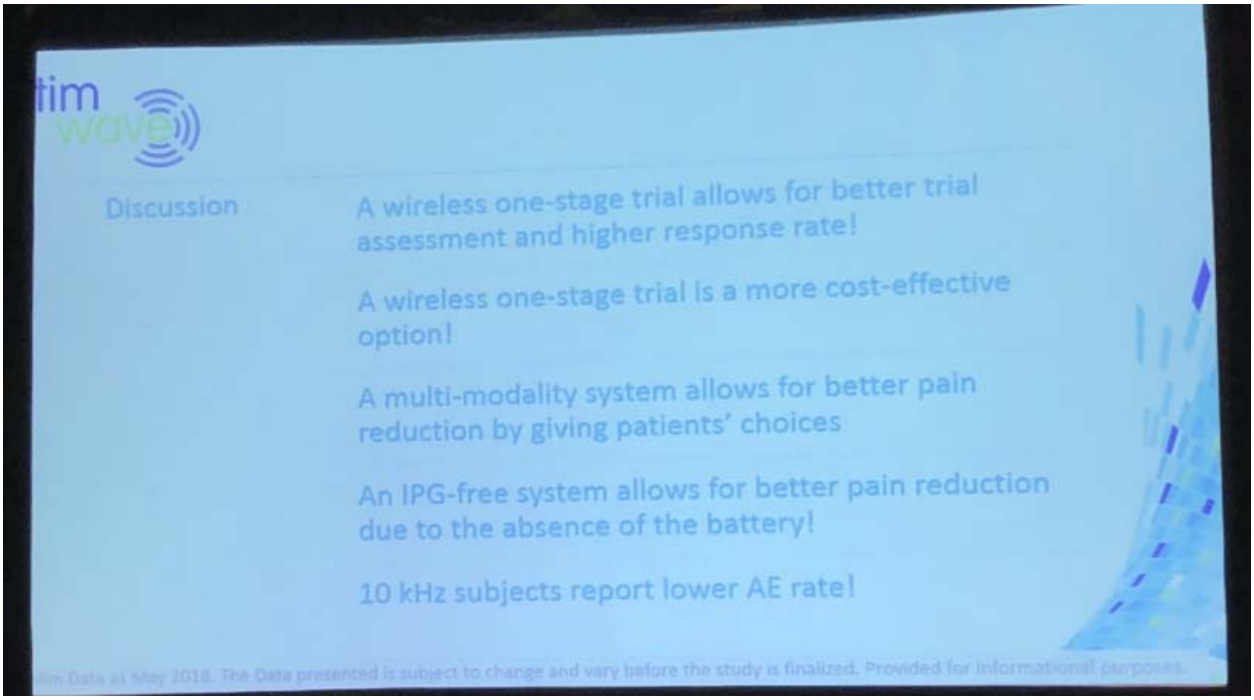
44. In the January 2019 press release announcing limited data from its "SURF" clinical trial, Stimwave claimed that "[t]he Freedom stimulators are designed to be a less-invasive alternative to treat patients with chronic pain, typically that would otherwise warrant surgery to place paddles leads or large IPGs, which have been reported to have substantial complications in at least a third of all patients." There are only a handful of companies in the world that make SCS systems, and Nevro's original Senza system has the largest IPG because of the extra power required to maintain Nevro's high frequency therapy.

45. The target audience of Stimwave's press release was physicians and others in the pain management field. Adverse event frequency is a quantifiable and meaningful metric. The target audience for the press release would interpret Stimwave's assertions as statements of objective fact, and would assume that the assertions are supported by competent and relevant clinical evidence.

46. Stimwave grossly overstates the rate of "substantial complications" with large IPGs to make its device, which it touts as the "world's smallest neurostimulator" (*see* http://stimwave.com/mobile/products/), appear to be superior. Stimwave is aware of the false and misleading nature of these claims: a 2017 Open Journal of Surgery article written by

Stimwave's CEO acknowledged that, in the Senza-RCT trial, only 4.0% of the high frequency therapy subjects (using Nevro Senza devices) had a study-related serious adverse effect (SAE) compared with 7.2% of conventional SCS subjects (who were using a Boston Scientific low frequency device). In both instances, the percentage of patients who experienced substantial complications is dramatically lower than what Stimwave represented in January 2019.

47. Stimwave also drew misleading comparisons between its SCS systems and "other SCS studies" during the 2018 Ohio and Kentucky Society of Interventional Pain Physicians annual meeting. Nevro and Stimwave were both sponsors of this conference and both companies had a presence at the conference. During a conference-wide presentation, as shown in the slide below, Stimwave claimed, without support, among other things, that "[a]n IPG-free system allows for better pain reduction due to the absence of battery!" and that a "wireless one-stage trial allows for better trial assessment and higher response rate!" This presentation would have been prepared in conjunction with, and using input from, Stimwave. Stimwave would have given ultimate approval for the representations and assertions made in this presentation. Attendees of this conference would have understood that Stimwave was representing that its Freedom SCS systems were the "wireless" or "IPG-free" devices, as compared to other SCS systems, including Nevro's Senza systems.



48. These assertions would be material to attendees of the conference, which included physicians and others in the pain management field. Response rate, trial assessment, and pain reduction are quantifiable and are meaningful metrics. Attendees of the conference would interpret these assertions as statements of objective fact, and would assume that the assertions are supported by competent and relevant clinical evidence.

49. Stimwave has no legitimate clinical evidence, and has not shown any evidence whatsoever, to support these assertions.

50. Stimwave's false and misleading statements have harmed and are likely to continue to harm Nevro. Claims of clinical efficacy or a lower risk of adverse events are important to hospitals, physicians, and patients considering different SCS systems. Stimwave's assertions damage the significant goodwill Nevro has built through its groundbreaking HF10 therapy by falsely leading consumers to doubt the efficacy of Nevro's SCS systems, including as compared to Stimwave's SCS systems. Stimwave's assertions are likely to cause to diversion of sales from Nevro to Stimwave.

