IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NEVRO CORP.,	)	
	)	
Plaintiff,	)	
	)	C.A. No. 20-291 (CFC)
v.	)	
	)	**DEMAND FOR JURY TRIAL**
NALU MEDICAL, INC.,	)	
	)	
Defendant.	)	

FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Nevro Corp. ("Nevro"), for its First Amended Complaint against Defendant Nalu Medical, Inc. ("Nalu"), alleges as follows:

1. This action concerns Nalu's infringement of Nevro's United States Patent Nos. 10,471,258; 9,333,358; 8,712,533; 8,359,102; 9,327,125; and 9,333,357 (attached as Exhibits 1-6 hereto). Nevro files this action to stop Nalu's deliberate infringement of Nevro's patents protecting its proprietary high frequency, paresthesia-free technology.

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 paresthesia-based 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 differentiated 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. Nalu is a medical device company that makes and sells the Nalu Neurostimulation System. Nalu represents that the Nalu Neurostimulation System delivers SCS therapy at frequencies up to 10,000 Hz. Nalu has FDA clearance to promote therapy with the Nalu Neurostimulation System at frequencies up to 1,500 Hz. Nalu represents that the therapy provided by the Nalu Neurostimulation System is paresthesia-free. Nalu has made commercial sales of the Nalu Neurostimulation System in the United States and initiated a full commercial

launch as early as January 2020. Nevro brings this action to obtain redress for Nalu's infringement and to prevent harm to Nevro's core 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 Nalu is Delaware corporation with its principal place of business at 2320 Faraday Avenue, Suite #100, Carlsbad, CA 92008.

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 Nalu as Delaware is Nalu's state of incorporation.

12. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and 1400(b), as Delaware is Nalu'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, Senza II™ system and Senza Omnia™ system (together, the "Senza systems"), utilize Nevro's unique and patented HF10® therapy. Among other distinctions, Nevro's HF10 therapy employs a much higher frequency than traditional "low frequency" SCS therapies. In its commercial embodiment, Nevro's HF10 therapy 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 therapies that utilize low frequency stimulation, typically between 50 Hz and 60 Hz. While the Senza systems are also capable of delivering traditional low frequency SCS therapies, HF10 therapy has been, and remains, Nevro's differentiated therapy and its front-line solution for patients with chronic pain. 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 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.

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

16. The first generation 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 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 United States SCS market.

20. Nalu is aware of Nevro's groundbreaking technology and the success that Nevro has enjoyed as a result of that technology.

21. Nevro has protected its innovative SCS technology through an extensive patent portfolio of over 200 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. Nevro is widely known in the SCS industry as the exclusive provider of high frequency, paresthesia-free therapy.

22. Nevro complies with and has complied with 35 U.S.C. § 287, and marks its patented products pursuant to 35 U.S.C. § 287(a).

Nalu's Infringement of Nevro's Patented Technology

23. Nalu represents that the Nalu Neurostimulation System can be used for SCS treatment of chronic, intractable pain of the trunk and/or limbs, including unilateral or bilateral pain.

24. The Nalu Neurostimulation System includes an implantable device, referred to by Nalu as an "implantable pulse generator (IPG)"[2] or an "Implantable Neuro Stimulator (INS)."[3] The IPG functions as a signal generator.

25. The Nalu IPG is "intended to provide relief from chronic pain by electrically stimulating the spinal cord."[4] The IPG "provides electrical stimulation pulses that are transmitted through the leads, through the dura, to the desired spinal cord site."[5]

26. The Nalu IPG "is not simply a conduit for generating electrical impulses controlled by the external unit, but acts to help control therapy delivery (i.e. a pulse generator)."[6] The Nalu IPG includes an embedded receiver and flexible circuit board.[7]

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[2] Ex. 7, FDA Letter Re: 510k Premarket Notification, at p. 5-2 ("Nalu FDA Clearance"), *available at* http://www.accessdata.fda.gov/cdrh_docs/pdf18/K183047.pdf.

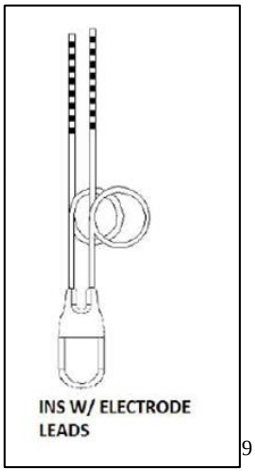
[3] Ex. 8, Nalu Medical Inc, External Transmitter Module (ETM) Instructions for Use ("Nalu IFU") at 3, *available at* https://usermanual.wiki/Nalu-Medical/34001-001/pdf.

[4] *Id.*

[5] Ex. 7, Nalu FDA Clearance at p. 5-2.

27. The Nalu IPG "is implanted in the body and connects to leads in the epidural space" and the leads are "designed to deliver electrical pulses to the spinal cord in the epidural space via an array of eight cylindrical electrodes at the distal end. Leads may be integrated with or connected to the IPG."[8] The leads in the Nalu system function as signal delivery devices that deliver a therapy signal to the patient's body.

28. The Nalu IPG and the Nalu leads are depicted below:



[9]

29. The Nalu Neurostimulation System is "available in two different implant architectures: an 'integrated' system with preattached leads and a 'ported' system where leads may be attached, via connector ports."[10]

30. The Nalu IPG is powered by an externally-worn, battery-powered device that Nalu refers to as the "Therapy Disc" or "External Transmitter Module (ETM)."[11]

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6 Ex. 9, Poree *et al.*, Design Elements and Clinical Needs for a Novel, Miniaturized Spinal Cord Stimulator System at Results.

