UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEVRO CORP.
Petitioner

v.

BOSTON SCIENTIFIC NEUROMODULATION CORPORATION
Patent Owner

Case IPR2019-01340
Patent 6,381,496

PETITION FOR *INTER PARTES* REVIEW
OF U.S. PATENT NO. 6,381,496

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EXHIBIT LIST

Nevro (Ex) Exhibit #	***Description***
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1003	Declaration of Dr. Mark W. Kroll (“Kroll Declaration”)
1004	Curriculum Vitae of Mark W. Kroll, PHD
1005	U.S. Patent No. 5,387,228 A to Shelton (“Shelton”)
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1010	Medtronic Pacemaker Information and Programming Guide (September 1995)
1011	Manak Bhavan, *Indian Standard Specification For Implantable Ventricular Pacemaker*, 1986
1012	*Implantable Cardioverter Defibrillator Therapy: The Engineering – Clinical Interface*, Mark Kroll, et al., eds., 1996; pp. 339-340
1013	*Medicare’s Policies and Prospective Payment Rates For Cardiac Pacemaker Surgeries Need Review and Revision*, Report to the Chairman, Special Committee on Aging, United States Senate (1985)

Boston Scientific Neuromodulation Corporation ("BSNC") is the assignee of U.S. Patent No. 6,381,496 (EX1001). Petitioner Nevro Corporation seeks inter partes review of claims 1-18 of the '496 patent.

I. Introduction

The '496 patent is directed to "parameter context switching for an implanted device." EX1001, Title. The patent explains that "[a]s used herein, 'context switching' means changing one set of operational parameters to another." EX1001, 3:8-10. The '496 patent specification then proceeds to describe the invention in the context of "a spinal cord stimulation (SCS) system." EX1001, 1:9-11. Indeed, the '496 patent explains that "[t]he present invention emphasizes the manner in which such SCS system, or any other programmable implant system, manages and changes its operational parameters." EX1001, 1:16-19. So while the described embodiment is set in an SCS system, the '496 patent makes clear its scope reaches beyond SCS systems. *See e.g.*, EX1001, 1:38-44. The claims are also not limited to SCS, or any other specific type of programmable implant system.

The '496 patent issued following a first action allowance. EX1002, 40-46. The examiner did not provide reasons for the allowance. The problem for the Patent Owner is that parameter context switching was a well-known and well-developed concept in the cardiac stimulation space by the earliest filing date of the '496 patent. Two of the three primary references—Shelton and Nappholz—both

describe cardiac stimulation devices with ability to change one set of operational parameters to another—i.e., to provide context parameter switching. And the third reference to Barreras I describes an SCS system that is also fully capable of parameter context switching. EX1003, ¶¶1-58.

The Office should not have allowed the ’496 patent to issue in view of the prior art applied herein. Petitioner Nevro therefore respectfully requests that the Board institute inter partes review on claims 1-18 so the those claims can be properly evaluated.

II. Identification of Challenge

A. Citation of Prior Art

The ’496 patent’s earliest priority date is October 1, 1999. Because the ’496 patent issued from an application filed prior to March 16, 2013, Petitioner applies pre-AIA versions of U.S. Patent laws and regulations. Petitioner relies on the following prior art patents to prove that the challenged claims 1-18 are unpatentable. EX1003, ¶¶1-14.

EX1005: U.S. Patent No. 5,387,228 A to Shelton (“Shelton”) qualifies as prior art under 35 U.S.C. § 102(b) because it issued more one year prior to the earliest priority date of the ’496 patent.

EX1006: U.S. Patent No. 5,720,770 A to Nappholz et al. ("Nappholz") qualifies as prior art under 35 U.S.C. § 102(b) because it issued more than one year prior to the earliest priority date of the '496 patent.

EX1007: U.S. Patent No. 5,591,217 A to Barreras et al. ("Barreras I") qualifies as prior art under 35 U.S.C. § 102(b) because it issued more than one year prior to the earliest priority date of the '496 patent.

EX1008: U.S. Patent No. 5,735,887 A to Barreras II et al. ("Barreras II") qualifies as prior art under 35 U.S.C. § 102(b) because it issued more than one year prior to the earliest priority date of the '496 patent.

EX1009: U.S. Patent No. 4,432,360 A to Mumford et al. ("Mumford") qualifies as prior art under 35 U.S.C. § 102(b) because it issued more than one year prior to the earliest priority date of the '496 patent.

B. Statutory Grounds for the Challenge

Based on these prior art references, Petitioner advances the following grounds of unpatentability. Claims 1, 8 and 14 are the independent claims.

Ground	References	Statutory Basis	Claims Challenged
1	Shelton in view of Nappholz	35 U.S.C. § 103(a)	1-3, 6
2	Shelton in view of Nappholz and Mumford	35 U.S.C. § 103(a)	4-5
3	Shelton in view of Nappholz and Barreras II	35 U.S.C. § 103(a)	7

Ground	References	Statutory Basis	Claims Challenged
4	Nappholz	35 U.S.C. § 103(a)	8-13
5	Barreras I	35 U.S.C. § 103(a)	14
6	Barreras I in view of Nappholz	35 U.S.C. § 103(a)	15-16
7	Barreras I in view of Nappholz and Mumford	35 U.S.C. § 103(a)	17-18

An invention cannot be patented, "though the invention is not identically disclosed or described as set forth in section 102," if, at the time of the invention, the differences between the claimed invention and the prior art would have rendered the claimed invention "obvious" to a person of ordinary skill in the art. 35 U.S.C. § 103(a). Indeed, it is well settled that "a disclosure that anticipates under § 102 also renders the claim invalid under § 103, for 'anticipation is the epitome of obviousness.'" *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548 (Fed. Cir. 1983) (quoting *In re Fracalossi*, 681 F.2d 792, 794 (CCPA 1982)). The obviousness inquiry examines (1) the scope and content of the prior art, (2) the differences between the claimed invention and the prior art, (3) the level of ordinary skill in the art, and (4) any objective indicia of non-obviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966).

The grounds below show that the challenged claims are obvious. Section IV describes the level of ordinary skill in the art, while Section VII – XIII examine the scope and content of the prior art, and prove that any differences between the

express teaching of the art and the challenged claims would have been obvious. Petitioner is not aware at this time of any objective indicia of non-obviousness having any nexus to the purported invention.

III. The ’496 Patent

A. Prosecution History Summary

The ’496 patent issued on April 30, 2002 following a first action allowance. EX1002, the ’496 patent file history, 0040-0046. The examiner thus did not apply or substantively consider any of the references relied upon below in the asserted grounds of unpatentability.

B. Technology Overview

The ’496 generally describes an implantable medical device designed to provide electrical stimulation to a particular part of the body. Though the ’496 patent describes a device for spinal cord stimulation (“SCS”), EX1001, ’496 patent, 5:47-50, neither the claims nor the specification are so limited, *Id.*, 1:9-11, 1:37-44, 19:47-64 (claim 1).

In particular, the ’496 patent focuses on what it calls “parameter context switching, i.e., defining and/or selecting different operational parameter sets for use by an implant device.” *Id.*, 5:44-47. The implant device stores a plurality of operational parameter sets (“OPS”) in an implanted pulse generator (“IPG”), and gives user (e.g., a patient) the ability to change the current OPS, either manually or automatically, using a hand-held programmer. *See e.g.*, *Id.*, 3:54-64, 5:44-50.

The IPG includes electrical circuitry for simulation, a power source, and a telemetry system. *Id.*, 6:18-22. In the context of SCS, the IPG provides electrical simulation through electrodes included in an electrode array. *Id.* Figure 2 illustrates various types of electrode arrays that may be used with an exemplary SCS system:

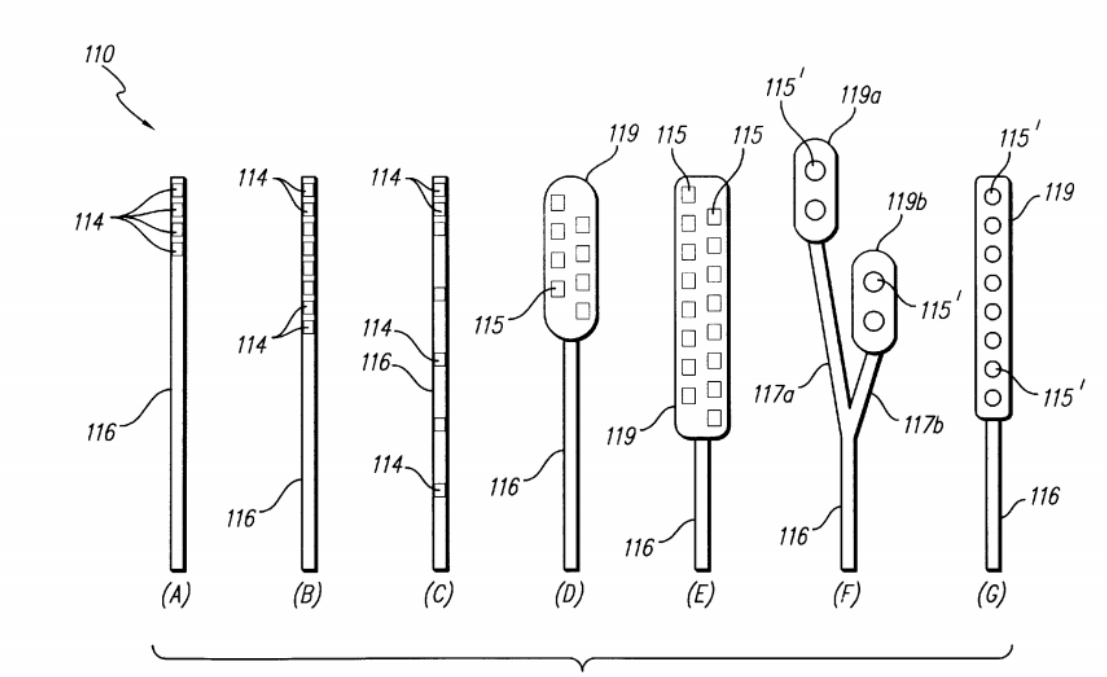


FIG. 2

EX1001, FIG. 2.

The operational parameter set ("OPS"), which is the focus of the purported invention, controls various aspects of the stimulation signal. *Id.*, 11:21-27. For example, the '496 patent explains that for the signal amplitude, "the currents can be individually set from ±0 to ±12.7 mA, in steps of 0.1 mA. In another embodiment, at least one channel of electrodes is capable of an output of at least

±20 mA (distributed among the electrodes included in the channel group)." *Id*., 11:42-48. The OPS may also control the ramp rate of the amplitude changes, *id*., 11:56-67, as well as the number of channels, simulation rate, and simulation pulse width, *id*., 14:32-35.

Once implanted in a patient's body, a clinician programming system programs the IPG. *Id*., 14:57-67. The IPG receives modulated RF signals from an external hand held programmer ("HPP"). The modulated RF signals include data that defines the operational parameters that make up a plurality of operational parameter sets. *Id*., 16:45-55. The IPG stores the plurality of OPSs in memory. *Id*., 16:55-67, 17:26-36.

Specifically, the '496 patent describes, "a plurality of different operational parameter sets, e.g., OPS0, OPS1, OPS2, . . . OPSn, where n is an integer, typically equal to at least four, are stored within the memory 162 of the implant device 100 or 100′ (or within the memory of the HHP 202, as described below)." *Id*., 17:27-32. Then, if the user wants to select a different OPS for controlling the implant device, the user can, "using manual selection controls on the HHP 202 select[] one of the plurality of OPS's, e.g., OPS3, that is stored within the implant device." *Id*., 17:33-36.

Turning to the memory, a control register in the IPG holds a selected operational parameter set. *Id*., 17:15-25. To change the selected (i.e., the currently

in use) OPS a user selects a different OPS using the HPP. *Id*., 17:26-45. The HHP transmits a selection signal to the IPG. *Id*. In response to the IPG receiving the signal, a memory access control circuit of the IPG retrieves the selected OPS and loads the selected OPS in the control register. *Id*.

The OPS loaded in the control register controls the IPG. *Id*. The plurality of OPSs stored in the memory may be within safe operational limits. *Id*., 17:46-52. Figure 6 illustrates the memory and control register of the IPG:

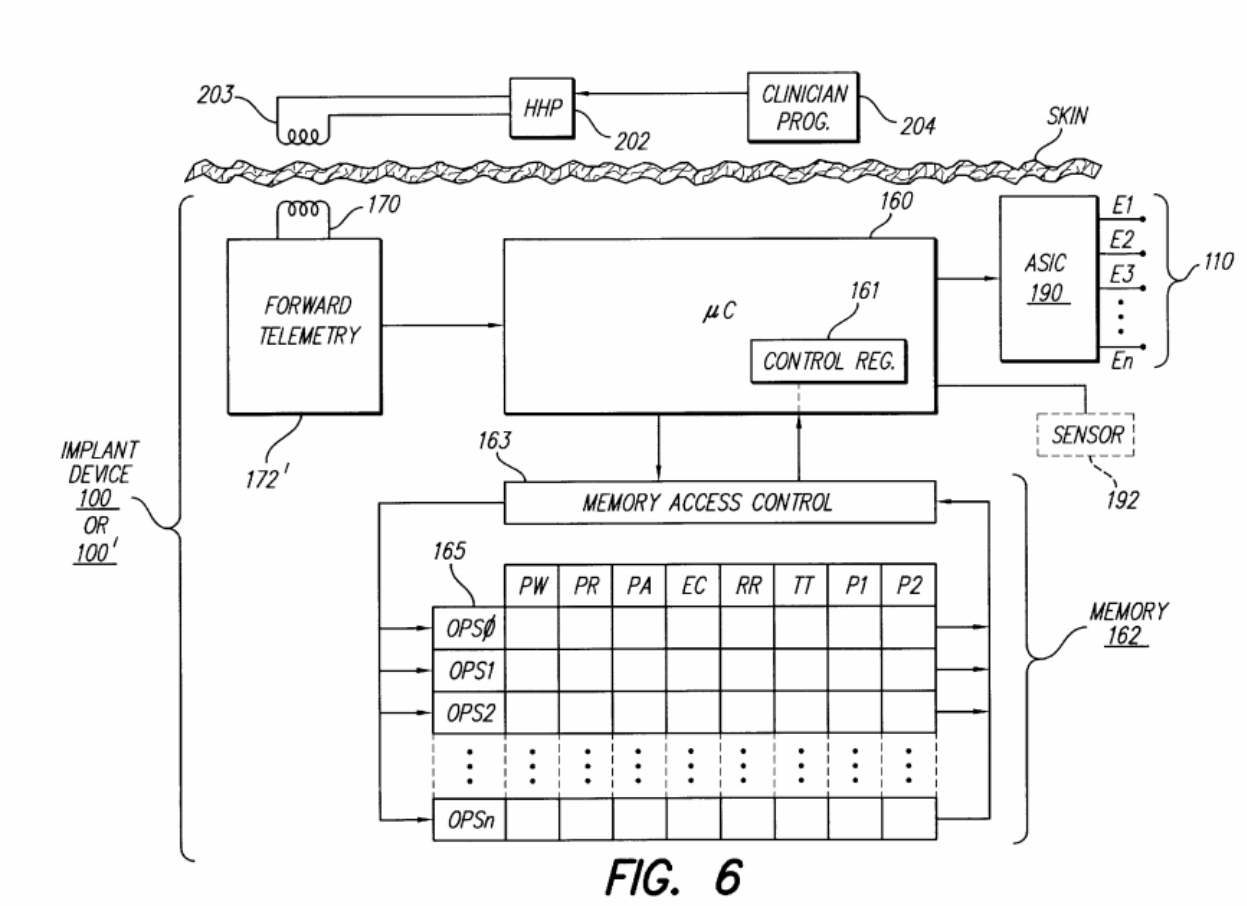


FIG. 6

EX1001, FIG. 6.