51. Stimwave's activities have caused and, unless restrained, will continue to cause further irreparable injury to Nevro for which Nevro has no adequate remedy at law.

FIRST CAUSE OF ACTION
(Infringement of U.S. Patent No. 9,333,358)

52. Nevro incorporates the foregoing allegations by reference.

53. Nevro is the owner of all right, title, and interest in and to U.S. Patent No. 9,333,358 (the '358 patent). The '358 patent issued on May 10, 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 '358 patent is attached as **Exhibit 1**.

54. The claims of the '358 patent cover a spinal cord modulation system for treating a patient. For example, claim 1 covers a system comprising: an implantable signal delivery device configured for delivering a therapy signal to one or more locations in the patient's spinal cord region; a signal generator programmed to generate a non-paresthesia-producing therapy signal, wherein at least a portion of the therapy signal has a frequency in a frequency range between 1.5 kHz and 50 kHz at an amplitude that provides pain relief without generating paresthesia; and wherein the signal generator is in electrical communication with the implantable signal delivery device; and a power source, wherein the power source is configured to power the signal generator.

55. Stimwave's SCS systems generate pulse frequencies between at least 1 and 20,000 Hz (or 20 kHz). As described above, Stimwave acknowledges that its SCS systems are used on patients to provide pain relief at 10,000 Hz (or 10 kHz) with an amplitude that does not generate paresthesia. Stimwave's SCS systems do so by using an implantable stimulator along with a signal generator programmed to generate such signals. The Stimwave implantable

stimulator and signal generator communicate with each other electrically, and are powered by a rechargeable battery.

56. Stimwave has infringed and continues to infringe the ’358 patent by supplying all or substantially all of the components of SCS systems from the United States to at least Europe and Australia, where such components are uncombined in whole or in part, in such manner as to actively induce the combination of such components outside of the United States in a manner that would infringe the patent if such combination occurred within the United States. Stimwave actively encourages such combination through promotional material, manuals, and sales representatives or clinical representatives. Stimwave knows that such combination constitutes infringement of Nevro’s patents. Stimwave’s conduct infringes one or more claims of the ’358 patent, including at least claim 1, literally or under the doctrine of equivalents, and violates 35 U.S.C. § 271(f)(1).

57. Stimwave has infringed and continues to infringe the ’358 patent by supplying from the United States components of its SCS systems that are especially made or adapted for use in the invention of the ’358 patent, and which are not staple articles or commodities of commerce. Stimwave knows that these components are so made or adapted and intends that these components be assembled in an infringing manner. Stimwave supplies the components of SCS systems from the United States and intends that these components be combined in a manner that infringes Nevro’s patents, pursuant to its training, instructions, and promotion of high frequency, paresthesia-free therapy. Stimwave’s conduct infringes one or more claims of the ’358 patent, including at least claim 1, literally or under the doctrine of equivalents, and violates 35 U.S.C. § 271(f)(2).

58. Moreover, Stimwave has long been telling physicians that the systems it sells in the United States can be used to provide high frequency paresthesia-free therapy and has been promoting that use, and Nevro believes that Stimwave is already manufacturing, selling, and offering to sell, in the United States, SCS systems that are programmed to generate non-paresthesia-producing signals within the frequency ranges specified in the '358 patent in a manner that directly infringes the '358 patent and induces infringement of the '358 patent. Nevro expects that, after a reasonable opportunity to take discovery, the allegations of this paragraph will have additional evidentiary support, and will, at the appropriate time, amend this complaint with such evidence and associated claims.

59. Stimwave's infringement is without the consent or other authority of Nevro. Stimwave is not licensed under the '358 patent.

60. Stimwave has actual and/or constructive notice of the '358 patent. Stimwave's actions are willful and deliberate, and render this an exceptional case under 35 U.S.C. § 285. Stimwave is aware of Nevro's patent portfolio via, at least, Nevro's patent markings, inquiries from physicians and analysts, information provided by the Patent and Trademark Office, and the personal knowledge of its CEO. Stimwave previously represented to Nevro that it believed activating high frequency therapy on its SCS systems would infringe Nevro's patents. Stimwave now represents to physicians and analysts that its SCS systems do not infringe Nevro's patents because its SCS systems do not have an "IPG." Stimwave is aware of, or willfully blind to, the fact that at least claim 1 of the '358 patent does not require an implantable IPG but rather only an implantable signal delivery device—a requirement met by Stimwave's implantable stimulator.

61. Nevro has been damaged by Stimwave's acts in an amount as yet unknown. Nevro has no adequate legal remedy. Unless enjoined by this Court, Stimwave'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 Stimwave from further infringement of the '358 patent.

SECOND CAUSE OF ACTION
(Declaratory Judgment of Infringement of U.S. Patent No. 9,333,358)

62. Nevro incorporates the foregoing allegations by reference.

63. Stimwave has engaged in substantial preparations and taken concrete steps to sell SCS systems in the United States that infringe at least one claim of the '358 patent, literally or under the doctrine of equivalents. As discussed in more detail above, Stimwave is already manufacturing SCS systems that operate at 10,000 Hz and provide pain relief without generating paresthesia in the United States for commercial sale in Europe and Australia. Stimwave has already applied for FDA approval to operate its SCS systems at 10,000 Hz without generating paresthesia. Further, Stimwave is reporting to the industry that FDA approval is imminent and that it intends to begin commercially marketing the Freedom SCS systems for high frequency, paresthesia-free therapy in the United States after receiving that approval. Moreover, Stimwave has long been telling physicians that the systems it sells in the United States can be used to provide high frequency paresthesia-free therapy and has been promoting that use. Additionally, Stimwave representatives are already making untrue and misleading statements to physicians concerning whether Stimwave's SCS systems infringe Nevro's patents. As such, an actual and justiciable controversy exists between Nevro and Stimwave.

64. Stimwave's infringement is without the consent or other authority of Nevro. Stimwave is not licensed under the '358 patent.