7 Ex. 7, Nalu FDA Clearance at p. 5-7.

8 Ex. 8, Nalu IFU at 5; *see also* Ex. 7, Nalu FDA Clearance at p. 5-2.

9 Ex. 8, Nalu IFU at 4.

10 Ex. 7, Nalu FDA Clearance at p. 5-2.

11 Ex. 8, Nalu IFU at 3; Ex. 7, Nalu FDA Clearance at p. 5-3.

31. The Therapy Disc powers the IPG using RF wireless transmission of energy.[12]

32. The Therapy Disc is depicted below:

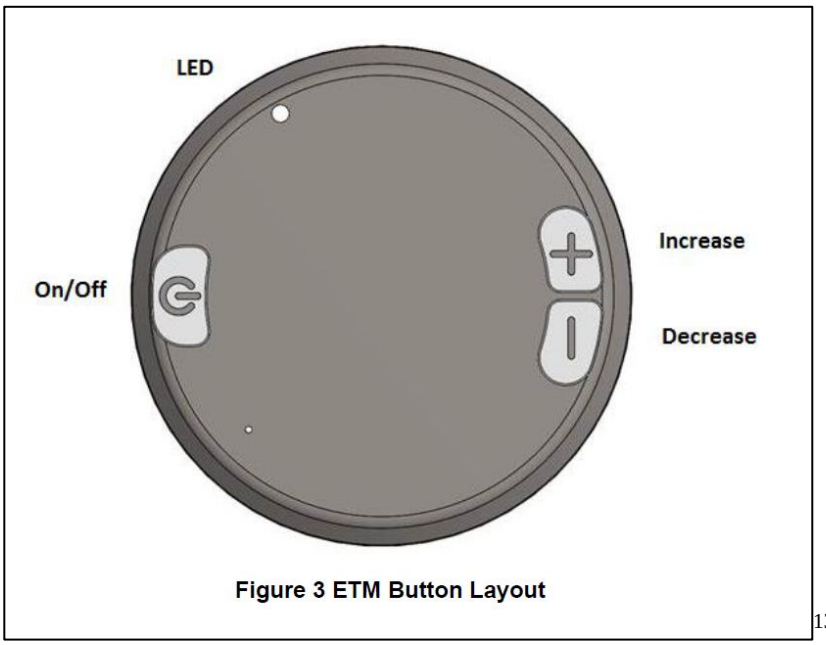

Figure 3 ETM Button Layout[13]

33. The Nalu Neurostimulation System is configured using a Clinician Programmer Application during surgery and programming.[14] During this process, "[t]he programmer is responsible for configuring the devices to deliver therapy according to clinician defined levels and patient preferences[.]"[15] (*Id.*) It is standard industry practice for the operator of the programmer to be an employee or agent of the SCS device company, and accordingly it is a Nalu employee or agent that performs the operation of programming the pulse generator to generate a therapy signal. Nalu has hired sales staff and field clinical engineers to work directly with physicians and program the Nalu Neurostimulation System.

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12 Ex. 7, Nalu FDA Clearance at p. 5-3.

13 Ex. 8, Nalu IFU at 6.

14 *Id.*

15 *Id.*

34. Nalu represents in its user manual that the available stimulation parameters for the Nalu Neurostimulation System include frequencies of 1 Hz to 10,000 Hz, pulse widths of 10 µsec to 2 ms, and amplitudes of 0 µA to 10.2 mA:

Parameter	Range
Frequency	1Hz - 10kHz
Pulse Width	10µsec – 2ms
Amplitude	0µA - 10.2mA

[16]

35. This user manual appears to be the only publicly-available user manual for the Nalu Neurostimulation System.

36. Nalu holds itself out as a Carlsbad, California based company, and it employs mechanical and software engineering employees in at least California. Nalu manufactures the Nalu Neurostimulation System in the United States, and according to FDA registration records, uses Cirtec Medical, a contract manufacturer located in the United States.

37. Nalu has received FDA clearance to promote the Nalu Neurostimulation System in the United States using pulse frequencies of 2 Hz to 1,500 Hz, pulse widths of 12 to 1000 µsec, and amplitudes of 0 to 10.2 mA.[17] Nalu's FDA clearance also indicates that the Nalu Neurostimulation System generates a charge balanced (delayed) biphasic asymmetrical waveform.[18]

38. According to a North American Neuromodulation Society ("NANS") 2019 Annual Meeting presentation on a multi-center clinical study using the Nalu Neurostimulation System, the system was programmed by Nalu employees with "no intra-operative paresthesia mapping" and the pain relief was "paresthesia-independent" (i.e.,

[16] Ex. 8, Nalu IFU at 10.

[17] Ex. 7, Nalu FDA Clearance at p. 5-10.

[18] *Id.* at p. 5-11.

paresthesia-free). In that study, the Nalu Neurostimulation System was used to treat chronic, intractable lower back and/or leg pain.

39. A poster by Salmon *et al.* that appears to describe the same or related multi-center clinical study states that the "[s]ubjects also demonstrated better pain relief when leads were positioned anatomically versus physiologically," and that "[p]atients reported no paresthesias" when using the Nalu Neurostimulation System.[19] The Salmon poster also references the advantages of "high frequency and burst SCS patterns" over low frequency patterns, and contrasted the therapy pattern used against traditional low frequency, tonic, paresthesia-based therapy.[20]

40. Another poster by Levy *et al*. that appears to describe another clinical study also demonstrates that the Nalu leads are placed anatomically at vertebral level T9.[21]

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[19] Ex. 10, Salmon *et al.*, Results from a Prospective, Multi-Center Clinical Study Testing a Novel, Pulsed Spinal Cord Stimulation Pattern, *available at* http://www.painresearch.co.uk/Posters_files/Results%20from%20a%20Prospective,%20Multi-Center%20Clinical%20Study%20Testing%20a%20Novel,%20Pulsed%20Spinal%20Cord%20Stimulation%20Pattern%2019Dec2018.pdf.

[20] *Id.*

[21] Ex. 12, Levy *et al.*, Superiority of Anatomically Based Lead Placements When Utilizing a Novel, Pulsed SCS Stimulation Pattern, Fig. 2, *available at* https://twitter.com/MetroPain/status/1133616479570726913; *see also* Ex. 9, Salmon *et al.*, Superiority of Anatomically Based Lead Placements When Utilizing a Hybrid SCS Stimulation Pattern; Ex. 11, Verrills *et al.*, Results from a Prospective, Multi-Center Clinical Study Testing a Novel, Hybrid Spinal Cord Stimulation Pattern.

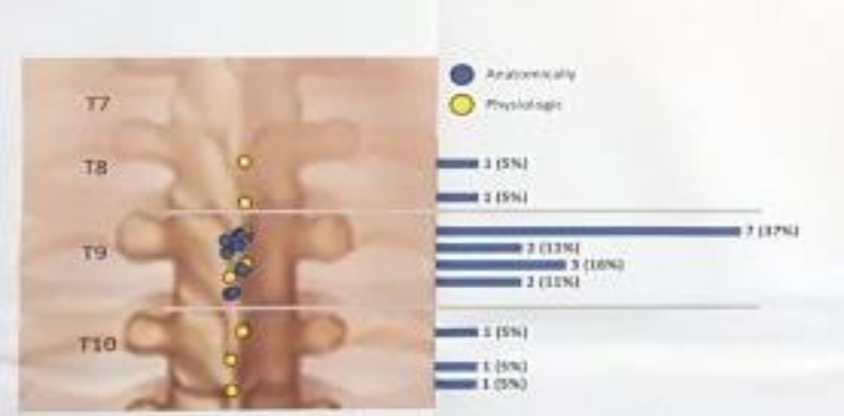

Figure 2. Contact cathode locations for leads placed physiologically and anatomically showing responders (legs or back) only.[22]

41. The studies referenced in these posters were not used in Nalu's application for FDA approval. Accordingly, the Nalu Neurostimulation Systems that Nalu manufactured, exported, and used in these studies are not subject to a regulatory safe harbor for patent infringement.

