

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Boston Scientific Corporation, and Boston Scientific Neuromodulation
Corporation,

Petitioners

v.

Nevro Corporation,

Patent Owner

Patent No. 10,556,112

Filing Date: July 27, 2018

Issue Date: February 11, 2020

Title: Spinal Cord Modulation for Inhibiting Pain Via Short Pulse Width
Waveforms, and Associated Systems and Methods

IPR2022-00511

DECLARATION OF MAROM BIKSON, Ph.D.

Neurent 1116
Neurent v. Foundry
IPR2024-00669

TABLE OF CONTENTS

	Page
I. PERSONAL AND PROFESSIONAL BACKGROUND.....	3
II. MATERIALS REVIEWED AND CONSIDERED.....	6
III. RELEVANT LEGAL STANDARDS.....	11
A. Level of Ordinary Skill in the Art	11
B. Prior Art	14
C. Obviousness.....	15
IV. SUMMARY OF OPINIONS	18
V. '112 PATENT OVERVIEW	19
A. The Specification.....	19
B. Challenged Claims	22
C. Prosecution History	23
1. The '978 Patent Prosecution History	24
2. The '112 Patent Prosecution History	27
VI. CLAIM CONSTRUCTION.....	28
VII. SUMMARY OF PRIOR ART	28
A. State Of The SCS Field As Of November 2013.....	28
1. SCS Systems and FDA-Approved Parameter Ranges.....	28
2. Paresthesia Based and Non-Paresthesia-Producing Therapy	29
3. Signal Delivery	33
B. Alataris675	33
C. Lee459	35
D. Eddicks	37
E. Shaw	39
VIII. GROUNDS 1-2: CLAIMS 1-12 WOULD HAVE BEEN OBVIOUS OVER ALATARIS675 COMBINED WITH LEE459 (GROUND 1), OR ALATARIS675 COMBINED WITH LEE459 AND EDDICKS (GROUND 2).....	40
A. Claim 1	40
1. 1[a] “A spinal cord stimulation system for reducing or eliminating pain in a patient, the system comprising”	40
2. 1[b] “an implantable signal generator that, in operation, generates a non-paresthesia-producing therapy signal,”	41

3.	1[c] “wherein at least a portion of the therapy signal is at a frequency of from 500 Hz to 1,200 Hz,”	44
4.	1[d] “with a pulse width in a pulse width range from 10 microseconds to 50 microseconds,”	45
5.	1[e] “and a current amplitude in a current amplitude range from 0.5 mA to 7 mA; and”	47
6.	1[f] “a signal delivery device electrically coupled to the implantable signal generator to deliver the therapy signal to the dorsal column of the patient’s spinal cord.”	50
B.	Claim 2: The system of claim 1, wherein the implantable signal generator generates the therapy signal at a duty cycle.....	55
C.	Claim 3: The system of claim 2, wherein the duty cycle is 100%.....	56
D.	Claim 4: The system of claim 2, wherein the duty cycle is 50-100%.....	56
E.	Claim 5: The system of claim 2, wherein the frequency is applied throughout the length of an on period in the duty cycle.	56
F.	Claim 6: The system of claim 2, wherein the frequency is applied during a portion of an on period in the duty cycle.	56
G.	Claim 7: The system of claim 1, wherein the therapy signal is delivered at a current amplitude of 2.5 mA.....	56
H.	Claim 8: The system of claim 1, wherein at least a portion of the therapy signal is a square-wave signal.	58
I.	Claim 9: The system of claim 1, wherein the signal delivery device is a percutaneous lead.	59
J.	Claim 10: The system of claim 1, wherein the signal delivery device is a paddle lead.....	62
K.	Claim 11: The system of claim 1, wherein the signal delivery device is an elongated lead having one or more electrodes.	63
L.	Claim 12: The system of claim 1, wherein the signal delivery device is an elongated lead having a bipole arrangement of electrodes.....	64
M.	A POSA Would Have Combined Alataris675 with Lee459, and with Lee459 and Eddicks	65
1.	The Art Provides a Motivation to Combine the References with a Reasonable Expectation of Success	66
2.	The Combination is the Obvious Result of Applying Known Techniques to a Known Device to Yield Predictable Results.....	71
3.	The Proposed Combination was Obvious to Try	72