65. Stimwave has actual and/or constructive notice of the '358 patent. Stimwave's actions are willful and deliberate, and render this an exceptional case under 35 U.S.C. § 285. Stimwave is aware of Nevro's patent portfolio via, at least, Nevro's patent markings, inquiries

from physicians and analysts, information provided by the Patent and Trademark Office, and the personal knowledge of its CEO. Stimwave previously represented to Nevro that it believed activating high frequency therapy on its SCS systems would infringe Nevro's patents. Stimwave now represents to physicians and analysts that its SCS systems do not infringe Nevro's patents because its SCS systems do not have an "IPG." Stimwave is aware of, or willfully blind to, the fact that at least claim 1 of the '358 patent does not require an implantable IPG, but rather only an implantable signal delivery device—a requirement met by Stimwave's implantable stimulator.

66. Nevro will be damaged by Stimwave's acts in an amount as yet unknown. Nevro has no adequate legal remedy. Unless enjoined by this Court, Stimwave's imminent infringement will cause Nevro substantial and irreparable harm. Under 35 U.S.C. § 283, Nevro is entitled to an injunction barring Stimwave from infringing the '358 patent.

67. Nevro is entitled to a declaratory judgment that Stimwave's future commercial manufacture, use, offer for sale, sale, and/or importation of high frequency SCS systems does and will infringe the '358 patent, directly and indirectly.

THIRD CAUSE OF ACTION
(Infringement of U.S. Patent No. 8,868,192)

68. Nevro incorporates the foregoing allegations by reference.

69. Nevro is the owner of all right, title, and interest in and to U.S. Patent No. 8,868,192 (the '192 patent). The '192 patent issued on October 21, 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 '192 patent is attached as **Exhibit 2**.

70. The claims of the '192 patent cover a spinal cord modulation system for treating a patient. For example, claim 1 covers an epidural spinal cord stimulation system for reducing or eliminating pain in a patient without using paresthesia to treat the patient, the system comprising:

a programmer having a therapy program that, when executed, directs delivery of a therapy signal by a spinal cord modulator to a signal delivery device configured to deliver the therapy signal to the patient's spinal cord, wherein the therapy signal at least partially reduces pain without generating paresthesia, and wherein the therapy signal includes a plurality of sequential biphasic pulses, with the pulses having pulse widths in a pulse width range from 25 microseconds to 166 microseconds.

71. Stimwave's SCS systems contain a programmer having a therapy program that, when executed, directs delivery of a therapy signal by a spinal cord modulator to an implantable stimulator, which is configured to deliver a therapy signal to a patient's spinal cord. Stimwave's SCS systems are programmed to at least partially reduce pain without generating paresthesia. Stimwave's SCS systems deliver therapy signals that include a plurality of sequential biphasic pulses, and are programmed with pulse widths in the range from 25 microseconds to 166 microseconds.

72. Stimwave has infringed and continues to infringe the '192 patent by supplying all or substantially all of the components of SCS systems from the United States, to at least Europe and Australia, where such components are uncombined in whole or in part, in such manner as to actively induce the combination of such components outside of the United States in a manner that would infringe the patent if such combination occurred within the United States. Stimwave actively encourages such combination through promotional material, manuals, and sales representatives or clinical representatives. Stimwave knows that such combination constitutes infringement of Nevro's patents. Stimwave's conduct infringes one or more claims of the '192 patent, including at least claim 1, literally or under the doctrine of equivalents, and violates 35 U.S.C. § 271(f)(1).

73. Stimwave has infringed and continues to infringe the ’192 patent by supplying from the United States components of its SCS systems that are especially made or adapted for use in the invention of the ’192 patent, and which are not staple articles or commodities of commerce. Stimwave knows that these components are so made or adapted and intends that these components be assembled in an infringing manner. Stimwave supplies the components of SCS systems from the United States and intends that these components be combined in a manner that infringes Nevro’s patents, pursuant to its training, instructions, and promotion of high frequency, paresthesia-free therapy. Stimwave’s conduct infringes one or more claims of the ’192 patent, including at least claim 1, literally or under the doctrine of equivalents, and violates 35 U.S.C. § 271(f)(2).

74. Moreover, Stimwave has long been telling physicians that the systems it sells in the United States can be used to provide high frequency paresthesia-free therapy and has been promoting that use, and Nevro believes that Stimwave is already manufacturing, selling, and offering to sell, in the United States SCS systems that are programmed to generate non-paresthesia-producing signals within the frequency ranges specified in the ’192 patent in a manner that directly infringes the ’192 patent and induces infringement of the ’192 patent. Nevro expects that, after a reasonable opportunity to take discovery, the allegations of this paragraph will have additional evidentiary support, and will, at the appropriate time, amend this complaint with such evidence and associated claims.

75. Stimwave’s infringement is without the consent or other authority of Nevro. Stimwave is not licensed under the ’192 patent.

76. Stimwave has actual and/or constructive notice of the ’192 patent. Stimwave’s actions are willful and deliberate, and render this an exceptional case under 35 U.S.C. § 285.

Stimwave is aware of Nevro's patent portfolio via, at least, Nevro's patent markings, inquiries from physicians and analysts, information provided by the Patent and Trademark Office, and the personal knowledge of its CEO. Stimwave previously represented to Nevro that it believed activating high frequency therapy on its SCS systems would infringe Nevro's patents. Stimwave now represents to physicians and analysts that its SCS systems do not infringe Nevro's patents because its SCS systems do not have an "IPG." Stimwave is aware of, or willfully blind to, the fact that at least claim 1 of the '192 patent does not require an implantable IPG but rather only a signal delivery device configured to deliver the therapy signal to the patient's spinal cord—a requirement met by Stimwave's implantable stimulator.

77. Nevro has been damaged by Stimwave's acts in an amount as yet unknown. Nevro has no adequate legal remedy. Unless enjoined by this Court, Stimwave'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 Stimwave from further infringement of the '192 patent.