The described IPG may put access limits on the plurality of OPSs. For example, a limited memory access control limits the access to certain OPSs, while the full memory access control provides full access to the memory and the OPSs which may be selected. *Id*., 19:1-25. *Id*. In this manner, a patient may have limited memory access to select certain OPSs that are known to be safe, while a physician may have full memory access control circuit. *Id*.

Finally, the IPG includes a rechargeable power source such as a rechargeable battery. *Id*., 9:49-61. An external charger recharges the rechargeable power source within the IPG through a charging coil. *Id*.; EX1003, ¶¶24-38.

C. The Purported Invention

Independent claim 1 is illustrative of the key features of the purported invention:

> 1. An implant device comprising:
>
> an implantable case;
>
> electronic circuitry housed within said implantable case for performing a prescribed function, the electronic circuitry including a control register wherein a control set of operational parameters is stored,
>
> a controller that controls the operation of the implant device as a function of the control set of operational parameters stored in the control register, and
>
> a plurality of sets of operational parameters; and

selection means for selecting one of the plurality of sets of operational parameters as the control set of operational parameters that is stored in the control register;

whereby the operation of the implant device may be changed through selection of a different set of operational parameters.

The salient features of the purported invention are an implanted device including a control register for storing a control set of operational parameters, a controller of the implanted device controlling the implanted device using the control set of operational parameters in the control register, and a selection means for selecting a set of operational parameters from a plurality of sets of operational parameters to change the operation of the implanted device.

Independent Claim 8 is a method claim directed to defining a plurality of sets of operational parameters, storing the plurality of sets of operational parameters and providing a control set of operational parameters for controlling the operation of an implant device.

Independent Claim 14 is a system claim directed to an implant device including a first memory element, replenishable power source, first telemetry circuit, and second telemetry circuit. The first telemetry circuit is configured to receive a set of operational parameters from an external control device to be stored in the first memory element of the implant device. The second telemetry circuit is configured to receive power from a power source of an external charging device, to

be transferred to the replenishable power source of the implant device. EX1003, 39-44.

IV. Level of Ordinary Skill in the Art

Patent claims must be analyzed from the perspective of a person of ordinary skill in the art (a "POSA") at the time of invention. On the face of the '496 patent, this appears to be the time period shortly before October 1, 1999. In ascertaining the appropriate level of ordinary skill in the art of a patent, several factors should be considered including (1) the types of problems encountered in the art; (2) the prior art solutions to those problems; (3) the rapidity with which innovations are made; (4) the sophistication of the technology; and (5) the educational level of active workers in the field of the patent. Moreover, a POSA is a person who is presumed to be aware of the pertinent art, thinks along the line of conventional wisdom in the art, and is a person of ordinary creativity.

In view of these factors, a POSA with respect to the '496 patent disclosure would have had general knowledge of implantable medical devices and various related technologies as of October 1, 1999. Further, a POSA would have had (1) at least a bachelor's degree in a relevant life sciences field, mechanical engineering, electrical engineering, biomedical engineering, or equivalent coursework, and (2) at least one year of experience researching or developing implantable medical devices, and/or methods of their manufacture. EX1003 ¶¶15-18.

V. Claim Construction

A. Generally

Here, no claim terms appear to be used outside their ordinary and customary meaning, as understood by a POSA and in view of the '496 patent specification. Accordingly, Petitioner believes the claim terms should receive their plain meaning, in the context of the '496 patent specification, and from the perspective of a POSA. At this juncture of the proceeding, no claim terms need be construed to demonstrate that the claims are unpatentable. *Vivid Techs., Inc. v. Amer. Science & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 2000) ("only those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy").

B. Means plus function claims

The '496 patent has at least several claims terms that appear to fall under 35 U.S.C. § 112, sixth paragraph. Petitioner thus identifies the following exemplary structure as corresponding to these claim terms.

Claim Number	**Functional Claim Limitation**	**Exemplary Corresponding Structure**
1.7	*selection means* for selecting one of the plurality of sets of operational parameters as the control set of operational parameters that is stored in the control register.	The ’496 patent describes a selection means in a hand-held programmer. EX1001, FIG. 7, elements 202, 208. EX1001, 18:17-20. Furthermore, the ’496 patent discloses, a microcontroller in the implanted device which is used to make the selection of the operating parameters. EX1001, 17:32-43. Therefore, a combination of the HHP and microcontroller is the corresponding structure for preforming function of selecting a set of operational parameter as the control set of operational parameters.
2.4	*memory access control means* for retrieving a selected set of operational parameters from the memory circuitry and loading it into the control register.	The ’496 patent describes a memory access control circuit. EX1001, FIG. 6, element 163.
3.2	*memory means* external to the implant device wherein the plurality of sets of operational parameters are stored.	The ’496 patent describes a memory of a hand-held programmer. EX1001, FIG. 7, elements 214, 216.

Claim Number	**Functional Claim Limitation**	**Exemplary Corresponding Structure**
3.3	*telemetry means* for transmitting a selected one of the plurality of sets of operational parameters to the electronic circuitry for loading into the control register.	The ’496 patent discloses a telemetry circuit. EX1001, 9: 32-38, 16:57-59.
4.2	*change means* for allowing a user of the implant device to change individual parameters included within a selected one of the plurality of operational parameters	“The patient user selects one of the plurality of OPS's as the desired OPS through appropriate manual patient selection means 208 included as part of the HHP 202. Such means typically comprise pressing appropriate keys or buttons on a keypad, or display screen, but any suitable input means may be used.” EX1001, 18:17-22.
5.2	wherein the *change means* allows the user of the implant device to change only certain ones of the individual parameters included within the selected one of the plurality of operational parameters.	“The patient user selects one of the plurality of OPS's as the desired OPS through appropriate manual patient selection means 208 included as part of the HHP 202. Such means typically comprise pressing appropriate keys or buttons on a keypad, or display screen, but any suitable input means may be used.” EX1001, 18:17-20.

Claim Number	Functional Claim Limitation	Exemplary Corresponding Structure
16.3	wherein the external control device includes *means for selecting one of the plurality of sets of operational parameters* and sending the selected set of operational parameters to the implant device…	The ’496 patent describes a selection means in a hand-held programmer. EX1001, FIG. 7, elements 202, 208, 18:17-20. The ’496 patent describes a telemetry circuit as a means to send the operational parameters to the implant device. EX1001, 18: 27:33.
16.3	storage in the first *memory means*….	The ’496 patent describes a memory. EX1001, FIG. 6, elements 162,163, and 165.

VI. Overview of the Applied References

A. Shelton – U.S. Patent No. 5,387,228 A (EX1005)

Shelton is the primary reference for grounds 1-4. It expressly discloses most of the claimed features for claims 1-7. Shelton discloses an implanted device programmable using an external programmer. Shelton’s FIG. 1 illustrates an implanted cardiac pacemaker 10:

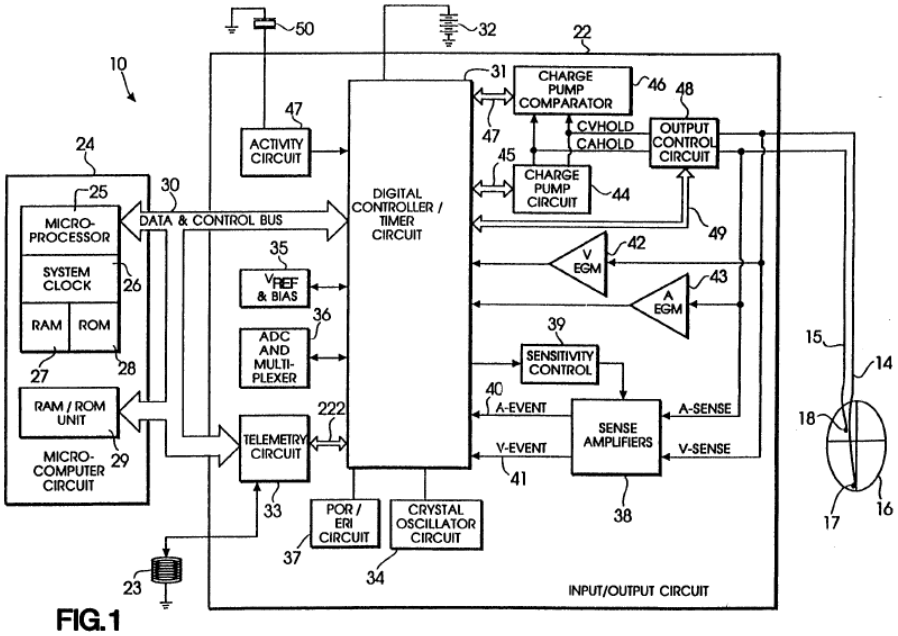


FIG. 1

EX1005, FIG. 1.

Shelton's external programmer programs the implanted device using telemetry methods. EX1005, Shelton, 8:22-50. The cardiac pacemaker 10 downloads and stores various pacing combinations—i.e., operational parameter sets—from the external device into RAM/ROM unit 29. *Id.*, 9:24-34. The digital controller/timer circuit 31 loads an operational parameter set into a pair of output control registers. *Id.*, 12:6-1313:4, 14:1-15:19. Controller 31 then uses the various pacing combinations to control the pacing operations of the implanted device. *Id.*, 12:17-24. Different combinations of programmable settings may be implemented by the implanted device. EX1005, 15:20-57. EX1003, ¶¶45-46.

B. Nappholz – U.S. Patent No. 5,720,770 A (EX1006)

Nappholz renders independent claims 8-13 obvious and is thus the primary reference for Ground 5. Nappholz is also used as a secondary reference for claims 1-3, and 6. Nappholz is directed to an implantable cardiac simulation device configured to deliver therapy without the supervision of a physician. *See* EX1006, Nappholz, Abstract. An external device programs, monitors, and communicates with the implanted device using telemetry methods. EX1006, 3:61 – 4:5, 6:10-19. The external programmer stores operational parameters, which the implanted device downloads. *Id.*, 6-7: 64-67 1-19. EX1003, ¶47.

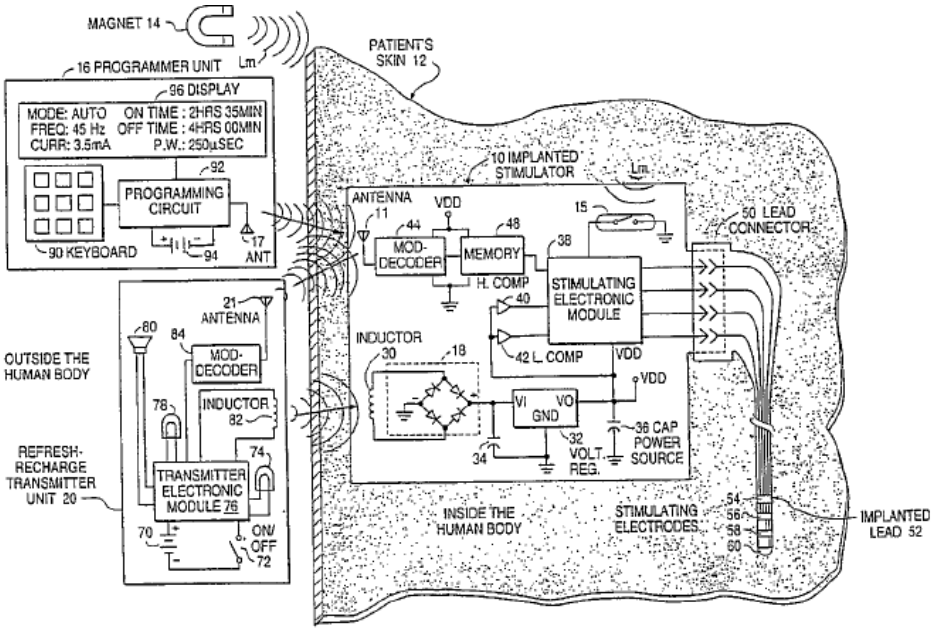
A user-patient can modify the operation of the implanted device remotely. EX1006, 7:38-49. In one example, the patient may change the mode of operation of the implanted device based on a level of activity selected by the user. *Id.*, 9:22-29, 9:39-52, FIG. 7. The user may make a selection to change the operational parameters of the implanted device by selecting the level of activity. *Id.*; EX1003, ¶48.

A physician may make also select from among different modes of operation. EX1006, 7:38-49. Nappholz discloses, for example, that in case a "persisting atrial fibrillation is detrimental to the patient … the physician may want this rhythm reverted. In such a case the patient would be alerted and asked to go to a medical center to have the arrhythmia reverted." EX1006, 9:41-52; EX1003, ¶49.