IX.	GROUND 3-4: CLAIMS 1-12 WOULD HAVE BEEN OBVIOUS OVER ALATARIS675 COMBINED WITH SHAW (GROUND 3), OR ALATARIS675 COMBINED WITH SHAW AND EDDICKS (GROUND 4).....	75
A.	Claim 1	76
1.	1[a] “A spinal cord stimulation system for reducing or eliminating pain in a patient, the system comprising”	76
2.	1[b] “an implantable signal generator that, in operation, generates a non-paresthesia-producing therapy signal,”	77
3.	1[c] “wherein at least a portion of the therapy signal is at a frequency of from 500 Hz to 1,200 Hz,”	78
4.	1[d] “with a pulse width in a pulse width range from 10 microseconds to 50 microseconds,”	79
5.	1[e] “and a current amplitude in a current amplitude range from 0.5 mA to 7 mA; and”	79
6.	1[f] “a signal delivery device electrically coupled to the implantable signal generator to deliver the therapy signal to the dorsal column of the patient's spinal cord.”	80
B.	Claim 2: The system of claim 1, wherein the implantable signal generator generates the therapy signal at a duty cycle.....	81
C.	Claim 3: The system of claim 2, wherein the duty cycle is 100%.....	82
D.	Claim 4: The system of claim 2, wherein the duty cycle is 50-100%.....	82
E.	Claim 5: The system of claim 2, wherein the frequency is applied throughout the length of an on period in the duty cycle.	82
F.	Claim 6: The system of claim 2, wherein the frequency is applied during a portion of an on period in the duty cycle.	82
G.	Claim 7: The system of claim 1, wherein the therapy signal is delivered at a current amplitude of 2.5 mA.....	82
H.	Claim 8: The system of claim 1, wherein at least a portion of the therapy signal is a square-wave signal.	83
I.	Claim 9: The system of claim 1, wherein the signal delivery device is a percutaneous lead.	83
J.	Claim 10: The system of claim 1, wherein the signal delivery device is a paddle lead.....	83
K.	Claim 11: The system of claim 1, wherein the signal delivery device is an elongated lead having one or more electrodes.	84

L.	Claim 12: The system of claim 1, wherein the signal delivery device is an elongated lead having a bipole arrangement of electrodes.....	84
M.	A POSA Would Have Combined Alataris675 with Shaw or Shaw and Eddicks	84
1.	The Art Provides a Motivation to Combine the References with a Reasonable Expectation of Success	84
2.	The Combination is the Obvious Result of Applying Known Techniques to a Known Device to Yield Predictable Results.....	86
3.	The Proposed Combination was Obvious to Try	86
X.	GROUND 5-6: CLAIMS 1-12 ARE OBVIOUS OVER LEE459 ALONE OR COMBINED WITH SHAW	87
A.	Claim 1	88
1.	1[a] “A spinal cord stimulation system for reducing or eliminating pain in a patient, the system comprising”	88
2.	1[b] “an implantable signal generator that, in operation, generates a non-paresthesia-producing therapy signal,”	90
3.	1[c] “wherein at least a portion of the therapy signal is at a frequency of from 500 Hz to 1,200 Hz,”	93
4.	1[d] “with a pulse width in a pulse width range from 10 microseconds to 50 microseconds,”	94
5.	1[e] “and a current amplitude in a current amplitude range from 0.5 mA to 7 mA; and”	94
6.	1[f] “a signal delivery device electrically coupled to the implantable signal generator to deliver the therapy signal to the dorsal column of the patient’s spinal cord.”	98
B.	Claim 2: The system of claim 1, wherein the implantable signal generator generates the therapy signal at a duty cycle.....	103
C.	Claim 3: The system of claim 2, wherein the duty cycle is 100%.....	105
D.	Claim 4: The system of claim 2, wherein the duty cycle is 50-100%.....	105
E.	Claim 5: The system of claim 2, wherein the frequency is applied throughout the length of an on period in the duty cycle.	105
F.	Claim 6: The system of claim 2, wherein the frequency is applied during a portion of an on period in the duty cycle.	105
G.	Claim 7: The system of claim 1, wherein the therapy signal is delivered at a current amplitude of 2.5 mA.....	106

