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

U.S. Patent 9,002,461
Filing Date: Mar. 26, 2014
Issue Date: Apr. 7, 2015

Title: Linked Area Parameter Adjustment for Spinal Cord Stimulation and Associated Systems and Methods

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IPR2021-00295

PETITION FOR *INTER PARTES* REVIEW

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I. MANDATORY NOTICES

A. Real Party-in-Interest

Boston Scientific Corporation and Boston Scientific Neuromodulation Corporation (collectively, "BSC" or "Petitioner") are the real parties-in-interest.

B. Related Matters

Petitioner filed petitions for *inter partes* review ("IPR") of Nevro's U.S. Patent 10,076,665 (the "'665 Patent") and U.S. Patent 9,002,460 (the "'460 Patent"). *Boston Scientific Corp. et al. v. Nevro Corp.*, IPR2020-01562 (P.T.A.B. 2020); *Boston Scientific Corp. et al. v. Nevro Corp.*, IPR2020-01563 (P.T.A.B. 2020). Nevro asserted the '461, '460, and '665 Patents in counterclaims against Petitioner in a currently pending patent infringement litigation captioned B*oston Scientific Corp. et al v. Nevro Corp.*, Nos. 16-cv-1163, 18-cv-644 (consolidated) (D. Del. 2018).

C. Lead and Back-Up Counsel

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D. Service Information

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E. Fees

Required fees are authorized to be charged under 37 C.F.R. §§ 41.103(a), 42.15(a). If any additional fees are due during this proceeding, the Office may charge such fees to Deposit Account No. 50-2310.

II. CERTIFICATION OF GROUNDS FOR STANDING

Petitioner certifies that the ’461 Patent is available for IPR and Petitioner is not barred or estopped from challenging claims.

III. STATEMENT OF PRECISE RELIEF REQUESTED

A. Claims for Which Review Is Requested

Petitioner requests review and cancellation of claims 1-8 and 10-17 of the '461 Patent under 35 U.S.C. § 311.

B. Statutory Grounds of Challenge

Ground	'461 Patent Claims	Unpatentable under 35 U.S.C. §§ 102, 103
1	1-4, 7-8, 10-17	Anticipated by *Meadows*
2	1-8, 10-17	Obvious over *Meadows*
3		Obvious over *Meadows* and *John*
4	6-8	Obvious over *Meadows* and *Goetz*
5		Obvious over *Meadows*, *John*, and *Goetz*
6	1-4, 7-8, 10-17	Anticipated by *Thacker*
7	1-8, 10-17	Obvious over *Thacker*
8		Obvious over *Thacker* and *Meadows*
9		Obvious over *Thacker* and *John*
10		Obvious over *Thacker*, *Meadows*, and *John*
11	6-8	Obvious over *Thacker* and *Goetz*
12		Obvious over *Thacker*, *Meadows*, and *Goetz*
13		Obvious over *Thacker*, *John*, and *Goetz*
14		Obvious over *Thacker*, *Meadows*, *John*, and *Goetz*
15	1-4, 10-17	Anticipated by *Nolan*

16	1-8, 10-17	Obvious over *Nolan*
17		Obvious over *Nolan* and *Meadows*
18		Obvious over *Nolan* and *John*
19		Obvious over *Nolan*, *Meadows*, and *John*
20	6-8	Obvious over *Nolan* and *Goetz*
21		Obvious over *Nolan*, *Meadows*, and *Goetz*
22		Obvious over *Nolan*, *John*, and *Goetz*
23		Obvious over *Nolan*, *Meadows*, *John*, and *Goetz*

IV. U.S. PATENT 9,002,461 (the "'461 Patent")

A. Summary

The '461 Patent discloses a spinal cord stimulation ("SCS") system for managing pain. EX1001, Abstract, 2:42-3:65; EX1008, ¶¶ 39-49. Because different areas of the spine require or tolerate different stimulation levels, clinicians determine a therapy range for the electrode(s) associated with each area. EX1001, 8:47-9:46, Figs. 3A-3B. A therapy range has a lower limit of at least a sensation or therapeutic threshold and an upper limit of no more than a discomfort threshold. *Id.* The purported novelty of the '461 Patent is automatically setting stimulation parameters, such as amplitude, for an electrode "based on a relationship" between therapy ranges. *Id.*, 2:42-3:59.

The ’461 Patent recognizes conventional multi-area “linked-mode” systems existed. EX1001, 3:2-21; EX1008, ¶¶ 31-38. Those systems allowed for automatically setting parameters within therapy ranges but, according to the patent, were limited because they “adjust the amplitudes equally across each area.” EX1001, 3:2-21.

Figure 1A shows a conventional SCS system, including waveform generator 101 and electrode device 109 with lead body 110. EX1001, 1:29-3:24, 4:58-6:44, 7:3-10:19.

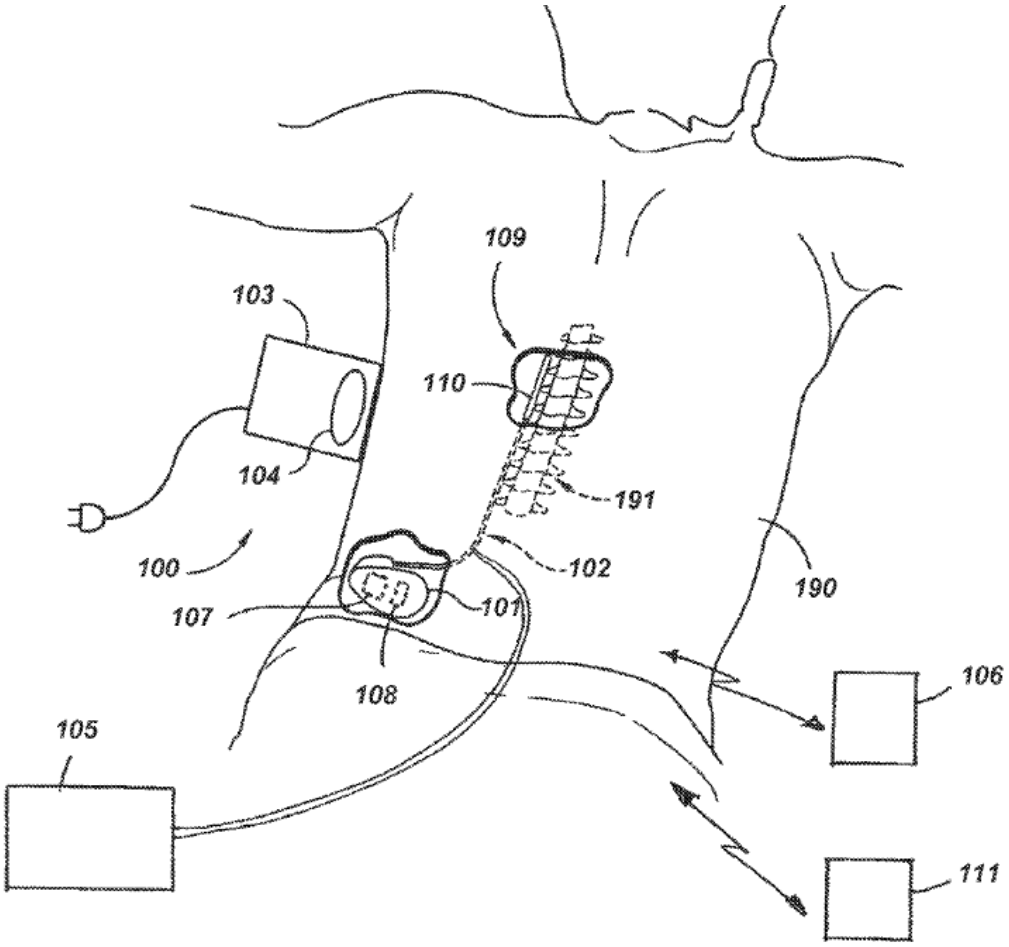


FIG. 1A

EX1001, Fig. 1A.

Figure 1B shows a conventional lead, with electrodes C1-C10 at areas A_1-A_4. *Id.*, 3:6-59, 6:45-8:36.

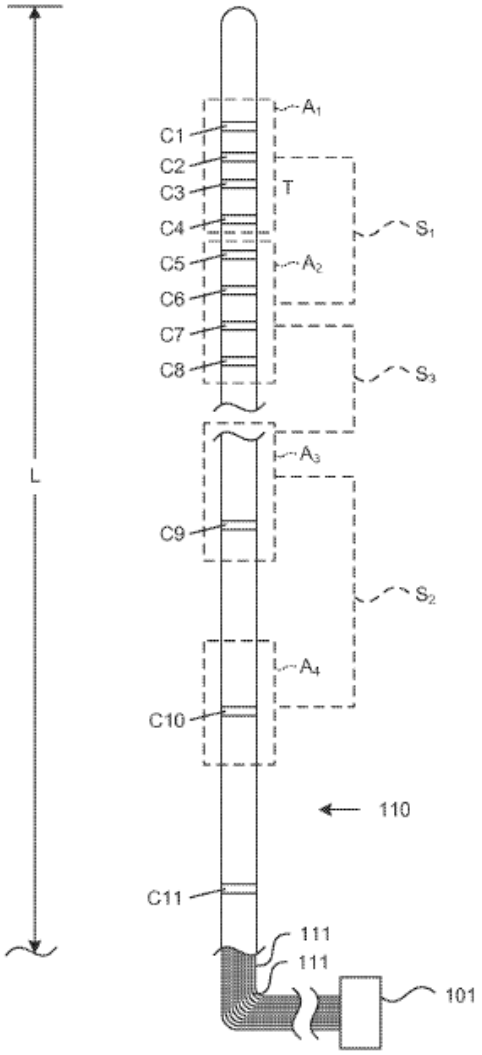
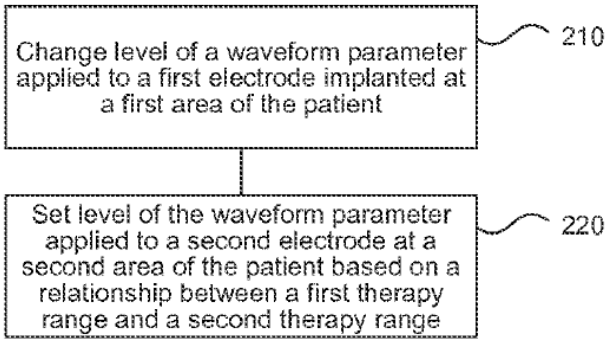


FIG. 1B

Id., Fig. 1B.

Figure 2 shows steps for using linked-area (or linked-mode) parameter modulation "based on a relationship between a first therapy range and a second therapy range." *Id.*, 7:3-54, 8:17-47, Fig. 2.



Id., Fig. 2, 12:35-13:3, Figs. 6-7. The second increment may be concurrent with the first increment, or after a delay. *Id.*, 7:30-54. A single change command can "change" the parameter for the first electrode and "set" the parameter for the second electrode. *Id.*, 1:65-67, 2:61-4:5, claims 1-4, 11-13.

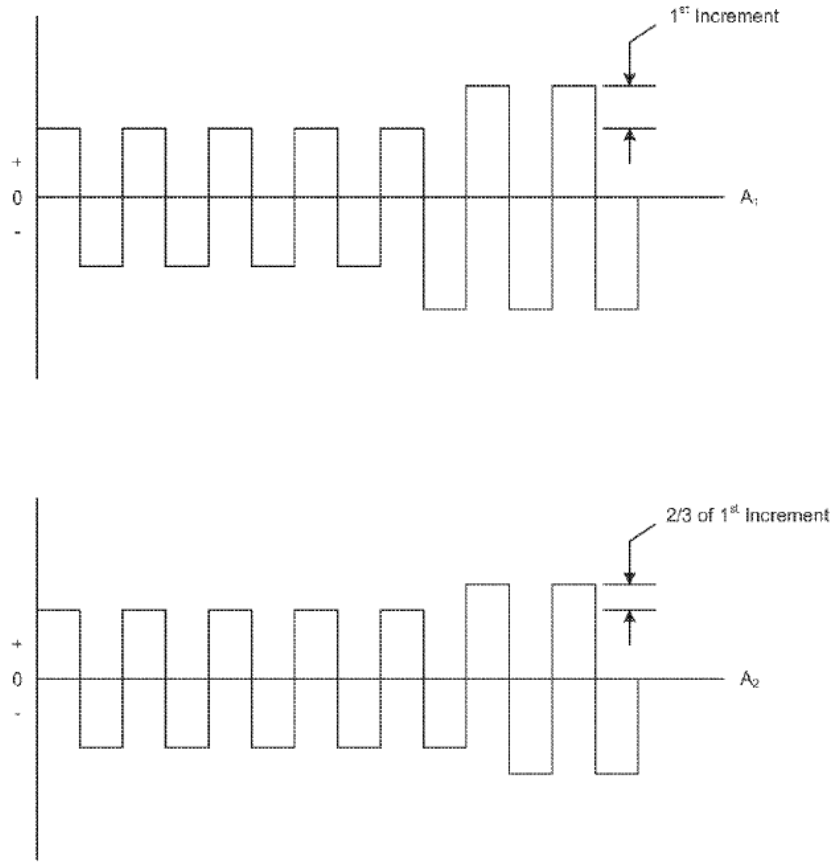
The '461 Patent discloses that the "relationship between a first therapy range and a second therapy range" can be a "therapy range ratio" or other scaling factor, defined, for example, as:

$$\text{Ratio} = \frac{A_{1P} - A_{1T}}{A_{2P} - A_{2T}}$$

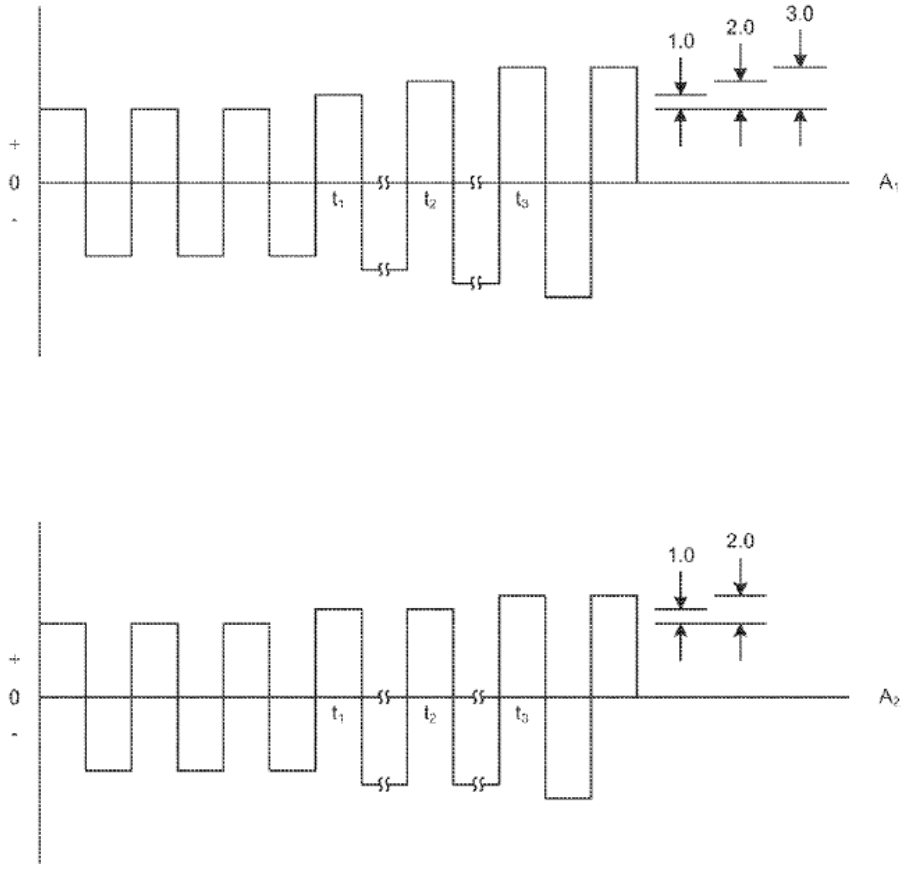
Id., Abstract, 7:13-18, 10:47-12:34. A_{1P} and A_{2P} are the amplitudes at which the patient experiences pain at the first and second areas, and A_{1T} and A_{2T} are the amplitudes at which the patient experiences a therapeutic effect at the first and second areas. The second increment is calculated and set based on this ratio, which is described as using "the product of the magnitude of the first increment that the waveform parameter was changed at the first area and the ratio." *Id.* The therapy

range ratio can be "less than 1:1, equal to 1:1, or greater than 1:1, depending on the size of the ranges." *Id.*

The second increment may be in "direct proportion" to the therapy range ratio or a "best-fit approximation" thereof, as shown in Figures 4 ("direct proportion") and 5 ("best-fit") with a 3:2 ratio. *Id.*, 10:47-12:19.



Id., Fig. 4.



Id., Fig. 5.

B. Challenged Claims of the ’461 Patent

This Petition challenges claims 1-8 and 10-17, reproduced in Appendix A. Independent claim 1 recites a system for managing pain, comprising an “electrode device” and “implantable device,” which includes a “computer-operable medium” programmed to change a parameter for a first electrode associated with a first area and automatically set a parameter for a second electrode associated with a second area based on a relationship between the therapy ranges of the first and second areas. Claims 2-8 and 10 depend from claim 1 and recite how the computer-

operable medium is further programmed, and the system further comprises a patient input device (claims 3-4), memory with usage history (claims 6-7), or another electrode associated with another area (claim 10).

Independent claim 11 recites a system like claim 1, and further recites "a patient input device" and "ratio of the first therapy range to the second therapy range." Claims 12-17 depend from claim 11 and recite further programming.

C. Prosecution History

The '461 Patent issued from the '644 Application (EX1002), filed March 26, 2014. EX1008, ¶¶ 39, 52-61. The '644 Application is a continuation of the '494 Application (EX1010), filed June 10, 2013, which is a continuation of the '930 Application (EX1011), filed July 28, 2009.

Original claim 1 of the '930 Application is substantially identical to issued claim 1 of the '461 Patent. EX1011, 23. The Examiner rejected claims as anticipated by *Meadows* (EX1003). *Id.*, 131-32. To overcome *Meadows*, Applicants amended claim 1 to recite "a therapy range is a range of the waveform parameter that provides therapeutic effect without inducing discomfort." *Id.*, 144, 159-60.

The Examiner again rejected claims over *Meadows* in view of *King* (EX1018) because it disclosed the new limitation. EX1011, 176-78. Applicants amended claims to "mathematical relationship," and argued "the claims should be

read to cover the embodiments of mathematical relationships described in the specification and all equivalents thereof." *Id.*, 197, 207-09. The Examiner allowed those claims because:

> The closest prior art, Meadows [] in view of King [], fails to disclose … the claimed invention since neither reference, alone nor in combination, discloses a means of setting parameters based on a mathematical relationship between therapy ranges for two electrodes.

Id., 226.

In the '494 Application, Applicants presented claims with the same amendments added for the '930 Application (EX1010, 98-106), and the Examiner allowed them for the same reasons (*id.*, 121).

In the '644 Application, Applicants re-filed the original claim 1 from the '930 Application. EX1002, 28. Even though the claims of the '461 Patent do not recite the "therapeutic effect" and "mathematical relationship" limitations, the Examiner allowed them for the same reasons as for the amended claims of the parent applications. *Id.*, 99 (Notice). The Examiner committed at least three material errors in allowing these claims, as explained below and by Dr. Mihran. *Infra* § X.B.2; EX1008, ¶¶ 35-37, 56-61.

D. Level of Ordinary Skill

A person of ordinary skill in the art ("POSA") would have a degree in electrical or biomedical engineering, or a related discipline, and 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) researching or developing neural stimulation systems or other implantable medical devices. EX1008, ¶¶ 20-22. Alternatively, a POSA would have an M.D. and experience practicing as a neurologist, neurosurgeon, or anesthesiologist, with 2-3 years of experience in neural stimulation. A POSA would have had general knowledge of implantable medical devices and related technologies as of July 28, 2009.

V. CLAIM CONSTRUCTION

Any term not expressly defined in the specification or discussed herein should be given its ordinary meaning.

A. "based on a relationship"

In litigation, Nevro argued "relationship" and "based on a relationship" were "non-technical, ordinary" phrases. EX1022.

BSC argued "relationship" means "ratio or other scaling factor"—the only types of relationships disclosed. EX1001, 3:41-4:45 ("scaling factor"; "ratio"; "therapy range ratio or other scaling factor"), 7:3-15:18, Figs. 6-7. BSC argued "based on a relationship" means "using the product of the magnitude of the first increment (i.e., the change to the waveform parameter applied to the first electrode) and the relationship"—the only disclosed way of setting the parameter

for the second electrode. *Id.*, 7:13-29, 10:66-11:36, 12:61-66, Fig. 4. Nevro also limited the claims to this embodiment during prosecution. *Supra* § IV.C.

The claims are unpatentable under either party's construction.

B. "computer-operable medium" terms

The '461 Patent discloses "computer-operable media, e.g., the processor(s) 107 and/or memory(s) 108." EX1001, 5:34-35.