Nappholz's various modes of operation for its implanted device thus correspond to different sets of operational parameters for the implanted device. Changing Nappholz's mode of operation of the implanted device modifies or reconfigures the operational parameters of the implanted device. EX1006, 9:22-29. Thus, Nappholz discloses an implanted device that may be programmed using an external device. *Id.*, 3:61-67; 4:1-5. A patient or a physician may change the mode of operation of the implanted device based on a variety of factors. EX1006, 8:46-58; 9:22-29; EX1003, ¶¶47-50.

C. Barreras I – U.S. Patent No. 5,591,217 A (EX1007)

Barreras I renders independent claim 14 obvious and is the primary reference for Grounds 6-8. Barreras I describes an implantable simulator for stimulating a patient's tissue. EX1007, Barreras I, 4:39-43. Barreras's Figure 1 is exemplary.



EX1007, FIG. 1.

The stimulator includes a rechargeable power source. *Id.*, 5:15-21. The implanted device receives operational commands from a programmer unit, via an RF telemetric data link. *Id.*, 8:2-15. The programming circuit transmits programming information through the antenna in the programming unit to an antenna disposed in the implanted device. *Id.*, 8:2-15. A modulator/demodulator and decoder of the implanted device decodes the programming data received by the antenna, and may store the programming data in memory within the implanted device. *Id.*, 8:2-15; EX1003, ¶51.

Barreras I further describes a refresh-rechargeable transmitter unit external to the implanted device. EX1007, 6:41-54. The refresh-rechargeable transmitter unit includes a power source, transmitter electronic module and an RF inductor

coil. *Id.*, 6:41-54. The RF inductor coil transmits power via telemetry to recharge a rechargeable power source within the implanted device to an inductor receiver coil within the implanted device. EX1007, 6:41-54. EX1003, ¶¶51-52.

VII. Ground 1: Shelton renders obvious claims 1-2, 4, and 6 of the '496 patent

Shelton discloses an implantable device with an outside shell housing electronic circuitry to provide pulses at various combinations of amplitudes. EX1005, 9: 12-14, 12:6-24.The operational commands for controlling the implantable device are downloaded into the implanted device and loaded into a pair of control registers. EX1005, 9:12-14, 12:6-13:7; 14:1-52. A controller uses data loaded into the control register to control the implanted device. EX1005, 9: 12-14, 12:6-24. Shelton's implanted device has programmable stimulating pulse amplitudes selectable by means of an external programming unit. *Id.*, Abstract. Shelton also discloses that operational commands for controlling the implantable device are downloaded into the implanted device, and loaded into Shelton's control registers. *Id.*, 9:12-14, 12:6-13:7; 14:1-52; EX1003, ¶59.

Shelton, however, may not expressly disclose downloading and using a plurality of operational parameter sets. Shelton is thus not as flexible as a device that has such features. A POSA seeking to improve Shelton would have looked to similar prior art to improve both Shelton's flexibility and ease of use for a patient. Nappholz (EX1006) is such similar art. EX1003, ¶60.

Nappholz, like Shelton, is directed to controlling the operation of an implanted device in the cardiac pacing space. EX1006, Title. Nappholz focuses on providing control of the operation of the device to a patient or a physician using an external unit called a Repeater, Programmer, and Phone (RPP). *Id.*, Abstract. Nappholz's RPP is configured to store sets of operational parameters, and transmit the sets of operational parameters to the implanted device using telemetry means. *Id.*, FIG 3, 7:50- 8:2; 9:17-29. Nappholz's implanted device stores the received sets of operational parameters. *Id*.; EX1003, ¶61.

Nappholz's operational parameter sets are different cardiac pacing sets that correspond to different levels of activity that a patient may experience. EX1006, FIG. 7, 9:17-29. A POSA would have also recognized the usefulness of Nappholz's techniques for storing multiple sets of operational parameters on an external programmer like Nappholz's RPP, and then on the implanted device. Such recognition is simply using a known technique to improve a similar device in the same way. EX1003, ¶62.

A POSA would have had an reasonable expectation of success in modifying Shelton to take advantage of this feature because Shelton expressly states that "[i]t is believed that one of skill in the art would be able to choose from any of a number of available pacemaker programmers and programming techniques to

accomplish the tasks necessary for practicing the present invention." EX1005, 8:44-48; EX1003, ¶63.

Thus, a POSA would have found claims 1, 2, 3, and 6 of the '496 patent to have been obvious in light of the disclosure of Shelton (Ex. 1005). EX1003, ¶¶59-64.

A. Independent claim 1

1. "An implant device comprising:"

Shelton describes an implantable pacemaker. EX1005, 7:56-60. Figure 1, element 10 of Shelton illustrates the implantable pacemaker:

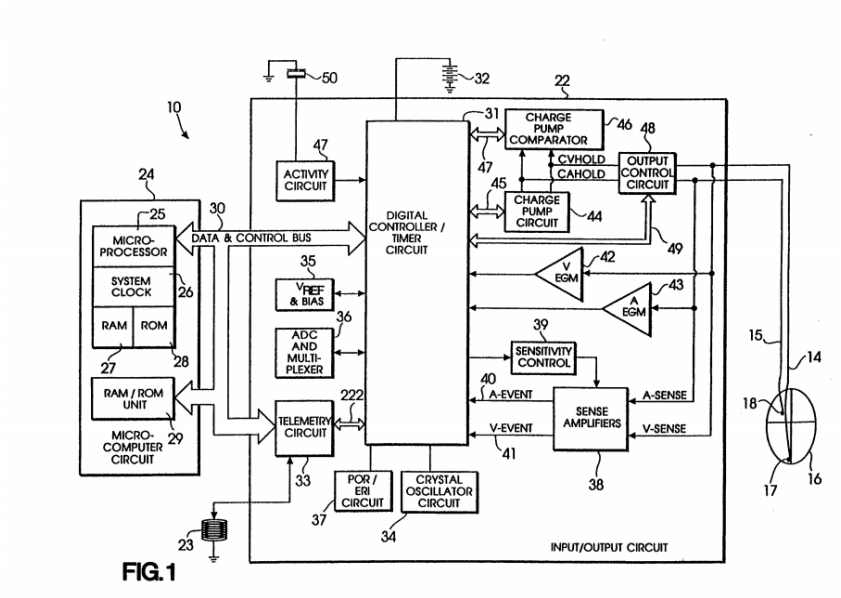


FIG. 1

EX1005, FIG. 1.

Shelton thus discloses an "implant device." EX1003, ¶¶65-66.

2. "an implantable case;"

Shelton discloses an outer protective shield around the implantable pacemaker. EX1005, 9:12-14. Shelton discloses, for example, that "activity sensor 50 is bonded to the inside of the pacemaker's outer, protective shield, in accordance with common practice in the art." *Id*. Thus, Shelton thus discloses an implantable case. EX1003, ¶67.

3. "electronic circuitry housed within said implantable case for performing a prescribed function,"

Shelton's Figure 1 illustrates a implantable pacemaker including an input/output circuit 22 housed within the pacemaker. EX1003, ¶68.

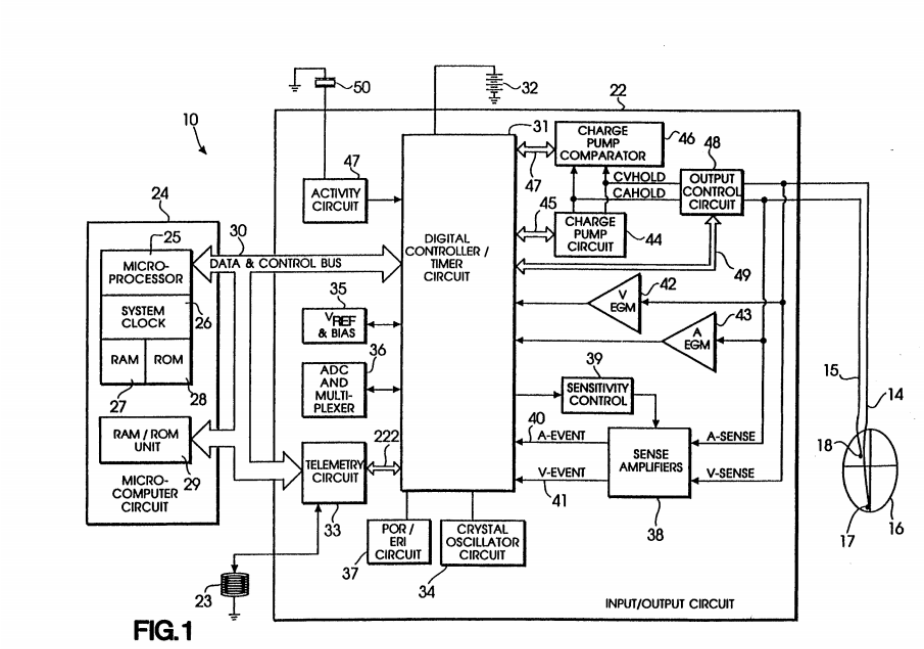


FIG.1

EX1005, FIG. 1.

The pacemaker 10 houses the input/output circuit 22, and the protective shield houses the pacemaker 10. EX1005, 9:10-24. Shelton's input/output circuit 22 performs the application of stimulating pulses to the heart and other prescribed algorithms. EX1003, ¶69. Shelton thus discloses this feature for cardiac pacing. *Id.*, ¶¶68-70.

4. "the electronic circuitry including a control register wherein a control set of operational parameters is stored"

Shelton discloses loading data to control the implanted pacemaker into an eight-bit atrial output control register that resides in digital controller/timer circuit 31. EX1005, 12:6-24. Shelton's Figure 2 illustrates the atrial control register:

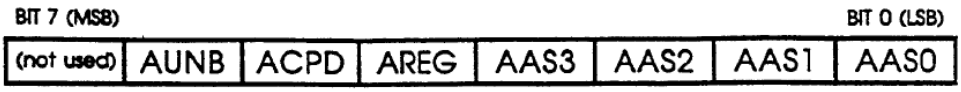


FIG.2

EX1005, FIG. 2.

Shelton also loads data to control the implanted pacemaker into a ventricular output control register. EX1005, 14:1-10. The controller retrieves the data from the control register to control the operation of the pacemaker. *Id.*, 12:6-24; EX1003, ¶66. Shelton thus discloses this feature. EX1003, ¶¶71-73.

5. "a controller that controls the operation of the implant device as a function of the control set of operational parameters stored in the control register, and"

Shelton's "digital controller/timer circuit 31 uses the data in the atrial output control register to control various aspects of atrial pacing by pacemaker 10." EX1005, 12:20-23; EX1003, ¶74. The data in the atrial output register, for example, is the control set of operating parameters. EX1005, 12:20-23, EX1003, ¶¶74-75. Shelton thus discloses this feature. EX1003, ¶¶74-75.

6. "a plurality of sets of operational parameters; and"

While Shelton discloses a pacemaker having a selectable output amplitudes, *Id.*, 23:33-42, 24:28-32, it may not expressly disclose a plurality of sets of operational control parameters. Nappholz discloses this useful feature for simplifying use by a patient. EX1003, ¶76

Nappholz's implant device has different modes of operation. EX1006, 9:19-29. The different modes correspond to different levels of activity for a patient. *Id*., 9:19-29. Nappholz reconfigures or modifies the operational parameters if a patient selects a new mode of operation. *Id*., 9:19-29. Each mode of operation thus corresponds to a different set of operational parameters for different activities such as sleep/rest, getting up, starting exercise, and taking medication. EX1006, FIG7, 9:17-29; EX1003, ¶¶76-78.

Thus, it would have been obvious to a POSA that a physician or a patient should have the capability to define a plurality of sets of operational parameters, each set including individual parameters that define respective characteristics associated with the operation of the implant device, as described in Nappholz. EX1003, ¶¶76-79.

Shelton in view of Nappholz thus describes a plurality of sets of programmable operational parameters for the implant device. EX1003, ¶¶76-80.

7. "selection means for selecting one of the plurality of sets of operational parameters as the control set of operational parameters that is stored in the control register;"

This term is written in a "means plus function" format. The corresponding structure that the '496 patent describes to carry out the recited function is a hand-held programmer in conjunction with the microcontroller on the implant device. *See e.g.*, EX1001, 4:1-14; FIG. 1 (202); EX1003, ¶¶81-82. Specifically, the '496 patent teaches that a patient selects an OPS using an HPP." EX1001, 18:17-20, *see also* EX1003, ¶¶83-84. The '496 patent imposes no specific restrictions on the programmers, stating that "[t]hose of skill in the art should be able to fashion various ways in which the IPB 100 or 100' could be programmed." EX1001, 14:65-67; EX1003, ¶¶85-86.

The '496 patent also relies on its microcontroller effect the selection made by the HPP because "the appropriate selection signal is then to the

[microcontroller] 160 within the implant device 100 via [telemetry circuitry]." EX1001, 17:32-43, EX1003, ¶87. The microcontroller then effects the change. EX1001, 17:37-45. Therefore, in the '496 patent, the HHP and microcontroller together are the corresponding structure for preforming function of selecting a set of operational parameter as the control set of operational parameters. EX1003, ¶87.

Shelton provides the same function using similar structure. Shelton's figure 1 is illustrative and is reproduced below:

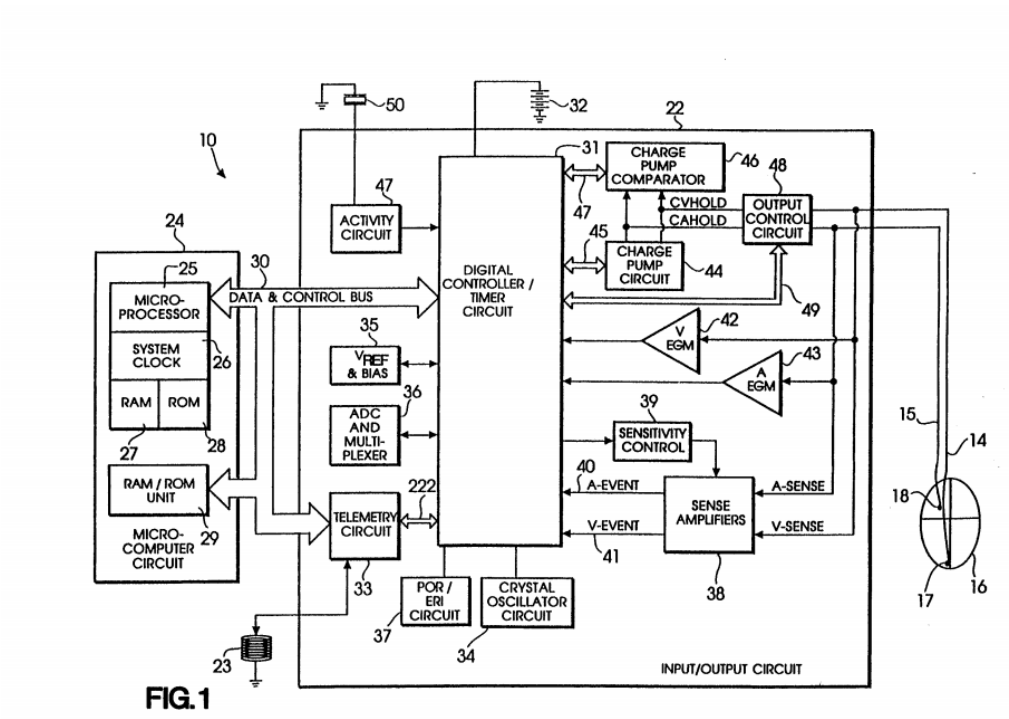


FIG. 1

EX1005, FIG. 1.