42. Moreover, two study abstracts presented at the NANS 2019 Annual Meeting and co-authored by Nalu's Vice President of Scientific and Clinical Affairs Dr. Jim Makous, as well as Nalu consultants and board members, disclose a "paresthesia-free epidural stimulation pattern" and testing of both "paresthesia and paresthesia-free stimulation patterns."[23]

43. One of these Nalu-authored abstracts discusses a clinical study in which "patterned high frequency" stimulation was used to provide "paresthesia-free pain relief."[24] Since the entry of Nevro into the market, "high frequency" is understood in this context to include frequencies of 1,500 Hz and above. The studies referenced in this abstract were not used

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[22] *Id.*, Fig. 2.

[23] Ex. 9, Salmon *et al.*, Superiority of Anatomically Based Lead Placements When Utilizing a Hybrid SCS Stimulation Pattern; Ex. 11, Verrills *et al.*, Results from a Prospective, Multi-Center Clinical Study Testing a Novel, Hybrid Spinal Cord Stimulation Pattern.

[24] Ex. 11 at ID: 13296.

in Nalu's application for FDA approval. Accordingly, the Nalu Neurostimulation Systems that Nalu manufactured, exported, and used in these studies are not subject to a regulatory safe harbor for patent infringement.

44. Yet another abstract presented at the NANS 2019 annual meeting lists Nalu's Vice President of Scientific and Clinical Affairs Dr. Jim Makous as the lead author. This abstract discusses an animal study involving "40-Hz tonic stimulation, 500 Hz burst pulse trains, 10kHz tonic, and 3 novel, hybrid stimulation patterns."[25]

45. Additionally, Nalu's attempts to obtain patents covering the Nalu Neurostimulation System include seeking protection for high frequency therapy. In its pending Patent Application No. 16/104,829 (the "'829 application") to an "Apparatus with Enhanced Stimulation Waveforms," Nalu describes a neurostimulation system that produces high frequency signals up to and above 10,000 Hz.[26] This same application notes that the system can provide "paresthesia-reduced (e.g., paresthesia-free)" therapy.[27]

46. Nalu has already made a "limited commercial launch" of the Nalu Neurostimulation System in the United States and plans to make a "full commercial launch in 2020":

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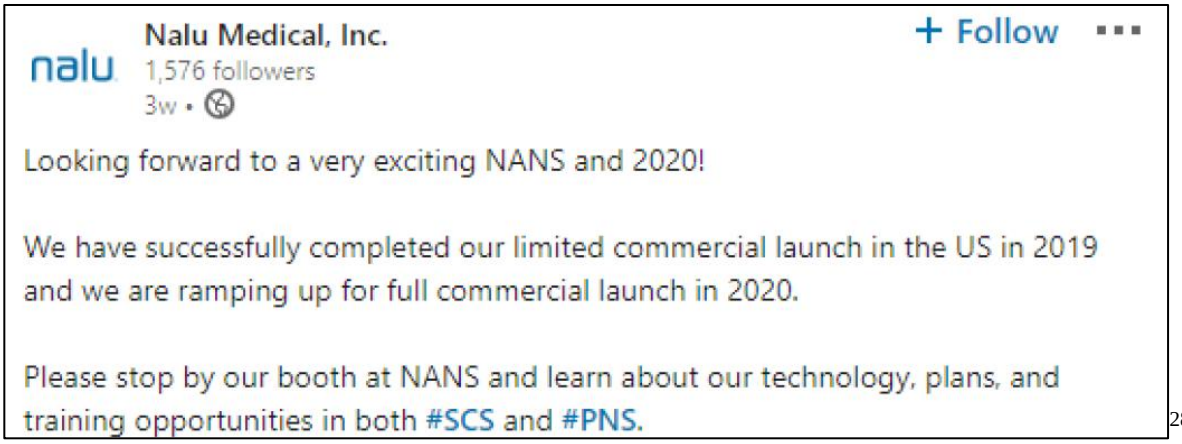
[25] Ex. 13, Makous *et al.*, Impact of a Novel, Hybrid Stimulation Pattern on Wide-Dynamic Range Neurons in the Dorsal Horn.

[26] *See, e.g.,* Ex. 14, U.S. Pat. Appl. Pub No. US 2019/0001139 Al, at cl. 55 (claiming "[t]he medical apparatus according to claim 53, wherein the high frequency carrier comprises a frequency between 1 Hz and *10 kHz*."), cl. 58 (claiming "[t]he medical apparatus according to claim 53, wherein the stimulation waveform comprises a biphasic pulse, *a high frequency carrier signal of approximately 10 kHz* and a low frequency envelope with a frequency of between 40 Hz and 100 Hz.") (emphasis added).

[27] *See, e.g., id.* at [0295]; *see also id.* at cl. 315 ("The medical apparatus according to any claim herein, wherein the apparatus is configured to vary one or more of the stimulation parameters to optimize at least one of: therapeutic benefit; system efficiency; *avoidance of paresthesia*; reduction of paresthesia; reduction of charge; and combinations thereof) (emphasis added).



[28]

47. Nalu specifically intends its employees and/or agents, and third parties (including at least clinicians) assisted by its employees and/or agents, to infringe the asserted patents. Nalu is aware of Nevro's patents. Nevro avails itself of the patent marking statutes by listing all of its issued patents on its website: www.nevro.com/patents. On December 9, 2016, Nevro announced that it had filed a lawsuit for patent infringement against Boston Scientific, asserting patents covering Nevro's groundbreaking high frequency, paresthesia-free therapy.[29] Nevro's lawsuit against Boston Scientific included the '533 patent, '102 patent, '125 patent, and '357 patent that are currently asserted against Nalu. On February 15, 2019, Nevro announced that it had filed a lawsuit for patent infringement against Stimwave Technologies, Inc., asserting the same family of patents covering Nevro's groundbreaking high frequency, paresthesia-free therapy.[30] Nevro's lawsuit against Stimwave included the '358 patent currently asserted against Nalu. Further, Nalu disclosed over a dozen Nevro patents and patent applications as prior art to the Nalu '829 application, including Nevro's '358 patent-in-suit, '533 patent-in-suit, '102 patent

[28] https://www.linkedin.com/company/nalu-medical-inc/.