In litigation, BSC argued that the "computer-operable medium" terms are means-plus-function with no corresponding structure. Nevro argued plain meaning or, alternatively, if means-plus-function, then the structure is a computer-operable medium disclosed at 2:35-38 and 5:34-35, and programmed to perform the claimed functions. EX1022, 20-23. Nevro served its '461 Patent counterclaim on December 9, 2019, and this dispute will likely be resolved before an institution decision here, as a *Markman* hearing is scheduled for January 6, 2021. If the court and Board agree these terms are not means-plus-function or that they are means-plus-function and the structure is disclosed, then this IPR should proceed with that interpretation because the asserted art discloses and renders obvious these terms under such interpretations, including "processor(s) [] and/or memory(s)."

VI. INTRODUCTION OF GROUNDS

The '461 Patent acknowledges conventional systems that automatically set parameters, within therapy ranges, applied to electrodes at different, linked areas.

It simply purports to add programming that sets parameters "based on a relationship between the first therapy range and the second therapy range," e.g., a therapy range ratio. This programming, however, was well-known.

Meadows provides a foundational disclosure of SCS technology, including components and programming in those conventional linked-mode systems. *Thacker* incorporates *Meadows* for this reason and teaches a "global" adjustment that automatically sets parameters for multiple electrodes at different areas based on therapy range ratios. *Nolan* discloses a similar approach.

Accordingly, this Petition is structured into three sections: ***first***, the foundational *Meadows* Grounds; ***second***, the *Thacker* Grounds, which incorporate *Meadows*; and ***third***, the *Nolan* Grounds, which use *Meadows* in alternative grounds for obviousness. Each of these references discloses and/or renders obvious conventional, linked-mode SCS systems programmed to achieve each of the challenged claims.

VII. GROUNDS 1-5: *MEADOWS* GROUNDS

Meadows anticipates and/or renders obvious all challenged claims, alone and with *John* and/or *Goetz*. EX1008, ¶¶ 66-160. *Meadows* is prior art under § 102(b). *Id.*

A. Overview of *Meadows*

Meadows discloses an SCS system for managing pain by delivering waveforms within therapy ranges to electrodes at different areas. EX1003, Abstract, 33:66-34:23; EX1008, ¶¶ 68-82. *Meadows* recognized conventional systems for adjusting parameters for different areas. EX1003, 1:19-2:41, 12:48-65, 33:66-35:25. *Meadows* discloses a programmable implantable pulse generator ("IPG") that maps therapy ranges to electrodes at different areas and automatically sets parameters based on therapy range ratios. *Id.*; EX1008, ¶¶ 31-38, 72-82.

Figure 1 illustrates *Meadows*' system. EX1003, 4:6-6:3, 8:28-67, 10:57-11:19, 17:50-27:54, Figs. 4A-4G, 5-7C.

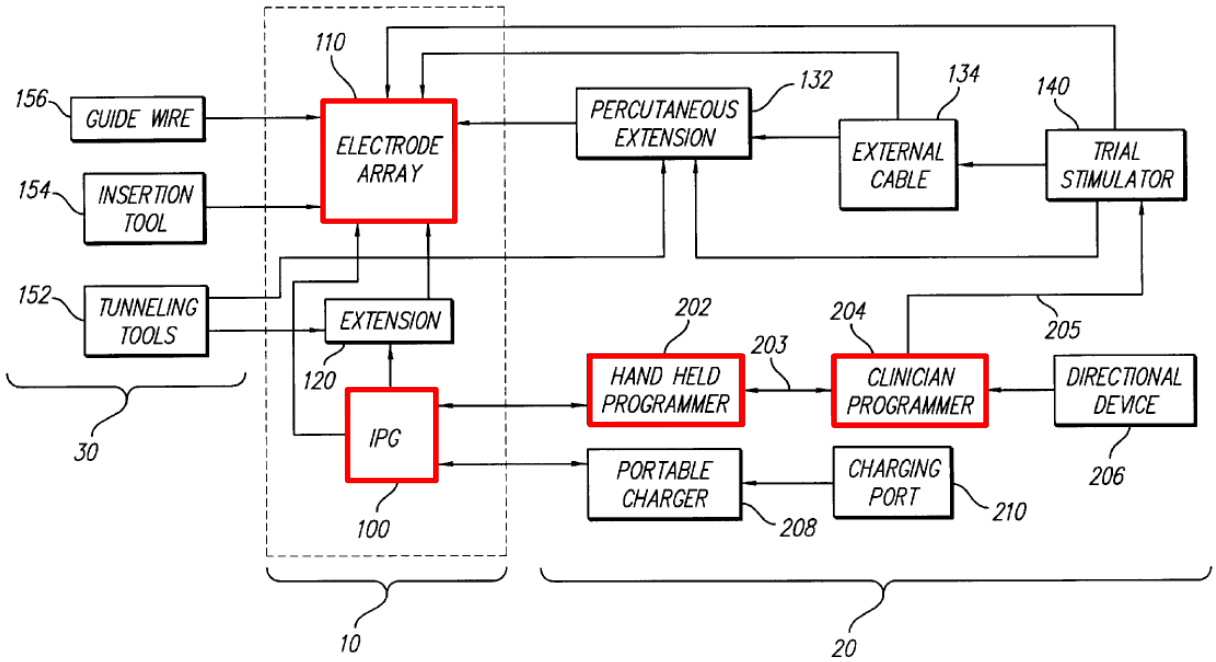


FIG. 1

EX1003, Fig. 1.[1] Figure 2A illustrates leads 110. *Id.*, 7:6-11, 9:1-11:19.

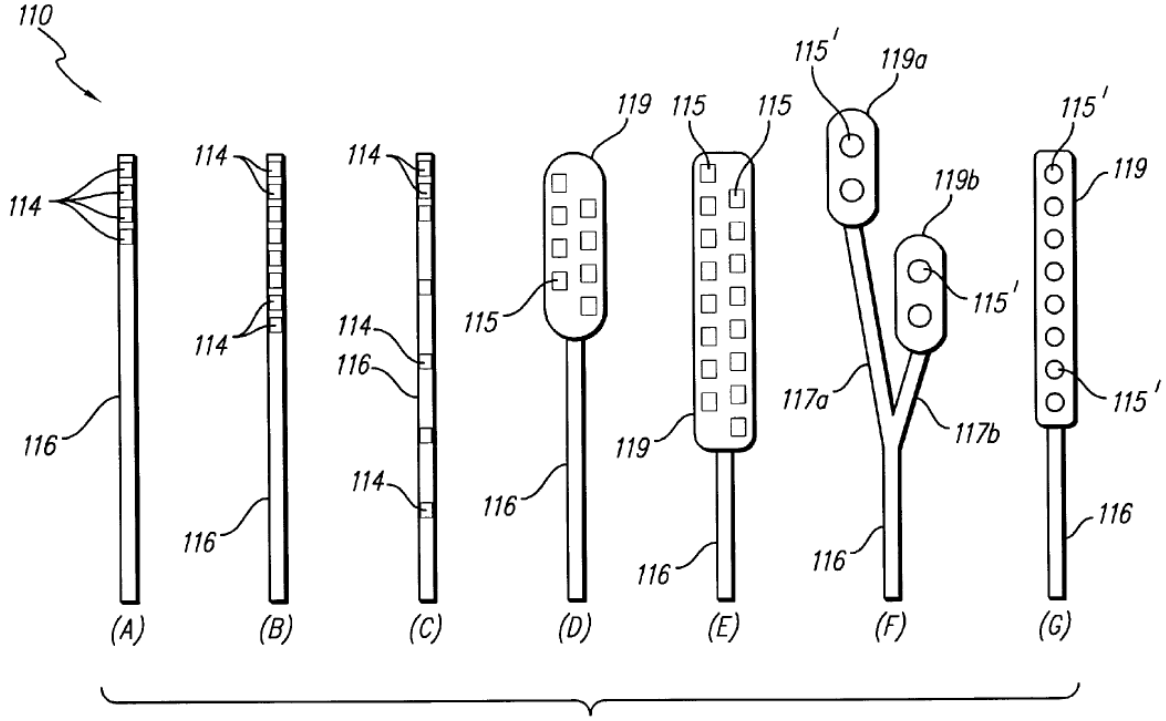


FIG. 2A

Id., Fig. 2A. The electrodes can be grouped in any combination (or "channel") to deliver therapy. *Id.*, 2:44-64, 6:38-49, 10:19-67, 12:13-16:49, 18:9-19:21, 26:43-27:15, Figs. 3A-3C. *Meadows* can stimulate simultaneously on multiple groups of electrodes (or "channels") in a "program." *Id.*, 35:26-35, 37:56-38:21; EX1008, ¶ 75.

Meadows describes determining therapy ranges for each electrode, from a lower limit based on a "sense" threshold to an upper limit based on a "maximum"

[1] Color in figures herein are annotations.

threshold. EX1003, 10:19-33, 12:48-65, 33:38-35:25, 38:22-54. These thresholds map to magnitude levels 1 to 10, where "1" is the "sense" threshold, "10" is the "maximum." *Id.* When a user sends a change command, the system simultaneously adjusts the parameter for the active electrodes (e.g., from level 1 to 2) based on their therapy range ratios. *Id.* For example, if the range for electrode 1 is twice the range for electrode 2, a change in level (e.g., from level 1 to 2) would change electrode 1 by twice the amount of electrode 2—a 2:1 ratio.

Meadows identifies and incorporates *Mann167* and *Mann217*, making them fully part of *Meadows*, including to describe the IPG's "programming," "thresholds," and "magnitude levels." *Id.*, 29:61-66, 34:14-19; *Paice LLC v. Ford Motor Co.*, 881 F.3d 894, 909 (Fed. Cir. 2018); EX1008, ¶¶ 69-71. References to *Meadows* herein include its entire disclosure, including *Mann167* and *Mann217*.

Through incorporated *Mann167*, *Meadows* further describes IPG programming and thresholds. EX1012, 1:5-2:29, 8:21-11:18, 25:1-16, Figs. 3A-3B; EX1008, ¶¶ 77-79.

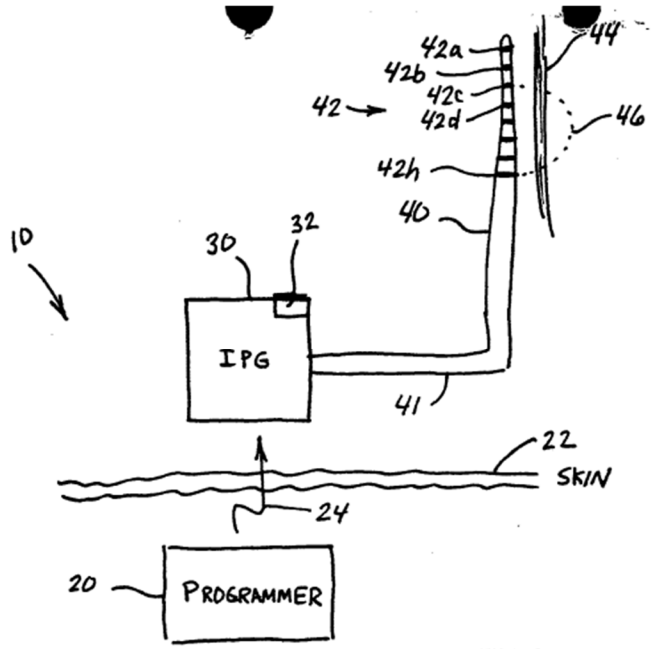


FIG. 1

EX1012, Fig. 1. *Mann167* describes determining therapy ranges for electrodes, and mapping those ranges to magnitude levels 1 to 10, where 1 is the "perception" threshold and 10 is the "most comfortable" or "maximum tolerable" threshold. *Id.*, 6:18-7:8, 12:10-15:16. This allows users to automatically set parameters for any combination of electrodes based on therapy range ratios. *Id.*, 2:10-4:14, 12:10-16:2, 18:19-19:5, Fig. 4.

Through incorporated *Mann217*, *Meadows* further describes setting parameters based on therapy range ratios. EX1013, 1:9-2:18, 27:3-28:29, 38:11-40:6; EX1008, ¶¶ 80-82.

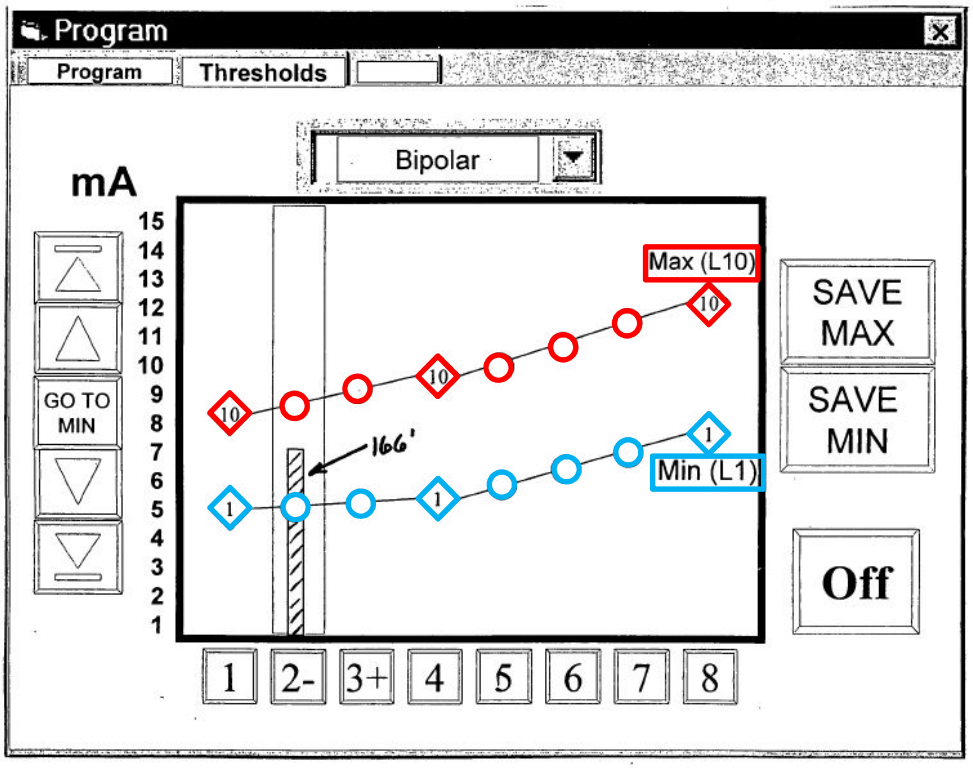


FIG. 13

EX1013, Fig. 13. Thresholds for certain electrodes can also be interpolated or estimated using determined thresholds from surrounding electrodes. *Id.*, 28:4-29:3, 38:11-22, 40:7-20, 43:9-44:21.

B. Claim 1

Claim 1 is anticipated and/or rendered obvious by *Meadows*, alone and with *John*. EX1008, ¶¶ 66-67, 83-121. As Dr. Mihran explains, Claim 1 recites a conventional linked-mode system, which *Meadows* discloses. EX1008, ¶¶ 31-38, 66-83. The only purported novelty is the portion of limitation [1h] that recites "based on a relationship between the first therapy range and the second therapy range," which just involves programming a conventional system. Moreover,

Meadows, alone and with *John*, discloses and/or renders obvious this limitation using a therapy range ratio.

1. [1a]

Meadows discloses an SCS system for managing pain in patients using electrical stimulation. EX1003, Abstract, 1:9-38 ("Spinal Cord Stimulation"; "pulse generating system used to treat chronic pain"), 3:57-5:35, 7:3-34 ("waveforms"), 9:1-32, 29:47-30:2 ("electrical stimuli"), 46:48-47:6, Figs. 1-4G; EX1008, ¶ 84.

2. [1b]

Meadows discloses an implantable electrode device (e.g., array or lead) with multiple electrodes. EX1003, Abstract ("multi-contact electrodes"), 1:9-30 ("electrode array placed epidurally near a patient's spine"; "implanted"), 2:44-64, 4:20-5:25, 8:48-10:56, Figs. 1, 2A; EX1008, ¶ 85.

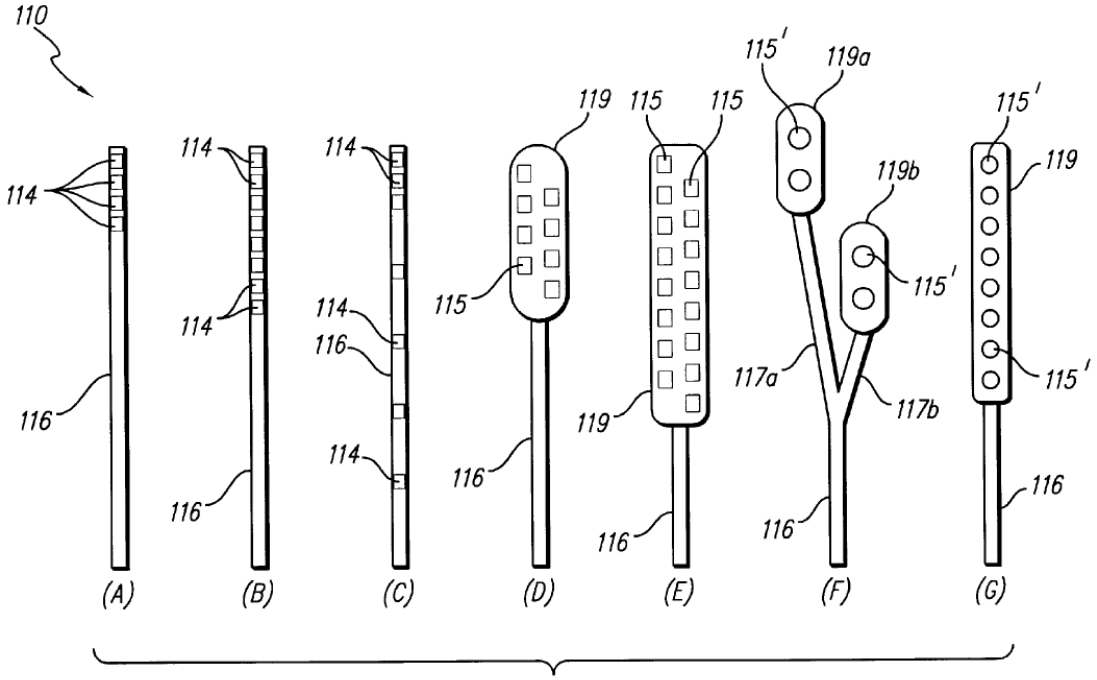
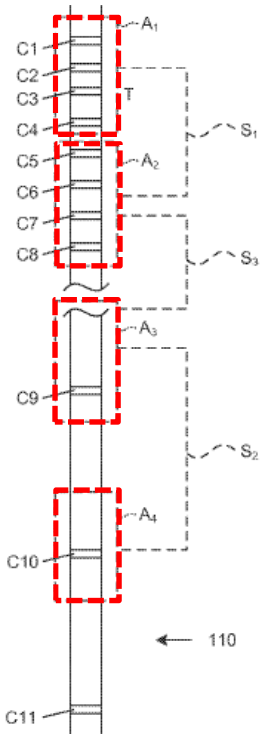


FIG. 2A

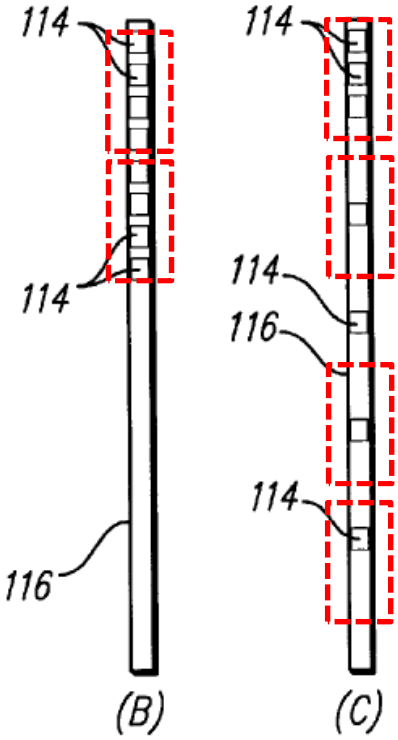
Id., Fig. 2A.

3. [1c]

Meadows discloses and renders obvious an electrode device, which, when implanted, has electrodes at or adjacent different areas or sites relative to the spine. EX1003, 1:65-2:6 ("sites of electrical stimulation"), 9:1-10:56 ("back pain typically requires a different stimulation site"; "array that covers a large … tissue area"), 33:28-34:42, Fig. 2A; EX1008, ¶¶ 86-88.



EX1001, Fig. 1B (partial)



EX1003, Fig. 2A (partial)

Meadows discloses any combination of electrodes—including electrodes at different areas—in a channel, e.g., a channel with an electrode in a first dashed box and another electrode in a second dashed box above, or in multiple channels, e.g., a channel with an electrode in a first dashed box and another channel with another electrode in a second dashed box. EX1003, Abstract, 1:65-2:6, 2:44-3:37 ("any electrode node can be grouped with any other electrode"), 4:5-20, 5:36-47, 7:11-15, 9:1-10:67, 12:13-65 ("any channel of the IPG may be programmably connected to any grouping of the electrodes"; "any number of electrodes may be grouped"), 18:41-53, 33:28-35:35, 37:56-38:21, Figs. 2A, 3A; EX1008, ¶¶ 87-88.