H.	Claim 8: The system of claim 1, wherein at least a portion of the therapy signal is a square-wave signal.	106
I.	Claim 9: The system of claim 1, wherein the signal delivery device is a percutaneous lead.	108
J.	Claim 10: The system of claim 1, wherein the signal delivery device is a paddle lead.....	109
K.	Claim 11: The system of claim 1, wherein the signal delivery device is an elongated lead having one or more electrodes.	110
L.	Claim 12: The system of claim 1, wherein the signal delivery device is an elongated lead having a bipole arrangement of electrodes.....	110
M.	A POSA Would Have Reason to Achieve the Challenged Claims Based on Lee459 Alone, and A POSA Would Have Combined Lee459 with Shaw	111
	1. Lee459 Alone Renders the Recited Claims Obvious.....	111
	2. A POSA Would Have Been Motivated to Combine Lee459 with Shaw.....	112
	3. The Proposed Combination was Obvious to Try	114
XI.	SECONDARY CONSIDERATIONS.....	115
XII.	RIGHT TO SUPPLEMENT	116

I declare that all statements made herein are of my own knowledge and are true, and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Date: February 15, 2022

Signature: _____

I, Marom Bikson, declare as follows:

1. I am over the age of twenty-one and I am competent to testify as to the matters set forth in this Declaration.

2. I have been retained by Petitioners, Boston Scientific Corp. and Boston Scientific Neuromodulation Corp. (collectively, “Petitioners” or “BSC”) to assess U.S. Patent No. 10,556,112 (“the ’112 Patent”). I have reviewed the ’112 Patent and a number of prior art references, which I address in detail below. I understand that Petitioners are accused of infringing claims of the ’112 Patent in a pending district court litigation, *Nevro Corp. v. Boston Scientific Corp. et al*, No. 1:21-cv-00258 (D. Del.) (the “Litigation”). I further understand that this Declaration is being submitted in connection with a petition for *inter partes* review (“IPR”) challenging the patentability of claims 1-12 of the ’112 Patent (the “Challenged Claims”).

3. I am being compensated at my standard rate of \$600 per hour. My compensation is not dependent in any way upon the substance of my testimony, or the outcome of Petitioners’ IPR petition or the district court litigation involving the ’112 Patent.

4. This declaration is based on information currently available to me. I intend to continue my investigation, and study, which may include a review of documents and information that may yet be produced, as well as deposition testimony from depositions for which transcripts are not yet available or that may

Exhibit No.	Description
1050	Oakley, J.C., <i>Spinal Cord Stimulation in Axial Low Back Pain: Solving the Dilemma</i> , 7 Pain Medicine S1, S58-S63 (2006)
1051	Response for Certificate of Correction; U.S. Patent No. 9,002,459; dated January 25, 2022
1052	Applicant's Reply to the Response to the Request for Certificate of Correction and Replacement Figure 6; U.S. Patent No. 9,002,459; dated July 28, 2021
1053	U.S. Patent Publication No. 2011/0184488 ("DeRidder1")
1054	U.S. Patent Publication No. 2006/0015153 ("Gliner")
1055	U.S. Patent Publication No. 2008/0051839
1056	U.S. Patent Publication No. 2004/0158298
1057	Spinal Cord Stimulation, Patient Management Guidelines for Clinicians (Medtronic 1999), available at https://web.archive.org/web/20060522070227/http://www.medtronic.com/neuro/paintherapies/pain_treatment_ladder/library.html (select "Spinal Cord Stimulation: Patient Management Guidelines for Clinicians - [Part 1] [Part 2] [Part 3]")
1058	Kilgore and Bhadra, <i>Nerve Conduction Block Utilising High-Frequency Alternating Current</i> , 42 Med. & Bio. Eng. & Comp. 394 (2004) ("Kilgore")
1059	U.S. Patent No. 6,892,097