[29] https://www.nevro.com/English/us/investors/investor-news/investor-news-details/2016/Nevro-Announces-Filing-of-Lawsuit-by-Boston-Scientific/default.aspx.

[30] https://www.nevro.com/English/us/investors/investor-news/investor-news-details/2019/Nevro-Files-Lawsuit-for-Patent-Infringement-Against-Stimwave-in-the-US/default.aspx.

in-suit, '125 patent-in-suit, and '357 patent-in-suit.[31] Nalu has knowledge of the scope of these patents, at the least because it identified them as relevant prior art to its own '869 patent application, and because the details of Nevro's prior patent litigations have been the subject of detailed industry reporting.

48. Even if Nalu did not have this direct awareness of Nevro's patents, Nalu could only avoid awareness of Nevro's patents through willful blindness, given Nevro's status as a lead innovator in the SCS industry, the widespread publicity surrounding Nevro's patent portfolio for high frequency, paresthesia-free SCS therapy, Nevro's practice of patent marking, and the up-to-date listing of Nevro's patents on its website.

49. Nalu specifically intends that its employees and/or agents engage in conduct that infringes the asserted patents, and that they assist and encourage others (including at least clinicians) in conduct that infringes the asserted patents, including the (i) use of the Nalu Neurostimulation System in an infringing manner and (ii) the combination of the components of the Nalu Neurostimulation System outside the United States in a manner would infringe the asserted patents if such combination occurred in the United States. Nalu sought and obtained FDA clearance to promote the Nalu Neurostimulation System for use at a frequency of 1,500 Hz (within the range of Nevro's patent claims); represents in a public user manual that the Nalu Neurostimulation System operates at 10,000 Hz (within the range of Nevro's claims); and has published literature encouraging the use of the Nalu Neurostimulation System for high frequency and paresthesia free therapies. Moreover, as set forth above, Nalu employees or agents assist and advise clinicians with the implantation and programming process, including by using Nalu's programming application to program the pulse generator to generate a therapy signal. Because

[31] Ex. 15, Information Disclosure by Applicant (listing Nevro's patents).

Nalu has knowledge of the scope of Nevro's patents, Nalu knows or is willfully blind to the fact that this conduct infringes the asserted patents.

50. Nalu's activities, unless restrained, will cause irreparable injury to Nevro for which Nevro has no adequate remedy at law.

FIRST CAUSE OF ACTION
(Infringement of U.S. Patent No. 10,471,258)

51. Nevro incorporates the foregoing allegations by reference.

52. Nevro is the owner of all right, title, and interest in and to U.S. Patent No. 10,471,258 (the '258 patent). The '258 patent issued on November 12, 2019, 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 '258 patent is attached as Exhibit 1.

53. The claims of the '258 patent cover a spinal cord system for treating a patient. For example, claim 1 covers: a spinal cord modulation system for treating a patient, the system comprising: a pulse generator that, in operation, generates 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 15 kHz; one or more implantable electrical contacts electrically coupled to the pulse generator and designed to deliver the therapy signal to the patient's spinal cord region; and an external power source, wherein the external power source is wirelessly coupleable to the pulse generator to transmit power to the pulse generator via RF signals.

54. The Nalu Neurostimulation System is a spinal cord modulation system for treating a patient, which includes a pulse generator that, in operation, generates a non-paresthesia-producing therapy signal. Nalu represents in its user manual that the Nalu Neurostimulation System generates frequencies up to and including 10,000 Hz. Nalu has FDA clearance to market the system in the United States for use at frequencies up to and *including*

1,500 Hz. A frequency of 1,500 Hz or above satisfies the frequency limitation of, *e.g.*, claim 1 of the '258 patent. The Nalu Neurostimulation System includes implantable leads with electrical contacts electrically coupled to the pulse generator, which are designed to deliver the therapy signal to the patient's spinal cord region. The Nalu Neurostimulation System includes an external power source, referred to by Nalu as the Therapy Disc. The Therapy Disc is wirelessly coupleable to the pulse generator to transmit power to the pulse generator via RF signals.

55. Nalu makes, sells, uses, and offers to sell the Nalu Neurostimulation System to operate with at least a portion of the therapy signal in a frequency range of 1,500 Hz or higher without generating paresthesia, and at least one patient has received such therapy. While the precise software parameters and therapy parameters used on patients are non-public and are uniquely within Nalu's control, Nevro believes that discovery in this case will further establish high frequency, paresthesia-free configuration and operation of the Nalu Neurostimulation System. Nevro discusses the availability and use of infringing parameters in further detail above, but notes that Nalu has disclosed studies involving use of the Nalu Neurostimulation System to deliver therapy without paresthesia and with high frequencies (since the entry of Nevro in this market, understood in this context to include frequencies of 1,500 Hz and above); Nalu specifically sought and obtained FDA clearance to market the Nalu Neurostimulation System for use at 1,500 Hz; Nalu's user manual represents that the Nalu Neurostimulation System operates as high as 10,000 Hz; and Nalu has sought patent protection for a neurostimulation system that generates a therapy signal with a frequency in a frequency range of 1,500 Hz or higher and that does not cause paresthesia.

56. Nalu has infringed and continues to infringe one or more claims of the '258 patent by using the Nalu Neurostimulation System in the United States, selling the Nalu

Neurostimulation System in the United States, and/or offering to sell the Nalu Neurostimulation System in the United States. Nalu has infringed and continues to infringe the '258 patent by manufacturing the Nalu Neurostimulation System in the United States and/or importing the Nalu Neurostimulation System into the United States, and/or has infringed the '258 patent pursuant to 35 U.S.C. § 271(f)(1)-(2) through export of the Nalu Neurostimulation System from the United States. Nalu's manufacture, use, offer to sell, import, and/or export of the Nalu Neurostimulation System infringes one or more claims of the '258 patent literally or under the doctrine of equivalents and violates 35 U.S.C. § 271.

