

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEVRO CORP.,
Petitioner

v.

BOSTON SCIENTIFIC NEUROMODULATION CORP.,
Patent Owner.

IPR2019-01340
Patent 6,381,496 B1

Before MICHAEL W. KIM, ROBERT A. POLLOCK, and
JASON W. MELVIN, *Administrative Patent Judges*.

POLLOCK, *Administrative Patent Judge*.

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

A. Background

Nevro Corp. (“Petitioner”) filed a Petition for an *inter partes* review of claims 1–18 of U.S. Patent No. 6,381,496 (“the ’496 patent,” Ex. 1001). Paper 2 (“Pet.”). Boston Scientific Neuromodulation Corp. (“Patent Owner”) timely filed a Preliminary Response. Paper 6 (“Prelim. Resp.”). We review the Petition, Preliminary Response, and accompanying evidence under 35 U.S.C. § 314.

B. Real Parties-in-Interest

Petitioner identifies itself, Nevro Corp., as the real party-in-interest. Pet. 77. According to Patent Owner, its real parties-in-interest are Boston Scientific Neuromodulation Corp. and Boston Scientific Corp. Paper 4, 2.

C. Related Proceedings

The ’496 patent is at issue in *Boston Scientific Corp. et al. v. Nevro Corp.*, Civil Action No. 1:18-cv-00644 (D. Del.). *See* Pet. 77; Paper 4, 2.

D. Summary of the Institution Decision

For the reasons provided below, we determine Petitioner has satisfied the threshold requirement set forth in 35 U.S.C. § 314(a). Because Petitioner has demonstrated a reasonable likelihood that at least one claim of the ’496 patent is unpatentable, we institute an *inter partes* review of the challenged claims.

E. Asserted Grounds of Unpatentability

Petitioner asserts seven grounds of unpatentability (Pet. 3–4):

Ground	Claims	Basis	Asserted References
1	1–3, 6	103(a) ¹	Shelton, ² Nappholz ³
2	4, 5	103(a)	Shelton, Nappholz, Mumford ⁴
3	7	103(a)	Shelton, Nappholz, Barreras ’887 ⁵
4	8–13	103(a)	Nappholz
5	14	103(a)	Barreras ’217 ⁶
6	15, 16	103(a)	Barreras ’217, Nappholz
7	17, 18	103(a)	Barreras ’217, Nappholz, Mumford

In support of its patentability challenges, Petitioner relies on, *inter alia*, the Declaration of Mark W. Kroll, Ph.D. Ex. 1003.

F. The ’496 Patent and Relevant Background

1. Specification

The ’496 patent’s Specification is broadly directed “to parameter context switching, i.e., defining and/or selecting different operational

¹ The Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) (“AIA”), amended 35 U.S.C. §§ 102 and 103. Because the challenged claims of the ’496 patent have an effective filing date before the effective date of the applicable AIA amendments, we refer to the pre-AIA versions of 35 U.S.C. § 103 throughout this Decision.

² U.S. Patent No. 5,387,228, issued Feb. 7, 1995, Ex. 1005.

³ U.S. Patent No. 5,720,770, issued Feb. 24, 1998, Ex. 1006.

⁴ U.S. Patent No. 4,432,360, issued Feb. 21, 1984, Ex. 1009.

⁵ U.S. Patent No. 5,735,887, issued Apr. 7, 1998, Ex. 1008.

⁶ U.S. Patent No. 5,591,217, issued Jan. 7, 1997, Ex. 1007.

parameters sets for use by an implant device,” where the device “include[es] all types of neural stimulators and sensors, deep brain stimulators, cochlear stimulators, drug delivery systems, muscle tissue stimulators and the like.” *Id.* at Title, 5:44–62; *see also id.* at 3:8–10 (defining “context switching” as “changing one set of operational parameters to another”). “[B]y providing an implant device having the ability to perform context switching . . . the patient may advantageously swap the current set of operational parameters with another set of operational parameters” thereby controlling the implant device. *Id.* at 3:6–15. The Specification exemplifies the use of context switching “with reference to the implanted pulse generator (IPG) and hand-held programmer (HHP) of a spinal cord stimulation (SCS) system. *Id.* at 5:47–65.