III. RELEVANT LEGAL STANDARDS

A. Level of Ordinary Skill in the Art

20. For the purposes of assessing whether prior-art references disclose the elements of a patent claim and/or would have rendered the claimed invention

obvious, I understand that the '112 Patent and the prior-art references must be assessed from the perspective of a person having ordinary skill in the art (“POSA” or “skilled artisan”) to which the patent is related as of the date of the invention. I understand that a POSA is presumed to be aware of all pertinent prior art and the conventional wisdom of the art, and is a person having ordinary creativity. I apply this standard throughout my Declaration.

21. I further understand that the factors used to determine the level of ordinary skill in the art include: (1) the type of problems encountered in the art; (2) prior art solutions to those problems; (3) rapidity with which innovations are made; (4) sophistication of the technology; and (5) the educational level of active workers in the field.

22. I have been asked to provide my opinion as to the state of the art in the SCS field as of November 7, 2013, which I understand is the earliest priority date for the Challenged Claims. When I offer an opinion in this Declaration regarding the knowledge of a POSA, the manner in which a POSA would have understood the Challenged Claims, the manner in which a POSA would have understood the prior art, or what a POSA would have been led to do based on the prior art, I am referencing the pre-November 7, 2013 timeframe, even if I do not say so explicitly in each instance. As explained herein, I am familiar with the state of the art and the SCS industry in the years leading up to November 7, 2013. I reserve the right to

modify the opinions provided in this declaration as needed if Nevro asserts that any claims of the '112 Patent are entitled to an earlier priority date.

23. Based on the above criteria and my own personal experience in the SCS industry, it is my opinion that a POSA at the time of the effective filing of the '112 Patent (November 7, 2013) would have had at least a degree in electrical engineering, biomedical engineering, or a related discipline, along with relevant experience (at least 2-3 years for a Ph.D., 3-5 years for a Master's, and 5+ years for a Bachelor's degree) researching or developing neural stimulation systems or other implantable medical devices. Alternatively, a POSA would have had an M.D. and experience practicing as a neurologist, neurosurgeon, or anesthesiologist, with 2-3 years of experience in neural stimulation. The person would have had general knowledge of implantable medical devices and various related technologies as of November 7, 2013.

24. I am well aware of the qualifications of such a person because I was myself a POSA by November 7, 2013. By that time, I had already earned my Ph.D. in Biomedical Engineering and also had over 10 years of relevant research and academic experience. Additionally, I have also worked with and trained engineers and doctors with similar capabilities.

25. By 2004, I had completed a Ph.D. in Biomedical Engineering and a postdoctoral fellowship in neurophysiology. After finishing my fellowship, I took

an active role in the biomedical engineering community. In 2005, for example, I became a Co-director of the New York Center for Biomedical Engineering, which is a consortium that promotes collaborative biomedical research. Additionally, through my professional activities, I came to know many POSAs in the field. Between 2004 and 2008, I attended almost 20 events related to biomedical engineering, like the IEEE Engineering in Medicine and Biology Society Conference. And by 2009, I knew numerous POSAs because of my teaching career—by then, many of my former students (from my biomedical engineering and medical courses) had become POSAs.

26. Because of my continuous and significant involvement in the biomedical engineering community, I am familiar with the understanding and knowledge of a POSA, as of November 7, 2013, with the qualifications I have identified above. Thus, I understand the perspective of a POSA, which I have applied in my analysis.

B. Prior Art

27. It is my understanding that “prior art” includes patents and printed publications in the relevant literature and information that predates the November 7, 2013 priority date of the ’112 Patent.