4. [1d]

Meadows discloses and renders obvious using "threshold measurements" to determine a therapy range of a parameter (e.g., amplitude) for each electrode or electrode set associated with an area—ranging from a "perception" or "sense" threshold to a "maximum" or "most comfortable" threshold. EX1003, 5:61-6:3, 13:18-28, 18:66-19:10, 21:48-67, 31:12-54, 33:38-34:23 ("determined for each electrode"), 35:5-36:16; 38:22-54; EX1008, ¶¶ 89-93. As explained, therapy ranges are mapped to levels "1" to "10." EX1003, 33:66-35:62, 38:41-56; EX1012, 2:10-29, 6:18-7:8, 12:10-15:16, 20:5-24:24 ("perception threshold and a maximum tolerable threshold for each of the [] electrode contacts"). Figures 3A and 3B show therapy ranges for four channels (electrode sets a-d). *Id.*, 12:17-14:20.

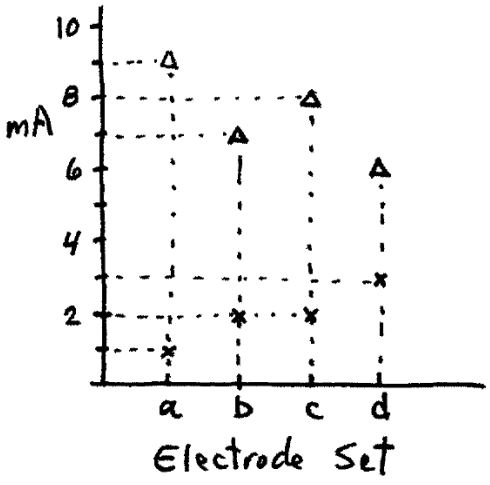


FIG. 3A

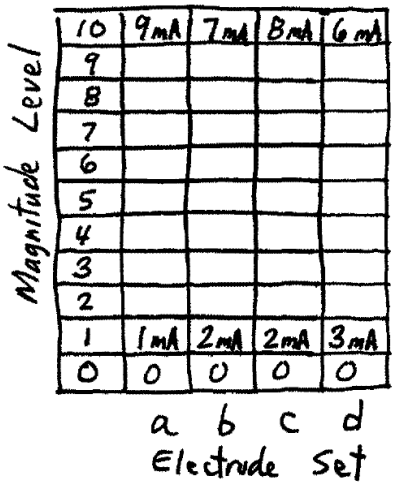


FIG. 3B

EX1012, Figs. 3A-3B. Figure 5 shows the distribution for Electrodes 1 and 2 ranging from 2 to 8 mA and 3 to 7 mA, respectively—a 3:2 ratio. *Id.*, 16:3-18:2.

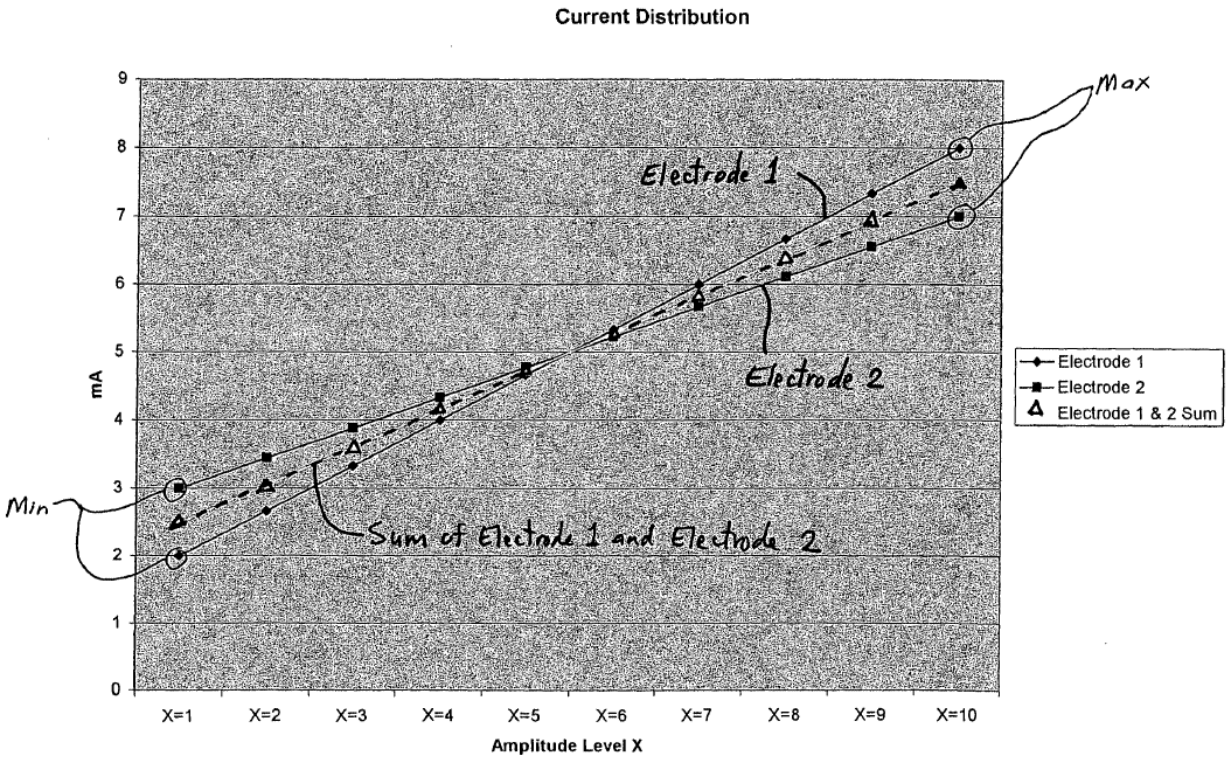


FIG. 5

Id., Fig. 5; *id.*, Fig. 6.

If Nevro argues this limitation is not disclosed, it would have been obvious for the first and second areas to have first and second therapy ranges, each ranging from a sensation or therapeutic threshold to a discomfort threshold. EX1008, ¶¶ 91-93. Determining thresholds for areas was conventional because it was well understood that different sites require and tolerate different stimulation levels. EX1001, 2:61-3:24. The '461 Patent admits therapy ranges were determined in conventional systems, just calling it "time-consuming." *Id.* As Dr. Mihran

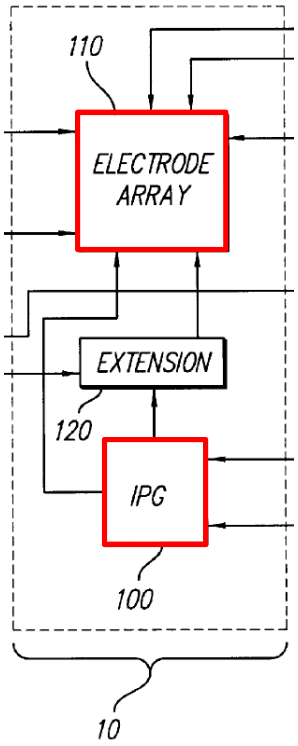
explains, therapy ranges in SCS systems were well-known before the 1990s, using various thresholds, including "therapeutic," "pain," and "discomfort." EX1001, 3:18-21, 13:46-66; EX1008, ¶ 91 (citing EX1018; EX1019; EX1020 at 1-2; EX1021 at 3).

It would have been obvious to set therapy ranges in *Meadows*' system. EX1003, 2:23-41, 5:61-6:3, 31:12-54, 33:38-35:62, 38:22-54; EX1008, ¶¶ 92-93. As explained, *Meadows* teaches such ranges to address each patient's needs. A POSA would have been motivated to set such ranges because delivering stimulation below where the patient can sense or feel relief would be pointless, and providing a waveform above a discomfort threshold would be uncomfortable. *Id.* A POSA would have had a reasonable expectation of success because setting therapy ranges—which *Meadows* teaches, e.g., using a "threshold" window or interpolation—requires no modification to *Meadows*' system. EX1003, 31:12-54 ("patient threshold measurements"), 33:58-34:54 ("set maximum and minimum thresholds"); EX1013, 28:4-29 ("interpolate or estimate the remaining thresholds").

5. [1e]

Meadows discloses an implantable pulse generator ("IPG") (e.g., IPG 100 or 100′) connected to the electrode device. EX1003, 1:19-30, 3:27-4:20 ("implantable pulse generator"), 5:10-46, 6:29-49 ("connection between the IPG

and the electrode array"), 7:3-29, 8:28-67 ("IPG 100 is connected to a lead"), 9:1-10:3, 12:13-30, 16:50-17:12, 21:8-22:52, 26:34-27:27, 49:55-51:4, 52:53-53:4, Figs. 2B, 4A-4C; EX1008, ¶ 94.



EX1003, Fig. 1 (partial).

6. [1f]

Meadows' IPG includes a power supply (battery). EX1003, Abstract, 2:44-64, 3:28-6:28, 8:27-59, 17:22-55 ("power source"), 20:61-21:8 ("battery"), 40:34-50, Figs. 4A-4E, 9A-9C; EX1008, ¶ 95.

Meadows' IPG includes a waveform generator configured to generate a waveform. EX1003, 1:9-29 ("pulse generator generates electrical pulses"), 4:20-

5:47, 7:11-15 ("current waveforms"), 8:28-59, 12:13-47, 18:9-20:60 ("pulses generated by the IPG 100"), 21:40-23:47, Figs. 3A-4G; EX1008, ¶ 96.

Meadows' IPG includes a "computer-operable medium" (e.g., circuitry including a processor and memory) that controls the pulse generator. EX1003, 4:20-5:47 ("IPG comprises: … electronic[] circuitry, including memory circuits"), 16:50-17:12 ("microcontroller (μC) 160 connected to memory circuitry 162"), 20:33-21:67 ("processor die, or chip, 160'"; "memory circuits 162′ (SEEROM) and 163 (SRAM)"), 50:32-51:4, 54:15-23 ("IPG processing circuitry"), Figs. 4A-4G; EX1008, ¶ 97.

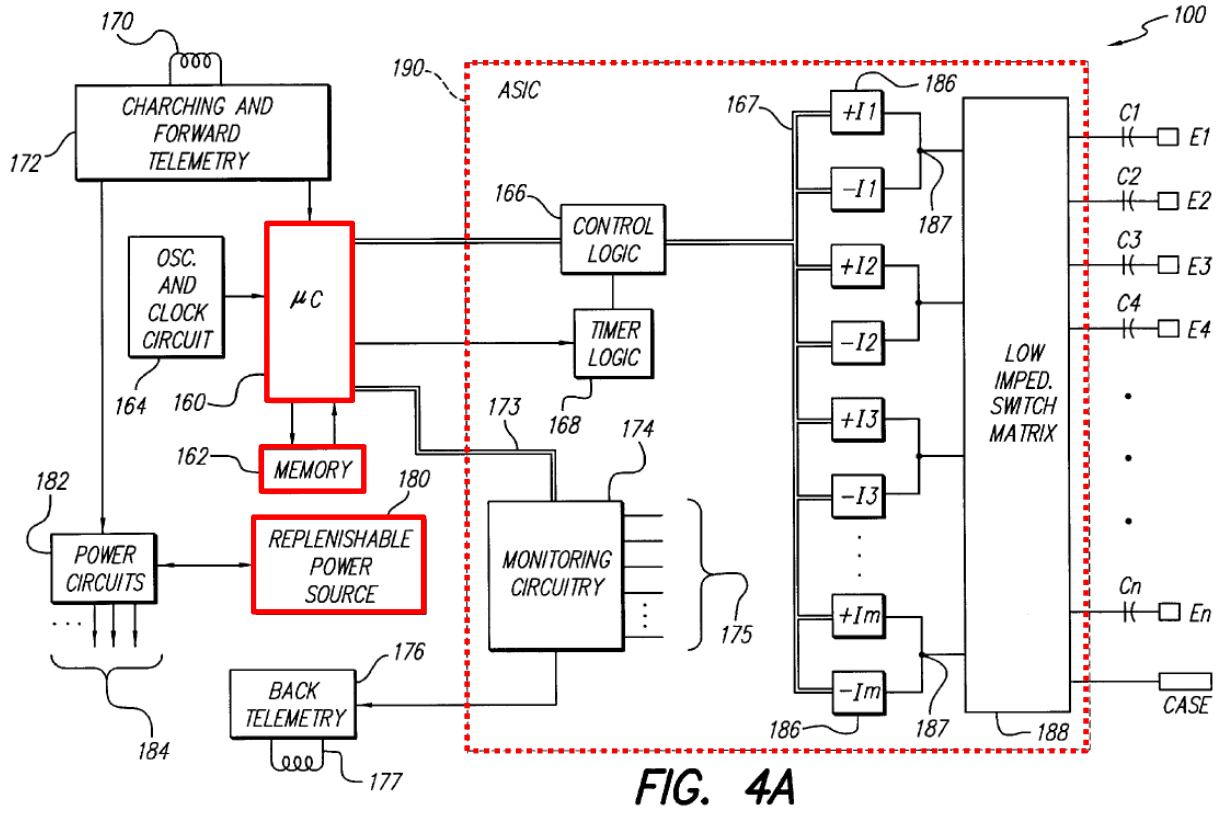
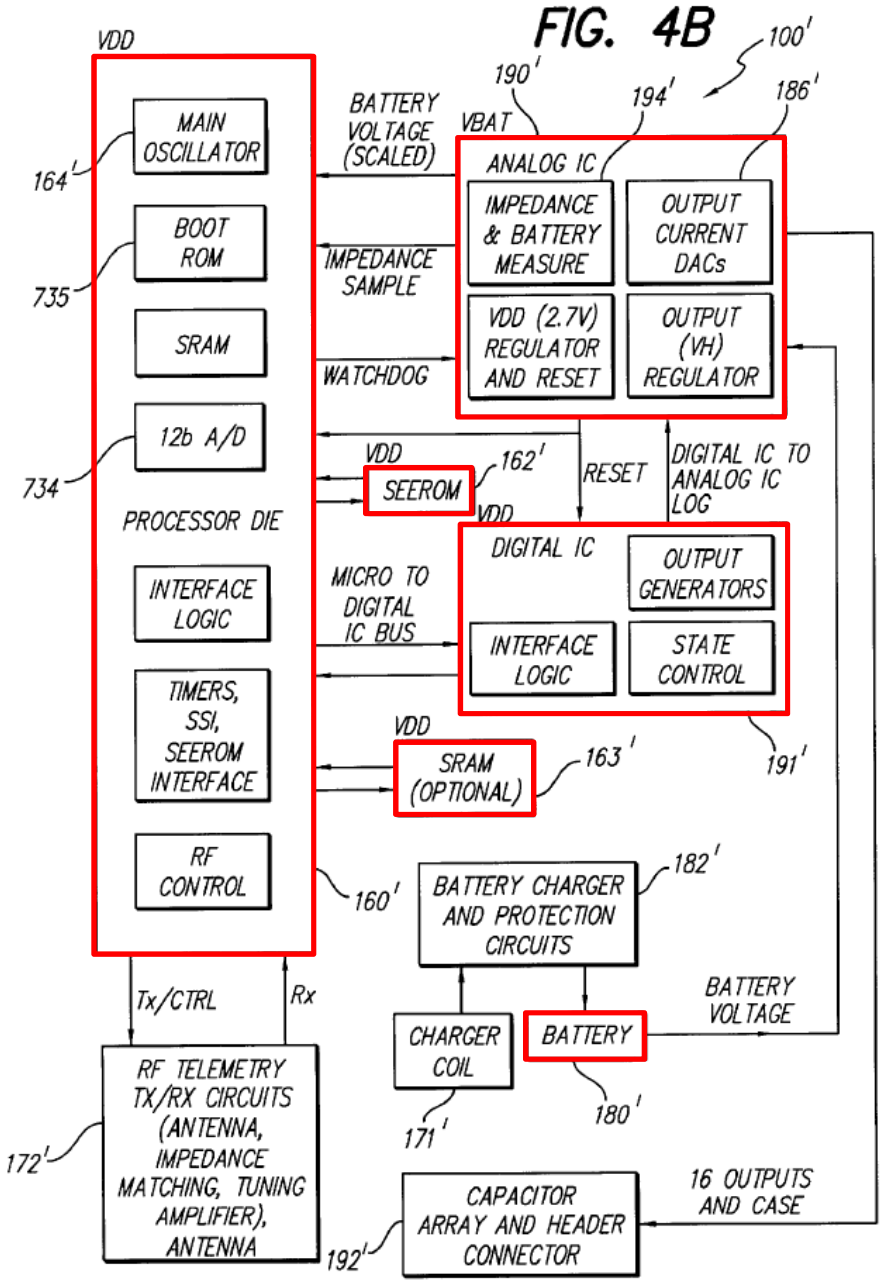


FIG. 4A

EX1003, Fig. 4A.



Id., Fig. 4B.

7. [1g]

Meadows discloses and renders obvious the computer-operable medium being programmed with operating programs, algorithms, and stimulation

parameters to control the IPG. EX1003, 1:9-18, 2:31-3:65, 5:61-6:3, 10:19-33, 12:48-13:28 ("any channel of the IPG may be programmably connected to any grouping of the electrodes"), 16:20-17:12 ("operating program and stimulation parameters are typically programmably stored within the memory"), 18:9-19:21, 21:14-67 ("program that is stored within its memory"), 24:34-25:8 ("stores the program and data section in the processor"), 26:34-27:37, 34:24-35:62, 40:14-25, 50:32-51:4, 54:15-23, Figs. 4D, 4F-4G; EX1008, ¶¶ 98-100.

As explained further for limitation [1h], the computer-operable medium is programmed to change a parameter (e.g., amplitude) applied to the first electrode, e.g., in response to a command to change the level (1-10) discussed for limitation [1d]. EX1003, 5:35-6:3 ("decode commands"; "change the stimulus parameters of the IPG"), 12:66-13:28 ("amplitude is programmable"), 13:56-65, 16:50-17:12 ("μC to control operation of the IPG in accordance with a selected operating program and stimulation parameters"), 17:55-19:37 ("Amplitudes … of electrodes on a channel may vary, e.g., as controlled by the patient"), 22:53-65 ("changes the stimulus levels"), 27:27-54, 29:18-38 ("adjust amplitude"), 30:22-54, 35:5-25, 36:65-39:14, 40:15-26 ("Command data"), 51:66-52:11 ("increasing … amplitude"), 54:15-23.

If Nevro argues that *Meadows* does not disclose limitation [1g] because the programming is not inside the IPG, it would have been obvious to program

Meadows' IPG with the claimed functionality for the reasons explained for limitation [1h]. EX1008, ¶ 100.

8. [1h]

Meadows, alone and with *John*, discloses and/or renders obvious limitation [1h]. EX1008, ¶¶ 101-21. If the Board construes "based on a relationship" to require using the first increment, such as using the disclosed "product" of the first increment and the relationship, *Meadows*, alone and with *John*, renders obvious this limitation. *Id.* If the Board applies a broader construction, such as "in accordance with a relationship" or Nevro's "non-technical, ordinary" meaning, *Meadows*, alone and with *John*, discloses and renders obvious this limitation. *Id.*

a. Grounds 1-2

Meadows, alone, discloses and renders obvious limitation [1h] in two alternative scenarios with first and second electrodes at first and second areas: (1) when adjusting the magnitude level of a single channel containing the first and second electrodes, and (2) when sequencing (or switching) from a first channel containing the first electrode to a second channel containing the second electrode. EX1008, ¶¶ 102-12.

As explained, *Meadows* discloses and renders obvious therapy ranges for first and second electrodes/areas and mapped to levels 1-10. EX1008, ¶¶ 72, 86-93, 103-05. This allows a user to "change" and "automatically set" the amplitude

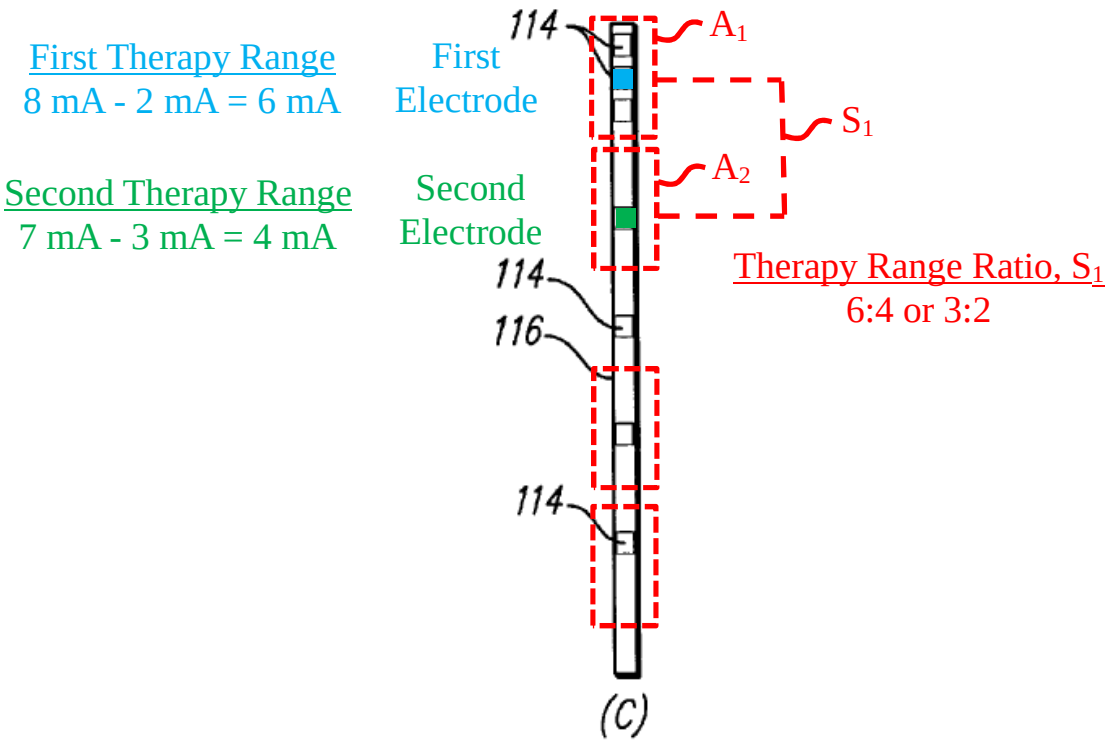
applied to electrodes at different areas based on their therapy range ratios by selecting a level for those areas. EX1003, 35:5-25 ("amplitude for the group may be selected as a level from 1-10").