Shelton discloses a microcomputer circuit including a data control bus connecting the digital controller (where the control register is located) and a RAM/ROM unit. EX1005, 9:24-34. Shelton discloses that the microcomputer

circuit 24 is a microcontroller. *Id.*, 9:30-34. Shelton further discloses operating commands for the pacemaker being communicated to the control register through the data control bus. *Id.*, 10:17-24. This is equivalent circuitry to the microcontroller 160 in the '496 patent. EX1003, ¶¶88-89

Shelton further discloses a telemetry circuit directly coupled to the microcomputer circuit in which the RAM/ROM unit is located. *Id.*, 9:46-54. The digital data for controlling the pacemaker is downloaded from an external programmer to the pacemaker via the telemetry link. *Id.,* 12:8-12. This is equivalent to the '496 patents HPP. EX1003, ¶90

Nappholz also discloses selection means. Specifically, Nappholz explains that a user can change the mode of operation of Nappholz's implant device by making a selection of a new level of activity using Nappholz's device or RPP. EX1006, FIG7, 9:17-29. In this regard, each mode of operation corresponds with a different set of operational parameters. *Id*; EX1003, ¶91

Therefore, reading Shelton in view of Nappholz, a POSA would have appreciated that Nappholz's operational parameter sets for controlling the pacemaker (e.g., from Nappholz's RPP) would be downloaded by the implanted device (e.g., Shelton's pacemaker) using Shelton's telemetry circuit and communicated to Shelton's RAM unit. In response to a selection of an activity level using Nappholz's RPP, a control set of operating parameters are transferred

from Shelton's RAM unit to Shelton's control registers, via the data and control bus. EX1003, ¶¶81-92.

With respect to the external programmer specifically, Shelton further discloses that POSA would have been able to implement the tasks of the invention using different programming units such as the Medtronic Model 9760. *Id.*, 8:14-50. The Medtronic Model 9760 is an external programmer which is used to control the operation of an implanted device by communicating operational parameters to the implanted device. EX1010, 0083-0086. The Medtronic Model 9760 and other pacemaker external programming units can select a set of operational parameters for controlling an implanted device. *Id*. Nappholz's RPP 14 could also perform this function. EX1006, FIG7, 9:17-29; EX1003, ¶93. In view of the above examination of Shelton in view of Nappholz, it would have been obvious to a POSA that an external programming unit such as Nappholz's RPP can transmit sets of operational parameters to be stored in memory of an implant device using a telemetry circuit. EX1003, ¶94.

For the reasons set forth above, the "selection means" of claim 1 would have been obvious over Shelton in view of Nappholz. EX1003, ¶¶81-95.

8. "whereby the operation of the implant device may be changed through selection of a different set of operational parameters."

Nappholz describes changing the operation of the implant device by selecting a new level of activity using Nappholz's RPP, which can select a set of operational parameters for controlling an implanted device. EX1006, 9:17-29. Shelton in view of Nappholz thus describes changing the operation of the implant device through selection of a different set of operational parameters. EX1003, ¶¶96-97.

B. Claim 2

1. "The implant device of claim 1:"

As discussed above in Section VII.A, Shelton in view of Nappholz renders the preamble of claim 2 obvious. EX1003, ¶¶98-99.

2. "wherein the electronic circuitry further includes memory circuitry wherein the plurality of sets of operational parameters are stored, and"

Shelton discloses a RAM/ROM unit within its microcomputer circuit 24. EX1005, 9:27-34; EX1003, ¶¶100-101. Shelton's micro-computer circuit includes a data control bus connecting the digital controller/timer circuit 31 (where the control register is located) and the RAM/ROM unit 29. EX1005, 9:24-34. Nappholz also discloses a RAM 49 in its implanted device for storing opertional parameter sets. EX1006, FIG. 2. EX1003, ¶¶100-101

Therefore, Shelton in view of Nappholz discloses this feature. EX1003, ¶¶100-102

3. "wherein the selection means comprises memory access control means for retrieving a selected set of operational parameters from the memory circuitry and loading it into the control register."

This limitation is written in "means plus function" format. The '496 patent, the memory access control 163, as illustrated in Figure 6, is exemplary corresponding structure for the memory access control means. EX1001, FIG. 6, 17:14-25; EX1003, ¶¶103-104.

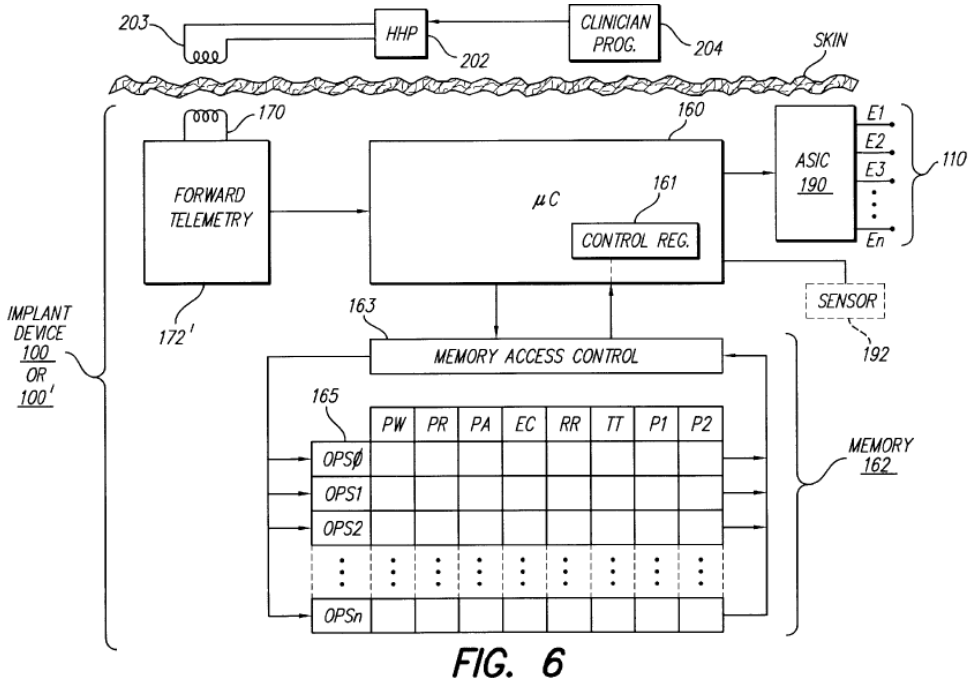


FIG. 6

EX1001, FIG. 6.

The corresponding structure in Shelton is the microcomputer circuit 24 with its standard RAM/ROM memory 29. EX1005, 9:30-34, FIG. 1; EX1003, ¶105. Shelton's Figure 1 is exemplary:

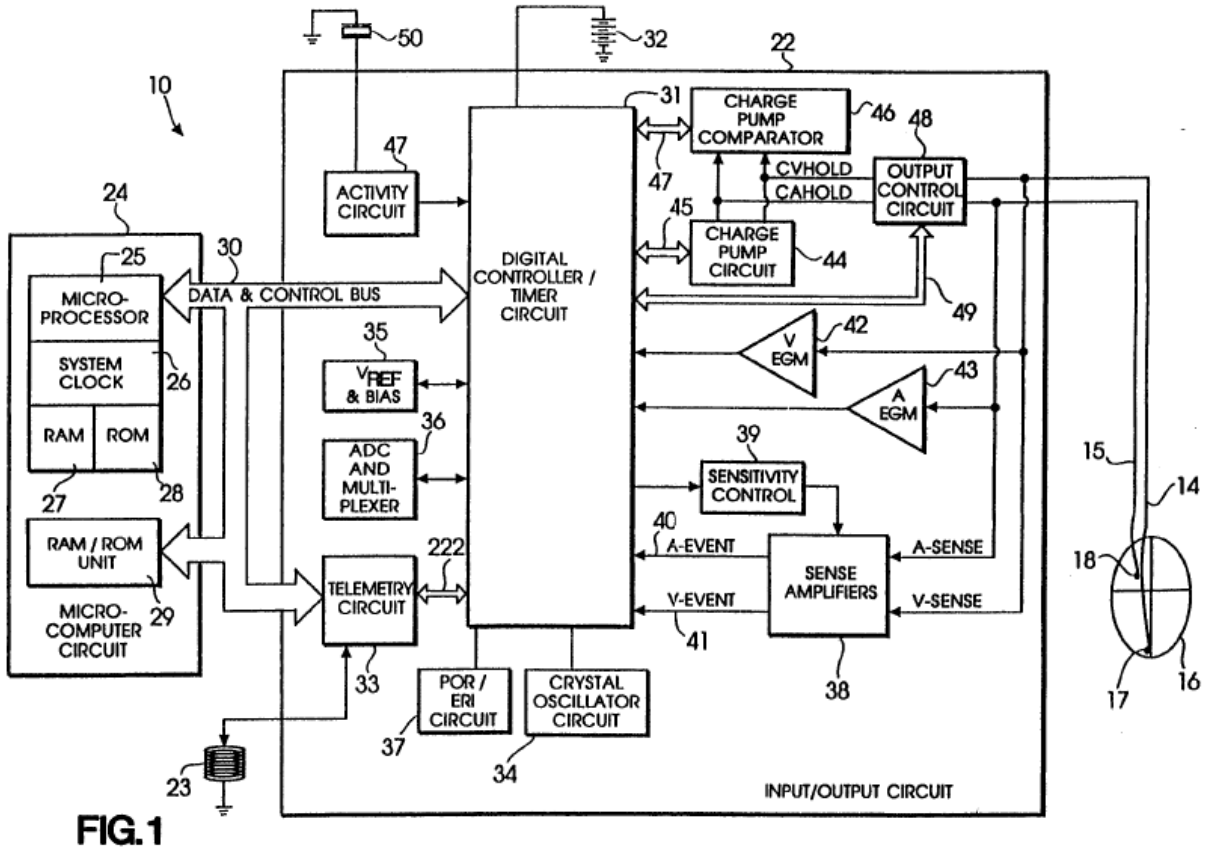


FIG.1

EX1005, FIG. 1.

A POSA would appreciate that all microcontrollers will have memory and memory access control circuitry as core components. EX1003, ¶¶99, 106.

Shelton in view of Nappholz discloses that it would have been obvious for a POSA to use external programming units, together with Shelton's microcomputer

circuit 24 and telemetry circuit 33, as a selection means for selecting a control set of operational parameters from Nappholz's plurality of sets of operational parameters. *See* Section VII.A.7; EX1003, ¶¶107-109.

Shelton's digital controller/timer circuit 31 transfers the operational parameters between the memory and control registers (e.g., the eight-bit atrial output control register). EX1005, 9:24-34; 12:6-24; 10:17-24; EX1003, ¶¶102-104. Shelton thus renders obvious memory access control means for retrieving a selected set of operational parameters from Nappholz's plurality of sets of operational parameters from the memory circuitry and loading it into a control register. EX1003, ¶¶107-110.

C. Claim 3

Dependent claim 3 further limits the "selection means" of independent claim 1 to include (1) "memory means" that are external to the implanted device, and that store the plurality of operational parameter sets, and (2) "telemetry means" for transmitting a selected one of the operational parameter sets for loading into the control register. EX1003, ¶111.

1. "The implant device of claim 1 wherein the selection means comprises:"

As discussed in Section VII.A and VII.A.7, Shelton in view of Nappholz renders the preamble of claim 3 obvious. EX1003, ¶112.

2. "memory means external to the implant device wherein the plurality of sets of operational parameters are stored; and"

The '496 patent describes a memory of a hand-held programmer configured to retrieve information stored in a memory 214 as shown in Figure 7, element 214, as the structure for memory means external to the implant device. EX1001, FIG. 7 214. EX1003, ¶113. The "memory means" is thus simply the memory.

Nappholz discloses a similar memory structure. Specifically, it explains that "[m]icroprocessor 90 is … connected through an external interface 104 to an external memory 106. Memory 106 is used to store programming data as well as other information required for the operation of the microprocessor 90." EX1006, 5:57-60. So the corresponding structure in Nappholz is the external memory 106. EX1003, ¶¶113-114.

Nappholz's structure is used for a similar purpose. For example, Nappholz stores operational parameters, ranges for the parameters, and other programming options in an external console—namely, Nappholz's RPP. EX1006, 3:1-10; 6:64-66; EX1003, ¶115-116. With respect to the RPP, Nappholz discloses that the operating parameters are downloaded into the RPP. EX1006, 7:59-64; EX1003, ¶115-116. Nappholz thus discloses this feature. EX1003, ¶¶113-117.

3. "telemetry means for transmitting a selected one of the plurality of sets of operational parameters to the electronic circuitry for loading into the control register."

This limitation is written in a "means plus function" format. The '496 patent describes a telemetry circuit as exemplary structure for the recited function. EX1001, 9: 32-38. Both Shelton and Nappholz disclose telemetry means. EX1003, ¶¶118-119.

For example, Shelton discloses a telemetry circuit 33 that is directly coupled to the microcomputer circuit 24 in which the RAM/ROM unit 29 is located. EX1005, FIG. 6, 9:46-54. The digital data for controlling Shelton's pacemaker is thus downloaded from an external programmer to the pacemaker via the telemetry link. EX1005, 12:8-12. This is equivalent to the telemetry circuit in the '496 patent. EX1003, ¶120.