FOURTH CAUSE OF ACTION

(Declaratory Judgment of Infringement of U.S. Patent No. 8,868,192)

78. Nevro incorporates the foregoing allegations by reference.

79. Stimwave has engaged in substantial preparations and taken concrete steps to sell SCS systems in the United States that infringe at least one claim of the '192 patent, literally or under the doctrine of equivalents. As discussed in more detail above, Stimwave is already manufacturing SCS systems that deliver a therapy signal to a patient's spinal cord that reduces pain without generating paresthesia for commercial sale in Europe and Australia. Stimwave has already applied for FDA approval to operate its SCS systems at 10,000 Hz without generating paresthesia. Further, Stimwave is reporting to the industry that FDA approval is imminent and that it intends to begin commercially marketing the Freedom SCS systems for high frequency,

paresthesia-free therapy in the United States after receiving that approval. Moreover, Stimwave has long been telling physicians that the systems it sells in the United States can be used to provide high frequency paresthesia-free therapy and has been promoting that use. Additionally, Stimwave representatives are already making untrue and misleading statements to physicians concerning whether Stimwave's SCS systems infringe Nevro's patents. As such, an actual and justiciable controversy exists between Nevro and Stimwave.

80. Stimwave's infringement is without the consent or other authority of Nevro. Stimwave is not licensed under the '192 patent.

81. Stimwave has actual and/or constructive notice of the '192 patent. Stimwave's actions are willful and deliberate, and render this an exceptional case under 35 U.S.C. § 285. Stimwave is aware of Nevro's patent portfolio via, at least, Nevro's patent markings, inquiries from physicians and analysts, information provided by the Patent and Trademark Office, and the personal knowledge of its CEO. Stimwave previously represented to Nevro that it believed activating high frequency therapy on its SCS systems would infringe Nevro's patents. Stimwave now represents to physicians and analysts that its SCS systems do not infringe Nevro's patents because its SCS systems do not have an "IPG." Stimwave is aware of, or willfully blind to, the fact that at least claim 1 of the '192 patent does not require an implantable IPG but rather only a signal delivery device configured to deliver the therapy signal to the patient's spinal cord—a requirement met by Stimwave's implantable stimulator.

82. Nevro will be damaged by Stimwave's acts in an amount as yet unknown. Nevro has no adequate legal remedy. Unless enjoined by this Court, Stimwave's imminent infringement will cause Nevro substantial and irreparable harm. Under 35 U.S.C. § 283, Nevro is entitled to an injunction barring Stimwave from infringing the '192 patent.

83. Nevro is entitled to a declaratory judgment that Stimwave's future commercial manufacture, use, offer for sale, sale, and/or importation of high frequency SCS systems does and will infringe the '192 patent, directly and indirectly.

FIFTH CAUSE OF ACTION

(Declaratory Judgment of Infringement of U.S. Patent No. 9,327,127)

84. Nevro incorporates the foregoing allegations by reference.

85. Nevro is the owner of all right, title, and interest in and to U.S. Patent No. 9,327,127 (the '127 patent). The '127 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 '127 patent is attached as **Exhibit 3**.

86. The claims of the '127 patent cover methods of treating patients with high frequency SCS without creating paresthesia. For example, claim 1 of the '127 patent is directed to a method for treating a patient comprising delivering an electrical signal to the patient's spinal cord via at least one implantable signal delivery device; and wherein the electrical signal has a frequency of from 1.5 kHz to 50 kHz and does not create paresthesia in the patient.

87. Stimwave does engage, and will engage, in the commercial manufacture, use, offer for sale, sale, and/or importation of SCS systems that have an implantable stimulator that can deliver high frequency electrical signals without creating paresthesia in the patient.

88. 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 system 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. Stimwave or its agents will program Stimwave's SCS systems to provide patients with paresthesia-free therapy using an electrical signal with a frequency of from 1.5 kHz and 50 kHz, especially at 10 kHz, delivered to

the patient's spinal cord via at least one implantable signal delivery device. This programming is accomplished by a clinical representative setting signal parameters in response, at least in part, to patient input on whether the patient is experiencing pain reduction and/or paresthesia. These actions will constitute direct infringement of one or more claims of the '127 patent, literally or under the doctrine of equivalents, in violation of 35 U.S.C. § 271.

89. In addition to directly infringing, Nevro believes that, upon FDA approval of Stimwave's paresthesia-free high frequency SCS systems, Stimwave will immediately induce infringement of the '127 patent by inducing others to directly infringe the '127 patent, literally or under the doctrine of equivalents.

90. Stimwave knows of the existence of the '127 patent. Stimwave is aware of Nevro's patent portfolio via, at least, Nevro's patent markings, inquiries from physicians and analysts, information provided by the Patent and Trademark Office, and the personal knowledge of its CEO. Stimwave previously represented to Nevro that it believed activating high frequency therapy on its SCS systems would infringe Nevro's patents. Stimwave now represents to physicians and analysts that its SCS systems do not infringe Nevro's patents because its SCS systems do not have an "IPG." Stimwave has intentionally made substantial preparation to and will instruct others, including doctors, patients, and health care providers to use its high frequency SCS in a manner that infringes the '127 patent. During the implantation, programming, and education of physicians and patients, Stimwave's clinical engineers and/or sales representatives will directly set therapy parameters or will induce physicians and/or patients to set therapy parameters to frequencies of between 1.5 kHz and 50 kHz and to amplitudes that do not create paresthesia in the patient. The foregoing actions by Stimwave will constitute direct or induced infringement of one or more claims of the '127 patent in violation of 35 U.S.C. §

271(a) and/or (b), literally or under the doctrine of equivalents. Stimwave specifically intends that its SCS systems be used in a manner that infringes the '127 patent—Stimwave has sought FDA approval to promote its systems for high frequency, paresthesia-free usage, and its clinical representatives will be trained to perform and/or direct the steps discussed above. Nevro expects that, after a reasonable opportunity to take discovery, the allegations of this paragraph will have additional evidentiary support, and will, at the appropriate time, amend this complaint with such evidence and associated claims.