In scenario one, a user sends a command to change the amplitude for a channel (e.g., from level 1 to 2), and the IPG changes the amplitude applied to the first electrode in the channel (e.g., to its level 2 magnitude), and automatically sets the amplitude applied to the second electrode (and any other electrodes) in the channel (e.g., to its level 2 magnitude) based on a therapy range ratio. EX1003, 5:48-60, 10:20-33, 18:41-53, 33:66-34:23, 35:5-62 ("'channel settings' area"; "Amplitude … is programmable by channel, and applied as a distribution between maximum and sense thresholds for a group of assigned electrodes"), 37:21-41, 38:41-56 ("amplitudes should be set at the sense threshold … as channel level 1"); EX1012, 2:10-29, 6:18-7:8, 12:10-15:16, 16:3-18:2, 20:5-24:24, Figs. 3A-3B, 5-6. This command simultaneously adjusts the amplitude for each electrode in the channel based on a therapy range ratio. *Id.*

In scenario two, the IPG changes the amplitude applied to the first electrode in a first channel (e.g., from level 1 to 2), and when the IPG sequences to a second channel, it automatically sets the amplitude applied to the second electrode in the second channel (e.g., to its respective level 2 amplitude) based on a therapy range ratio. EX1012, 2:10-3:25, 4:11-5:3 ("applying a stimulus having a selected

equalized magnitude level to a selected combination of … electrode contacts"), 12:10-14:20, 15:17-16:2, 18:19-19:5, Figs. 4-6. The advantage of this approach is to automatically maintain a constant perceived therapy intensity when sequencing from the first to the second electrode. *Id*.

In both scenarios, the IPG automatically sets the amplitude applied to the second electrode "based on a relationship between the first therapy range and the second therapy range"—e.g., based on a therapy range ratio. EX1008, ¶¶ 104-06. For example, a user may determine a therapy range of 2 to 8 mA for the first electrode (in **blue**) at Area A_1, and a therapy range of 3 to 7 mA for the second electrode (in **green**) at Area A_2, resulting in therapy range ratio or scaling factor S_1 of 3:2 — $S_1 = \frac{8-2}{7-3} = \frac{6}{4} = \frac{3}{2}$. EX1012, 2:10-29, 12:10-14:20, 16:3-18:2, Figs. 3A-3B, 5-6.



EX1003, Fig. 2A. Here, level 1 is 2 mA for the first electrode and 3 mA for the second electrode. When increasing to level 2, the first electrode changes to 2.6 mA (0.6 mA increase), and the second electrode is automatically set to 3.4 mA (0.4 mA increase) based on the 3:2 therapy range ratio.

In addition, *Meadows* discloses other ways of using a "relationship" between first and second therapy ranges to automatically set the parameter applied to the second electrode. For example, per Figure 13 below, the IPG can interpolate the therapy range (in **red**) for the second electrode (in **green**) at Area A_2 based on a therapy range (in **orange**) (the "second therapy range") associated with Area A_2

and a therapy range (in **purple**) (the "first therapy range") associated with Area A_1. EX1013, 28:4-29:3, 38:11-22, 40:7-20, 43:9-44:21; EX1008, ¶ 107.

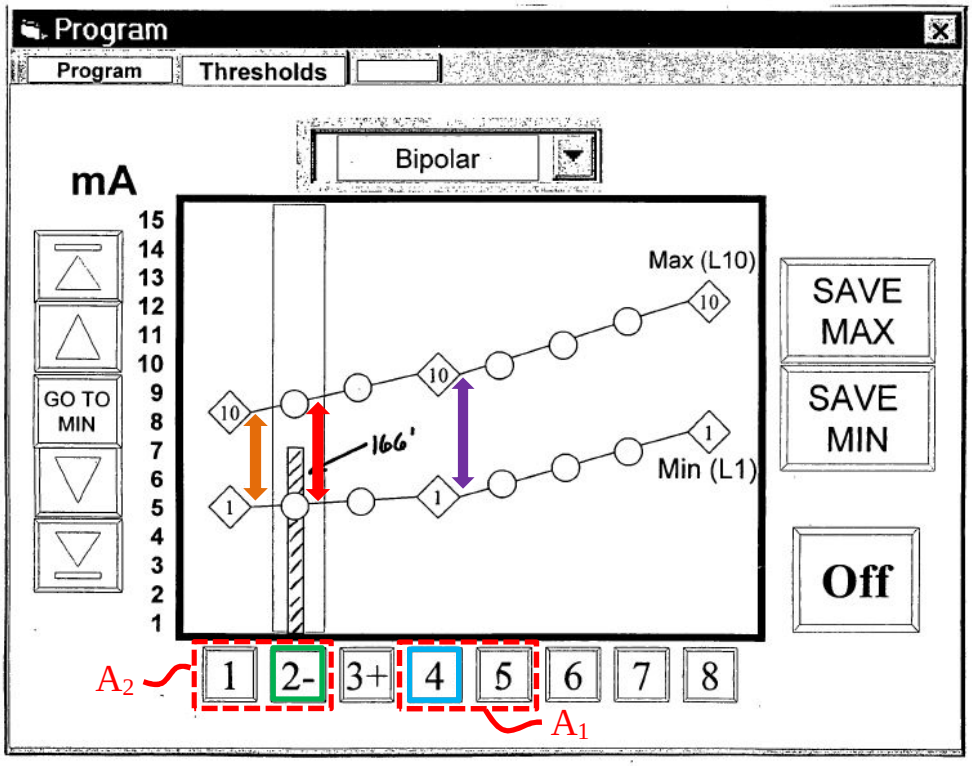


FIG. 13

EX1013, Fig. 13. Once the interpolated therapy range (in **red**) is mapped to levels 1 to 10 and a user adjusts from one level to another, the IPG will automatically set the amplitude of the second electrode (in **green**) using the interpolated range derived from and set based on the first and second therapy ranges (in **purple** and **orange**). Accordingly, *Meadows* discloses automatically setting a waveform parameter (amplitude) for the second electrode (in **green**) of Area A_2 based on a

relationship between a therapy range (in **orange**) associated with Area A_2 and a therapy range (in **purple**) associated with Area A_1.

If Nevro argues that *Meadows* does not disclose limitation [1h] (or any other programming limitation herein) because the programming is not inside the IPG, it would have been obvious to program *Meadows*' IPG with the claimed functionality. EX1008, ¶¶ 108-09. As explained, *Meadows* teaches a programmable IPG with respect to setting parameters, and *Meadows* teaches storing programs, algorithms, and parameters in the IPG. *Id.* It is a design choice to locate this programming in the IPG versus an external device. *Id.* A POSA would have been motivated to program the IPG itself because the programming stays with the IPG, simplifying compatibility and functionality of external devices. *Id.* (citing EX1007, ¶ 64). A POSA would have had a reasonable expectation of success because no hardware modifications would be necessary, and programming would have been predictable. *Id.* The '461 Patent teaches no particular configuration or algorithm for the IPG "being programmed" with any of the claimed programming because programmable IPGs were already known and there was nothing patentably distinct about locating programming for the claimed functionality in an IPG instead of an external device. *Id.*

If Nevro argues that *Meadows* does not disclose the "based on a relationship between the first therapy range and the second therapy range" limitation, it would

have been obvious to program *Meadows*' IPG to automatically set the parameter of the second electrode based on such a relationship, e.g., setting the parameter in accordance with the therapy range ratio or, alternatively, using the product of the first increment and the therapy range ratio. EX1008, ¶¶ 110-12. As explained, the '461 Patent acknowledges there were conventional devices that automatically set a parameter for linked areas having therapy ranges, and *Meadows* expressly teaches determining therapy ranges for electrodes across areas and mapping them to levels 1-10. *Id.* And these levels beneficially allow setting the parameter of multiple electrodes automatically at a relative intensity based on a therapy range ratio. *Id.*

A POSA also would have been motivated to program *Meadows*' IPG in this way because it fulfills *Meadows*' purpose of safer, easier programming to address the patient's needs—pain relief without discomfort. *Id.* Automatically setting the second electrode based on a "ratio … equal to 1:1" (the claimed "relationship") was also well-known, according to the '461 Patent, but still claimed. *Id.* (citing EX1001, 3:14-18, 10:54-57, 13:59-63). Because no modification of the hardware is necessary to program the claimed "relationship"—it is just math implemented in programming and therefore a predictable design choice—a POSA would have a reasonable expectation of success. *Id.* Indeed, the '461 Patent teaches no particular configuration or algorithm to achieve setting a parameter "based on a

relationship," except a mathematical formula: using the product of the first increment and the relationship. *Id.*

b. Ground 3

Meadows with *John* also renders obvious limitation [1h]. EX1008, ¶¶ 113-21. *John* is prior art under § 102(b) and discloses implantable neuromodulation devices for treating pain and improved programming for such devices. EX1006, Abstract.

John discloses delivering stimulation to electrodes at one or more target areas. EX1006, ¶¶ 4-5 ("Neuromodulation"), 39 ("pain disorders"), 54, 60, 71 ("leads … have one or more electrical contacts … which are placed to stimulate the target areas"). *John* recognizes that interactions (e.g., functional or anatomical) exist between different areas, which *John* uses to improve treatment. EX1006, ¶¶ 5-8, 12, 62-64, 78, 85, 127-28.

John "links" two or more target areas and establishes "linking rules" for delivering therapy to those areas. EX1006, ¶¶ Abstract ("Linking rules may guide in the setting and subsequent adjusting of the therapy"), 9, 12, 17, 20, 127, 130 ("Linking rules can be used for both generating the stimulation signal and also for adjusting … treatment"), 138.

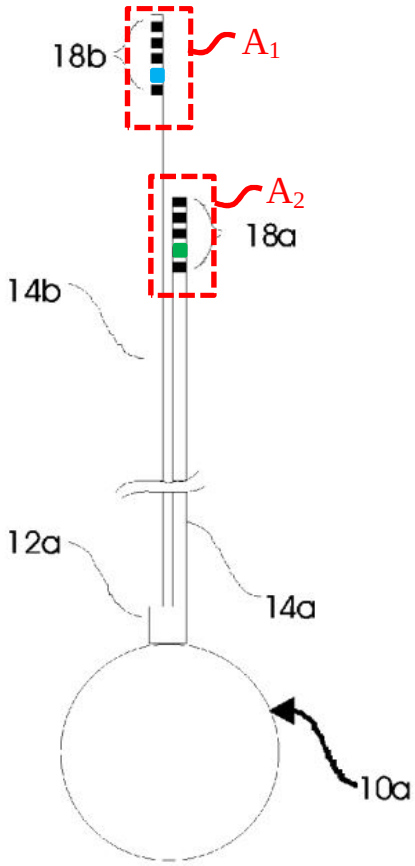


FIG 1a

EX1006, Fig. 1a.

These linking rules are implemented based on "data collected during assessment procedures … [or] the experience of the patient." EX1006, ¶ 131. For example, a linking rule can be used to adjust a parameter applied to a second area (by a second increment) using the product of the parameter change applied to a first area (a first increment) and a value derived from characteristics of stimulation parameters and ratios. EX1006, ¶¶ 9 ("linking rules to adjust the stimulation provided at one target region according to the neurostimulation provided at a

different target region"), 20 ("link the neuromodulation protocol of one stimulated area to those used at a different modulated area"), 46 ("reference values stored in the database"), 48 ("'reference values' refer to … values determined by an equation … or ratio values"), 108, 113, 127-40 ("linked rules may be incorporated into algorithms, … and can also be … discontinuous, only being implemented across certain ranges"), 144 ("if the patient chooses to increase modulation directed at these areas, this increase occurs proportionately for the two areas, as defined by the linking rule"), 149-50. Thus, *John* teaches "automatically adjusting stimulation to a second area if the stimulation in a first area is adjusted by the patient," e.g., increasing the stimulation "proportionately for the two areas, as defined by the linking rule." *Id.*, ¶¶ 138, 144. This means that, like in the '461 Patent, the first increment for a first electrode is used in the "linking rule" to calculate and automatically set the parameter applied to the second electrode. *Id.*

Accordingly, it would have been obvious to program *Meadows*' IPG using John's "linking rule" technique to "automatically set the waveform parameter applied to the second electrode based on a relationship between the first therapy range and the second therapy range." EX1008, ¶¶ 114-18. Specifically, the combined teachings of *Meadows* and *John* render obvious programming *Meadows*' IPG with a "linking rule," so that when a user changes the amplitude of the first electrode, the IPG automatically sets the amplitude applied to the second electrode

based on a therapy range ratio—e.g., according to a "linking rule" that uses the product of the first increment and the therapy range ratio. *Id.*

A POSA would have been motivated to incorporate *John*'s "linking rule" technique into *Meadows* to achieve the claimed invention because it involves substituting known elements of *John* for analogous elements in *Meadows*. EX1008, ¶ 119. The brain stimulation in *John* and spinal cord stimulation in *Meadows* are similar and implement interchangeable technologies. *Id.*; EX1032, 17:24-20:10; *see* EX1003, 1:30-37.

It would have been further obvious to incorporate *John*'s "linking rule" technique to improve *Meadows*' system in the same way. EX1008, ¶ 120. As *John* teaches, "linking rules" optimize programming, increase therapy efficacy, and recognize that different areas respond to different levels of stimulation. EX1006, ¶¶ 5-8, 12, 62-64, 78, 85, 127-28; *see* EX1001, 1:57-67.

It would have been also obvious to incorporate *John*'s "linking rule" technique into *Meadows*' system according to known methods. EX1008, ¶ 121. Incorporating this technique merely requires programming a mathematical equation. Such combination of known, predictable programming techniques provides a reasonable expectation of success.

C. Claim 2

Claim 2 is anticipated and/or rendered obvious by *Meadows*, alone and with *John*, as explained for limitations [1d], [1g], and [1h]. EX1008, ¶ 122. *Meadows*' IPG limits the parameter (e.g., amplitude) applied to each electrode to its therapy range—the lower limit at level 1 and the upper limit at level 10 and doing so would have been obvious based on the teachings of *Meadows*.

D. Claim 3

Claim 3 is anticipated and/or rendered obvious by *Meadows*, alone and with *John*. EX1008, ¶¶ 123-130.

1. [3a]

As explained for limitations [1d], [1g], and [1h], *Meadows*, alone and with *John*, discloses amplitude as the parameter. *Id.*

2. [3b]

As explained for limitations [1d] and [1h], *Meadows*, alone and with *John*, discloses and/or renders obvious determining therapy ranges for the amplitude of first and second areas, ranging from a sensation/therapeutic threshold (level 1) to a discomfort threshold (level 10). *Id.*

3. [3c]

As explained for limitation [1h], *Meadows*, alone and with *John*, discloses and/or renders obvious the relationship comprising a ratio of the first and second amplitude ranges, e.g., a 3:2 therapy range ratio. *Id.*

4. [3d]

Meadows discloses a patient input device (e.g., HHP 202). EX1003, 5:36-41, 16:50-17:12, 18:41-53, 29:39-46, 31:36-47, 36:7-37:16, 39:15-40:26 ("HHP 202 sends and receives RF command signals"; "command data"), 58:1-20, Figs. 1, 7A-7E; EX1008, ¶¶ 127-28.

The HHP includes a controller (e.g., processor IC 620) that generates a change command (e.g., programming data, command data, or command signal), e.g., in response to the patient pressing "up" or "down"; and a transmitter (e.g., transmitter 654) configured to transmit the change command to the IPG which "contains the necessary electronics to decode commands." *Id.*

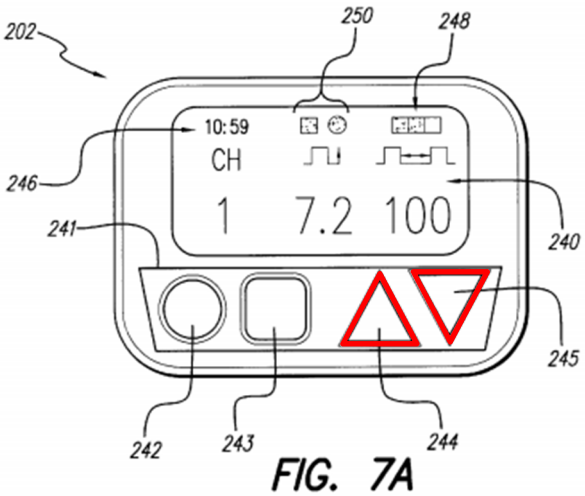
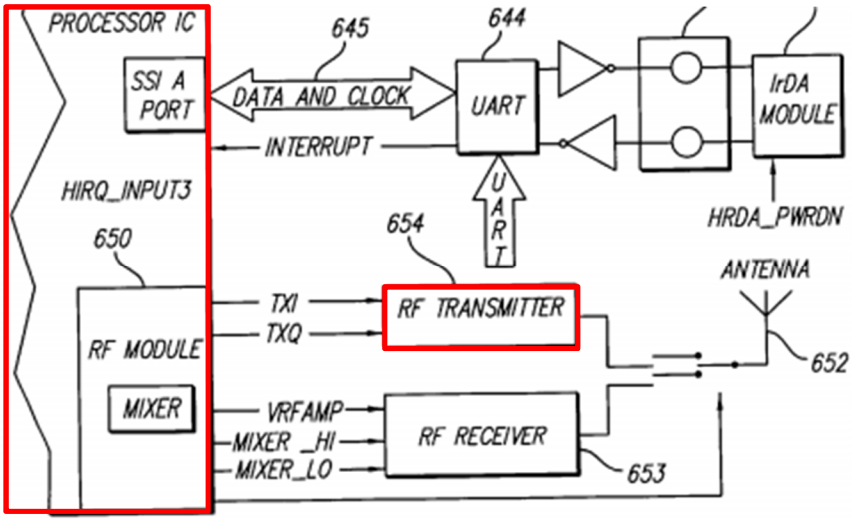


FIG. 7A

EX1003, Fig. 7A.



EX1003, Fig. 7D-1.

5. [3e]

As explained for limitations [1g] and [1h], *Meadows*, alone and with *John*, discloses and/or renders obvious that the computer-operable medium is programmed to change the amplitude applied to the first electrode by a first increment (e.g., 0.6 mA), and set the amplitude applied to the second electrode by a second increment (e.g., 0.4 mA) in direct proportion to the ratio of the first and second amplitude ranges (e.g., 3:2 ratio). EX1008, ¶ 129.