Furthermore, Shelton's RAM/ROM unit 29 within a microcomputer circuit is coupled by a data and control bus 30 to a digital controller/timer circuit 31. EX1005, FIG. 1. Shelton's digital controller/time circuit 31, in turn, transfers the operational parameters between the memory and control registers such as the eight-bit atrial output register, which is maintained in the digital controller. EX1005, 9:24-34, 12:17-24. So Shelton at least render obvious telemetry means for transmitting a selected one of the plurality of sets of operational parameters to the electronic circuitry for loading into the control register. EX1003, ¶121.

Nappholz, like Shelton, also discloses a telemetry circuit. EX1006, 5:15-19, FIG. 2; EX1003, ¶128. Nappholz also stores operational parameters, ranges for the parameters, and other programming options in its external console or RPP. EX1006, 6:64-67; EX1003, ¶122. Thus, Shelton in view of Nappholz discloses and renders obvious this feature. EX1003, ¶¶118-123.

D. Claim 6

1. "The implant device of claim 1"

As discussed in Section VII.A, Shelton in view of Nappholz renders the preamble of claim 6 obvious. EX1003, ¶124.

2. "wherein the prescribed function performed by the electronic circuitry comprises a stimulation pulse generator, and"

Shelton discloses a pacemaker that generates a stimulating pulse via input/output circuit 22. EX1005, 11:52-63, 11:44-51; EX1003, ¶¶125-126. Shelton thus discloses this feature.

3. "wherein the operational parameters included within the control set of operational parameters include pulse width, pulse amplitude and pulse rate"

It was well known that implant devices could be programmed with numerous operational parameters. EX1003, ¶127. Shelton's background section references parameters such as pulse rate, pulse width and/or pulse amplitude, pacing mode, sensing mode and sensitivity, activity/rate response settings, refractory periods, AV-delay settings, and others. EX1005, 3:18-24; EX1003,

¶¶128-129. Furthermore, Shelton itself discloses different pulse rates, pulse amplitudes and pulse width as operational parameters. EX1005, 8:51-54, 16:56-61; EX1003, ¶¶127-129. Shelton thus discloses this feature.

VIII. Ground 2: The combination of Shelton, Nappholz and Mumford renders obvious dependent claims 4 and 5.

These two claims describe "change means" that give a user the ability change certain operational parameters of the stimulation algorithm. EX1003, ¶130. Shelton, Nappholz and Mumford render the claimed "change means" obvious. *Id*.

Shelton recognizes that "the application of a stimulating pulse to one chamber of the heart is a multiple-step process." EX1005, 15:33-35. Shelton further explains that the "details of the pacing algorithm, i.e., the various conditions, time intervals, algorithms, and the like that define the pacing functions of pacemaker 10, are not critical to an understanding of the present invention, and will not be described herein in substantial detail." EX1005, 15:42-47. As Shelton did with the details of the external programmer, it leaves the implementation details of the pacing algorithm to the skilled artisan. EX1005, 15:47-52; EX1003, ¶131.

Thus, a POSA reading Shelton in view of Nappholz would have been expressly directed to search elsewhere for details on how to implement various pacing algorithms. This would include how and whether to limit an individual's ability to change operational parameters. This is especially true because Shelton in

view of Nappholz offers the ability to select between a variety of operational parameter sets by either physician/clinician or a patient. A POSA would have been motivated by safety and even liability concerns to therefore impose limits on which individual parameters of the operational parameter sets can be modified. EX1003, ¶¶131-132.

Mumford fills that need. Like Shelton and Nappholz, Mumford is directed to controlling the operation of biomedical implanted devices, like cardiac pacemakers. EX1009, 1:30-38, 4:1-8. Mumford focuses on providing either limited access to change the parameters of the implanted device, or full access to change the parameters of the implanted device, based on determined permissions. EX1003, ¶133.

A POSA reading Shelton in view of Nappholz would have thus turned to the teachings of Mumford and implemented Mumford's teachings to safely operate Shelton's implanted device by providing user-specific access for changing the operational parameters of an implanted device as compared to a patient. Application of Mumford's techniques on Shelton is an example of using a known technique to improve a similar devices or methods, in the same way. EX1003, ¶¶130-134.

A. Claim 4

1. "The implant device of claim 1 further including:"

As discussed in Section VII.A, Shelton in view of Nappholz renders the preamble of claim 4 obvious. EX1003, ¶135.

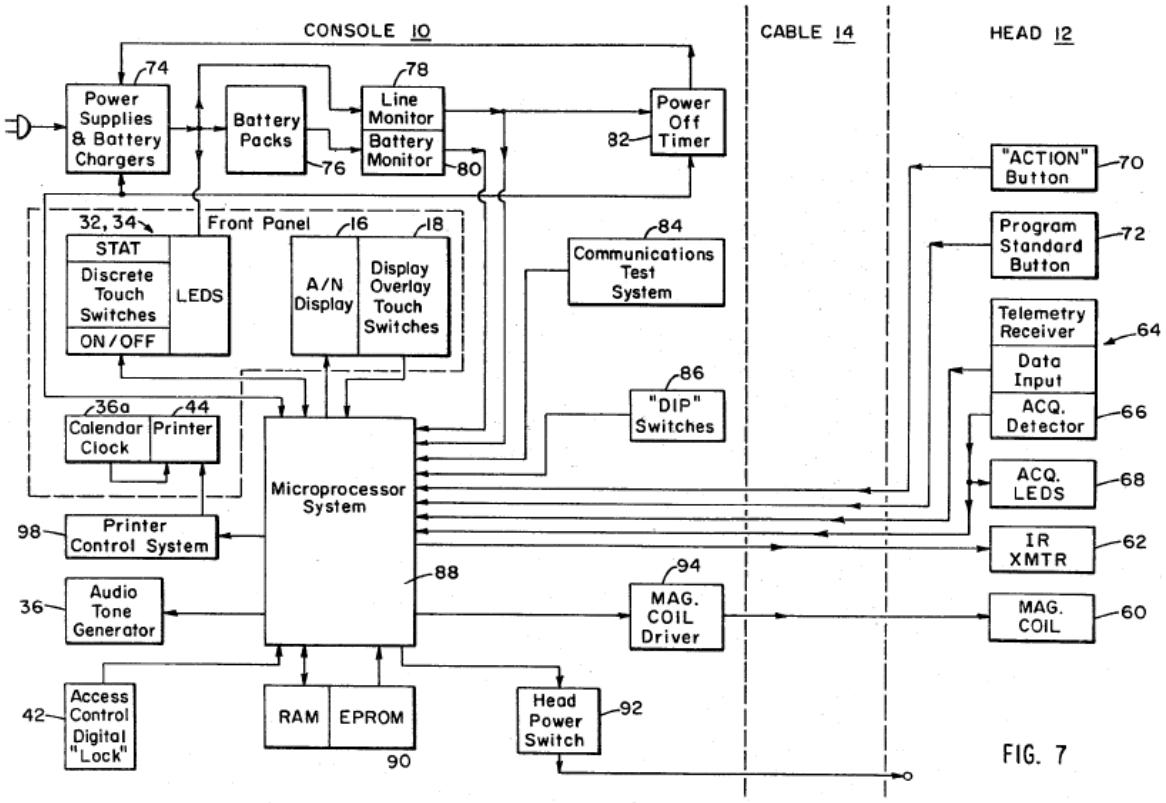
2. "change means for allowing a user of the implant device to change individual parameters included within a selected one of the plurality of operational parameters."

This term is written in "means plus function" format. The '496 patent describes a change means as a part of the hand-held programmer, such as a buttons on a keypad, display screen, or any suitable input means. EX1001, 18:17-20, EX1003, ¶¶136-137. Shelton describes similar structure for the change means in the exemplary Medtronic Model 9760, which provides a selection means for selecting individual operational parameters via a keypad-operated handheld programmer. EX1005, 8:44-50, EX1003, ¶138.

Mumford also discloses an external programmer with input controls for changing only certain ones of the individual parameters included within the selected one of the plurality of operational parameters. EX1009, 4:1-8, 5:33-67 (describing limited access mode). Therefore, Shelton and Mumford describe the same, or equivalent, structure for preforming the function of the change means to that in the '496 patent. EX1003, ¶139.

Mumford also describes an interactive programmer configured to control individual parameter settings of implantable pulse generators. EX1009, 4:1-8. In

that regard, Mumford discloses an external programmer with input controls for changing only certain ones of the individual parameters included within the selected one of the plurality of operational parameters. *Id.*, 5:55-66, EX1003, ¶140. Mumford's Figure 7 is illustrative:



EX1009, FIG. 7.

Element 42 is an "access control digital 'lock'." EX1009, FIG. 7. Also referred to as a "combination lock," Mumford discloses that it "is used to control the level of access to the interactive programmer." *Id.*, 5:55-56. Mumford's "interactive programmer is designed to that when the user attempts to program a particular implant or a particularly sensitive parameter, the system will check to

see if access is restricted." *Id.*, 5:59-62. Mumford thus limits access by a patient certain ranges of values of parameters and certain parameters." *Id.*, 3:2-9; EX1003, ¶141. And if a correct "combination lock" is provided to Mumford's interactive programmer, the limited access switch board in the interactive programmer, provides full access to change the parameters and the ranges of the parameters. EX1009, 5:55-66. EX1003, ¶¶141-143.

Thus, Mumford discloses a change means for allowing a user of the implant device to change individual parameters included within a selected one of the plurality of operational parameters. EX1003, ¶¶136-144.

B. Claim 5

1. "The implant device of claim 4"

As discussed in Section VIII.A, Shelton in view of Nappholz and Mumford renders the preamble of claim 5obvious. EX1003, ¶145.

2. "wherein the change means allows the user of the implant device to change only certain ones of the individual parameters included within the selected one of the plurality of operational parameters."

As discussed in detail in Section VIII.A.2, Shelton and Mumford describe the same, or equivalent, structure for preforming the function of the change means to that in the '496 patent. EX1003, ¶¶146-147. And Mumford limits access by a patient to only change certain ones of the individual parameters of the implanted

device. EX1009, 3:2-7, 5:55-62; *see also* Section IX.A.2. *supra*; EX1003, ¶¶146-147. Mumford thus discloses this feature. EX1003, ¶¶146-148.

IX. Ground 3: The combination of Shelton, Nappholz and Barreras II renders obvious claim 7.

Dependent claim 7 further defines the particular operational parameters that are available to "electrode configuration, ramp rate, and treatment time." EX1003, ¶¶149-150. Shelton explains that "various pacing algorithms and implementations of pacemakers are known and/or commercially available, and that the present invention may be readily adapted for use in different systems." EX1005, 15:47-52; *see also* 8:7-13. Shelton thus expressly leaves the implementation details of the pacing algorithm—that is, the details of the operational parameter sets—to the skilled artisan. Shelton thus expressly directs a POSA to look at the state of the art for assistance in defining various pacing algorithms. EX1003, ¶¶149-150.

Shelton in view of Nappholz generally discloses multiple different sets of operational parameters. EX1005, Abstract, 8:51-56, 23:33-37. In particular, Nappholz's RPP is configured to store sets of operational parameters, and transmit the sets of operational parameters to the implanted device using telemetry means. Nappholz's implanted device stores the received sets of operational parameters. EX1006, 7:50- 8:2; 9:17-29. EX1005, 8:51-56. But Shelton in view of Nappholz does not disclose, in particular, electrode configuration, ramp rate, and treatment time. EX1003, ¶151.

However, there are only a limited number of different operational parameters. Barreras II, like Shelton, is directed to controlling the operation of an implantable, electrically operated medical device system. EX1008, Barreras II, 10:36-42. In particular, Barreras II is directed to adjusting other operational parameters of an implanted device, such as, electrode configuration, ramp rate, and treatment time. EX1008, 11:34-57. Based on the teachings of Barreras II, POSA would have had motivation to modify Shelton in view of Nappholz with Barreras II's additional parameters to provide further options for modifying the operation of the implanted device, thereby rendering Shelton more useful over a wider variety implantable medical devices, as Shelton desires, EX1005, 8:7-14. This is an example of applying a solution from a finite number of identified, predictable solutions, with a reasonable expectation of success in improving Shelton. EX1003, ¶¶149-152.

A. Claim 7

1. "The implant device of claim 6"

As discussed in Section VII.D, Shelton renders the preamble of claim 7 obvious. EX1003, ¶153.

2. "wherein the operational parameters included within the control set of operational parameters further include electrode configuration, ramp rate, and treatment time"

Barreras II discloses operational parameters for an implanted device including electrode configuration (e.g., electrode selection and polarity) and treatment time. EX1008, 11:34-57. Barreras II discloses an output voltage on/off duration which corresponds with the treatment time. EX1008, 11:34-57. Furthermore, Barreras, II discloses the operational parameters including amplitude, rate, pulse width, amplitude ramp-up time at the start of stimulation, amplitude ramp-down time when stimulation ceases, and electrode polarity. EX1008, 8:48-64; EX1003, ¶¶154-156.

Thus, Barreras II discloses the operational parameters of an implanted device including electrode configuration, ramp rate, and treatment time. EX1003, ¶¶154-157. A POSA would have recognized the addition of these additional operational parameters in making Shelton in view of Nappholz more useful over a wide range of implantable medical devices. EX1003, ¶¶153-157.

X. Ground 4: Claims 8-13 are rendered obvious by Nappholz.

A. Independent claim 8

1. "A method of changing the operational parameters used to control an implant device, comprising:"

Nappholz discloses using a device 14 which is a "repeater programmer and telephone" or "RPP" to change the operational parameters of an implant device.

EX1006, 3:60-67; 9:19-29; EX1003, ¶158. Nappholz thus renders obvious the preamble. EX1003, ¶¶158-159.