91. Stimwave has engaged in substantial preparations and taken concrete steps with the intent to conduct these infringing activities. As discussed in more detail above, Stimwave is already manufacturing SCS systems for use in providing pain relief at frequencies of up to 20,000 Hz, without creating paresthesia, in the United States for commercial sale in Europe and Australia. Stimwave has already applied for FDA approval to operate its SCS systems at 10,000 Hz without generating paresthesia. Further, Stimwave is reporting to the industry that FDA approval is imminent and that it intends to begin commercially marketing the Freedom SCS systems for high frequency, paresthesia-free therapy in the United States after receiving that approval. As such, Nevro believes that Stimwave will immediately begin directly infringing the '127 patent upon receiving FDA approval. Moreover, Stimwave has long been telling physicians that the systems it sells in the United States can be used to provide high frequency paresthesia-free therapy and has been promoting that use, and Nevro believes that Stimwave representatives are already programming Stimwave's SCS systems in a manner that directly infringes the '127 patent, and inducing the infringement of the '127 patent. Nevro expects that, after a reasonable opportunity to take discovery, the allegations of this paragraph will have additional evidentiary

support, and will, at the appropriate time, amend this complaint with such evidence and associated claims.

92. An actual and justiciable controversy exists between Nevro and Stimwave. Stimwave is actively seeking FDA approval to use its SCS systems in an infringing manner, and such FDA approval is believed to be imminent. Stimwave SCS systems are currently used in an infringing manner in Europe and Australia.

93. Stimwave's imminent infringement will be without the consent or other authority of Nevro. Stimwave is not licensed under the '127 patent.

94. Nevro is entitled to a declaratory judgment that Stimwave's future commercial manufacture, use, offer for sale, sale, and/or importation of high frequency SCS systems does and will infringe the '127 patent, directly and indirectly.

95. Stimwave has actual and/or constructive notice of the '127 patent. Stimwave's actions are willful and deliberate, and render this an exceptional case under 35 U.S.C. § 285. Stimwave is aware of Nevro's patent portfolio via, at least, Nevro's patent markings, inquiries from physicians and analysts, information provided by the Patent and Trademark Office, and the personal knowledge of its CEO. Stimwave previously represented to Nevro that it believed activating high frequency therapy on its SCS systems would infringe Nevro's patents. Stimwave now represents to physicians and analysts that its SCS systems do not infringe Nevro's patents because its SCS systems do not have an "IPG." Stimwave is aware of, or willfully blind to, the fact that at least claim 1 of the '127 patent does not require an implantable IPG but rather only an implantable signal delivery device—a requirement met by Stimwave's implantable stimulator.

96. Nevro has been and will be damaged by Stimwave's acts in an amount as yet unknown. Nevro has no adequate legal remedy. Unless enjoined by this Court, Stimwave's

imminent infringement will cause Nevro substantial and irreparable harm. Under 35 U.S.C. § 283, Nevro is entitled to an injunction barring Stimwave from infringing the '127 patent.

SIXTH CAUSE OF ACTION
(Declaratory Judgment of Infringement of U.S. Patent No. 8,874,222)

97. Nevro incorporates the foregoing allegations by reference.

98. Nevro is the owner of all right, title, and interest in and to U.S. Patent No. 8,874,222 (the '222 patent). The '222 patent issued on October 28, 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 '222 patent is attached as **Exhibit 4**.

99. The claims of the '222 patent cover methods of treating patients with high frequency SCS without creating paresthesia. For example, claim 1 of the '222 patent is directed to a method for configuring a signal generator to deliver a therapy signal to a patient's spinal cord via an implantable signal delivery device, wherein the implantable signal delivery device is implantable proximate to the patient's spinal cord, the method comprising: programming the signal generator to (1) generate a therapy signal, wherein at least a portion of the therapy signal is at a frequency in a frequency range between 5 kHz and 15 kHz, and at an amplitude that provides pain relief without generating paresthesia; and (2) deliver the therapy signal to the patient's spinal cord via the implantable signal delivery device.

100. Stimwave does engage, and will engage, in the commercial manufacture, use, offer for sale, sale, and/or importation of SCS systems that have a stimulator and a signal delivery device and that delivery high frequency electrical signals without creating paresthesia in the patient.

101. 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

system 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. Stimwave or its agents will configure Stimwave's SCS systems to provide patients with relief without generating paresthesia, but configuring a signal generator to deliver a therapy signal to a patient's spinal cord via an implantable stimulator, where the implantable stimulator is proximate to the patient's spinal cord. Stimwave or its agents will configure Stimwave's SCS systems to provide at least a portion of the therapy signal at a frequency in a frequency range between 5 kHz and 15 kHz and at an amplitude that provides pain relief without generating paresthesia. These actions will constitute direct infringement of one or more claims of the '222 patent, literally or under the doctrine of equivalents, in violation of 35 U.S.C. § 271.

102. In addition to directly infringing, Nevro believes that, upon FDA approval of Stimwave's paresthesia-free high frequency SCS systems, Stimwave will immediately induce infringement of the '222 patent by inducing others to directly infringe the '222 patent, literally or under the doctrine of equivalents.

103. Stimwave knows of the existence of the '222 patent. Stimwave is aware of Nevro's patent portfolio via, at least, Nevro's patent markings, inquiries from physicians and analysts, information provided by the Patent and Trademark Office, and the personal knowledge of its CEO. Stimwave previously represented to Nevro that it believed activating high frequency therapy on its SCS systems would infringe Nevro's patents. Stimwave now represents to physicians and analysts that its SCS systems do not infringe Nevro's patents because its SCS systems do not have an "IPG." Stimwave has intentionally made substantial preparation to and will instruct others, including doctors, patients, and health care providers to use its high frequency SCS in a manner that infringes the '222 patent. During the implantation,

programming, and education of physicians and patients, Stimwave's clinical engineers and/or sales representatives will directly set therapy parameters or will induce physicians and/or patients to set therapy parameters to frequencies of between 1.5 kHz and 15 kHz and to amplitudes that do not create paresthesia in the patient. The foregoing actions by Stimwave will constitute direct or induced infringement of one or more claims of the '222 patent in violation of 35 U.S.C. § 271(a) and/or (b), literally or under the doctrine of equivalents. Stimwave specifically intends that its SCS systems be used in a manner that infringes the '222 patent—Stimwave has sought FDA approval to promote its systems for high frequency, paresthesia-free usage, and its clinical representatives will be trained to perform and/or direct the steps discussed above. Nevro expects that, after a reasonable opportunity to take discovery, the allegations of this paragraph will have additional evidentiary support, and will, at the appropriate time, amend this complaint with such evidence and associated claims.