57. Nalu has intentionally instructed, and will intentionally instruct, others, including doctors and health care providers, to use the Nalu Neurostimulation System in a manner that infringes the '258 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. Consistent with this industry practice, Nalu states that its stimulation parameters are set using a Clinical Programming application by a Field Clinical Engineer employed by Nalu. As set forth above, Nalu knows or has been willfully blind to the fact that such actions infringe Nevro's patents. Alternatively, Nalu's Field Clinical Engineer instructs a patient's doctor or healthcare provider on how to use the Clinical Programming application to program the Nalu Neurostimulation System, and said actions by Nalu constitute, and will constitute, induced infringement of one or more claims of the '258 patent in violation of 35 U.S.C. § 271(b).

58. Nalu's infringement of the '258 patent has been willful and continues to be willful. Nalu has known of the '258 patent since at least February 28, 2020. Nalu has acted despite having knowledge of its infringement or being willfully blind to its infringement.

59. Nalu's infringement is without the consent of Nevro. Nalu is not licensed under the '258 patent.

60. Nevro marks its patented products pursuant to 35 U.S.C. § 287(a).

61. As a result of Nalu's infringement, Nevro has suffered damages and will continue to suffer damages, including damages awardable under 35 U.S.C. §§ 284 and 285. Nevro has no adequate legal remedy. Unless enjoined by this Court, Nalu's infringement will cause Nevro substantial and irreparable harm. Under 35 U.S.C. § 283, Nevro should be awarded an injunction barring Nalu from further infringement of the '258 patent.

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

62. Nevro incorporates the foregoing allegations by reference.

63. 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 2.

64. 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.

65. The Nalu Neurostimulation System is a spinal cord modulation system for treating a patient, which includes an implantable signal delivery device configured to deliver a therapy signal to one or more locations in the patient's spinal cord that, in operation, generates a non-paresthesia-producing therapy signal. Nalu represents in its user manual that the Nalu Neurostimulation System generates frequencies up to and including 10,000 Hz. Nalu has FDA clearance to market the system in the United States for use at frequencies up to and *including* 1,500 Hz. A frequency of 1,500 Hz or above satisfies the frequency limitation of, *e.g.*, claim 1 of the '358 patent. The Nalu Neurostimulation System has a signal generator that is in electrical communication with the implantable signal delivery device and a power source, referred to by Nalu as the Therapy Disc, that is configured to power the signal generator.

66. Nalu makes, sells, uses, and offers to sell the Nalu Neurostimulation System configured and programmed to deliver therapy with a portion of the therapy signal in a frequency range of 1,500 Hz or higher without generating paresthesia, and at least one patient has received such therapy. While the precise software parameters and therapy parameters used on patients are non-public and are uniquely within Nalu's control, Nevro believes that discovery in this case will further establish high frequency, paresthesia-free configuration and operation of the Nalu Neurostimulation System. Nevro discusses the availability and use of infringing parameters in further detail above, but notes that Nalu has disclosed studies involving use of the Nalu Neurostimulation System to deliver therapy without paresthesia and with high frequencies (since the entry of Nevro in this market, understood in this context to include frequencies of

1,500 Hz and above); Nalu specifically sought and obtained FDA clearance to market the Nalu Neurostimulation System for use at 1,500 Hz; Nalu's user manual represents that the Nalu Neurostimulation System operates as high as 10,000 Hz; and Nalu has sought patent protection for a neurostimulation system that generates a therapy signal with a frequency in a frequency range of 1,500 Hz or higher and that does not cause paresthesia.

67. Nalu has infringed and continues to infringe one or more claims of the '358 patent by using the Nalu Neurostimulation System in the United States, selling the Nalu Neurostimulation System in the United States, and/or offering to sell the Nalu Neurostimulation System in the United States. Nalu has infringed and continues to infringe the '358 patent by manufacturing the Nalu Neurostimulation System in the United States and/or importing the Nalu Neurostimulation System into the United States, and/or has infringed the '358 patent pursuant to 35 U.S.C. § 271(f)(1)-(2) through export of the Nalu Neurostimulation System from the United States. Nalu's manufacture, use, offer to sell, import, and/or export of the Nalu Neurostimulation System infringes one or more claims of the '358 patent literally or under the doctrine of equivalents and violates 35 U.S.C. § 271.

68. Nalu has intentionally instructed, and will intentionally instruct, others, including doctors and health care providers, to use the Nalu Neurostimulation System in a manner that infringes the '358 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. Consistent with this industry practice, Nalu states that its stimulation parameters are set using a Clinical Programming application by a Field Clinical Engineer

employed by Nalu. As set forth above, Nalu knows or has been willfully blind to the fact that such actions infringe Nevro's patents. Alternatively, Nalu's Field Clinical Engineer instructs a patient's doctor or healthcare provider on how to use the Clinical Programming application to program the Nalu Neurostimulation System, and said actions by Nalu constitute, and will constitute, induced infringement of one or more claims of the '358 patent in violation of 35 U.S.C. § 271(b).

69. Nalu's infringement of the '358 patent has been willful and continues to be willful. Nalu has known of the '358 patent since at least February 25, 2019, when it disclosed the '358 patent as prior art to its '829 patent application. Nalu has acted despite having knowledge of its infringement or being willfully blind to its infringement.

70. Nalu's infringement is without the consent of Nevro. Nalu is not licensed under the '358 patent.

71. Nevro marks its patented products pursuant to 35 U.S.C. § 287(a).

72. As a result of Nalu's infringement, Nevro has suffered damages and will continue to suffer damages, including damages awardable under 35 U.S.C. §§ 284 and 285. Nevro has no adequate legal remedy. Unless enjoined by this Court, Nalu's infringement will cause Nevro substantial and irreparable harm. Under 35 U.S.C. § 283, Nevro should be awarded an injunction barring Nalu from further infringement of the '358 patent.

THIRD CAUSE OF ACTION
(Infringement of U.S. Patent No. 8,712,533)

73. Nevro incorporates the foregoing allegations by reference.

74. 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 as Exhibit 3.