2. "defining a plurality of sets of operational parameters, each set including individual parameters that define respective characteristics associated with the operation of the implant device;"

Nappholz discloses an implant device having different modes of operation for an implant device. EX1006, 9:19-29. A physician enters instructions for initializing or changing the modes— the operational parameter sets—of the implant device. EX1006, 7:8-9, 7:50-64. Nappholz's Figure 6 is illustrative:

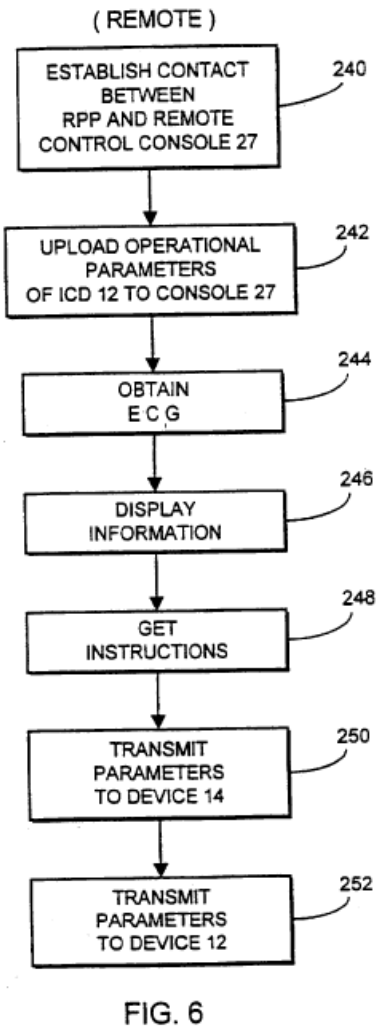


FIG. 6

EX1006, FIG. 6.

The different modes correspond to different levels of activity for a patient,. EX1006, 8:60-9:29, *see also* 9:39-66 (changing modes of operation); EX1003, ¶160. Nappholz reconfigures or modifies the operational parameters if a patient selects a new mode of operation. EX1006, 9:19-29, EX1003, ¶¶160-162. Nappholz's Figure 7 is illustrative:

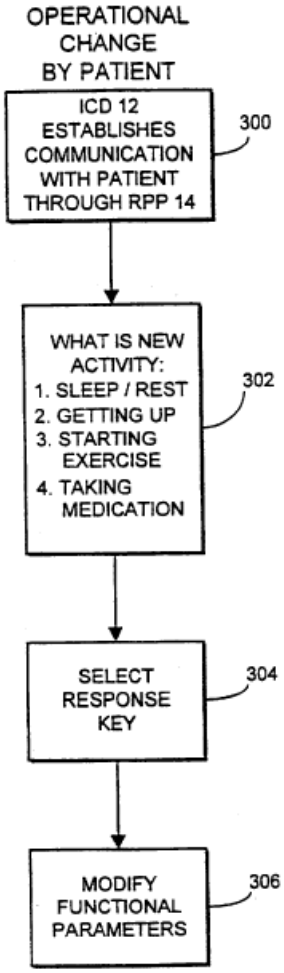


FIG. 7

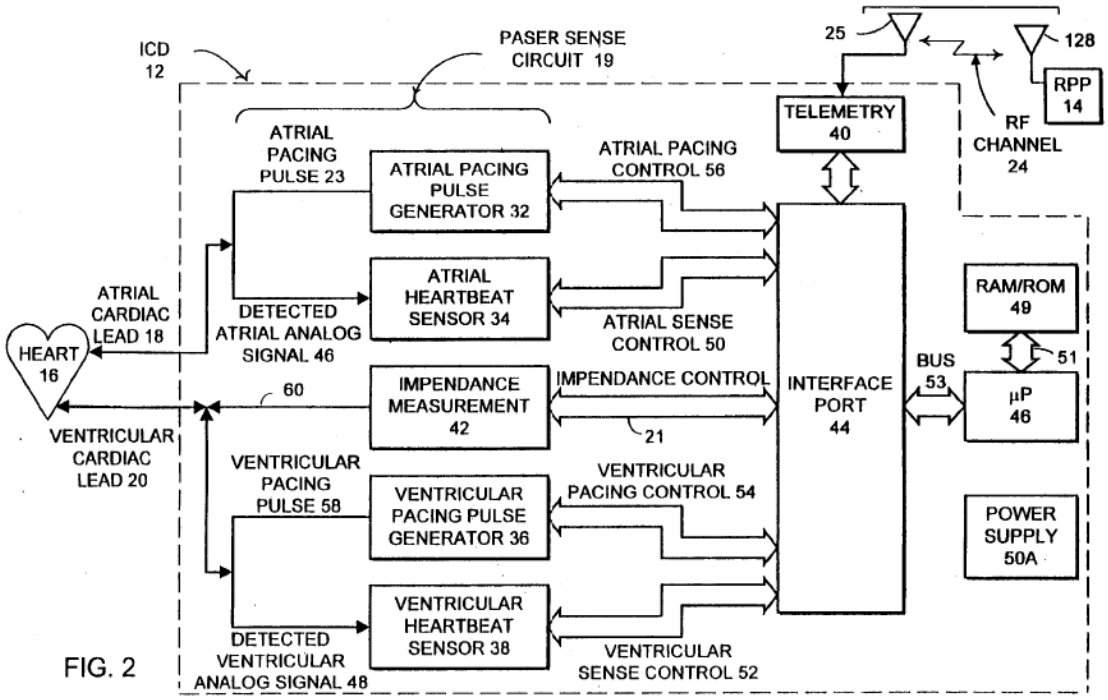
EX1006, FIG. 7.

Nappholz explains that its cardiac stimulating device "must be customized for the patient and the disease." EX1006, 6:56-63. Nappholz must customize the individual parameters in each set of operational parameters. EX1006, 6:64-67, 7:7-8; EX1003, ¶160-162. Thus, it would have been obvious to a POSA that a physician or a patient have the capability to define a plurality of sets of operational parameters, each set including individual parameters that define respective

characteristics associated with the operation of the implant device, as described in Nappholz. EX1003, ¶¶160-162.

3. "storing the plurality of sets of operational parameters;"

Nappholz discloses a microprocessor 46 connected to a random access memory/read only memory unit 49 of the implanted device 12. EX1006, 4:48-50. Nappholz's Figure 2 is illustrative:



EX1006, FIG. 2.

Nappholz discloses the implanted device downloading functional parameters that make up an operational parameter set of the implanted device from the RPP 14. EX1006, 7:63-64. Therefore, the operational parameters corresponding to the various modes of operation are also downloaded and stored into the memory of Nappholz's implanted device. EX1003, ¶163. As Nappholz explains, the RPP

includes a memory 106. EX1006, 5:57-60. Nappholz thus stores operational parameters, ranges for the parameters, and other programming options in an external console as well—namely, Nappholz's RPP. EX1006, 6:64-67, EX1003, ¶164. Nappholz thus discloses this feature. EX1003, ¶¶163-165.

4. "selecting one of the stored sets of operational parameters as a control set of operational parameters; and"

Nappholz discloses an implant device having different modes of operation for the implant device. EX1006, 9:19-29. Furthermore, Nappholz discloses the implant device reconfiguring or modifying the operational parameters if a new mode of operation is selected, either automatically, EX1006, 9:39-66, or when initiated by the patient, EX1006, 9:19-29, EX1003, ¶166. For example, Nappholz discloses that a user may select a different mode of operation for the implant device by selecting a different level of activity. EX1006, 9:19-29. Each mode of operation is a different operational parameter set. EX1003, ¶167. Therefore, Nappholz discloses a plurality of sets of operational parameters. EX1003, ¶167. In response to selecting the level of activity the operational parameters for Nappholz's implant device are modified. EX1003, ¶167.

Thus, it would have been obvious to a POSA that if a user selects a different level of activity the user is selecting one of the stored sets of operational parameters as a control set of operational parameters, EX1003, ¶¶166-168.

5. "providing the control set of operational parameters to the implant device, and using the provided control set of operational parameters to control the operation of the implant device"

Nappholz discloses the implanted device downloading functional parameters of the implanted device from the RPP. EX1006, 7:50-67. A physician may define functional parameters for the implanted device. EX1006, 7:50-67. The functional parameters may first be downloaded to the RPP, and then downloaded to the implanted device, for controlling the operation of the implanted device. EX1006, 7:50-8:2; EX1003, ¶169.

Furthermore, Nappholz discloses the implant device having different modes of operation of the implant device. EX1006, 9:19-29. As stated above, a user may select a different mode of operation for the implant device by selecting a different level of activity. *Id.* Additionally, Nappholz's device stimulates the patient's heart according to operational parameters associated with the currently selected mode. *Id.*, 10:1-4; EX1003, ¶170.

Thus, it would be obvious to a POSA by selecting a control set of operating parameters using Nappholz's RPP, the control set of operating parameters are provided to the implant device, and are used as the provided control set of operational parameters to control the operation of the implant device, as described in Nappholz. EX1003, ¶¶169-171.

B. Claim 9

1. "The method of claim 8 wherein the defining step comprises"

See Section XI.A. and XI.A.2 *supra*; EX1003, ¶172.

2. "defining each set of the plurality of sets of operational parameters so that each of the individual parameters within each set are within prescribed safe operating limits.

Nappholz explains that at implant, the device "is provided with a variety of programmable cardiac monitoring and pacing defibrillation options suitable for a large cross-section of patients and pathologies at implant of the device 12." EX1006, 6:56-61. As such, Nappholz teaches that the device, at implant, "must be customized for the patient and the disease." *Id.*, 6:60-61. To do this, the RPP stores "a complete set of operational parameters, and allowable ranges for these parameters." *Id.*, 6:64-67. After reading Nappholz, a POSA would find it obvious the allowable ranges of the parameters corresponds with defining each set of the plurality of sets of operational parameters so that each of the individual parameters within each set are within prescribed safe operating limits for the individual patient. Patient safety is paramount in Nappholz. EX1006, 10:1-28; EX1003, ¶¶173-174.

Accordingly, it would have been obvious that the allowable ranges for the operational parameters would be within prescribed safe operating limits. EX1003, ¶174. Furthermore, it is obvious that at implant the responsible physician will

customize an operational parameter set for the particular patient and for the particular condition for which stimulation is sought. *Id.* And absent any bad intent, it would have been obvious for the physician, at that time, to define individual parameters that are within safe operating limits. *Id.*

Indeed, Nappholz further gives the physician the ability to define certain alert and operational limits. *Id.* If the operational limits are crossed, the physician may be alerted. EX1006, 7:15-19. Thus, Nappholz not only enables the physician customize the device to the patient at the time of implant, but also allows the physician to monitor the device to ensure patient safety and to further refine the operational parameters. *See* EX1006, 8:34-58; EX1003, ¶175.

A POSA reading Nappholz would have thus found it obvious that a physician would have defined each set of the plurality of sets of operational parameters so that each of the individual parameters within each set are within prescribed safe operating limits. EX1003, ¶¶172-176.

C. Claim 10

1. "The method of claim 9 wherein the storing step comprises"

As discussed above, Nappholz discloses this limitation. EX1003, ¶177.

2. "storing each of the sets of operational parameters within memory circuitry included within the implant device."

Nappholz discloses a microprocessor 46 connected to a random access memory/read only memory unit 49 of the implanted device 12. EX1006, 4:48-50,

FIG. 2. Nappholz discloses the implanted device downloading functional parameters of the implanted device from the RPP. *Id.*, 7:63-64. Therefore, it would have been obvious to a POSA that the operational parameters are downloaded into the memory of the implanted device. EX1003, ¶178.

D. Claim 11

1. "The method of claim 9 wherein the storing step comprises"

As discussed above, Nappholz discloses this limitation. EX1003, ¶179.

2. "storing each of the sets of operational parameters within memory circuitry that is external to the implant device."

Nappholz discloses storing operational parameters, allowable ranges, and other programmable options in an external console or RPP 14. EX1006, 6:64-67, EX1003, ¶180. RPP 14 has a memory 106. EX1006, 5:57-60, FIG. 3; EX1003, ¶181. A POSA would have understood that "programming data" includes the various operational parameter sets. *See, e.g.*, EX1006, 6:64-67; EX1003, ¶181. Nappholz thus discloses this feature. EX1003, ¶¶179-182.

E. Claim 12

1. "The method of claim 9"

See Section XI.B, *supra*; EX1003, ¶183.

2. "further including allowing a user of the implant device to define a new set of operational parameters that replaces an existing set of operational parameters."

Nappholz discloses an external console or RPP that includes a complete set of operational parameters. EX1006, 6:64-67. The physician must customize the implanted device for the particular patient and the patient's condition. *Id.*, 6:56-63. The physician thus enters instructions for initializing or changing the functional parameters of the implant device. *Id.*, 7:50-64; EX1003, ¶184.

Thereafter, Nappholz discloses that the RPP monitors and collects information from the device, EX1006, 7:8-13. The physician can then, "[a]fter reviewing and analyzing this information, … change the operational parameters and download them through RPP 14 to device 12 as shown in FIG. 6." *Id.*, 8:46-58. The changed functional parameters can be a new set of operational parameters replacing the existing set of operational parameters to control the implant device. EX1003, ¶185. Furthermore, the physician can initialize or change the functional parameters of the implanted device. EX1006, 7:59-64. The physician thus can define a new set of operational parameters to replace existing operational parameters, based on feedback from the device. EX1003, ¶185.

Nappholz also discloses an embodiment where the patient herself can elect to change the operational parameter set based on her level of activity. EX1006 9:17-29. The patient may make a selection to change the operational parameters of

the implanted device by selecting the level of activity. EX1003, ¶186. The patient directs the device to define new set of operational parameters replacing the current set of operational parameters by selecting the level of activity. EX1006, 9:22-29; EX1003, ¶186. Indeed, a POSA would appreciate that in Nappholz a patient defines a new set of operational parameters by selecting the patient's level of activity. EX1006, 9:22-29; EX1003, ¶186.

Thus, a POSA reading Nappholz would find it obvious to allow a user (e.g., a physician or a patient) of the implant device to define a new set of operational parameters that replaces an existing set of operational parameters. EX1003, ¶¶183-187.

F. Claim 13

1. "The method of claim 9"

See Section XI.B, *supra*; EX1003, ¶188.

2. "further including the step of limiting changes made to a set of operational parameters to changes in just prescribed ones of the individual parameters included within the set of operational parameters."

Nappholz discloses that its cardiac stimulating device 12 "is provided with a variety of programmable cardiac monitoring and pacing defibrillation options suitable for a large cross-section of patients and pathologies…." EX1006, 6:56-61. Further, Nappholz discloses that "a complete set of operational parameters, and

allowable ranges for these parameters and other programmable options is stored in the external console 27 or RPP 14. EX1003, ¶189.