104. Stimwave has engaged in substantial preparations and taken concrete steps with the intent to conduct these infringing activities. As discussed in more detail above, Stimwave is already manufacturing SCS systems for use in providing pain relief at frequencies of up to 20,000 Hz, without creating paresthesia, in the United States for commercial sale in Europe and Australia. Stimwave has already applied for FDA approval to operate its SCS systems at 10,000 Hz without generating paresthesia. Further, Stimwave is reporting to the industry that FDA approval is imminent and that it intends to begin commercially marketing the Freedom SCS systems for high frequency, paresthesia-free therapy in the United States after receiving that approval. As such, Nevro believes that Stimwave will immediately begin directly infringing the '222 patent upon receiving FDA approval. Moreover, Stimwave has long been telling physicians that the systems it sells in the United States can be used to provide high frequency paresthesia-

free therapy and has been promoting that use, and Nevro believes that Stimwave representatives are already programming Stimwave's SCS systems in a manner that directly infringes the '222 patent, and inducing the infringement of the '222 patent. Nevro expects that, after a reasonable opportunity to take discovery, the allegations of this paragraph will have additional evidentiary support, and will, at the appropriate time, amend this complaint with such evidence and associated claims.

105. An actual and justiciable controversy exists between Nevro and Stimwave. Stimwave is actively seeking FDA approval to use its SCS systems in an infringing manner, and such FDA approval is believed to be imminent. Stimwave SCS systems are currently used in an infringing manner in Europe and Australia.

106. Stimwave's imminent infringement will be without the consent or other authority of Nevro. Stimwave is not licensed under the '222 patent.

107. Nevro is entitled to a declaratory judgment that Stimwave's future commercial manufacture, use, offer for sale, sale, and/or importation of high frequency SCS systems does and will infringe the '222 patent, directly and indirectly.

108. Stimwave has actual and/or constructive notice of the '222 patent. Stimwave's actions are willful and deliberate, and render this an exceptional case under 35 U.S.C. § 285. Stimwave is aware of Nevro's patent portfolio via, at least, Nevro's patent markings, inquiries from physicians and analysts, information provided by the Patent and Trademark Office, and the personal knowledge of its CEO. Stimwave previously represented to Nevro that it believed activating high frequency therapy on its SCS systems would infringe Nevro's patents. Stimwave now represents to physicians and analysts that its SCS systems do not infringe Nevro's patents because its SCS systems do not have an "IPG." Stimwave is aware of, or willfully blind to, the

fact that at least claim 1 of the ’222 patent does not require an implantable IPG but rather only a percutaneous lead—a requirement met by Stimwave’s implantable stimulator.

109. Nevro has been and will be damaged by Stimwave’s acts in an amount as yet unknown. Nevro has no adequate legal remedy. Unless enjoined by this Court, Stimwave’s imminent infringement will cause Nevro substantial and irreparable harm. Under 35 U.S.C. § 283, Nevro is entitled to an injunction barring Stimwave from infringing the ’222 patent.

SEVENTH CAUSE OF ACTION

(Declaratory Judgment of Infringement of U.S. Patent No. 9,327,126)

110. Nevro incorporates the foregoing allegations by reference.

111. Nevro is the owner of all right, title, and interest in and to U.S. Patent No. 9,327,126 (the ’126 patent). The ’126 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 ’126 patent is attached as **Exhibit 5**.

112. The claims of the ’126 patent cover methods of treating patients with high frequency SCS without creating paresthesia. For example, claim 31 of the ’126 patent is directed to a method for programming a spinal cord stimulation system to alleviate pain or discomfort in a patient without using paresthesia or tingling to mask the patient’s sensation of pain or discomfort, wherein a percutaneous lead is positioned in the patient’s spinal cord region so as to be proximate to a dorsal root, dorsal root entry zone, or dorsal root ganglion, the method comprising: programming a signal generator to deliver a non-paresthesia-producing electrical therapy signal; wherein at least a portion of the electrical therapy signal is at a frequency in a frequency range between 3 kHz and 20 kHz, and an amplitude in an amplitude range between 1 mA and 4 mA, and wherein the electrical therapy signal at least partially alleviates pain or

discomfort without generating or using paresthesia to mask the patient's sensation of pain or discomfort.

113. Stimwave does engage, and will engage, in the commercial manufacture, use, offer for sale, sale, and/or importation of SCS systems that have a percutaneous lead and can deliver high frequency electrical signals without creating paresthesia in the patient.

114. 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 system 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. Stimwave or its agents will program Stimwave's SCS Systems to provide patients with non-paresthesia producing pain relief using a frequency between 3 kHz and 20 kHz, especially at 10 kHz, and an amplitude between 1 mA and 4 mA, wherein a percutaneous lead is positioned in the patient's spinal cord region so as to be proximate to a dorsal root, dorsal root entry zone, or dorsal root ganglion. These actions will constitute direct infringement of one or more claims of the '126 patent, literally or under the doctrine of equivalents, in violation of 35 U.S.C. § 271.

115. In addition to directly infringing, Nevro believes that, upon FDA approval of Stimwave's paresthesia-free high frequency SCS systems, Stimwave will immediately induce infringement of the '126 patent by inducing others to directly infringe the '126 patent, literally or under the doctrine of equivalents.