6. [3f]

As explained for limitations [1g], [1h], and [3d], *Meadows*, alone and with *John*, discloses and/or renders obvious that the IPG receives the change command from the HHP via telemetry circuitry (e.g., circuitry 172) and decodes the

command. EX1008, ¶ 130. In response to a command to increase or decrease the amplitude, the IPG performs the functions in limitation [3e]. *Id.*

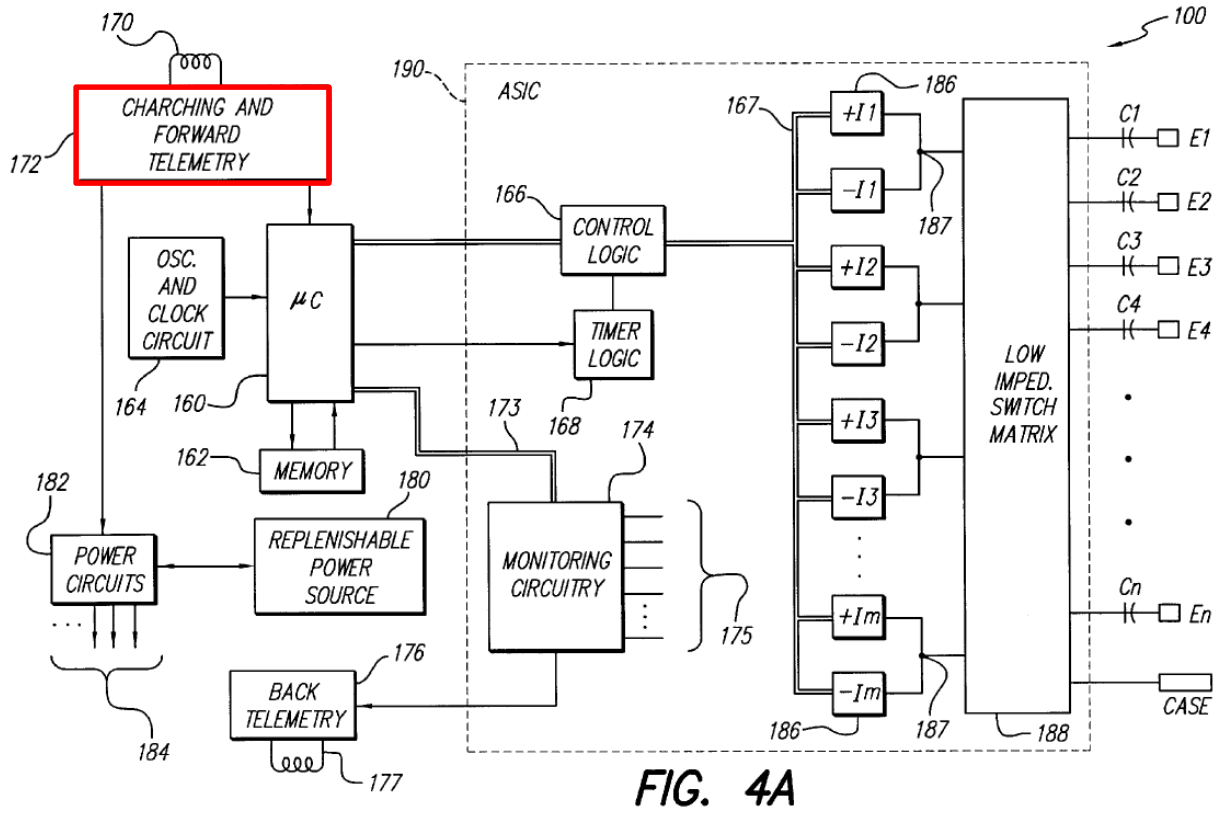
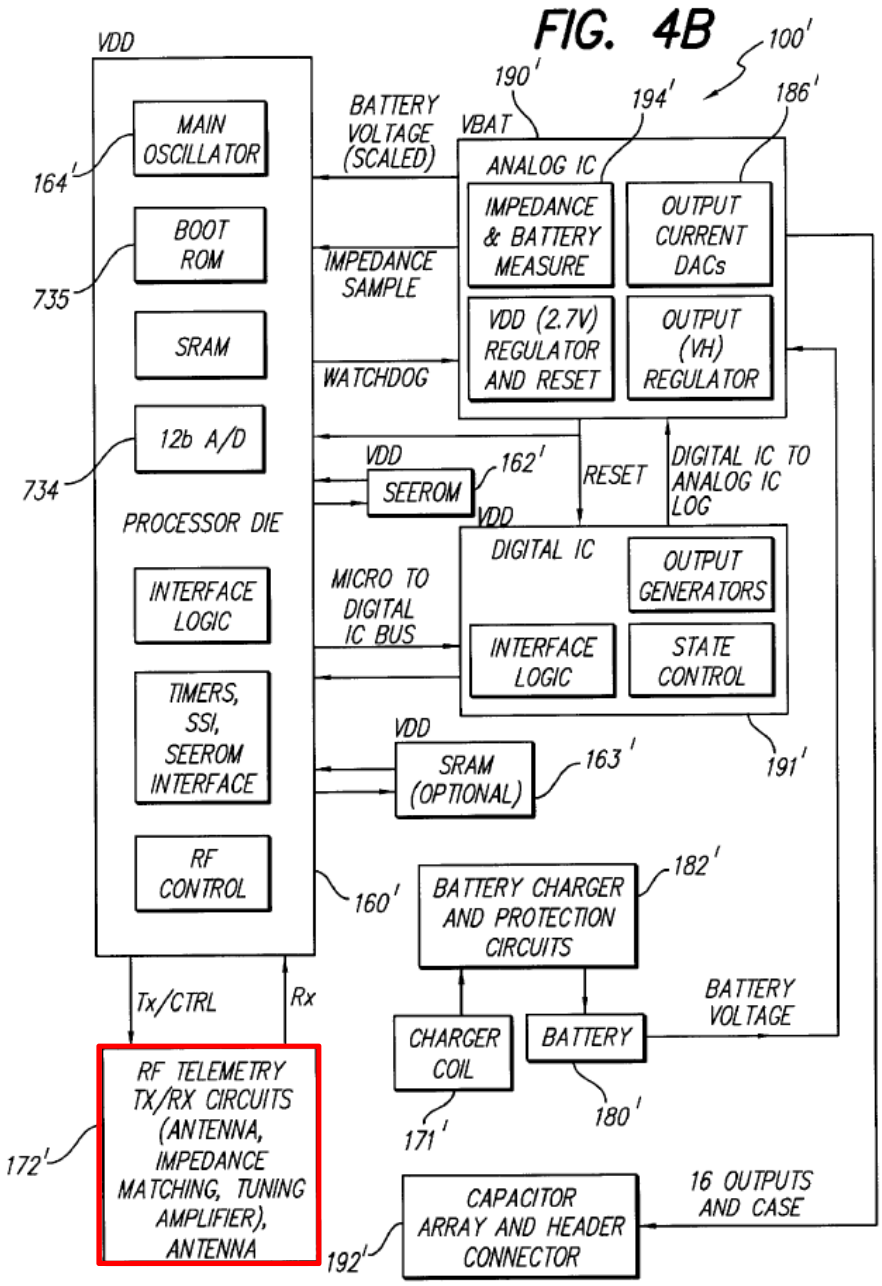


FIG. 4A

EX1003, Fig. 4A.



EX1003, Fig. 4B.

E. Claim 4

Claim 4 is anticipated and/or rendered obvious by *Meadows*, alone and with *John*. EX1008, ¶¶ 131-35. Claim 4 recites the limitations of claim 3, except

instead of setting the amplitude by a second increment "*in direct proportion to* the ratio" ([3e]), claim 4 recites "*according to the best-fit approximation of* the ratio" ([4e]).

Meadows, alone and with *John*, discloses and/or renders obvious claim 4 for the same reasons as claim 3, because setting the second amplitude "in direct proportion to the ratio" can result in setting the second amplitude "according to the best-fit approximation to the ratio" (e.g., for a 3:1 ratio, incrementing the first amplitude by 1 mA, and incrementing the second amplitude by 0.3 mA instead of 0.333… (1/3) mA). EX1008, ¶¶ 132-35. Conventional rounding or truncating of the second amplitude value is necessary to accommodate the finite resolution of the IPG. *Id.* No IPG has infinite resolution when adjusting parameters—e.g., one *Meadows* embodiment has 0.1 mA increments. EX1003, 13:18-20. A POSA would have known that setting the second amplitude "in direct proportion to the ratio" will necessarily require an approximation when the adjustment requires a finer resolution than the IPG allows. *Id.* A POSA would understand that *Meadows* discloses such approximation. *Id.*; EX1012, 13:9-14:2 ("increments of 8/9 mA, or approximately [] 0.89 mA").

If Nevro argues "best-fit approximation" is not disclosed, it would have been obvious. *Meadows*, through incorporated *Mann167*, teaches setting the amplitude applied to the second electrode according to an approximation. EX1012, 13:9-14:2

("increments of 8/9 mA, or approximately a 0.89 mA increase"; "other relationships, i.e., other than linear"). A POSA would have been motivated to use a "best-fit approximation" because it was well-known and may be required based on the IPG's capabilities. EX1008, ¶¶ 132-35. Programming a "best-fit approximation"—or any type of mathematical approximation—would have been a predictable design choice, requiring no hardware change, resulting in an expectation of success. *Id.*

If Nevro argues "best-fit approximation" is limited to the increment-the-same-or-hold-constant embodiment, it would have been obvious for the same reasons as claim 5. *Id.*

F. Claim 5

Claim 5 is rendered obvious by *Meadows*, alone and with *John*. EX1008, ¶¶ 136-37. Claim 5 limits claim 4 to require "changing the amplitude applied to the second electrode by the first change increment or holding the amplitude applied to the second electrode constant for each change command received by the implantable device."

Meadows, alone and with *John*, renders obvious claim 5 for the same reasons as claim 4 because claim 5 simply uses a mathematical formula to approximate the second increment. *Id.* According to the '461 Patent, conventional linked-mode systems were limited to "adjust[ing] the amplitudes equally across

each area," and thus, claim 5 recites a common-sense approach—and indeed the only option—for approximating the ratio in systems that only allow amplitudes to be incremented by the same amount or not at all. *Id.* Claim 5's technique is a predictable programming design choice that would have been obvious for a POSA to try among finite options. *Id.* Incrementing or holding constant requires only programming *Meadows'* IPG, without any hardware modifications, providing a reasonable expectation of success. *Id.*

G. Claim 6

Claim 6 is rendered obvious by *Meadows*, alone and with *John* and/or *Goetz*. EX1008, ¶¶ 138-46.

a. Grounds 2-3

Meadows, alone and with *John*, discloses and renders obvious "a memory containing a history of patient usage patterns of the waveform applied to the first and second electrodes," because it stores programming data and usage history in the IPG's memory—discussed for limitation [1f]—to generate program reports and determine thresholds. EX1003, 27:39-54 ("programmable settings stored within the implant system"), 33:38-57 ("patient-specific reports"; "reports may include … program report, i.e., the details of those programs used by the patient to provide stimulation … and the like; [and] the measurement history, i.e., a … representation of the measurements (…threshold and maximum levels) for each electrode"),

33:66-34:24; EX1008, ¶¶ 139-42. *Meadows* also discloses storing usage history in the programmer's memory for program reports and measurement history, including usage patterns of the waveform applied to the first and second electrodes. EX1003, 31:36-32:21 ("patient data[-]base"), 33:3-57, Figs. 6A-6B.

If Nevro argues that storing usage history in memory is not disclosed, it would have been obvious. EX1008, ¶ 140. *Meadows* teaches and motivates a POSA to store usage history for the purpose of generating reports, and a POSA would have had a reasonable expectation of success because it requires no hardware modifications to *Meadows*' processor-and-memory-based system, which can be predictably programmed to store usage history. *Id.* The '461 Patent discloses no configuration or algorithm for such storing. *Id.*

Meadows, alone and with *John*, renders obvious "the computer-operable medium is further programmed to calculate a ratio of the first parameter range to the second parameter range based on the history of patient usage patterns" in claim 6. EX1008, ¶ 141. As explained, *Meadows* teaches an IPG that is fully programmable with respect to changing and setting parameters, and *Meadows* discloses and renders obvious storing usage history, including in the IPG, to optimize stimulation programs and parameters. EX1008, ¶¶ 72-82, 139-42. *Meadows*, including through incorporated *Mann167*, teaches a need for this optimization. EX1003, 34:24-54 ("algorithms to automate the programming

process"); EX1012, 2:10-15 ("[w]hat is needed is a system and method … that automates much of the programming process"). *Meadows* also teaches using algorithms to automate determining the therapy ranges. EX1003, 33:66-35:62.

Thus, it would have been an obvious design choice to program the IPG to calculate a ratio of the first and second ranges based on usage history, e.g., using the automated algorithm in *Meadows*. EX1008, ¶ 142. A POSA would have been motivated to do so because it would optimize and automate the parameters, as *Meadows* suggests. *Id.* A POSA would have had a reasonable expectation of success because this limitation requires only predictable programming to calculate a number from available information. *Id.*

b. Grounds 4-5

Meadows, alone and with *John*, and further with *Goetz*, renders obvious claim 6. EX1008, ¶¶ 143-46. *Goetz* is prior art under § 102(b). *Id.*

Goetz discloses storing and maintaining patient programming data, including usage history, to identify optimum therapy programs in implantable SCS systems. EX1007, ¶¶ 1-8, 24. *Goetz* teaches an IPG's memory can store this data:

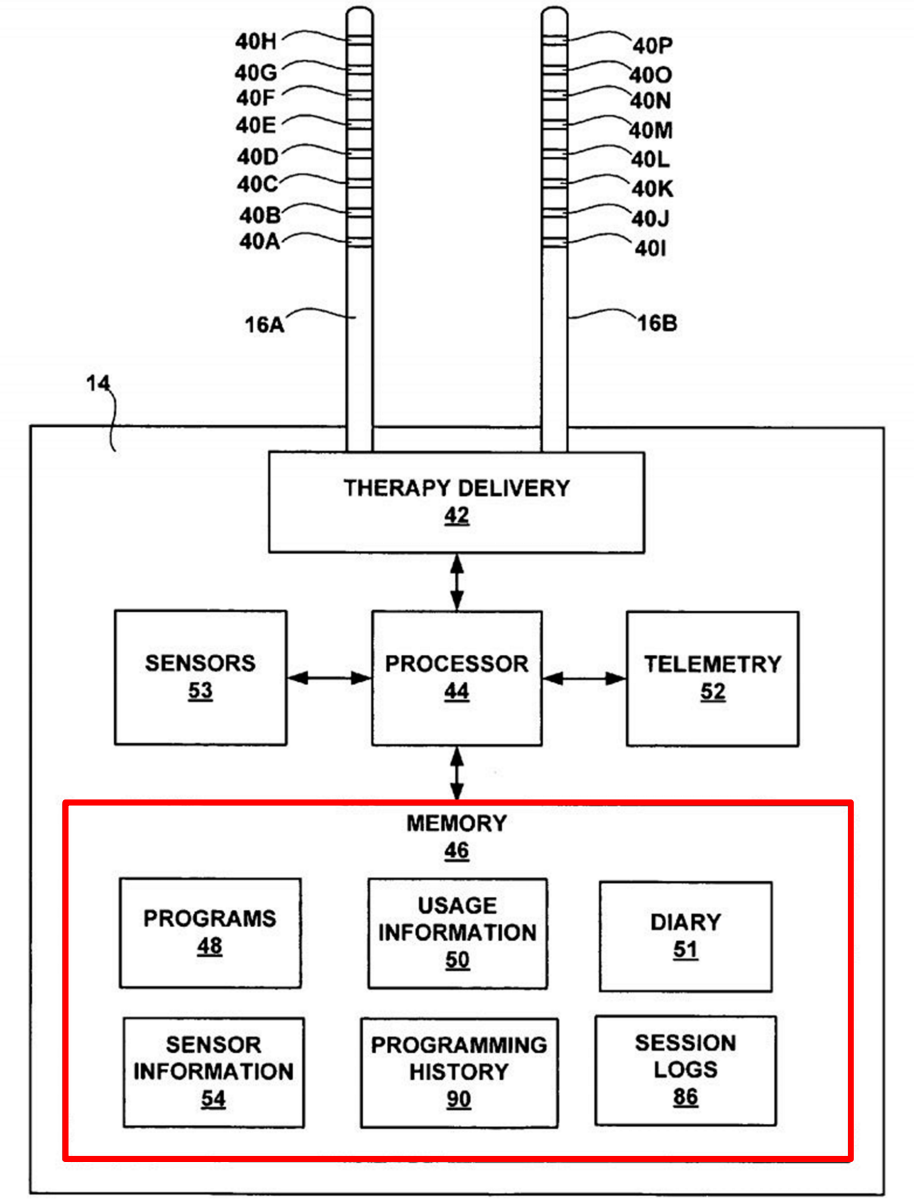


FIG. 2

EX1007, Fig. 2; *id.*, ¶¶ 8, 11-13, 16-20, 53-65, 115-19. Usage information refers to the "extent or times of use for one or more programs" and programming history can be "a record of programs, e.g., combinations of therapy parameters, tested during … prior programming sessions." *Id.* The programmer can analyze that data. *Id.*

A POSA would have been motivated to implement *Goetz*'s teachings on storing usage history in the memory of *Meadows*' IPG. EX1008, ¶¶ 145-46. Doing so would have been "advantageous in situations where [a patient] may visit a different clinic[ian]" or "where [the device] may communicate with different [external devices]." EX1007, ¶ 64. It would have been obvious to substitute the known elements of *Goetz* (e.g., programming data) for analogous elements in *Meadows* according to known methods, and the result of such substitution would have been predictable. EX1008, ¶¶ 145-46. *Meadows* discloses a substantially similar system as *Goetz*, making the data stored in memory easily interchangeable and requiring a mere programming change. *Id.*

Meadows, alone and with *John*, and further with *Goetz*, also renders obvious calculating "a ratio of the first parameter range to the second parameter range based on the history of patient usage patterns" for the same reasons above. *Id.* Also, *Goetz* teaches the programming data can be analyzed and used to "quickly identify[] … desirable programs" and improve therapy efficacy. EX1007, ¶¶ 8, 24.

H. Claim 7

Claim 7 is anticipated and/or rendered obvious by *Meadows*, alone and with *John* and/or *Goetz*. EX1008, ¶¶ 147-49. The "memory" limitation in claim 7 is disclosed and rendered obvious for the same reasons as the "memory" limitation in claim 6. *Id.*

Meadows, alone and with *John* and/or *Goetz*, also discloses and renders obvious "the computer-operable medium is further programmed to determine whether the first area of the patient is linked to the second area of the patient." EX1008, ¶ 148. As explained, *Meadows* discloses that any combination of electrodes may be linked or grouped into one or more channels, including electrodes at first and second areas. When a user activates a channel or group of channels, the IPG must determine which electrodes are associated with which channels, based on program settings stored in the device.

If Nevro argues this determination is not disclosed, it would have been a predictable, obvious design choice to program a determination in the IPG to determine whether the first and second areas are linked, e.g., a POSA would have been motivated to do so for increased optimization and functionality such as to determine and display which electrodes are included within a channel, or to implement the "linking rules" in *John*. EX1003, 18:41-53, 34:55-35:4, 38:22-39:14; EX1008, ¶ 149. The '461 Patent discloses no such algorithm for doing so, confirming a reasonable expectation of success.

I. Claim 8

Claim 8 is anticipated and/or rendered obvious by *Meadows*, alone and with *John* and/or *Goetz*, for the same reasons as claim 7. EX1008, ¶¶ 150-51. For example, if *Meadows*' IPG determines that the first and second areas are not

linked, the IPG is programmed to change the parameter applied to the first electrode and set the parameter applied to the second electrode independently, e.g., the user can manually change the independently programmable electrodes or the IPG can program the first and second electrodes independently when sequencing from the first electrode in one channel to the second electrode in a second channel, as explained for limitation [1h]. EX1003, 12:48-13:28 ("independently programmable"), 18:41-53 ("channel identifies which electrodes are selected"), 35:5-25 ("amplitude, pulse width and rate are adjustable … for the selected channel"), 38:22-54 ("associated channel may also be selected"; "For a highlighted (selected) electrode, the parameters may be adjusted").

J. Claim 10

Claim 10 is anticipated and/or rendered obvious by *Meadows*, alone and with *John*, for the same reasons as limitations [1b]-[1d], [1g], and [1h]. EX1008, ¶ 152. As explained, *Meadows*' IPG can apply any number of electrodes/areas, including the "additional electrode associated with an additional area." *Id.* *Meadows*, alone and with *John*, teaches and renders obvious grouping any combination of electrodes, including three electrodes at three areas, in one channel or in three separate channels, and setting the amplitude applied to the third electrode based on a ratio of the additional therapy range to the first or second therapy range. *Id.* *Meadows* discloses up to four channels, each with any

combination of electrodes, but it also would have been obvious to add an electrode at a third area having a therapy range, as the '461 Patent describes nothing patentably distinct about doing so. *Id.*

K. Claims 11-14

Claims 11-14 are anticipated and/or rendered obvious by *Meadows*, alone and with *John*, for the same reasons as:

Claim 11: claim 1 and limitations [3c] and [3d];

Claim 12: limitations [3e] and [3f];

Claim 13: limitations [4e] and [4f]; and

Claim 14: claim 5.

EX1008, ¶ 153.

L. Claim 15

Claim 15 is anticipated and/or rendered obvious by *Meadows*, alone and with *John*, for same reasons as limitations [3a], [3b], and [3d]-[3f]. EX1008, ¶¶ 154-58. Claim 15 recites substantially those limitations, except it recites "power" instead of "amplitude."

Meadows teaches modulating any parameter associated with the waveform, including a power parameter. EX1003, 31:21-29 ("setting amplitude, pulse width, rate, etc."), 46:48-47:6 ("stimulation systems depend upon the stability of the

devices to be able to convey electrical pulses of known energy"); EX1012, 11:26-12:9, 14:3-11; EX1013, 4:5-20, 9:12-17, 17:5-17, 37:10-15.

It would have been obvious to try, and a POSA would have been motivated to use, the design choice of a parameter comprising power—e.g., as Dr. Mihran explains, a parameter encompassing both amplitude and pulse width as *Meadows* teaches, such as an average power parameter—to control the "energy content" of the signal. EX1012, 14:3-11; EX1008, ¶¶ 155-58. It also would have been obvious because the power parameter was known and the number of parameters associated with electrical pulses used in SCS systems is finite. EX1008, ¶¶ 155-58. A POSA would have had a reasonable expectation of success in substituting power for amplitude because predictable programming is all that is required. *Id.* The '461 Patent describes no particular configuration or programming for a power parameter. *Id.*

M. Claim 16

Claim 16 is anticipated and/or rendered obvious by *Meadows*, alone and with *John*, for same reasons as limitations [4a], [4b], and [4d]-[4f] and claim 15. EX1008, ¶ 159. Claim 16 recites substantially the same limitations as claim 4, except it recites "power."

N. Claim 17

Claim 17 is anticipated and/or rendered obvious by *Meadows*, alone and with *John*, for same reasons as claims 5 and 15. EX1008, ¶ 160. Claim 17 recites substantially claim 5, except it recites "power."