31. I understand that in order for a claimed invention to be considered obvious, there must be some rationale for combining prior art references in the manner that renders the claimed invention obvious. I understand that for a reference to be considered in the obviousness determination, the reference must be analogous to the claimed invention. I further understand that a reference is analogous art to the claimed invention if it is from the same field of endeavor as the claimed invention (even if it addresses a different problem), or the reference is reasonably pertinent to the problem faced by the inventor (even if it is not in the same field of endeavor as the claimed invention).

32. I further understand that obviousness may be shown by establishing that it would have been obvious to combine the teachings of more than one prior art reference. In determining whether a prior art reference would have been combined with other prior art or with other information within the knowledge of a person of ordinary skill in the art, I have been informed the following are examples of approaches and rationales that may be considered:

- a. Combining prior art elements according to known methods to yield predictable results;
- b. Simple substitution of one known element for another to obtain predictable results;

V. '112 PATENT OVERVIEW

A. The Specification

36. The '112 Patent is generally directed to an SCS system and methods of programming it for inhibiting pain without paresthesia (a tingling sensation). The '112 Patent purports to achieve this non-paresthesia-producing therapy using “short pulse widths.” EX1001, 2:22-25. According to the specification:

[T]he short pulse width characteristics of the signal, alone or in combination with other signal parameters (*e.g.*, frequency and/or amplitude) can produce pain relief without using the generation of paresthesia[.]

EX1001 2:29-33. According to the '112 Patent, the therapy signal can have pulse widths “from about 10-50 microseconds.” EX1001, 5:55-59.

37. Figure 1A of the '112 Patent illustrates a prior art SCS system:

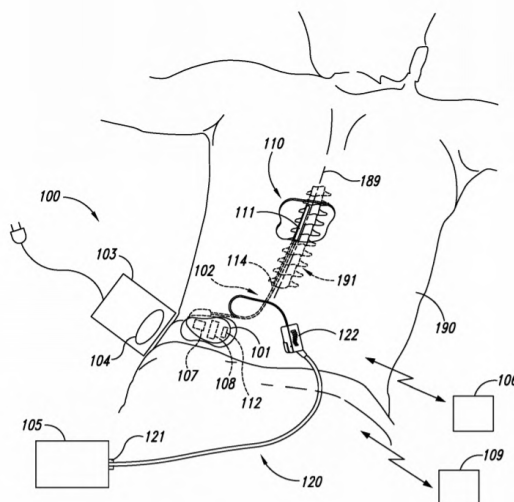


Fig. 1A

EX1001, Fig. 1A, 2:64-3:6. The elements identified in Figure 1A include: “an implantable pulse generator 101, which may be implanted subcutaneously within a patient 190 and may be coupled to a signal delivery element 110. In a representative example, the signal delivery element 110 includes a lead or lead body 111 that carries features for delivering therapy to the patient 190 after implantation. The pulse generator 101 can be connected directly to the lead 111, or it can be coupled to the lead 111 via a communication link 102 (e.g., an extension).” EX1001, 2:64-3:9.

38. The '112 Patent does not describe any unique programming steps or unique structural features. As was standard with all prior art SCS systems, the '112 Patent discloses that “[o]nce the implantable pulse generator 101 has been positioned within the patient 190, the signal delivery parameters provided by the pulse generator 101 can still be updated remotely via a wireless external programmer 109 (e.g., a physician's remote, laptop, PDA, tablet, etc.) and/or a wireless patient programmer 106 (e.g., a patient remote). Generally, the patient 190 has control over fewer parameters than does the practitioner.” EX1001, 4:57-64.