From this wide open set of monitoring, pacing and defibrillation options, Nappholz discloses that at implant of the device and the leads, "the ICD must be customized for the patient and the disease." EX1006, 6:56-61. A POSA reading Nappholz would thus appreciate that upon implant it would have been obvious to limit the changes made to a set of operational parameters to a prescribed set of individual parameters that are specific and customized to the patient's needs in view of the patient's particular disease. EX1003, ¶190. Indeed, this the purpose of the customized programming performed by the physician at implant. For example, if the purpose of the stimulation is cardiac defibrillation, the OPS will be different than if the purpose of the stimulation is cardiac pacing. *Id*.

Nappholz also discloses the particular manner in which a physician can customize and configure specific functional parameters of the implanted device based on an obtained electrocardiogram or "ECG." EX1006, 7:50-64. Nappholz discloses that a physician can change or initialize the functional parameters, the functional parameters are downloaded to the RPP, and then to the implanted device. EX1006, 7:59-64; EX1003, ¶191. Still further, after the initial customization based on the particular patient and disease, Nappholz discloses further refinement of the operational parameter after "reviewing and analyzing"

feedback from the device, as shown in Figure 6. Therefore, a physician can modify specific operational/functional parameters. EX1003, ¶192.

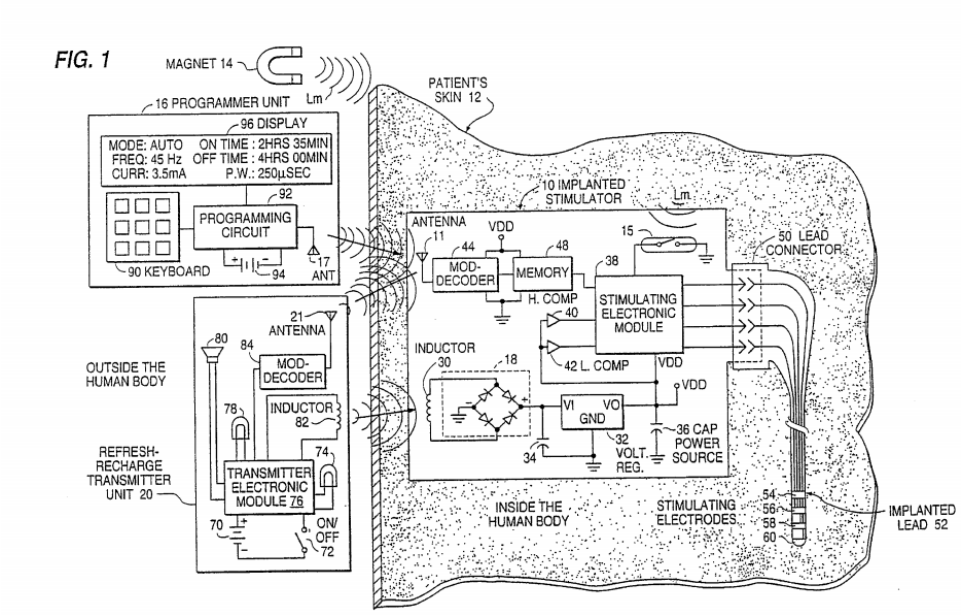
Thus, a POSA reading Nappholz would have found it obvious to limit changes made to a set of operational parameters to changes in just prescribed ones of the individual parameters included within the set of operational parameters. *Id.*, ¶¶188-193.

XI. Ground 5: Claim 14 is rendered obvious by Barreras I.

A. Independent Claim 14

1. "An implant system that permits parameter context switching comprising:"

Barreras I discloses a stimulator implanted with respect to a patient's skin. EX1007, 5:48-49, FIG. 1; EX1003, ¶194. A physician programs a programming unit. EX1007, 8:3-6. The program includes operating parameters (or programming information) such as frequency, pulse, width, and ON time. *Id.* The programming information is communicated to the implanted device. *Id.*, 8:11-16. As shown in detail below, Barreras's programming information allows the stimulating electronic module to change operational parameters. *Id.*; EX1003, ¶194. Figure 1 of Barreras I illustrates the implant system:



EX1007, FIG. 1.

Thus, Barreras I discloses an implant system that permits parameter context switching. EX1003, ¶¶194-195.

2. "an implant device comprising:"

Barreras I's stimulator is an implanted device. EX1007, 5:48-49; EX1003, ¶196. Thus, Barreras I discloses an implanted device. EX1003, ¶196.

(a) "electronic circuitry that performs a prescribed function as controlled by a set of operational parameters,"

Figure 1 of Barreras I illustrates electronic circuitry of an implanted device which is controlled by the operational parameters. EX1007, FIG. 1. Barreras I recites, "[u]pon receipt of this programming data, modulator/ demodulator and decoder 44 decodes and conditions these signals and the digital programming information is captured by memory 48. This digital programming information is

further processed by stimulating electronic module 38." EX1007, 8:11-16; EX1003, ¶197-198.

Thus, Barreras I discloses this feature. EX1003, ¶197-199.

(b) "a first memory element wherein the set of operational parameters is stored,"

Barreras I discloses a memory 48 in which the set of operational parameters—e.g., Barreras's "programming data"—for the implanted device are stored. EX1007, 8:11-16, FIG. 1; EX1003, ¶200. Barreras I explains that, "memory 48 stores information regarding the pulse width, pulse amplitude and stimulating frequency, for the delivery of substantially continual stimulation pulses." EX1007, 7:42-46. Barreras I's pulse width, pulse amplitude and stimulating frequency enable a set of operating parameters. EX1003, ¶¶200-201. Barreras I thus discloses this feature. *Id.*

(c) "a replenishable power source that provides operating power for the implant device,"

Barreras I discloses a "capacitive power source 36" that provides power to the implant device. EX1007, FIG. 1. Power source 36 is replenishable, *id.*, 8:22-24, and is located within the implant device, *id.*, FIG. 1; EX1003, ¶202. Barreras I thus discloses this feature. EX1003, ¶¶202-203.

(d) "a first telemetry circuit that receives control data from an external source, and"

Barreras I explains that "programming commands are sent via telemetry to the memory and programmable devices incorporated within implantable stimulator 10." EX1007, 10:37-39. To receive the programming commands, Barreras I's implant device has a mod-decoder 44 coupled to a memory 48 and an antenna 11. *Id.*, FIG. 1, 5:48-6:14, 8:3-15. Barreras I thus discloses this feature. EX1003, ¶¶204-205.

(e) "a second telemetry circuit that receives power to replenish the replenishable power source;"

Barreras I discloses, a "refresh-recharge transmitter unit 20." EX1007, FIG. 1, 6:34-40. Barreras also discloses an inductor receiving coil in Figure 1, element 30. *Id.*, FIG. 1. Barreras I recites, "[i]nductor coil 82 emits RF waves establishing EMF wave fronts which are received by inductor 30." *Id.*, 6:44-46. The inductor coil 30 is configured to receive power signals to charge the replenishable power source of the implant device. *Id.*, 6:53-61. EX1003, ¶206. Further, antenna 11 in the implant device also receives signals from the refresh-recharge transmitter antenna 21. EX1007, FIG. 1. A POSA would thus have understood the inductor coil and antenna 11 to comprise a second telemetry circuit that receives power to replenish the replenishable power source. EX1003, ¶206.

3. "an external control device comprising a first transmission circuit that transfers control data through the first telemetry circuit of the implant device that defines the set of operational parameters stored in the first memory element of the implant device; and"

Barreras I discloses a programming circuit 92 and antenna 17 as part of its external programming unit 16. EX1007, FIG. 1. Barreras I discloses transmitting programming information to the implant device from a programming unit 16 to the implant device using the programming circuit 92 and antenna 17. *Id.*, 8:3-15. The programming information defines the operational parameters of the implant device, such as frequency, pulse width, or ON time. *Id.*, 8:3-15, EX1003, ¶207.

Furthermore, Barreras I discloses digital programming information being transmitted to the device using a telemetric link (i.e., the antenna) that can be used to control the implanted device. EX1007, 10:37-39; EX1003, ¶211. Barreras I discloses that the programming information is transferred to the implanted stimulator 10 through the antenna 17 and antenna 11. EX1007, 8:3-16; EX1003, ¶¶208-209. Barreras I thus discloses this feature. EX1003, ¶¶207-210.

4. "an external charging device comprising:"

Barerras I discloses an external refresh-replenish transmitter unit 20. EX1007, FIG. 1. The refresh-replenish transmitter unit 20 transmits power signals to the inductor coil 30. *Id.*, 8:22-24. The inductor coil 30 is configured to receive power signals to charge the replenishable power source of the implant device.

EX1007, 6:53-61, 8:22-24; EX1003, ¶213. Barreras I thus discloses this feature. EX1003, ¶¶211-212.

(a) "a power source, and"

Barreras I discloses a rechargeable battery 70 in the refresh-replenish transmitter unit 20. EX1007, 6:35-39, FIG. 1. Barreras I thus discloses this feature. EX1003, ¶213.

(b) "a second transmission circuit that transfers power from the power source through the second telemetry circuit to the replenishable power source of the implant device."

Barreras I discloses a refresh-replenish transmitter unit 20 that includes inductor coil 82. EX1007, FIG. 1. Barreras I recites, "[i]nductor coil 82 emits RF waves establishing EMF wave fronts which are received by inductor 30." EX1007, 6:44-46. Barreras I discloses that the refresh-replenish transmitter unit 20 uses the battery 70 to provide power through the inductor coil 82 to the indictor coil 30 of the implant stimulator 10. *Id.*, 6:35-39, FIG. 1. The inductor coil 30 is configured to receive power signals to charge the replenishable power source 36 of the implant device. *Id.*, 6:53-61, FIG. 1; EX1003, ¶215. Barreras I thus discloses this feature. EX1003, ¶¶214-215.

XII. Ground 6: The combination of Barreras I and Nappholz renders obvious claims 15-16.

Dependent claim 15 further defines the first memory element, which is *internal* to the implant device. Dependent claim 16 further defines a second

memory element, which is *external* to the memory device. Barreras and Nappholz together render these features obvious. EX1003, ¶216.

Barreras I describes an implantable simulator for stimulating a patient's tissue. EX1007, 4:39-43. The implanted device receives operational commands from a programmer unit, via an RF telemetric data link. *Id.*, 8:2-15. A modulator/demodulator and decoder of the implanted device decodes the programming data received by the antenna, and stores the programming data in memory within the implanted device. *Id.*, 8:2-15. Barreras I does not specifically disclose transferring *a plurality* of sets operational parameters to the implanted device which are stored in a memory different than the one in the implanted device. EX1003, ¶217.

Barreras, however, is directed to a wide variety of stimulators that are used for a wide variety of purposes. For example, Barreras I discloses that "[i]mplantable stimulators have been utilized to stimulate nerves in the spinal cord (paresthesia), to stimulate the bladder and control bladder functions, to stimulate the sphincter in control of that bodily function, and to stimulate the brain." EX1007, 1:16-21. Barreras I also references implantable devices for diagnostic monitoring and drug delivery. EX1007, 1:21-23; EX1003, ¶218.

With such a wide variety of possible uses, a POSA would have recognized the benefit of transferring more than a single set of operational parameters to the

implanted device. To not allow a plurality of operational parameters would unnecessarily limit Barreras I's functionality. A POSA would have thus sought to improve Barreras I by permitting it to transfer a plurality of operational parameter sets. EX1003, ¶219.

Nappholz, like Barreras I, is directed to an implantable simulation device. *See* EX1006, Abstract. A POSA would have turned to Nappholz to improve Barreras I because Nappholz is configured to deliver therapy, for example, without the supervision of a physician. *Id.* In Nappholz, an external device programs, monitors, and communicates with the implanted device using telemetry methods. *Id.*, 3:61-4:5, 6:10-19. The external programmer stores operational parameters, which the implanted device downloads. EX1006, 6:64-7:19. EX1003, ¶220. A user-patient in Nappholz can modify the operation of the implanted device remotely. EX1006, 7:38-49. In one example, the patient may change the mode of operation of the implanted device based on a level of activity selected by the user. EX1006, 9:39-52; EX1003, ¶221.

Based on the teachings of Nappholz and Barreras, a POSA would have had motivation to modify Barreras I with Nappholz's expanded programming capabilities, so that Barreras would have the capability to employ the different modes of operation associated with sets of operational parameters of the implanted device, and so that a patient can change the mode of operation and implement new

sets of operational parameters using the device. Such an improvement is obvious because it uses a known technique to improve a similar device in the same way. EX1003, ¶¶216-222.

A. Claim 15

1. "The implant system of claim 14 wherein the first memory element within the implant device has a plurality of sets of operational parameters stored therein,"

Nappholz discloses an implanted device having a microprocessor 46 connected to a random access memory/read only memory unit 49. EX1006, 4:48-50. Nappholz's implanted device downloads functional parameters to the implanted device from RPP 14. *Id.*, 7:63-64. Nappholz discloses that its "cardiac stimulating device 12 is provided with a variety of programmable cardiac monitoring and pacing defibrillation options suitable for a large cross-section of patients and pathologies at implant of the device 12 and the leads 18-20 and the ICD must be customized for the patient and the disease." *Id.*, 6:56-61. Nappholz thus discloses that a plurality of operational parameter sets are stored into the memory of the implanted device. EX1003, ¶223.

Thus, Nappholz discloses the first memory element within the implant device storing plurality of sets of operational parameters. *Id.*, ¶¶223-224.

2. "and wherein the external control device transfers control data to the implant device that selects one of the plurality of sets of operational parameters as a control set of operational parameters to be used to control the electronic circuitry."

Nappholz discloses a cardiac stimulating device 12 is implanted in the patient. EX1006, 4:30-35. Nappholz further discloses operational parameters, ranges for the parameters, and other programming options in an external console. *Id.*, 6:64-67. Nappholz discloses a physician transmitting operating parameters from the RPP to the implant device. *Id.*, 7:59-64. The RPP is a Repeater, Programmer, and Phone which can provide communication between the ICD, the patent, the physician, and/or other health care providing facility and personnel. *Id.*, 2:66-3:10; EX1003, ¶225. Nappholz also explains that a user may change the operational parameters of the implanted device by selecting the level of activity using the unit (i.e., Repeater, Programmer, and Phone (RPP)). EX1006, 9:19-29; EX1003, ¶226.

Thus, Nappholz discloses this feature. EX1003, ¶¶225-226.