VIII. GROUNDS 6-14: *THACKER* GROUNDS

Thacker anticipates and/or renders obvious all challenged claims, alone and with *Meadows*, *John*, and/or *Goetz*. EX1008, ¶¶ 161-197. *Thacker* incorporates *Meadows* and thus discloses and renders obvious these claims for the same reasons. Also, *Thacker* discloses an SCS system like *Meadows* and adds a third scenario where an IPG is programmed to "automatically set the waveform parameter applied to the second electrode" based on a therapy range ratio—i.e., a "global" adjustment feature that allows simultaneously changing and setting a parameter not only across multiple *electrodes*, but also across multiple *channels*. *Id.* *Thacker* discloses and renders obvious this third scenario in at least two ways: (1) *Meadows*' system using *Thacker*'s "global" adjustment feature, and (2) *Thacker*'s system using *Meadows*' "therapy ranges." *Id.* Both are referred to herein as the "*Thacker-Meadows* IPG."

Thacker is prior art under § 102(e) based on its filing date, July 10, 2009. *Id.* In addition, *Thacker* is entitled to the priority date of *Thacker187*—a July 11, 2008 provisional application—because *Thacker187* discloses all subject matter in

Thacker and supports at least one claim. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015). *Thacker187* and *Thacker* are substantially identical, and all disclosure in *Thacker* relied on here is in *Thacker187*. *Compare, e.g.*, EX1004, 14:57-15:67, Fig. 18, *with* EX1015, ¶¶ 89-91, Fig. 18. Claim 1 of *Thacker* is a method claim that is described verbatim and claimed in *Thacker187*. *Compare* EX1004, claim 1, *with* EX1015, ¶¶ 18-21, claims 1, 4; EX1017.

A. Overview of *Thacker*

Thacker discloses a system for managing pain by delivering waveforms to different areas of a patient. EX1004, 1:15-63, 2:21-3:12, 7:65-8:31, 9:39-53, 12:23-50, 15:10-43, Figs. 1-6; EX1008, ¶¶ 163-67. *Thacker*'s system comprises an implantable device (IPG 14) and leads with multiple electrodes. EX1004, 1:21-63, 2:34-46, 4:45-57, 6:4-23, Figs. 1-2.

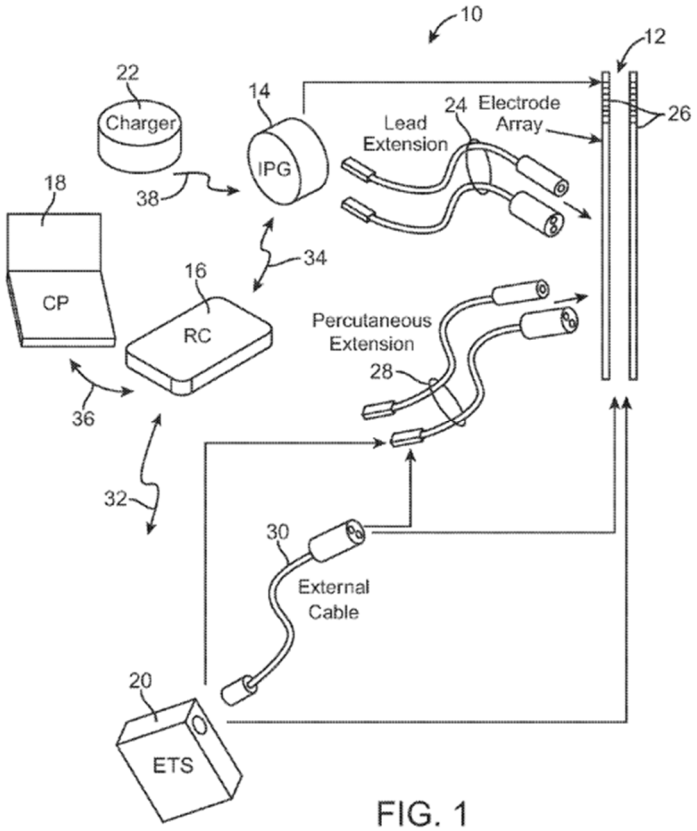


FIG. 1

Id., Fig. 1.

Thacker recognizes that patients perceive pain in different parts of the body that are associated with different areas relative to the spinal cord, and *Thacker*'s electrodes are at or adjacent to these areas. *Id.*, 1:64-3:12, 15:10-30. *Thacker*'s electrodes may be grouped in up to four channels, which *Thacker* calls "stimulation" or "coverage" areas. *Id.* A user may activate two or more coverage areas to stimulate multiple areas simultaneously. *Id.*, 2:64-3:12, 15:10-67, 19:47-61, 20:24-30, Figs. 16-20. When multiple areas are selected, *Thacker* provides a "global" adjustment feature that allows the user to adjust a parameter (e.g.,

amplitude), automatically and simultaneously, for those areas based on a therapy range ratio. *Id.*

Thacker incorporates *Meadows* to further describe "the detailed structure and function of IPGs," and thus, *Meadows* is part of *Thacker*. *Id.*, 10:19-23; *Paice*, 881 F.3d at 909; EX1008, ¶¶ 166-67. References to *Thacker* herein include its entire disclosure, including *Meadows*.

B. Claim 1

Claim 1 is anticipated and/or rendered obvious by *Thacker*, alone and with *Meadows* and/or *John*. EX1008, ¶¶ 168-186.

To the extent Nevro argues that *Thacker* does not sufficiently incorporate the cited disclosures of *Meadows* for any challenged claim, it would have been obvious to combine the teachings of *Thacker* and *Meadows* to achieve such limitation because *Thacker* teaches combining the features of its system with *Meadows'* system, including combining known features to similar systems in known, predictable ways to achieve beneficial functionality for the reasons described in *Thacker* and *Meadows*. EX1008, ¶ 169.

1. Limitations [1a]-[1f]

Because *Meadows* is part of *Thacker*, *Thacker* discloses and renders obvious limitations [1a]-[1f] for the same reasons as *Meadows*. EX1008, ¶ 170. *Thacker*

without *Meadows* also discloses and renders obvious limitations [1a]-[1c] and [1e]-[1f]. EX1008, ¶¶ 170-78.

[1a] *Thacker* discloses an SCS system that treats pain using electrical waveforms. EX1004, Abstract, 1:15-6:27, 7:65-12:50, 15:3-17:16, Figs. 1-6, 16-20; EX1008, ¶ 171.

[1b] *Thacker* discloses an implantable electrode device (e.g., array or lead) with multiple electrodes. EX1004, 1:47-6:55, 7:57-10:34, 12:51-19:3, Figs. 1-3, 9-10, 16; EX1008, ¶ 172.

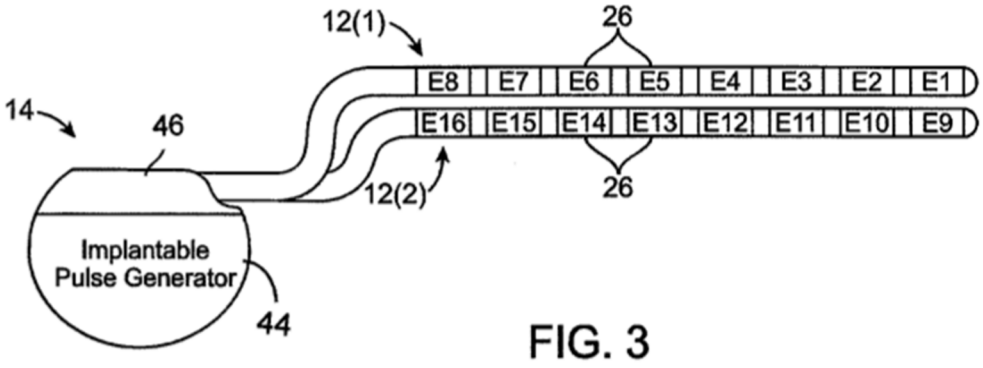


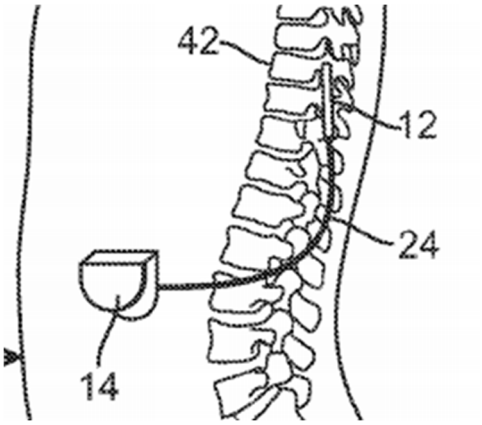
FIG. 3

EX1004, Fig. 3.

[1c] *Thacker* discloses and renders obvious an electrode device with electrodes at or adjacent different areas or sites relative to the spine when implanted. EX1004, 1:64-3:38 ("stimulation region or areas correlating to the pain"; "stimulation regions relative to the electrode array"), 6:12-23, 8:13-10:34, 12:23-50, 15:10-19:46 ("parameters … that correspond[] to the … area of the stimulation region"), 19:47-21:36, Figs. 1-3, 16-25; EX1008, ¶ 173.

[1d] *Thacker* discloses and renders obvious—through incorporation of *Meadows* and combined with *Meadows*—first and second areas having first and second therapy ranges for the same reasons as *Meadows*. *Supra* § VII.B.[1d]; EX1008, ¶ 174.

[1e] *Thacker* discloses an implantable device (IPG 14) connected to the electrode device (lead 12). EX1004, 1:21-63, 8:13-10:34, 14:42-15:67, 19:47-21:36, Figs. 1-3; EX1008, ¶ 175.



EX1004, Fig. 2 (partial).

[1f] *Thacker*'s IPG includes a power supply (battery), waveform generator (pulse generation circuitry), and computer-operable medium (controller and memory) connected to the waveform generator. EX1004, 1:21-2:46 ("control circuitry … power supply"), 4:45-57 ("controller that controls electrical stimulation"; "controller stores a set of programmed stimulation parameters"), 6:4-11 ("computer[-]readable medium for programming"), 7:66-9:53 ("IPG 14 includes

a battery and pulse generation circuitry that delivers electrical stimulation energy … in accordance with a set of stimulation parameters programmed into the IPG"), 10:6-11:7, 20:38-59, Figs. 1-3; EX1008, ¶¶ 176-78.

2. Limitations [1g]-[1h]

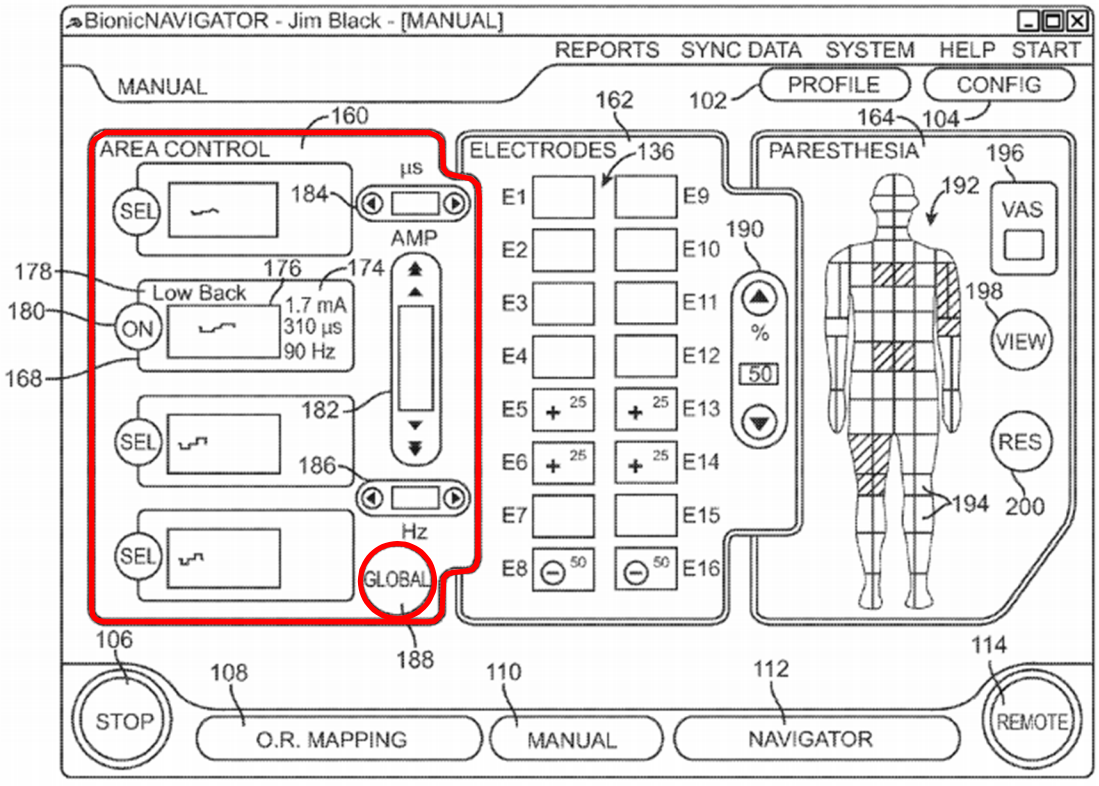
Thacker discloses and/or renders obvious limitations [1g]-[1h], alone and with *Meadows* and/or *John*. *Supra* § VII.B.[1g]-[1h] (*Thacker* through incorporated *Meadows*); EX1008, ¶¶ 179-86. If the Board construes "based on a relationship" to require using the first increment, such as using the disclosed "product" of the first increment and the relationship, *Thacker*, alone and with *Meadows* and/or *John*, renders obvious limitation [1h]. *Id.* If the Board applies a broader construction, such as "in accordance with a relationship" or Nevro's "non-technical, ordinary" meaning, *Thacker*, alone and with *Meadows* and/or *John*, discloses and renders obvious limitation [1h]. *Id.*

a. Grounds 6-8

Thacker discloses a fully programmable, multi-channel stimulation system. EX1008, ¶ 180. *Thacker* teaches that electrodes, in any combination, may be grouped into "channels" (or "stimulation"/"coverage" areas), and the *Thacker-Meadows* IPG can provide stimulation simultaneously on multiple channels. EX1004, 1:64-2:7 ("combination of electrodes used to deliver electrical pulses"), 2:64-3:12 ("stimulation … areas correlating to the pain"), 15:10-30 ("four

coverage areas 166-172 with which up to four stimulation parameter sets can respectively be associated to create a stimulation program").

Thacker teaches that, by selecting a "global" button, a user may select two or more coverage areas and "globally" adjust a parameter (e.g., amplitude) simultaneously for the electrodes in multiple selected areas based on a therapy range ratio between those areas, as explained for limitation [1h] in the *Meadows* grounds. EX1004, 2:64-3:12, 14:57-65, 15:10-67 ("four coverage areas with different electrical pulse parameters can be activated"; "coverage areas 166-172 can be simultaneously activated"; "global button … can be clicked … to globally modify … amplitude of selected … coverage areas"), 19:47-61 ("multiple coverage areas … can be simultaneously stimulated"), 20:24-30, Figs. 16-20; EX1008, ¶ 181.



EX1004, Fig. 18.

Thacker discloses incorporating "global" adjustment into any IPG (e.g., the *Thacker-Meadows* IPG), and it would have been obvious to do so. EX1004, 7:66-8:12 ("invention may be used with any type of implantable electrical circuitry used to stimulate"); EX1008, ¶ 182. When the user sends a change command to the *Thacker-Meadows* IPG using "global" adjustment, the IPG is programmed to change the parameter (e.g., amplitude) applied to the first electrode in the first channel (e.g., from level 1 to 2), and automatically set the parameter of the second electrode in the second channel (e.g., amplitude at level 2) based on a therapy

range ratio (e.g., 3:2 ratio), as explained for limitation [1h] in the *Meadows* grounds.

A POSA would have been motivated to implement either *Thacker*'s "global" adjustment into *Meadows*' system or *Meadows*' "therapy ranges" into *Thacker*'s system to achieve the claimed programming because the references expressly teach doing so and it would involve improving the similar system in *Meadows* or *Thacker* in the same way and according to known methods. EX1004, 10:19-23; EX1008, ¶ 183. "Global" adjustment and "therapy ranges" were known elements and implementing these features would have been predictable, requiring only programming changes—providing a reasonable expectation of success. *Id.* Allowing a user to globally adjust parameters for multiple channels/areas (or to set therapy ranges for those parameters) would, as *Thacker* teaches, improve efficiency, reduce the number of manual adjustments, and provide a simpler method of programming for *Meadows*' system. *Id.*

If Nevro argues that *Thacker* does not disclose limitation [1h] (or any other programming limitation herein) because the programming is not inside the IPG, it would have been obvious to program the *Thacker-Meadows* IPG with the claimed functionality for the same reasons in the *Meadows* grounds. *Supra* § VII.B.[1h]; EX1008, ¶ 184.

If Nevro argues that *Thacker* does not disclose the "based on a relationship between the first therapy range and the second therapy range" limitation, it would have been obvious to program the *Thacker-Meadows* IPG to automatically set the parameter of the second electrode based on the claimed relationship, e.g., setting the parameter in accordance with the therapy range ratio or, alternatively, using the product of the first increment and the therapy range ratio, for the same reasons in the *Meadows* grounds. *Supra* § VII.B.[1h]; EX1008, ¶ 185.

b. Grounds 9-10

Thacker, alone and with *Meadows*, and further with *John* also renders obvious limitation [1h], for the same reasons as *Meadows* with *John* because *Thacker* discloses a programmable IPG like *Meadows*. *Supra* § VII.B.[1h]; EX1008, ¶ 186. As explained, it would have been obvious to program the *Thacker-Meadows* IPG to use a "linking rule," as *John* teaches, between first and second electrodes so that when a user changes the amplitude of the first electrode, the IPG automatically sets the amplitude applied to the second electrode based on a therapy range ratio—e.g., according to a "linking rule" that uses the product of the first increment and the therapy range ratio. EX1008, ¶ 186. *Thacker* teaches its invention may be used with DBS systems, like *John* discloses. EX1004, 8:3-12.

C. Claim 2

Claim 2 is anticipated and/or rendered obvious by *Thacker*, alone and with *Meadows* and/or *John*, as explained for limitations [1d], [1g], and [1h] above and for the same reasons as claim 2 in the *Meadows* grounds. EX1008, ¶ 187.

D. Claim 3

Claim 3 is anticipated and/or rendered obvious by *Thacker*, alone and with *Meadows* and/or *John*, as explained for limitations [1d], [1g], and [1h] above and for the same reasons as claim 3 in the *Meadows* grounds. EX1008, ¶¶ 188-89. As explained, a user can use the "global" adjustment feature to change the amplitude of multiple channels. When the user sends a change command, the *Thacker-Meadows* IPG changes the amplitude of the first electrode in the first channel, and automatically sets the amplitude of the second electrode in the second channel in direct proportion to the ratio of the first and second amplitude ranges.

Thacker also discloses a patient input device (remote control) having a controller (processor) that generates a change command (when a user presses the up or down button) and a transmitter (telemetry circuitry) configured to transmit the change command to the IPG. EX1004, 8:13-18 (" external remote controller RC 16"), 8:46-58, 10:35-11:27 ("RC 16 generally includes a processor 64"); EX1008, ¶ 189.

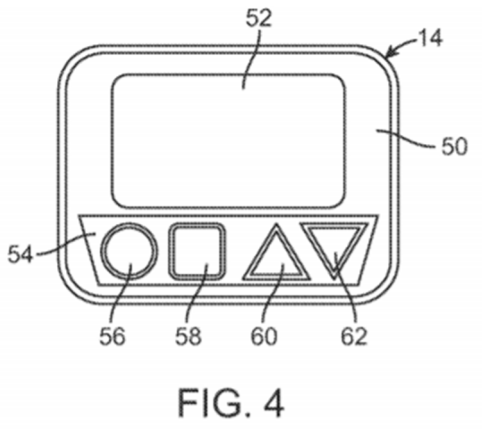


FIG. 4

EX1004, Fig. 4.

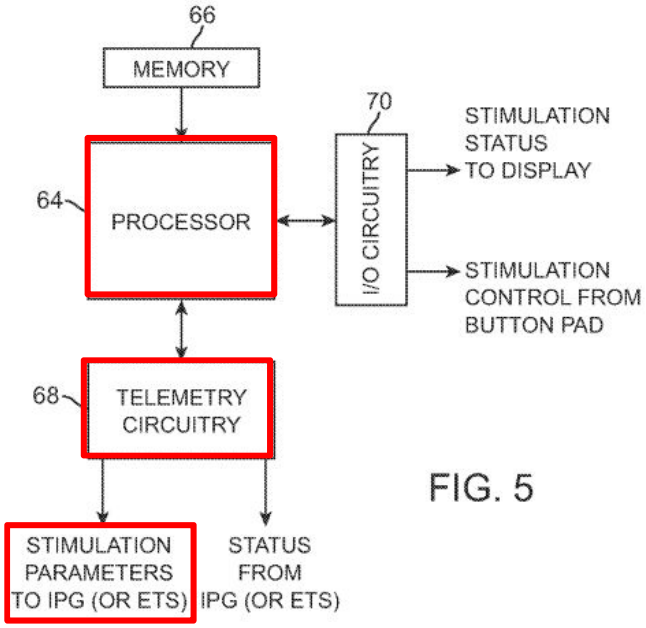


FIG. 5

Id., Fig. 5.

E. Claim 4

Claim 4 is anticipated and/or rendered obvious by *Thacker*, alone and with *Meadows* and/or *John*, for the same reasons as claim 3 above, and as claim 4 in the *Meadows* grounds. EX1008, ¶ 190.