75. The claims of the '533 patent cover a spinal cord system for treating a patient. For example, claim 1 covers: a spinal cord modulation system for reducing or eliminating pain in a patient, the system comprising: a signal generator configured to generate a non-paresthesia-producing therapy signal, wherein at least a portion of the therapy signal is at a frequency in a frequency range from 1.5 kHz to 100 kHz; and an implantable signal delivery device electrically coupleable to the signal generator and configured to deliver the therapy signal to the patient's spinal cord region. The Nalu Neurostimulation System is a spinal cord modulation system for reducing or eliminating pain in a patient, which includes a signal generator configured to generate a non-paresthesia-producing therapy signal. Nalu represents in its user manual that the Nalu Neurostimulation System generates frequencies up to and including 10,000 Hz. Nalu has FDA clearance to market the system in the United States for use at frequencies up to and *including* 1,500 Hz. A frequency of 1,500 Hz or above satisfies the frequency limitation of, *e.g.*, claim 1 of the '533 patent. The Nalu Neurostimulation System includes implantable leads with electrical contacts electrically coupled to the pulse generator, which are designed to deliver the therapy signal to the patient's spinal cord region.

76. Nalu makes, sells, uses, and offers to sell the Nalu Neurostimulation System configured and programmed to deliver therapy with at least a portion of the therapy signal in a frequency range of 1,500 Hz or higher without generating paresthesia, and at least one patient has received such therapy. While the precise software parameters and therapy parameters used on patients are non-public and are uniquely within Nalu's control, Nevro believes that discovery in this case will further establish high frequency, paresthesia-free configuration and

operation of the Nalu Neurostimulation System. Nevro discusses the availability and use of infringing parameters in further detail above, but notes that Nalu has disclosed studies involving use of the Nalu Neurostimulation System to deliver therapy without paresthesia and with high frequencies (since the entry of Nevro in this market, understood in this context to include frequencies of 1,500 Hz and above); Nalu specifically sought and obtained FDA clearance to market the Nalu Neurostimulation System for use at 1,500 Hz; Nalu's user manual represents that the Nalu Neurostimulation System operates as high as 10,000 Hz; and Nalu has sought patent protection for a neurostimulation system that generates a therapy signal with a frequency in a frequency range of 1,500 Hz or higher and that does not cause paresthesia.

77. Nalu has infringed and continues to infringe one or more claims of the '533 patent by using the Nalu Neurostimulation System in the United States, selling the Nalu Neurostimulation System in the United States, and/or offering to sell the Nalu Neurostimulation System in the United States. Nalu has infringed and continues to infringe the '533 patent by manufacturing the Nalu Neurostimulation System in the United States and/or importing the Nalu Neurostimulation System into the United States, and/or has infringed the '533 patent pursuant to 35 U.S.C. § 271(f)(1)-(2) through export of the Nalu Neurostimulation System from the United States. Nalu's manufacture, use, offer to sell, import, and/or export of the Nalu Neurostimulation System infringes one or more claims of the '533 patent literally or under the doctrine of equivalents and violates 35 U.S.C. § 271.

78. Nalu has intentionally instructed, and will intentionally instruct, others, including doctors and health care providers, to use the Nalu Neurostimulation System 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. Consistent with this industry practice, Nalu states that its stimulation parameters are set using a Clinical Programming application by a Field Clinical Engineer employed by Nalu. As set forth above, Nalu knows or has been willfully blind to the fact that such actions infringe Nevro's patents. Alternatively, Nalu's Field Clinical Engineer instructs a patient's doctor or healthcare provider on how to use the Clinical Programming application to program the Nalu Neurostimulation System, and said actions by Nalu constitute, and will constitute, induced infringement of one or more claims of the '533 patent in violation of 35 U.S.C. § 271(b).

79. Nalu's infringement of the '533 patent has been willful and continues to be willful. Nalu has known of the '533 patent since at least February 25, 2019, when it disclosed the '533 patent as prior art to its '829 patent application. Nalu has acted despite having knowledge of its infringement or being willfully blind to its infringement.

80. Nalu's infringement is without the consent of Nevro. Nalu is not licensed under the '533 patent.

81. Nevro marks its patented products pursuant to 35 U.S.C. § 287(a).

82. As a result of Nalu's infringement, Nevro has suffered damages and will continue to suffer damages, including damages awardable under 35 U.S.C. §§ 284 and 285. Nevro has no adequate legal remedy. Unless enjoined by this Court, Nalu's infringement will cause Nevro substantial and irreparable harm. Under 35 U.S.C. § 283, Nevro should be awarded an injunction barring Nalu from further infringement of the '533 patent.

FOURTH CAUSE OF ACTION
(Infringement of U.S. Patent No. 8,359,102)

83. Nevro incorporates the foregoing allegations by reference.

84. Nevro is the owner of all right, title, and interest in and to U.S. Patent No. 8,359,102 (the '102 patent). The '102 patent issued on January 22, 2013, 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 '102 patent is attached as Exhibit 4.

85. The claims of the '102 patent cover methods of treating patients with high frequency spinal cord stimulation without creating paresthesia. For example, claim 1 covers: a method for treating a patient, comprising: delivering or instructing delivery of 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 about 1.5 kHz to about 50 kHz and does not create paresthesia in the patient.

86. The Nalu Neurostimulation System is a spinal cord modulation system for reducing or eliminating pain in a patient without creating paresthesia. Nalu represents in its user manual that the Nalu Neurostimulation System generates frequencies up to and including 10,000 Hz. Nalu has FDA clearance to market the system in the United States for use at frequencies up to and *including* 1,500 Hz. A frequency of 1,500 Hz or above satisfies the frequency limitation of, *e.g.*, claim 1 of the '102 patent. The Nalu Neurostimulation System includes implantable leads with electrical contacts electrically coupled to the pulse generator, which are designed to deliver the therapy signal to the patient's spinal cord.

87. Nalu makes, sells, uses, and offers to sell the Nalu Neurostimulation System configured and programmed to deliver therapy with at least a portion of the therapy signal in a frequency range of 1,500 Hz or higher without generating paresthesia, and at least one

patient has received such therapy. While the precise software parameters and therapy parameters used on patients are non-public and are uniquely within Nalu's control, Nevro believes that discovery in this case will further establish high frequency, paresthesia-free configuration and operation of the Nalu Neurostimulation System. Nevro discusses the availability and use of infringing parameters in further detail above, but notes that Nalu has disclosed studies involving use of the Nalu Neurostimulation System to deliver therapy without paresthesia and with high frequencies (since the entry of Nevro in this market, understood in this context to include frequencies of 1,500 Hz and above); Nalu specifically sought and obtained FDA clearance to market the Nalu Neurostimulation System for use at 1,500 Hz; Nalu's user manual represents that the Nalu Neurostimulation System operates as high as 10,000 Hz; and Nalu has sought patent protection for a neurostimulation system that generates a therapy signal with a frequency in a frequency range of 1,500 Hz or higher and that does not cause paresthesia. Nalu's use of such systems to provide high frequency spinal cord stimulation without generating paresthesia constitutes 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.