B. Claim 16

1. "The implant system of claim 14 wherein the external control device includes a second memory element wherein a plurality of sets of operational parameters are stored, and"

Nappholz's RPP 14 has a memory106 coupled to microprocessor 90. EX1006, FIG. 3 (RPP 14), 5:57-60; EX1003, ¶228. Nappholz's RPP 14 stores

operational parameters and allowable ranges. EX1006, 6:64-67. Nappholz thus discloses this feature. EX1003, ¶¶228-229.

2. "further wherein the external control device includes means for selecting one of the plurality of sets of operational parameters and sending the selected set of operational parameters to the implant device for storage in the first memory means, from which location the selected set of operational parameters controls the operation of the electronic circuitry within the implant device."

This term is written in "means plus function" form. The '496 patent describes a hand-held programmer, *see e.g.*, EX1001, 4:4-14; FIG. 1 (202), or a clinician programmer, *see e.g.*, *id.*, 14:57-67, 9:32-38, as the structure for carrying out the "means for selecting." The '496 patent further describes a telemetry circuit as the structure for carrying out the "means for sending." *Id.*, 9:32-38. Furthermore, in the '496 patent, the first memory means is memory 162, as illustrated in Figure 6. *Id.*, FIG. 6, 16:62-17:25; EX1003, ¶¶230-231.

Nappholz discloses equivalent structure that performs the same function. Nappholz explains that a physician can initialize or change the functional parameters of an implanted device using its RPP 14—i.e., its external control device. EX1006, 7:59-64. Furthermore, Nappholz discloses an implant device having a telemetry circuit 40 that receives operating parameters from RPP 14. *Id.*, 7:63-64, FIG. 2. This corresponds with means for selecting one of the plurality of

sets of operational parameters and sending the selected set of operational parameters to the implant device. EX1003, ¶232.

With respect to the, "the first memory means" as recited in claim 16, it is unclear and vague as "the first memory means" is not introduced in claim 14 from which claim 16 depends or earlier in claim 16. EX1003, ¶233. Nonetheless, interpreting "the first memory means" to correspond to the first memory element as recited in claim 14 of the '496 patent, Nappholz discloses an implanted device having a microprocessor 46 connected to a random access memory/read only memory unit 49 which stores sets of operational parameters. EX1006, 4:48-50. So the corresponding structure in Nappholz is the random access memory/read only memory unit 49. EX1003, ¶235.

Nappholz discloses operational parameters, ranges for the parameters, and other programming options in an external console. EX1006, 6:64-67. Nappholz discloses a physician loading operational parameters and the allowable ranges for the parameters onto the RPP from the implant device. *Id.*, 7:59-64. The RPP is a Repeater, Programmer, and Phone which can provide communication between the ICD, the patent, the physician, and/or other health care providing facility and personnel. *Id.*, 2:66-67, 3:1-10, EX1003, ¶235.

Furthermore, Nappholz discloses that a user may make a selection to change the operational parameters of the implanted device by selecting the level of activity using the unit (i.e., the RPP). EX1006, 9:19-29; EX1003, ¶236.

Thus, Nappholz discloses this feature. EX1003, ¶¶230-236.

XIII. Ground 7: The combination of Barreras I, Nappholz and Mumford renders obvious claims 17-18.

Dependent claim 17 adds to claim 16 "memory access control circuitry" in the "external control device" to either limit a user's access to individual operating parameters, or to grant full access to those operating parameters. Dependent claim 17 also adds a "patient selection circuit" and a "clinician programmer." Dependent claim 18 adds to claim 17 "limit checking circuitry" that prevents alteration of certain individual operating parameters. Adding Mumford's teaching to the combination of Barreras I and Nappholz renders claims 17 and 18 obvious. EX1003, ¶238.

Mumford, like Barreras I and Nappholz, is directed to controlling the operation of an implanted device. EX1009, 4:1-8. Mumford focuses on providing limited access to change the parameters of the implanted device or full access to change the parameters of the implanted device based on determined permissions. *Id.*, 3:2-8. Given the broad applicability of Barreras I, EX1007, 1:16-24, and Nappholz's focus on customization and patient safety, EX1006, 6:55-67, 7:8-19, a POSA would have had motivation to modify Barreras I in view of Nappholz with

Mumford to maintain device safety and to provide a medical professional more access for changing the operational parameters of an implanted device as compared to a patient. EX1003, ¶¶238-239.

A. Claim 17

1. "The implant system of claim 16 further including:"

As described above, in Section XIII.B. Barreras I and Nappholz discloses this preamble of claim 17. EX1003, ¶240.

2. "limited memory access control circuitry within the external control device that allows access to a selected plurality of individual operating parameters within each of the sets of operational parameters included within the plurality of sets of operational parameters stored within the second memory element;"

Nappholz discloses storing operational parameters, allowable ranges, and other programmable options in an external console 27 or RPP 14. EX1006, 6:64-67. Nappholz discloses storing operational parameters and allowable ranges for the operational parameters in RPP 14's memory 106. *Id.*, 5:57-60; 6:64-67; EX1003, ¶241.

Nappholz thus discloses an external control device (RPP14) that includes a second memory element (memory 106) wherein a plurality of sets of operational parameters are stored. EX1003, ¶¶240-242.

Mumford discloses a limited access switch board. EX1009, 8:15-21. The limited access switch board includes two sets of thumbwheel switches for

switching between limited access and full access. *Id.*, 5:55-66. In operation, Mumford explains that "[t]he interactive programmer is designed so that when the user attempts to program a particular implant or a particularly sensitive parameter, the system will check to see if access is restricted. If it is, the system will check to see if the correct combination has been entered on combination lock 42. If it has been entered, the interactive programmer will be in the full access mode; if not, it will be in the 'limited access' mode." EX1009, 5:59-66, EX1003, ¶245. Mumford's limited access switch board is therefore the same as the claimed "limited memory access control circuitry." EX1003, ¶243.

Barreras I and Nappholz in further view of Mumford thus discloses this feature. EX1003, ¶¶241-246.

3. "full memory access control circuitry within the external control device that allows access to all of the individual operating parameters of each of the sets of operational parameters included within the plurality of sets of operational parameters stored within the second memory element;"

As described in Section XIII.A.2, Nappholz discloses an external control device (RPP 14) includes a second memory element (memory 106) wherein a plurality of sets of operational parameters are stored. EX1003, ¶247.

Mumford, in turn, discloses providing full access mode to physicians and other qualified individuals to change any of the operational parameters. EX1009, 3:2-8. The limited access switch board which can include two sets of thumbwheel

switches for switching between limited access and full access. *Id.*, 5:55-66. In this regard, the switch must be activated when providing limited or full access. *Id.* Mumford's limited access switch board enables the full memory access control circuitry. EX1003, ¶248.The limited access switchboard may provide limited or full access mode to the user of the implanted device. EX1009, 5:59-66; EX1003, ¶249.

Thus, Barreras I and Nappholz, in further view of Mumford, discloses this feature. EX1003, ¶¶247-250.

4. "a manual patient selection circuit that allows a patient user of the external control device to selectively alter the selected plurality of individual operating parameters accessible through the limited memory access control circuitry; and"

Mumford discloses a programmer that enables selectively changing individual operating parameters. EX1009, 3:2-7. Mumford discloses a limited access switch board. *Id.*, 8:15-20. The limited access mode limits the operational parameters of the implant device a user may adjust or change. *Id.*, 3:2-7; EX1003, ¶251.

In operation, Mumford explains that, "[t]he interactive programmer is designed so that when the user attempts to program a particular implant or a particularly sensitive parameter, the system will check to see if access is restricted. If it is, the system will check to see if the correct combination has been entered on combination lock 42. If it has been entered, the interactive programmer will be in

the full access mode; if not, it will be in the 'limited access' mode." EX1009, 5:59-66; EX1003, ¶252.

Thus, Mumford's interactive programmer, corresponds to the manual patient circuit which allows a patient user of the external control device to selectively alter the selected plurality of individual operating parameters accessible through the limited memory access control circuitry. EX1003, ¶¶251-253. As explained above, POSA would have found it obvious to incorporate Mumford's teaching in the combination of Barreras I and Nappholz.

5. "a clinician programmer selectively coupled to the full memory access control circuitry that allows a clinician user of the clinician programmer to selectively alter all of the individual operating parameters of each of the sets of operational parameters included within the plurality of sets of operational parameters stored within the second memory element."

As described in Section XIII.A.2, Nappholz discloses the external control device includes a second memory element wherein a plurality of sets of operational parameters are stored. EX1003, ¶254.

Mumford discloses a physician (or clinician) using a programmer to change the operational parameters of the implanted device. Mumford's limited access switch board include two sets of thumbwheel switches for switching between limited access and full access. EX1009, 5:55-66. In this regard, the switch must be activated when providing limited or full access. *Id.* Therefore, Mumford's limited

access switch board enables both limited and full memory access control circuitry. EX1003, ¶¶255.

In operation, Mumford explains that "[t]he interactive programmer is designed so that when the user attempts to program a particular implant or a particularly sensitive parameter, the system will check to see if access is restricted. If it is, the system will check to see if the correct combination has been entered on combination lock 42. If it has been entered, the interactive programmer will be in the full access mode; if not, it will be in the "limited access" mode." EX1009, 5:59-66. The limited access switch board is coupled to the interactive programmer. *Id.*; EX1003, ¶257.

The interactive programmer may thus function as a physician (or clinician) programmer or as the patient programmer, depending on the status of the interactive programmer's combination lock. *Id.*; EX1003, ¶258.

A POSA would have also found it obvious to give a physician or clinician full access to all of the individual operating parameters. EX1003, ¶¶258. Indeed, for Nappholz's device, "the ICD must be customized for the patient and the disease," and it the physician or clinician that would perform such customization in view of the Nappholz's "variety of programmable cardiac monitoring and pacing defibrillation options suitable for a large cross-section of patients and pathologies at implant." EX1006, 6:55-67.

Thus, after reading Mumford, a POSA would have found it obvious to incorporate Mumford's teaching into Nappholz's external programmer so that the RPP may more safely function as a physician (or clinician) programmer to selectively provide full memory access control circuitry. Such access safely allows a clinician user of the programmer to selectively alter all of the individual operating parameters of each of the sets of operational parameters included within the plurality of sets of operational parameters stored within the second memory element when the physician provides the correct combination lock to the interactive programmer, as described in Mumford. EX1003, ¶¶254-259.

B. Claim 18

1. "The implant system of claim 17 wherein the external control device further includes limit checking circuitry that prevents an alteration of individual operating parameters contained within the plurality of sets of operational parameters that exceeds a respective predefined limit."

As disclosed directly above, Mumford discloses preventing a user's access to certain parameters or ranges of parameters. EX1009, 5:59-66. Mumford also provides a "STAT SET button 72 … for emergency programming of standard parameter values and modes considered safe for most patients without having to leave the patient to return to the console." EX1009, 6:34-37.

Nappholz similarly discloses that RPP 14 stores "a complete set of operational parameters, and allowable ranges for these parameters." EX1006, 64-

67. So Nappholz also puts limits on the allowable ranges for individual operating parameters. EX1003, ¶260-261. Nappholz further gives the physician the ability to define certain alert and operational limits. EX1006, 7:15-19. Nappholz explains how RPP 14 collects the data from the implant device, and if the operational limits are crossed, the physician may be alerted. EX1006, 7:15-19. After reading Nappholz it would have been obvious to a POSA that the controller 66 and microprocessor 90 of Nappholz's RPP 14, EX1006 5:49-67, functions as the claimed limit checking circuitry. Furthermore, a POSA would have found it obvious that the controller 66 and microprocessor 90 of Nappholz's 90 check and prevent the parameters from crossing an allowable range as defined by the operational limits. EX1003, ¶260-261.

Thus, the combination of Barreras, Mumford and Nappholz disclose this feature.

XIV. Mandatory Notices (37 C.F.R. § 42.8(a)(1))

REAL PARTY IN INTEREST: The real party-in-interest is Petitioner Nevro Corp.

RELATED MATTERS: The '496 patent is involved in the following pending litigation proceeding: *Boston Scientific Corp. et al. v. Nevro Corp.*, Case No. 1:18-cv-00644 (DED).

LEAD AND BACKUP COUNSEL: Under 37 C.F.R. § 42.8(b)(3) and 42.10(a), Petitioner appoints **Jon E. Wright** (Reg. No. 50,720) as lead counsel and **Ian Soule** (Reg. No. 74,290) as back-up counsel, both at the address: STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C., 1100 New York Avenue, N.W., Washington, D.C., 20005, phone (202) 371-2600, and facsimile (202) 371-2540. Additional back-up counsel include **Ching-Lee Fukuda** (Reg. No. 44,334, clfukuda@sidley.com, 212-839-7364) at the address: Sidley Austin LLP, 787 Seventh Avenue, New York, New York 10019, and **Thomas A. Broughan**, III (Reg. No. 66,001, tbroughan@sidley.com, 202-736-8314) and **Sharon Lee**[1] (sharon.lee@sidley.com, 202-736-8510), both at the address: Sidley Austin LLP, 1501 K Street N.W., Washington, DC 20005.

SERVICE INFORMATION: Petitioner consents to electronic service by email at: **jwright-PTAB@sternekessler.com**, **isoule-PTAB@sternekessler.com**,

[1] Nevro will file a motion for Sharon Lee to appear *pro hac vice* according to the Board's orders and rules.

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XV. Grounds for Standing (37 C.F.R. § 42.104(a))

The undersigned and Petitioner certify that the '496 patent is available for *inter partes* review. Petitioner is not barred or estopped from requesting this *inter partes* review on the grounds herein.

XVI. Conclusion

For the reasons above, *inter partes* review of claims 1-18 of U.S. Patent No. 6,381,496 is requested.

Respectfully submitted,

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Date: July 18, 2019

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CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATION, TYPEFACE REQUIREMENTS, AND TYPE STYLE REQUIREMENTS

1. This Petition complies with the type-volume limitation of 14,000 words, comprising 13,873 words, excluding the parts exempted by 37 C.F.R. § 42.24(a).

2. This Petition complies with the general format requirements of 37 C.F.R. § 42.6(a) and has been prepared using Microsoft® Word 2010 in 14 point Times New Roman.

Respectfully submitted,

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CERTIFICATION OF SERVICE (37 C.F.R. §§ 42.6(e), 42.105(a))

The undersigned hereby certifies that on July 18, 2019, true and correct copies of the foregoing **PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 6,381,496**, Petitioner's Power of Attorney, and all associated exhibits were served in their entireties on the following parties via FedEx Express®:

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