F. Claim 5

Claim 5 is rendered obvious by *Thacker*, alone and with *Meadows* and/or *John*, for the same reasons as claim 4 above, and as claim 5 in the *Meadows* grounds. EX1008, ¶ 191.

G. Claim 6

Claim 6 is rendered obvious by *Thacker*, alone and with *Meadows*, *John*, and/or *Goetz*, for the same reasons as claim 6 in the *Meadows* grounds. EX1008, ¶ 192.

H. Claim 7

Claim 7 is anticipated and/or rendered obvious by *Thacker*, alone and with *Meadows*, *John*, and/or *Goetz*, for the same reasons as claim 6 above, and as claim 7 in the *Meadows* grounds. EX1008, ¶¶ 193-94.

Thacker also discloses and renders obvious that "the computer-operable medium is further programmed to determine whether the first area of the patient is linked to the second area of the patient." *Id.* As explained, *Thacker* discloses that channels or coverage areas (each having any combination of electrodes) may be linked or grouped into a program. For "global" adjustment, the *Thacker-Meadows* IPG determines which channels/areas are linked based on program settings stored in the device.

I. Claim 8

Claim 8 is anticipated and/or rendered obvious by *Thacker*, alone and with *Meadows*, *John*, and/or *Goetz*, for the same reasons as claim 7 above, and as claim 8 in the *Meadows* grounds. EX1008, ¶ 195.

J. Claim 10

Claim 10 is anticipated and/or rendered obvious by *Thacker*, alone and with *Meadows* and/or *John*, as explained for limitations [1b]-[1d], [1g], and [1h] above, and for the same reasons as claim 10 in the *Meadows* grounds. EX1008, ¶ 196. *Thacker* discloses up to four channels/areas, each having any combination of electrodes, including the "additional electrode associated with an additional area."

K. Claims 11-17

Claims 11-17 are anticipated and/or rendered obvious by *Thacker*, alone and with *Meadows* and/or *John*, for the same reasons as claims 11-17 in the *Meadows* grounds based on the corresponding limitations in the *Thacker* grounds. EX1008, ¶ 197.

IX. GROUNDS 15-23: *NOLAN* GROUNDS

Nolan anticipates and/or renders obvious all challenged claims, alone and with *Meadows*, *John*, and/or *Goetz*. EX1008, ¶¶ 198-231. *Nolan* discloses an SCS system with a fully programmable IPG connected to electrodes in different "programs," each having a therapy range. The programs may be combined into a

"group." Like *Thacker*, *Nolan* discloses "global" adjustment to allow adjusting a parameter for a group of programs simultaneously, thus disclosing an IPG programmed to automatically set the parameter applied to a second electrode "based on a relationship" between first and second therapy ranges—e.g., based on a therapy range ratio. *Id.*

Nolan is prior art under § 102(b). *Id.* In March 2018, the European Opposition Division found a substantively identical claim to claim 1 of the '461 Patent lacked novelty in view of *Nolan*. *Id.*, ¶ 200 (side-by-side comparison); EX1030, 1-4, 10; EX1031.

A. Overview of *Nolan*

Nolan discloses an SCS system for managing pain by delivering electrical stimulation to different areas. EX1005, ¶¶ 2, 27-28; EX1008, ¶¶ 201-03. *Nolan*'s system has an implantable device (IMD 14) and leads 16. EX1005, ¶¶ 2, 27-34.

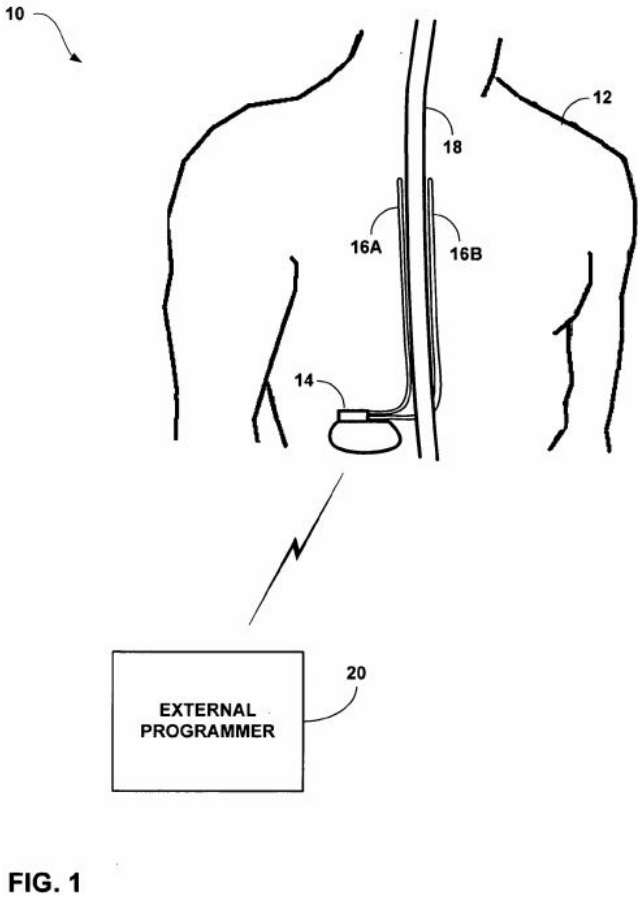


FIG. 1

EX1005, Fig. 1.

Nolan recognizes that patients perceive pain in different parts of the body that are associated with different areas relative to the spinal cord, and *Nolan*'s electrodes are located at or adjacent to these different areas. EX1005, ¶¶ 2-3, 25-34. Any combination of *Nolan*'s electrodes may be combined into multiple programs, correlating to multiple areas. *Id.*, ¶¶ 2-3, 25-26, 29-30, 52, 73, 85. A user may select multiple programs to apply stimulation at multiple areas to treat different regions of pain simultaneously. *Id.*, ¶¶ 4-6, 11, 25-33, 40-47, 94, claim 7. *Nolan* allows the user to "globally" adjust a parameter (e.g., amplitude),

automatically and simultaneously, for those programs based on a therapy range ratio. *Id.*, ¶¶ Abstract, 5-6, 24-25, 30-35, 40-51, 56-66, 69-75, 78-98.

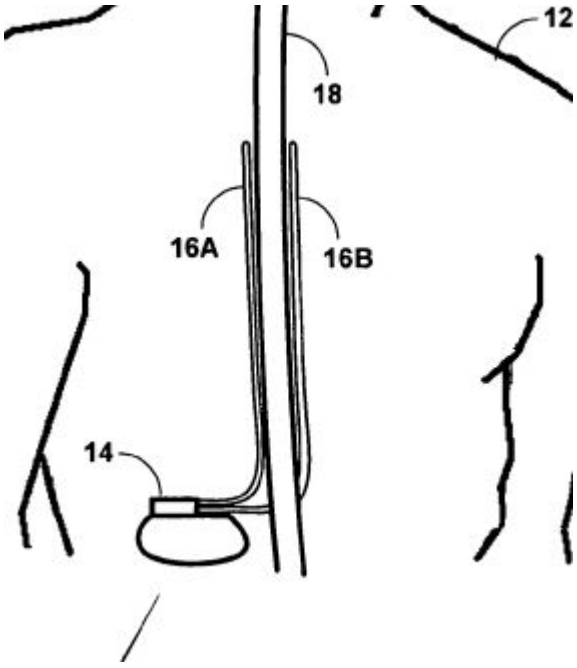
B. Claim 1

Claim 1 is anticipated and/or rendered obvious by *Nolan*, alone and with *Meadows* and/or *John*. EX1008, ¶¶ 204-219.

1. Limitations [1a]-[1f]

[1a] *Nolan* discloses an SCS system that treats pain using electrical waveforms. EX1005, ¶¶ Abstract, 1-3, 5-12, 22-35, Figs. 1-9; EX1008, ¶ 205.

[1b]-[1c] *Nolan* discloses implantable leads with multiple electrodes, that when implanted, are at or adjacent to different areas relative to the spine. EX1005, ¶¶ 2-3, 25-30, 32, 34-35, 71; EX1008, ¶ 206.



EX1005, Fig. 1 (partial).

[1d] *Nolan* discloses first and second areas having first and second therapy ranges based on "measurements" to determine the range of a parameter (e.g., amplitude) from a "perception" threshold (in **blue** below) to a "discomfort" threshold (in **red** below). EX1005, ¶¶ 26, 42, 52-53 ("limits are set such that patient 12 will not encounter uncomfortable stimulation past the maximum limit nor receive stimulation below the minimum limit that is known to be effective"), 54-66 ("lower limit may be a measured perception threshold and the upper limit may be a measured discomfort threshold"), 67-71, 92, Figs. 4A-4B, claims 10, 14; EX1008, ¶ 207.

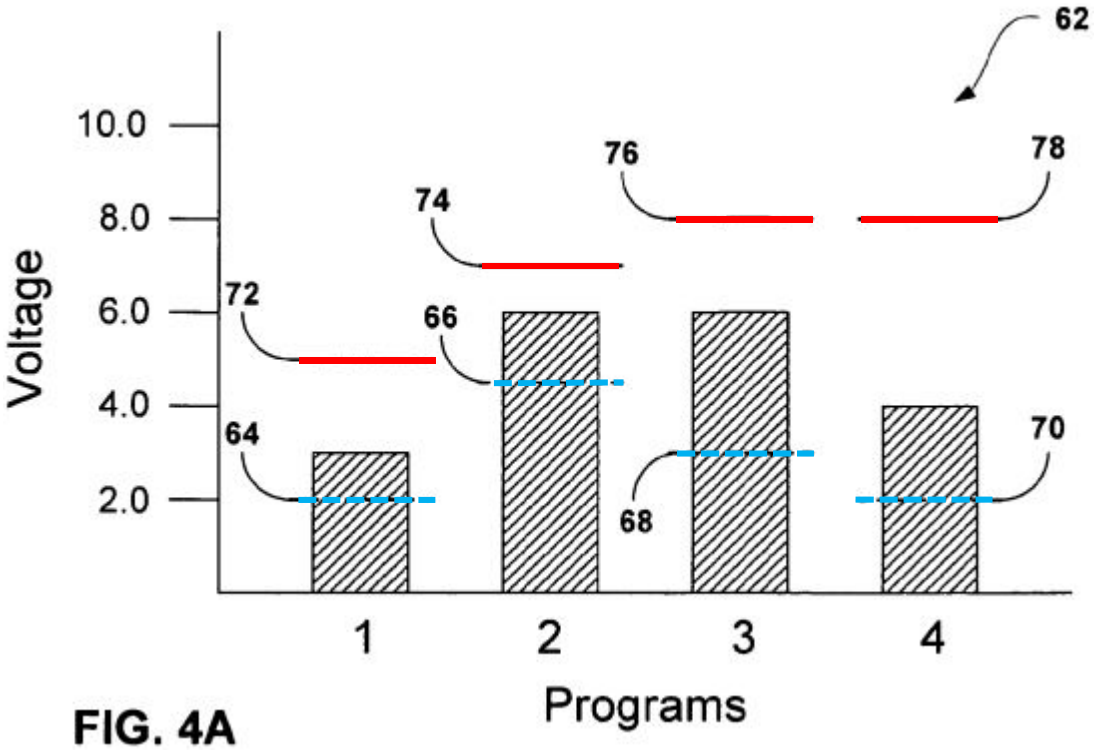
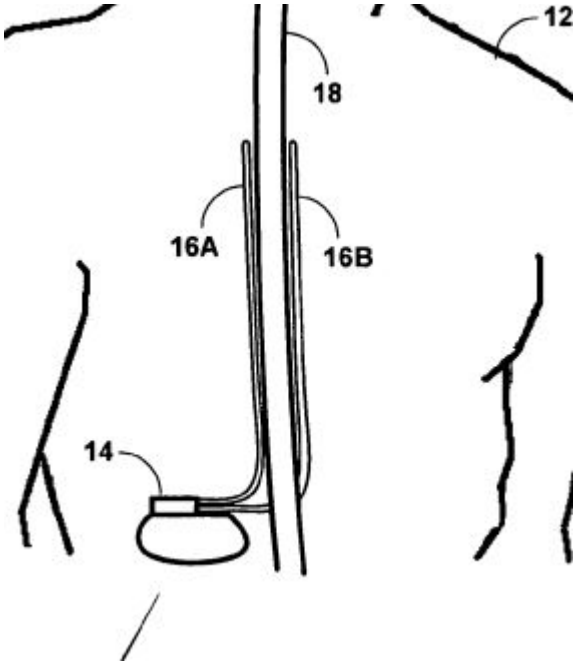


FIG. 4A

EX1005, Fig. 4A. *Nolan* discloses mapping these ranges to levels that can be adjusted. *Id.*, ¶¶ 6 ("step value calculated for each stimulation program to keep

parameter ratios equal between the plurality of stimulation programs during the global adjustment"), 24-26, 42 ("programs may have different adjustment step sizes, maximum, cumulative adjustments, or parameter minima or maxima"), 57 ("global adjustment feature has increased … amplitude of each program 1-4 by the same percentage of the adjustment range for each program"; "adjustment range for each program was divided by a resolution value … to calculate a step value"), 58-60, 61-64 ("global adjustment may cause the voltage amplitude of each stimulation program to change proportionately to one another"), 65-68, 92.

[1e] *Nolan* discloses an implantable medical device (IMD) connected to leads. EX1005, ¶¶ 2-4, 25-34 ("IMD 14 delivers stimulation therapy … via leads 16A and 16B"), 49; EX1008, ¶ 208.



EX1005, Fig. 1 (partial).

[1f] *Nolan*'s IMD includes a power supply (battery), waveform generator (pulse generator), and computer-operable medium (processor and memory) connected to the waveform generator. EX1005, ¶¶ 2 ("implantable pulse generator (IPG)"), 6, 10, 25 ("programs stored within an implantable medical device (IMD), including an [IPG]"), 27-28, 33, 37, 50, 52, 72 ("IMD battery"), 76, 85, 99 ("one or more processors"; "several different types of storage methods to hold computer-readable instructions"), Fig. 5, claims 1-17, 32-38; EX1008, ¶ 209.

If Nevro argues "computer-operable medium" is not disclosed, including one in *Nolan*'s IMD would have been obvious because programmable IMDs with a processor and memory were conventional. EX1008, ¶¶ 209-10. A POSA would have been motivated to incorporate a computer-operable medium, like *Meadows* discloses, into *Nolan*'s IMD ("*Nolan-Meadows* IMD") to change and set parameters for the electrical stimulation. *Id.* It would have been obvious to incorporate the known computer-operable medium of *Meadows* into the similar *Nolan* IMD, according to known methods, to improve efficiency/operability, and the result would have been predictable, offering a reasonable expectation of success.

2. Limitations [1g]-[1h]

Nolan discloses and/or renders obvious limitations [1g]-[1h], alone and with *Meadows* and/or *John*. EX1008, ¶¶ 211-19. If the Board construes "based on a

relationship" to require using the first increment, such as using the disclosed "product" of the first increment and the relationship, *Nolan*, alone and with *Meadows* and/or *John*, renders obvious limitation [1h]. *Id.* If the Board applies a broader construction, such as "in accordance with a relationship" or Nevro's "non-technical, ordinary" meaning, *Nolan*, alone and with *Meadows* and/or *John*, discloses and renders obvious limitation [1h]. *Id.*

a. Grounds 15-17

As explained, *Nolan*, alone and with *Meadows*, discloses and renders obvious a programmable, multi-channel stimulation system. EX1008, ¶¶ 212-18. *Nolan* teaches that electrodes, in any combination, are grouped into "programs" having therapy ranges and correlating to different areas, and the IMD provides stimulation simultaneously on multiple programs. EX1005, ¶¶ 5 ("parameter may be readily adjusted across several programs simultaneously"), 26, 48.

Like *Thacker*, *Nolan* teaches that, with "global" adjustment, a user may select two or more programs and "globally" adjust a parameter (e.g., amplitude) simultaneously for the selected programs based on a therapy range ratio between those programs. EX1005, ¶¶ 5-6 ("single command … make the parameter change on a 'global' basis among a plurality of stimulation programs"), 26, 52-69, 78-98, Figs. 4A-4B, 6-9; EX1008, ¶ 213.

Nolan discloses implementing "global" adjustment in the IMD, and it would have been obvious to do so. EX1005, ¶¶ 10, 48-49 ("global adjustments to IMD 14 may be governed by system 10 functionality, power conservation, or the implementation of the global adjustment"), 99, claims 1-17, 32-38; EX1008, ¶ 214. When the user sends a change command to the IMD, it is programmed to change the parameter applied to the first electrode in the first program (e.g., from level 1 to 2), and automatically set the parameter of the second electrode in the second program (e.g., the amplitude at level 2) based on a ratio of the first and second therapy ranges (e.g., 3:2 ratio), as explained for limitation [1h] in the *Meadows* grounds. EX1008, ¶ 214.

If Nevro argues that *Nolan* does not disclose limitation [1h] (or any other programming limitation herein) because the programming is not inside the IMD, it would have been obvious to program the *Nolan* IMD and *Nolan-Meadows* IMD with the claimed functionality for the same reasons in the *Meadows* grounds. *Supra* § VII.B.[1h]; EX1008, ¶ 215.

If Nevro argues that *Nolan* does not disclose the "based on a relationship between the first therapy range and the second therapy range" limitation, it would have been obvious to program the *Nolan* IMD and *Nolan-Meadows* IMD, to automatically set the parameter of the second electrode based on the claimed relationship, e.g., setting the parameter in accordance with the therapy range ratio

or, alternatively, using the product of the first increment and the therapy range ratio, for the same reasons in the *Meadows* grounds. *Supra* § VII.B.[1h]; EX1008, ¶ 216.

It would have been further obvious because *Nolan* discloses using "ratios between the programs" for "global" adjustment. EX1005, ¶¶ 6 ("step value calculated for each stimulation program to keep parameter ratios equal between … stimulation programs"), 24 ("magnitude of the adjustment may be different in each stimulation program to maintain current or predefined amplitude ratios between the programs"), 30, 64 ("global adjustment may cause … each stimulation program to change proportionately to one another"), 69 ("result is the ratio that is multiplied by the step value"); EX1008, ¶¶ 217-18.

Thus, it would have been obvious to program the *Nolan* IMD and *Nolan-Meadows* IMD such that, when the user sends a change command to change the amplitude applied to the first electrode in the first program (e.g., using a first step value), the IMD automatically sets the amplitude of the second electrode in the second program based on a therapy range ratio—e.g., setting the parameter in accordance with the therapy range ratio or, alternatively, using the product of the first increment and the therapy range ratio. In view of *Nolan*'s teachings on calculating a ratio, it would have been an obvious design choice and predictable to calculate the ratio between the first and second therapy ranges and multiply that

ratio with the first increment because doing so would have simply required programming a mathematical equation according to known methods, resulting in a reasonable expectation of success. EX1008, ¶ 218.

b. Grounds 18-19

Nolan, alone and with *Meadows*, and further with *John* also renders obvious limitation [1h], for the same reasons as *Meadows* with *John* because the *Nolan* IMD and *Nolan-Meadows* IMD are programmable like the *Meadows* IPG. *Supra* § VII.B.[1h]; EX1008, ¶ 219. As explained, it would have been obvious to program the *Nolan* IMD and *Nolan-Meadows* IMD, to use a "linking rule" between first and second electrodes so that when a user changes the magnitude level of the first electrode, the IMD automatically sets the amplitude applied to the second electrode based on a therapy range ratio—e.g., according to a "linking rule" that uses the product of the first increment and the therapy range ratio. EX1008, ¶ 219. *Nolan* teaches its invention may be used with DBS systems, like *John* discloses. EX1005, ¶ 34.

C. Claim 2

Claim 2 is anticipated and/or rendered obvious by *Nolan*, alone and with *Meadows* and/or *John*, as explained for limitations [1d], [1g], and [1h] above, and for the same reasons as claim 2 in the *Meadows* grounds. EX1008, ¶ 220.

D. Claim 3

Claim 3 is anticipated and/or rendered obvious by *Nolan*, alone and with *Meadows* and/or *John*, as explained for limitations [1d], [1g], and [1h] above, and for the same reasons as claim 3 in the *Meadows* grounds. EX1008, ¶¶ 221-23. As explained, a user can select multiple programs in the *Nolan* IMD and *Nolan-Meadows* IMD, and use "global" adjustment to simultaneously change their amplitude. When the user sends a change command, the IMD changes the amplitude of the first electrode in the first program, and automatically sets the amplitude of the second electrode in the second program in direct proportion to the ratio of the first and second amplitude ranges. *Id.*

Nolan discloses and renders obvious a patient input device (external programmer) having a controller (processor) that generates a change command (when the increase or decrease button is pressed) and a transmitter (telemetry interface) configured to transmit the change command to the IPG. *Id.*; EX1004, ¶¶ 31-33, 36-51 ("interface 58 may communicate with IMD 14 regarding global adjustments in separate commands for each program … or as one command covering all programs"), Figs. 2-3.