88. Nalu has intentionally instructed, and will intentionally instruct, others, including doctors and health care providers, to use the Nalu Neurostimulation System in a manner that infringes the '102 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. Consistent with this industry practice, Nalu states that its stimulation parameters are set using a Clinical Programming application by a Field Clinical Engineer

employed by Nalu. As set forth above, Nalu knows or has been willfully blind to the fact that such actions infringe Nevro's patents. Alternatively, Nalu's Field Clinical Engineer instructs a patient's doctor or healthcare provider on how to use the Clinical Programming application to program the Nalu Neurostimulation System, and said actions by Nalu constitute, and will constitute, induced infringement of one or more claims of the '102 patent in violation of 35 U.S.C. § 271(b).

89. Nalu's infringement of the '102 patent has been willful and continues to be willful. Nalu has known of the '102 patent since at least February 25, 2019, when it disclosed the '102 patent as prior art to its '829 patent application. Nalu has acted despite having knowledge of its infringement or being willfully blind to its infringement. Nalu's infringement is without the consent of Nevro. Nalu is not licensed under the '102 patent.

90. Nevro marks its patented products pursuant to 35 U.S.C. § 287(a).

91. As a result of Nalu's infringement, Nevro has suffered damages and will continue to suffer damages, including damages awardable under 35 U.S.C. §§ 284 and 285. Nevro has no adequate legal remedy. Unless enjoined by this Court, Nalu's infringement will cause Nevro substantial and irreparable harm. Under 35 U.S.C. § 283, Nevro should be awarded an injunction barring Nalu from further infringement of the '102 patent.

FIFTH CAUSE OF ACTION
(Infringement of U.S. Patent No. 9,327,125)

92. Nevro incorporates the foregoing allegations by reference.

93. 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 as Exhibit 5.

94. The claims of the ’125 patent cover a spinal cord system for treating a patient. For example, claim 18 covers: A spinal cord modulation system for reducing or eliminating pain in a patient, the system comprising: means for generating a paresthesia-free therapy signal with a signal frequency in a frequency range from 1.5 kHz to 100 kHz; and means for delivering the therapy signal to the patient's spinal cord at a vertebral level of from T9 to T12, wherein the means for delivering the therapy signal is at least partially implantable.

95. The Nalu Neurostimulation System is a spinal cord modulation system for reducing or eliminating pain in a patient, which includes a signal generator configured to generate a non-paresthesia-producing therapy signal. Nalu represents in its user manual that the Nalu Neurostimulation System generates frequencies up to and including 10,000 Hz. Nalu has FDA clearance to market the system in the United States for use at frequencies up to and *including* 1,500 Hz. A frequency of 1,500 Hz or above satisfies the frequency limitation of, *e.g.*, claim 18 of the ’125 patent. The Nalu Neurostimulation System includes implantable leads with electrical contacts electrically coupled to the pulse generator, which deliver the therapy signal to the patient’s spinal cord between vertebral levels T9 and T12.

96. Nalu makes, sells, uses, and offers to sell the Nalu Neurostimulation System configured and programmed to deliver therapy with at least a portion of the therapy signal in a frequency range of 1,500 Hz or higher without generating paresthesia, and at least one patient has received such therapy. While the precise software parameters and therapy parameters used on patients are non-public and are uniquely within Nalu’s control, Nevro believes that discovery in this case will further establish high frequency, paresthesia-free configuration and operation of the Nalu Neurostimulation System. Nevro discusses the availability and use of infringing parameters in further detail above, but notes that Nalu has disclosed studies involving

use of the Nalu Neurostimulation System to deliver therapy without paresthesia and with high frequencies (since the entry of Nevro in this market, understood in this context to include frequencies of 1,500 Hz and above); Nalu specifically sought and obtained FDA clearance to market the Nalu Neurostimulation System for use at 1,500 Hz; Nalu's user manual represents that the Nalu Neurostimulation System operates as high as 10,000 Hz; and Nalu has sought patent protection for a neurostimulation system that generates a therapy signal with a frequency in a frequency range of 1,500 Hz or higher and that does not cause paresthesia.

97. Nalu has infringed and continues to infringe one or more claims of the '125 patent by using the Nalu Neurostimulation System in the United States, selling the Nalu Neurostimulation System in the United States, and/or offering to sell the Nalu Neurostimulation System in the United States. Nalu has infringed and continues to infringe the '125 patent by manufacturing the Nalu Neurostimulation System in the United States and/or importing the Nalu Neurostimulation System into the United States, and/or has infringed the '125 patent pursuant to 35 U.S.C. § 271(f)(1)-(2) through export of the Nalu Neurostimulation System from the United States. Nalu's manufacture, use, offer to sell, import, and/or export of the Nalu Neurostimulation System infringes one or more claims of the '125 patent literally or under the doctrine of equivalents and violates 35 U.S.C. § 271.

98. Nalu has intentionally instructed, and will intentionally instruct, others, including doctors and health care providers, to use the Nalu Neurostimulation System 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. Consistent with this industry practice, Nalu states that its stimulation parameters are set using a Clinical Programming application by a Field Clinical Engineer employed by Nalu. As set forth above, Nalu knows or has been willfully blind to the fact that such actions infringe Nevro's patents. Alternatively, Nalu's Field Clinical Engineer instructs a patient's doctor or healthcare provider on how to use the Clinical Programming application to program the Nalu Neurostimulation System, and said actions by Nalu constitute, and will constitute, induced infringement of one or more claims of the '125 patent in violation of 35 U.S.C. § 271(b).

99. Nalu's infringement of the '125 patent has been willful and continues to be willful. Nalu has known of the '125 patent since at least February 25, 2019, when it disclosed the '125 patent as prior art to its '829 patent application. Nalu has acted despite having knowledge of its infringement or being willfully blind to its infringement.

100. Nalu's infringement is without the consent of Nevro. Nalu is not licensed under the '125 patent.

101. Nevro marks its patented products pursuant to 35 U.S.C. § 287(a).

102. As a result of Nalu's infringement, Nevro has suffered damages and will continue to suffer damages, including damages awardable under 35 U.S.C. §§ 284 and 285. Nevro has no adequate legal remedy. Unless enjoined by this Court, Nalu's infringement will cause Nevro substantial and irreparable harm. Under 35 U.S.C. § 283, Nevro should be awarded an injunction barring Nalu from further infringement of the '125 patent.