39. According to the '112 Patent, any combination of a frequency from “at or below 1.5 kHz,” pulse width from “10-50 microseconds,” and current amplitude “from about 0.5-20 mA” can be programmed to generate a non-paresthesia-producing therapy signal, and the only guide to selecting among those parameters appears to be the existing knowledge of a POSA. EX1001, 5:57-6:7. “In one

representative example, the waveform includes a frequency of 1,200 Hz, a pulse width of 30 microseconds, and an amplitude that provides pain relief without generating paresthesia (generally between 0.5-20 mA).” EX1001, 6:3-7. The ’112 Patent also discloses that amplitude is not critical: “For example, the process of applying a short pulse width waveform (block 630) can include doing so over a wide amplitude range (e.g., over any of the amplitude ranges described immediately above) without creating unwanted side effects, such as undesirable sensations and/or motor interference (block 631).” EX1001, 6:22-27.

40. Similarly, the ’112 Patent does not disclose any novel lead placements. Instead, as was common in the art, the ’112 Patent explains that: “The leads 110 (indicated by leads 110 b) can be positioned just off the spinal cord midline 189 (e.g., about 1 mm. offset) in opposing lateral directions so that the two leads 110 b are spaced apart from each other by about 2 mm, in particular embodiments. In other embodiments, a single lead 110 a can be positioned at the midline 189. In still further embodiments, lead(s) can be positioned at or proximate to the dorsal root 193 (as shown by lead 110 c) and/or at or proximate to the dorsal root ganglia 194 (as shown by lead 110 d).” EX1001, 5:27-36.

41. Figure 1B (below) illustrates “representative” lead (110) locations:

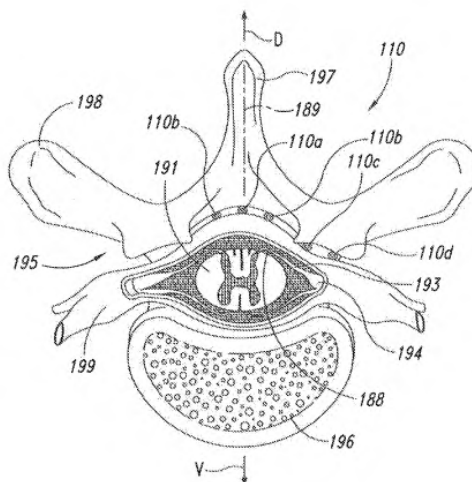


Fig. 1B

EX1001, 1:64-67, 5:15-36. “[L]eads 110 (indicated by leads 110b) can be positioned just off the spinal cord midline 189” or “a single lead 110 a can be positioned at the midline 189.” EX1001, 5:27-29.

42. The ’112 Patent also discloses that its “block” may occur at any location in the spinal cord: “In one embodiment, one or more of the above-described waveform parameters and lead placements are used to produce an incomplete conduction block (e.g., an incomplete block of afferent and/or efferent signal transmission) at the dorsal root level. This block may occur at the dorsal column, dorsal horn, and/or dorsal root entry zone, in addition to or in lieu of the dorsal root.” EX1001, 7:56-62.

B. Challenged Claims

43. Independent claim 1 recites:

1. A spinal cord stimulation system for reducing or eliminating pain in a patient, the system comprising:
 an implantable signal generator that, in operation, generates a non-paresthesia-producing therapy signal, wherein at least a portion of the therapy signal is at a frequency of from 500 Hz to 1,200 Hz, with a pulse width in a pulse width range from 10 microseconds to 50 microseconds, and a current amplitude in a current amplitude range from 0.5 mA to 7 mA; and
 a signal delivery device electrically coupled to the implantable signal generator to deliver the therapy signal to the dorsal column of the patient's spinal cord.

44. The dependent claims add standard and well known features of SCS systems. For example, dependent claims 2-6 recite that the therapy signal is generated at some form of a duty cycle. Dependent claim 7 recites an amplitude of 2.5 mA. Dependent claim 8 recites that a portion of the therapy signal is a square wave. And dependent claims 9-12 further identify the signal delivery element as a percutaneous lead, paddle lead, or elongated lead with known electrode arrangements.

C. Prosecution History

45. The '112 Patent issued on February 11, 2020 from an application filed on July 27, 2018, and claims priority to Provisional Application 61/901,255, filed on November 7, 2013, and U.S. Patent No. 10,149,978 ("the '978 Patent).