116. Stimwave knows of the existence of the '126 patent. Stimwave is aware of Nevro's patent portfolio via, at least, Nevro's patent markings, inquiries from physicians and analysts, information provided by the Patent and Trademark Office, and the personal knowledge of its CEO. Stimwave previously represented to Nevro that it believed activating high frequency

therapy on its SCS systems would infringe Nevro's patents. Stimwave now represents to physicians and analysts that its SCS systems do not infringe Nevro's patents because its SCS systems do not have an "IPG." Stimwave has intentionally made substantial preparation to and will instruct others, including doctors, patients, and health care providers to use its high frequency SCS in a manner that infringes the '126 patent. During the implantation, programming, and education of physicians and patients, Stimwave's clinical engineers and/or sales representatives will directly set therapy parameters or will induce physicians and/or patients to set therapy parameters to frequencies of between 3 kHz and 20 kHz and to amplitudes that do not create paresthesia in the patient. The foregoing actions by Stimwave will constitute direct or induced infringement of one or more claims of the '126 patent in violation of 35 U.S.C. § 271(a) and/or (b), literally or under the doctrine of equivalents. Stimwave specifically intends that its SCS systems be used in a manner that infringes the '126 patent—Stimwave has sought FDA approval to promote its systems for high frequency, paresthesia-free usage, and its clinical representatives will be trained to perform and/or direct the steps discussed above. Nevro expects that, after a reasonable opportunity to take discovery, the allegations of this paragraph will have additional evidentiary support, and will, at the appropriate time, amend this complaint with such evidence and associated claims.

117. Stimwave has engaged in substantial preparations and taken concrete steps with the intent to conduct these infringing activities. As discussed in more detail above, Stimwave is already manufacturing SCS systems for use in providing pain relief at frequencies of up to 20,000 Hz, without creating paresthesia, in the United States for commercial sale in Europe and Australia. Stimwave has already applied for FDA approval to operate its SCS systems at 10,000 Hz without generating paresthesia. Further, Stimwave is reporting to the industry that

FDA approval is imminent and that it intends to begin commercially marketing the Freedom SCS systems for high frequency, paresthesia-free therapy in the United States after receiving that approval. As such, Nevro believes that Stimwave will immediately begin directly infringing the '126 patent upon receiving FDA approval. Moreover, Stimwave has long been telling physicians that the systems it sells in the United States can be used to provide high frequency paresthesia-free therapy and has been promoting that use, and Nevro believes that Stimwave representatives are already programming Stimwave's SCS systems in a manner that directly infringes the '126 patent, and inducing the infringement of the '126 patent. Nevro expects that, after a reasonable opportunity to take discovery, the allegations of this paragraph will have additional evidentiary support, and will, at the appropriate time, amend this complaint with such evidence and associated claims.

118. An actual and justiciable controversy exists between Nevro and Stimwave. Stimwave is actively seeking FDA approval to use its SCS systems in an infringing manner, and such FDA approval is believed to be imminent. Stimwave SCS systems are currently used in an infringing manner in Europe and Australia.

119. Stimwave's imminent infringement will be without the consent or other authority of Nevro. Stimwave is not licensed under the '126 patent.

120. Nevro is entitled to a declaratory judgment that Stimwave's future commercial manufacture, use, offer for sale, sale, and/or importation of high frequency SCS systems does and will infringe the '126 patent, directly and indirectly.

121. Stimwave has actual and/or constructive notice of the '126 patent. Stimwave's actions are willful and deliberate, and render this an exceptional case under 35 U.S.C. § 285. Stimwave is aware of Nevro's patent portfolio via, at least, Nevro's patent markings, inquiries

from physicians and analysts, information provided by the Patent and Trademark Office, and the personal knowledge of its CEO. Stimwave previously represented to Nevro that it believed activating high frequency therapy on its SCS systems would infringe Nevro's patents. Stimwave now represents to physicians and analysts that its SCS systems do not infringe Nevro's patents because its SCS systems do not have an "IPG." Stimwave is aware of, or willfully blind to, the fact that at least claim 1 of the '126 patent does not require an implantable IPG but rather only a percutaneous lead—a requirement met by Stimwave's implantable stimulator.

122. Nevro has been and will be damaged by Stimwave's acts in an amount as yet unknown. Nevro has no adequate legal remedy. Unless enjoined by this Court, Stimwave's imminent infringement will cause Nevro substantial and irreparable harm. Under 35 U.S.C. § 283, Nevro is entitled to an injunction barring Stimwave from infringing the '126 patent.

EIGHTH CAUSE OF ACTION

(False Advertising, Lanham Act Section 43(a), 15 U.S.C. § 1125(a))

123. Nevro incorporates the foregoing allegations by reference.

124. Stimwave has knowingly and intentionally misled consumers by making false and unsupported statements about the clinical efficacy and risks associated with use of Nevro's Senza system. Stimwave has falsely and misleadingly asserted that "large IPGs . . . have been reported to have substantial complications in at least a third of all patients." Stimwave lacks clinical data to support this claim. To the contrary, Stimwave is aware that only 4.0% of Senza-RCT patients using the Senza device (a "large IPG") had a study-related serious adverse effect, compared with 7.2% of conventional SCS subjects using a Boston Scientific device.

125. Stimwave has also knowingly and intentionally misled consumers by making false and unsupported statements about the clinical efficacy and benefits associated use of its own SCS systems. Stimwave informed attendees of the 2018 Ohio and Kentucky Society of

Interventional Pain Physicians conference that "[a]n IPG-free system allows for better pain reduction due to the absence of battery!" and that a "wireless one-stage trial allows for better trial assessment and higher response rate!". Stimwave has no legitimate evidence to support these claims of clinical efficacy.

126. Stimwave's statements have misled, or have the tendency to mislead, a substantial segment of the market for SCS systems. Stimwave's statements mislead physicians and others in the pain management field as to, *inter alia*, the efficacy and performance of the Stimwave SCS systems as compared to the Nevro SCS systems—Stimwave has no legitimate clinical evidence, and has not shown any evidence whatsoever, to support these statements.

127. Stimwave's statements are deliberate and intentional misrepresentations of material facts. Stimwave is aware of clinical data that contradicts its claims, and/or lacks clinical data to support its claims about clinical performance.