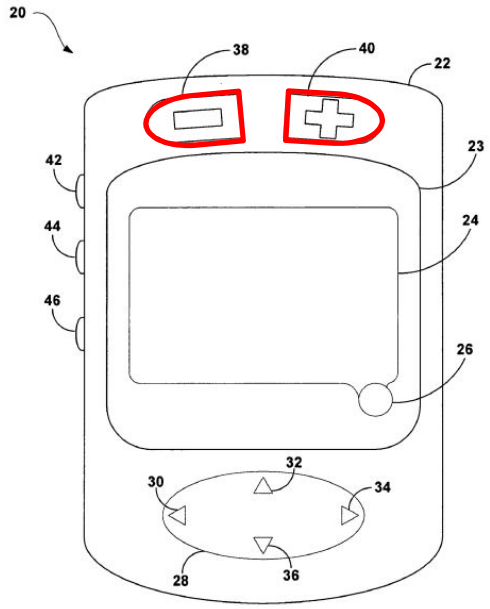


FIG. 2

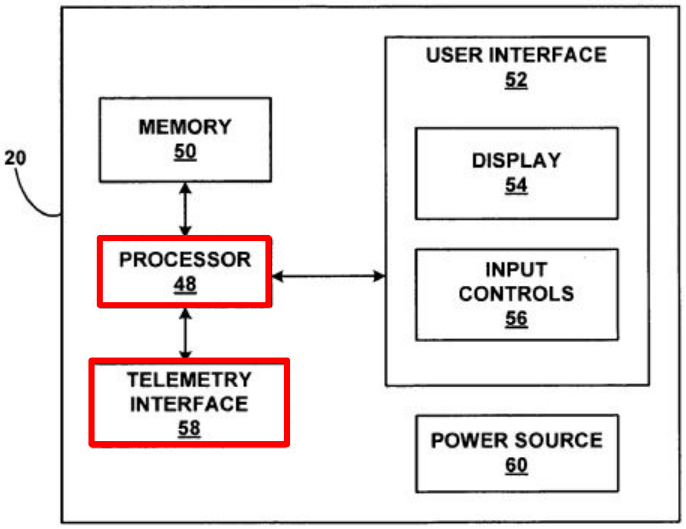


FIG. 3

EX1005, Figs. 2-3.

E. Claim 4

Claim 4 is anticipated and/or rendered obvious by *Nolan*, alone and with *Meadows* and/or *John*, for the same reasons as claim 3 above, and claim 4 in the *Meadows* grounds. EX1008, ¶ 224.

F. Claim 5

Claim 5 is anticipated and/or rendered obvious by *Nolan*, alone and with *Meadows* and/or *John*, for the same reasons as claim 4 above, and claim 5 in the *Meadows* grounds. EX1008, ¶ 225.

G. Claim 6

Claim 6 is rendered obvious by *Nolan*, alone and with *Meadows*, *John*, and/or *Goetz*, for the same reasons as claim 6 in the *Meadows* grounds. EX1008, ¶ 226.

Nolan also discloses a programmable device that can store data to determine threshold values and maintain ratios when parameters are adjusted. *Id.*; EX1005, ¶¶ 25, 33, 48 ("memory 50 may store all stimulation programs programmed and their original and most recent set of parameter values"), 52, 70-71.

H. Claim 7

Claim 7 is rendered obvious by *Nolan*, alone and with *Meadows*, *John*, and/or *Goetz*, for the same reasons as claim 6 above, and claim 7 in the *Meadows* grounds. EX1008, ¶¶ 227-28.

Nolan also discloses and renders obvious programming "to determine whether the first area of the patient is linked to the second area of the patient." *Id.* As explained, *Nolan* discloses that programs (having any combination of electrodes) may be linked into a group, including electrodes at first and second areas. For "global" adjustment, the *Nolan* IMD and *Nolan-Meadows* IMD determine which programs (and corresponding electrodes) are linked based on program settings stored in the device. EX1005, ¶¶ 41 ("select one or more programs within a group …, and then apply the parameter adjustment to such

programs"), 94 ("processor [] determines if another program in the group needs to be adjusted").

I. Claim 8

Claim 8 is rendered obvious by *Nolan*, alone and with *Meadows*, *John*, and/or *Goetz*, for the same reasons as claim 7 above, and claim 8 in the *Meadows* grounds. EX1008, ¶ 229.

J. Claim 10

Claim 10 is anticipated and/or rendered obvious by *Nolan*, alone and with *Meadows* and/or *John*, as explained for limitations [1b]-[1d], [1g], and [1h] above, and for the same reasons as claim 10 in the *Meadows* grounds. EX1008, ¶ 230. *Nolan* discloses up to four programs, each with any combination of electrodes, including the "additional electrode associated with an additional area." *Id.*

K. Claims 11-17

Claims 11-17 are anticipated and/or rendered obvious by *Nolan*, alone and with *Meadows* and/or *John*, for the same reasons as claims 11-17 in the *Meadows* grounds based on the corresponding limitations in the *Nolan* grounds. EX1008, ¶ 231.

X. THE BOARD SHOULD INSTITUTE REVIEW

A. 35 U.S.C. § 314(a)

The *Fintiv* factors support institution. *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 (P.T.A.B. Mar. 20, 2020) (Precedential). The Board has recognized that it should institute review in certain circumstances, like here, despite a trial scheduled before the final written decision's due date. *Sand Revolution II, LLC v. Continental Intermodal Grp.—Trucking LLC*, IPR2019-01393, Paper 24 (P.T.A.B. June 16, 2020) (Informative).

1. At Nevro's Request, the Court Granted Two Stays Based on Instituted IPRs in Related Proceedings; There is Evidence the Court Will Stay Again

Approximately four months before trial, the court stayed *Boston Scientific Corp.*, v. *Nevro Corp.*, No. 1:16-cv-01163 (D. Del.) at Nevro's request because the Board instituted review of a subset of patents in that litigation. EX1023; EX1027. Similarly, at Nevro's request, the court stayed BSC's patent claims asserted in 2018 because the Board instituted review of some of those patents. There, Nevro waited until the day before the 1-year bar date to file its petitions.

Here, a stay based on institution would occur over three months before trial and could occur earlier based on institution of related IPRs (IPR2020-01562; IPR2020-01563).

Because BSC's 2018 patent claims are stayed—including patents not subject to any IPR—there will be another unscheduled trial over at least some of those claims. Thus, the court has a readily available option to stay Nevro's counterclaims upon institution here and resolve them with BSC's claims. There is ample evidence the court will stay Nevro's counterclaims if the Board institutes here.

2. There is No Trial Date Scheduled for BSC's Infringement Claims; the Current Trial Date for Nevro's Counterclaims is October 18, 2021

The court has not scheduled the trial date for BSC's 2018 claims.

If the schedule for Nevro's counterclaims holds, trial will occur about eight months before the Board's final written decision. Nevro, however, has suggested that deadlines should be extended for COVID-19 reasons. EX1024 at 1, 5-6. It would be inequitable for Nevro to argue against institution based upon the current trial date and then turn around to the court after discretionary denial and argue for delay.

3. Investment in the Litigation by the Court and Parties

Nevro asserted the '461 Patent in counterclaims served on December 9, 2019. BSC has not answered due to a pending motion to dismiss. Expert discovery has not begun, and a *Markman* hearing has not occurred. Like in *Sand Revolution*, this factor weighs in favor of institution.

4. The Petition Raises Issues that the District Court Will Not Resolve

The Petition challenges claims 1-8 and 10-17. On July 16, Nevro identified only claims 1, 3-4, 7, and 11-13 to pursue in litigation. Accordingly, the IPR will resolve nine claims the court will not address. Moreover, BSC stipulated that, if the Board institutes, BSC will not pursue district court invalidity challenges on the same grounds herein. EX1025. Such stipulation alleviates concerns of duplicative efforts and conflicting decisions. *Sand Revolution*, IPR2019-01393, Paper 24 at 11-12; *Apple v. Seven Networks*, IPR2020-00266, Paper 12 at 15 (P.T.A.B. Aug. 14, 2020).

Finally, the litigation is not the full extent of the parties' disputes. The parties are competitors involved in extensive litigation related to a number of similar products. EX1026; EX1027. Due to the one-year time bar, BSC's opportunity to challenge the '461 Patent via an IPR is now, regardless of whether claims of this patent become relevant to any future BSC products. This is important where, as here, the claims have a relatively recent priority date and significant remaining term.

5. The Petitioner and Defendant are the Same Entity

BSC is the Counterclaim-Defendant in the litigation and the Petitioner here.

6. Other Circumstances Impact the Board's Exercise of Discretion, Including the Merits

The circumstances of this case weigh heavily in favor of institution. The merits of BSC's challenge are strong. The challenged claims are unpatentable based on work by at least BSC and other competitors in the SCS market.

As stated, there are efficiency reasons that suggest the Board should resolve validity of more than Nevro's seven claims in the litigation.

The Board is already reviewing other patents in the litigation. *See Seven Networks*, IPR2020-00266, Paper 12 at 19. Earlier this year, the Board instituted review of five BSC Patents in the litigation.[2] The subject matter of some of those patents is similar to the subject matter here, e.g., IPR2019-01313 (U.S. 7,496,404) and IPR2019-01340 (U.S. 6,381,496).

Finally, BSC prefers to challenge the '461 Patent claims before the agency—as Nevro has done repeatedly with BSC's patents—and the events in the litigation should not foreclose BSC's ability to challenge these claims.[3] These considerations weigh strongly in favor of institution.

[2] IPR2019-01284, -01313, -01318, -01340, -01341.

[3] Because of Nevro's motion to dismiss, Nevro did not file its counterclaims until fifteen months after BSC's first amended complaint.

* * *

Most of the *Fintiv* factors favor institution. An earlier trial date is *always* present if the Board is considering these factors, and the parties will often be the same in an IPR and co-pending litigation. *Sand Revolution*, IPR2019-01393, Paper 24 at 12-13. All other factors favor institution, and as a whole, strongly counsel in favor of institution. *See Seven Networks*, IPR2020-00266, Paper 12 at 9-21.

B. 35 U.S.C. § 325(d)

The Board should not deny institution under § 325(d), which provides the Board may deny institution if a petitioner relies on the same or substantially the same prior art or arguments as those previously presented to the Office, unless the petitioner demonstrates that the Office committed a material error. *Advanced Bionics, LLC v. Med-El Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 at 7-11 (Feb. 13, 2020) (Precedential).

1. The Prior Art and Arguments Here Are Different

The prior art and arguments here are different than those presented in prosecution. Although the Examiner mentioned in its Allowance that *Meadows* in view of *King* was the "closest prior art," there is no indication the Examiner actually applied *Meadows* against the instant claims because the reasons for allowance address a limitation—"mathematical relationship"—not recited in the issued claims. Also, the Examiner never discussed or rejected claims over *Nolan*,

Thacker, or *John*. *Id.* ("[A] material error may include misapprehending or overlooking specific teachings of the relevant prior art where those teaching impact patentability"); *Zip-Top LLC v. Stasher, Inc.*, IPR2018-01216, Paper 14 at 35-36 (P.T.A.B. Jan. 17, 2019). The European Opposition Division found that a substantively identical claim to claim 1 of the '461 Patent lacked novelty over *Nolan*. EX1008, ¶ 200 (side-by-side comparison); EX1030, 1-4, 10; EX1031.

This Petition, as supported by Dr. Mihran's declaration, also uses *Meadows* differently than how the Examiner used it. For example, the Examiner never cited *Mann167* and *Mann217*. EX1003, 33:38-34:23.

2. Examiner Committed Material Errors

The Examiner committed at least three material errors. First, the Examiner failed to explain how the claims were allowed without the "therapeutic effect" and "mathematical relationship" limitations that were required for claims in the parent applications. The Examiner rejected a claim *verbatim* to claim 1 of the '461 Patent (except a "the" was changed to an "a") during prosecution of the parent applications. *Compare* EX1011, 23, *with* EX1003, 14:12-31. Without explanation, the Examiner allowed claim 1 after previously rejecting the same claim as anticipated by *Meadows*. EX1011, 131-32; EX1002, 99.

Second, the Examiner's allowance is a copy-and-paste from the notices for parent applications and based on a limitation ("mathematical relationship") not in the allowed claims. *Compare* EX1002, 99, *with* EX1011, 226, *and* EX1010, 121.

Finally, Nevro misled the Examiner to believe *Meadows* could not anticipate the claims because "the electrodes are 'independently programmable.'" EX1011, 197, 207-09. As Dr. Mihran explains, "individually addressable" electrodes are disclosed in the '461 Patent and required to implement the claimed functionality since different electrodes are incremented differently. EX1001, 6:45-62, 9:36-42, 13:13-19; EX1008, ¶¶ 35-37, 56-61.

XI. CONCLUSION

For these reasons, challenged claims 1-8 and 10-17 are unpatentable, and Petitioner respectfully requests that the Board institute trial.

Date: December 7, 2020

Respectfully submitted,

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CERTIFICATION UNDER 37 C.F.R. § 42.24(d)

Under the provisions of 37 C.F.R. § 42.24(d), the undersigned hereby certifies that the word count for the foregoing Petition for *Inter Partes* Review totals 13,814 which is less than the 14,000 allowed under 37 C.F.R. § 42.24(a)(i).

Date: December 7, 2020

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing Petition for *Inter Partes* Review was served on counsel of record on December 7, 2020, by filing this document through the End-to-End System, as well as delivering a copy via Priority Mail Express to the counsel of record for the Patent Owner at the following address:

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XII. APPENDIX A: CLAIM LISTING

U.S. Patent 9,002,461

Claim	Claim Language
[1a]	A system for managing pain in a patient using an electrical waveform, comprising:
[1b]	an electrode device configured to be implanted into a patient and including a plurality of electrodes
[1c]	having at least a first electrode associated with a first area of the patient and a second electrode associated with a second area of the patient,
[1d]	wherein the first area has a first therapy range for a waveform parameter and the second area has a second therapy range for the waveform parameter; and
[1e]	an implantable device configured to be coupled to the electrode device,

Claim	Claim Language
[1f]	the implantable device including a power supply, a waveform generator configured to generate the waveform and a computer-operable medium operatively coupled to the waveform generator,
[1g]	the computer-operable medium being programmed to change the waveform parameter applied to the first electrode and
[1h]	automatically set the waveform parameter applied to the second electrode based on a relationship between the first therapy range and the second therapy range.
2	The system of claim 1, wherein the computer-operable medium is programmed to limit the waveform parameter applied to the first electrode to within the first therapy range and to limit the waveform parameter applied to the second electrode to within the second therapy range.
[3a]	The system of claim 1, wherein: the waveform parameter comprises the amplitude of the waveform,

Claim	Claim Language
[3b]	the first therapy range comprises a first amplitude range between (a) a sensation threshold and/or a therapeutic threshold and (b) a discomfort threshold for the first area, and the second therapy range comprises a second amplitude range between (a) a sensation threshold and/or a therapeutic threshold and (b) a discomfort threshold for the second area;
[3c]	the relationship between the first therapy range to the second therapy range comprises a ratio of the first amplitude range to the second amplitude range;
[3d]	the system further comprises a patient input device having a controller that generates a change command and a transmitter configured to transmit the change command to the implantable device; and
[3e]	the computer-operable medium is programmed to (a) change the amplitude of the waveform applied to the first electrode by a first amplitude increment and (b) set the amplitude of the waveform applied to the second electrode by a second amplitude increment in

Claim	Claim Language
	direct proportion to the ratio of the first amplitude range to the second amplitude range,
[3f]	in response to the change command being received by the implantable device.
[4a]	The system of claim 1, wherein: the waveform parameter comprises the amplitude of the waveform,
[4b]	the first therapy range comprises a first amplitude range between (a) a sensation threshold and/or a therapeutic threshold and (b) a discomfort threshold for the first area, and the second therapy range comprises a second amplitude range between (a) a sensation threshold and/or a therapeutic threshold and (b) a discomfort threshold for the second area;
[4c]	the relationship between the first therapy range and the second therapy range comprises a ratio of the first amplitude range to the second amplitude range;

Claim	Claim Language
[4d]	the system further comprises a patient input device having a controller that generates a change command and a transmitter configured to transmit the change command to the implantable device; and
[4e]	the computer-operable medium is programmed to (a) change the amplitude of the waveform applied to the first electrode by a first change increment for each change command received by the implantable device and (b) set the amplitude of the waveform applied to the second electrode according to a best-fit approximation of the ratio of the first amplitude range to the second amplitude range,
[4f]	in response to a set of change commands being received by the implantable device.
5	The system of claim 4, wherein the computer-operable medium is programmed to set the amplitude of the waveform applied to the second electrode by changing the amplitude applied to the second electrode by the first change increment or holding the amplitude

Claim	Claim Language
	applied to the second electrode constant for each change command received by the implantable device.
6	The system of claim 1, further comprising a memory containing a history of patient usage patterns of the waveform applied to the first and second electrodes, and wherein the computer-operable medium is further programmed to calculate a ratio of the first parameter range to the second parameter range based on the history of patient usage patterns.
7	The system of claim 1, further comprising a memory containing a history of patient usage patterns of the waveform applied to the first and second electrodes, and wherein the computer-operable medium is further programmed to determine whether the first area of the patient is linked to the second area of the patient.
8	The system of claim 7, wherein the computer-operable medium is programmed to change the first waveform parameter applied to the first electrode and set the second waveform parameter applied to the second electrode independently of each other, in response to the

Claim	Claim Language
	computer-operable medium determining that the first area of the patient is not linked to the second area of the patient.
10	The system of claim 1, wherein the electrode device includes at least one additional electrode associated with an additional area of the patient having an additional therapy range for the waveform parameter, and wherein computer-operable medium is further programmed to change the waveform parameter applied to the additional electrode based on a ratio of the additional therapy range to the first therapy range and/or the second therapy range.
[11a]	A system for managing pain in a patient using an electrical waveform, comprising:
[11b]	an electrode device configured to be implanted into a patient and including a plurality of electrodes
[11c]	having at least a first electrode associated with a first area of the patient and a second electrode associated with a second area of the patient,

Claim	Claim Language
[11d]	wherein the first area has a first therapy range for a waveform parameter and the second area has a second therapy range for the waveform parameter;
[11e]	an implantable device configured to be coupled to the electrode device,
[11f]	the implantable device including a power supply, a waveform generator configured to generate the waveform, and a computer-operable medium operatively coupled to the waveform generator,
[11g]	the computer-operable medium being programmed to change the waveform parameter applied to the first electrode and
[11h]	automatically set the waveform parameter applied to the second electrode based on a relationship between the first therapy range and the second therapy range; and
[11i]	a patient input device having a controller that generates a change command and a transmitter configured to transmit the change command to the implantable device, and

Claim	Claim Language
[11j]	wherein the relationship between the first therapy range and the second therapy range comprises a ratio of the first therapy range to the second therapy range.
[12a]	The system of claim 11, wherein the computer-operable medium is programmed to (a) change the waveform parameter applied to the first electrode by a first increment and (b) set the waveform parameter applied to the second electrode by a second increment in direct proportion to the ratio of the first therapy range to the second therapy range,
[12b]	in response to the change command being received by the implantable device.
[13a]	The system of claim 11, wherein the computer-operable medium is programmed to (a) change the waveform parameter applied to the first electrode by a change increment for each change command received by the implantable device and (b) set the waveform parameter applied to the second electrode according to a best-fit

Claim	Claim Language
	approximation of the ratio of the first therapy range to the second therapy range,
[13b]	in response to a set of change commands being received by the implantable device.
14	The system of claim 13, wherein the computer-operable medium is programmed to set the waveform parameter applied to the second electrode by changing the parameter applied to the second electrode by the change increment or holding the parameter applied to the second electrode constant for each change command received by the implantable device.
[15a]	The system of claim 11, wherein: the waveform parameter comprises the power of the waveform,
[15b]	the first therapy range comprises a first power range between (a) a sensation threshold and/or a therapeutic threshold and (b) a discomfort threshold for the first area, and the second therapy range comprises a second power range between (a) a sensation threshold

Claim	Claim Language
	and/or a therapeutic threshold and (b) a discomfort threshold for the second area;
[15c]	the system further comprises a patient input device having a controller that generates a change command and a transmitter configured to transmit the change command to the implantable device; and
[15d]	wherein the computer-operable medium is programmed to (a) change the power of the waveform applied to the first electrode by a first power increment and (b) set the power of the waveform applied to the second electrode by a second power increment in direct proportion to a ratio of the first power range to the second power range,
[15e]	in response to the change command being received by the implantable device.
[16a]	The system of claim 11, wherein: the waveform parameter comprises the power of the waveform,

Claim	Claim Language
[16b]	the first therapy range comprises a first power range between (a) a sensation threshold and/or a therapeutic threshold and (b) a discomfort threshold for the first area, and the second therapy range comprises a second power range between (a) a sensation threshold and/or a therapeutic threshold and (b) a discomfort threshold for the second area;
[16c]	the system further comprises a patient input device having a controller that generates a change command and a transmitter configured to transmit the change command to the implantable device; and
[16d]	wherein the computer- operable medium is programmed to (a) change the power of the waveform applied to the first electrode by a first change increment for each change command received by the implantable device and (b) set the power of the waveform applied to the second electrode according to a best-fit approximation of the ratio of the first power range to the second power range,

Claim	Claim Language
[16e]	in response to a set of change commands being received by the implantable device.
17	The system of claim 16, wherein the computer-operable medium is programmed to set the power of the waveform applied to the second electrode by changing the power applied to the second electrode by the first change increment or holding the power applied to the second electrode constant for each change command received by the implantable device.