SIXTH CAUSE OF ACTION
(Infringement of U.S. Patent No. 9,333,357)

103. Nevro incorporates the foregoing allegations by reference.

104. Nevro is the owner of all right, title, and interest in and to U.S. Patent No. 9,333,357 (the '357 patent). The '357 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 '357 patent is attached as Exhibit 6.

105. The claims of the '357 patent cover a spinal cord system for treating a patient. For example, claim 1 covers: a spinal cord modulation system for delivering an electrical therapy signal to a patient's spinal cord, wherein the system is configured to deliver the electrical therapy signal to the patient's spinal cord via one or more implantable signal delivery devices, the system comprising: a signal generator coupleable to the one or more signal delivery devices and having executable instructions to generate and deliver the electrical therapy signal to the patient's spinal cord from an epidural location via the one or more signal delivery devices, wherein the electrical therapy signal has a plurality of sequential bi-phasic pulses having a pulse width between 10 microseconds and 333 microseconds, and an amplitude between 0.5 mA and 10 mA, which at least partially reduces the patient's sensation of pain without generating paresthesia.

106. The Nalu Neurostimulation System is a spinal cord modulation system for reducing or eliminating pain in a patient, which includes a signal generator configured to generate a non-paresthesia-producing therapy signal. Nalu represents in its user manual that the Nalu Neurostimulation System generates amplitudes from 0 mA to 10.2 mA and pulse widths between 10 microseconds and 2,000 microseconds. Nalu has FDA clearance to market the system in the United States for use at amplitudes between 0 mA and 10.2 mA and pulse widths between 12 microseconds and 1,000 microseconds. These amplitudes and pulse widths include parameters that fall within the amplitude and pulse width limitations of, *e.g.*, claim 1 of the '357

patent. The Nalu Neurostimulation System generates a charge balanced (delayed) biphasic asymmetrical waveform, which Nevro understands to constitute sequential bi-phasic pulses. The Nalu Neurostimulation System includes implantable leads with electrical contacts electrically coupled to the pulse generator, which are implanted in the epidural space and deliver the therapy signal to the patient's spinal cord.

107. Nalu makes, sells, uses, and offers to sell the Nalu Neurostimulation System configured and programmed to deliver therapy without generating paresthesia, and at least one patient has received such therapy. While the precise software parameters and therapy parameters used on patients are non-public and are uniquely within Nalu's control, Nevro believes that discovery in this case will further establish paresthesia-free configuration and operation of the Nalu Neurostimulation System. Nevro discusses the availability and use of infringing parameters in further detail above, but notes that Nalu has disclosed studies involving use of the Nalu Neurostimulation System to deliver therapy without paresthesia; Nalu specifically sought and obtained FDA clearance to market the Nalu Neurostimulation System for use at amplitudes and pulse widths within Nevro's claimed ranges; Nalu's user manual represents that the Nalu Neurostimulation System operates at amplitudes up to 10.2 mA and pulse widths between 10 microseconds and 2,000 microseconds; and Nalu has sought patent protection for a neurostimulation system that generates a therapy signal that does not cause paresthesia.

108. Nalu has infringed and continues to infringe one or more claims of the '357 patent by using the Nalu Neurostimulation System in the United States, selling the Nalu Neurostimulation System in the United States, and/or offering to sell the Nalu Neurostimulation System in the United States. Nalu has infringed and continues to infringe the '357 patent by

manufacturing the Nalu Neurostimulation System in the United States and/or importing the Nalu Neurostimulation System into the United States, and/or has infringed the '357 patent pursuant to 35 U.S.C. § 271(f)(1)-(2) through export of the Nalu Neurostimulation System from the United States. Nalu's manufacture, use, offer to sell, import, and/or export of the Nalu Neurostimulation System infringes one or more claims of the '357 patent literally or under the doctrine of equivalents and violates 35 U.S.C. § 271.

109. Nalu has intentionally instructed, and will intentionally instruct, others, including doctors and health care providers, to use the Nalu Neurostimulation System 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. Consistent with this industry practice, Nalu states that its stimulation parameters are set using a Clinical Programming application by a Field Clinical Engineer employed by Nalu. As set forth above, Nalu knows or has been willfully blind to the fact that such actions infringe Nevro's patents. Alternatively, Nalu's Field Clinical Engineer instructs a patient's doctor or healthcare provider on how to use the Clinical Programming application to program the Nalu Neurostimulation System, and said actions by Nalu constitute, and will constitute, induced infringement of one or more claims of the '357 patent in violation of 35 U.S.C. § 271(b).

110. Nalu's infringement of the '357 patent has been willful and continues to be willful. Nalu has known of the '357 patent since at least February 25, 2019, when it disclosed

the ’357 patent as prior art to its ’829 patent application. Nalu has acted despite having knowledge of its infringement or being willfully blind to its infringement.

111. Nalu’s infringement is without the consent of Nevro. Nalu is not licensed under the ’357 patent.

112. Nevro marks its patented products pursuant to 35 U.S.C. § 287(a).

113. As a result of Nalu’s infringement, Nevro has suffered damages and will continue to suffer damages, including damages awardable under 35 U.S.C. §§ 284 and 285. Nevro has no adequate legal remedy. Unless enjoined by this Court, Nalu’s infringement will cause Nevro substantial and irreparable harm. Under 35 U.S.C. § 283, Nevro should be awarded an injunction barring Nalu from further infringement of the ’357 patent.

PRAYER FOR RELIEF

WHEREFORE, Nevro prays for relief as follows:

1. A judgment that Nalu has infringed one or more claims of U.S. Patent Nos. 10,471,258, 9,333,358, 8,712,533, 8,359,102, 9,327,125, and 9,333,357;

2. An order and judgment temporarily, preliminarily and permanently enjoining Nalu 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 U.S. Patent Nos. 10,471,258, 9,333,358, 8,712,533, 8,359,102, 9,327,125, and 9,333,357;

3. A judgment awarding Nevro all damages suffered by Nevro as a result of Nalu’s infringement, and in no event less than a reasonable royalty for

Nalu's acts of infringement, including all pre-judgment and post-judgment interest at the maximum rate permitted by law;

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

5. Costs of suit and reasonable attorney fees; and

6. 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.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Rodger D. Smith II

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June 1, 2020

CERTIFICATE OF SERVICE

I hereby certify that on June 1, 2020, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on June 1, 2020, upon the following in the manner indicated:

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