128. Stimwave caused its false and misleading statements to enter interstate commerce. Stimwave made false and misleading statements on the Internet and at a conference of United States pain physicians and others in the SCS field.

129. Stimwave's false and misleading statements have harmed and are likely to continue to harm Nevro and are likely to cause to diversion of sales from Nevro to Stimwave. Claims of clinical efficacy or a lower risk of adverse events are important to hospitals, physicians, and patients considering different SCS systems.

130. The conduct alleged above constitutes false advertising, in violation of Section 43(a) of the Lanham Act (15 U.S.C. § 1125(a)).

131. Stimwave's acts have caused, and will continue to cause, substantial monetary harm to Nevro and have damaged Nevro's reputation and goodwill, including the goodwill

associated with Nevro's Senza system and HF10 therapy. Stimwave's activities, unless restrained, will continue to cause further irreparable injury to Nevro for which Nevro has no adequate remedy at law.

132. On information and belief, Stimwave undertook the acts described herein with full knowledge and intent to cause harm to Nevro.

NINTH CAUSE OF ACTION
(Deceptive Trade Practices, 6 Del. C. Section 2532)

133. Nevro incorporates the foregoing allegations by reference.

134. In the course of its business, Stimwave has knowingly and intentionally misled consumers by making false and unsupported statements about the clinical efficacy and risks associated with use of Nevro's Senza system. Stimwave has falsely and misleadingly asserted that "large IPGs . . . have been reported to have substantial complications in at least a third of all patients." Stimwave lacks clinical data to support this claim. To the contrary, Stimwave is aware that only 4.0% of Senza-RCT patients using the Senza device (a "large IPG") had a study-related serious adverse effect, compared with 7.2% of conventional SCS subjects using a Boston Scientific device.

135. These statements disparage Nevro's SCS systems by a false or misleading statement of fact. These statements represent that both Stimwave's SCS systems and Nevro's SCS systems have characteristics, benefits, or detriment that they do not have. These statements cause a likelihood of confusion or misunderstanding among consumers of SCS systems and others in the SCS field.

136. Stimwave has also knowingly and intentionally misled consumers by making false and unsupported statements about the clinical efficacy and benefits associated use of its own SCS systems. Stimwave informed attendees of the 2018 Ohio and Kentucky Society of

Interventional Pain Physicians conference that "[a]n IPG-free system allows for better pain reduction due to the absence of battery!" and that a "wireless one-stage trial allows for better trial assessment and higher response rate!" Stimwave has no legitimate evidence to support these claims of clinical efficacy.

137. These statements disparage Nevro's SCS systems by a false or misleading statement of fact. These statements represent that both Stimwave's SCS systems have characteristics, or benefits, that they do not have, and that, by comparison, represent that Nevro's SCS systems lack these traits. These statements cause a likelihood of confusion or misunderstanding among consumers of SCS systems and others in the SCS field.

138. Stimwave's statements have created confusion and misunderstanding within the market for SCS systems. Stimwave's statements mislead physicians and others in the pain management field as to, *inter alia*, the efficacy and performance of the Stimwave SCS systems as compared to the Nevro SCS systems. Stimwave has no legitimate evidence to support these claims of clinical efficacy.

139. Stimwave's statements are deliberate and intentional misrepresentations of material facts. Stimwave is aware of clinical data that contradicts its claims, and/or lacks clinical data to support its claims about clinical performance.

140. Stimwave's false and misleading statements have harmed and are likely to continue to harm Nevro and are likely to cause to diversion of sales from Nevro to Stimwave. Claims of clinical efficacy or a lower risk of adverse events are important to hospitals, physicians, and patients considering different SCS systems.

141. The conduct alleged above constitutes deceptive trade practices in violation of 6 Del. C. Section 2532.

142. Stimwave's acts have caused, and will continue to cause, substantial monetary harm to Nevro and have damaged Nevro's reputation and goodwill, including the goodwill associated with Nevro's Senza system and HF10 therapy. Stimwave's activities, unless restrained, will continue to cause further irreparable injury to Nevro for which Nevro has no adequate remedy at law.

143. On information and belief, Stimwave undertook the acts described herein with full knowledge and intent to cause harm to Nevro.

PRAYER FOR RELIEF

WHEREFORE, Nevro prays for relief as follows:

1. A judgment that Stimwave has infringed one or more claims of the '358, '192, '127, '222, and '126 patents;

2. A judgment and a declaration that making, using, selling, offering for sale, importing, or supplying from the United States, Stimwave's high frequency SCS systems and devices infringes one or more claims of the '358, '192, '127, '222, and '126 patents, directly and indirectly;

3. An order and judgment temporarily, preliminarily and permanently enjoining Stimwave and its officers, directors, agents, servants, employees, and all others acting in privity or in concert with them, and their parents, subsidiaries, divisions, successors and assigns, from further acts of infringement of the '358, '192, '127, '222, and '126 patents;

4. An order and judgment temporarily, preliminarily and permanently enjoining Stimwave and its officers, directors, agents, servants, employees, and all others acting in privity or in concert with them, and their parents, subsidiaries, divisions, successors and assigns, from engaging in further acts of false advertising and deceptive trade practices;

5. A judgment awarding Nevro all damages suffered by Nevro as a result of Stimwave's infringement, and in no event less than a reasonable royalty for Stimwave's acts of infringement, including all pre-judgment and post-judgment interest at the maximum rate permitted by law;

6. A judgment awarding Nevro all damages suffered by Nevro as a result of Stimwave's false advertising and deceptive trade practices;

7. A judgment finding Stimwave's infringement willful and enhancing damages pursuant to 35 U.S.C. § 284;

8. A judgment finding this an exceptional case pursuant to 35 U.S.C. § 285;

9. A judgment trebling any damages to the extent permitted by law;

10. Exemplary or punitive damages to the extent permitted by law;

11. Costs of suit and reasonable attorney fees; and

12. Any other remedy to which Nevro may be entitled.

DEMAND FOR JURY TRIAL

Nevro demands a trial by jury on all issues so triable in this action.

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