According to the Specification, “[a] spinal cord stimulation (SCS) system treats chronic pain by providing electrical stimulation pulses from an electrode array placed epidurally near a patient’s spinal cord.” Ex. 1001, 1:9–14. “The operation of an implanted device depends upon the storage and use of certain operational parameters.” *Id.* at 1:21–22. “[T]hese parameters might include: stimulation pulse amplitudes, pulse durations, channel frequencies, electrode configurations, ramp rates and treatment times, and the like.” *Id.* at 1:23–26. The Specification states that known SCS systems “use different approaches for modifying or changing the operational parameters that control operation of the device,” generally requiring an appointment with a medical professional. *Id.* at 2:48–55. The Specification states that “what is needed is a way for the patient to readily make appropriate changes to the operating parameters of an implant device so long as such operating parameter changes maintain the device operation within safe operating limits.” *Id.* at 2:64–3:1.

The SCS system may include an implanted pulse generator (IPG) and hand-held programmer (HHP). *Id.* at 5:47–50. The IPG is shown in Figure 4 of the '496 patent, reproduced below.

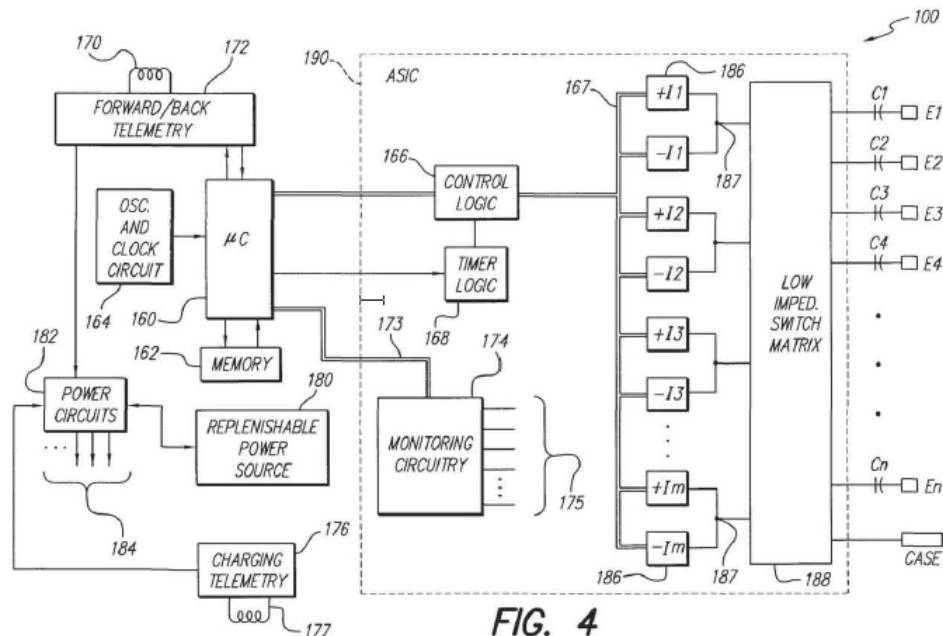


Figure 4 depicts a block diagram of the main components of IPG 100. *Id.* at 5:5–8.

The '496 patent's Specification describes IPG 100 including microcontroller 160 connected to memory circuit 162. *Id.* at 9:7–11. Microcontroller 160 controls “the operation of the IPG in accordance with a selected operating program and operational parameter set (OPS).” *Id.* at 9:15–17. “The operating program and OPS are programably stored within different locations of [] memory 162 by transmitting an appropriate modulated carrier signal through [] receiving coil 170 and forward/back telemetry circuitry 172 from an external programing unit, e.g., [HHP] 202 and/or [] clinician programmer 204.” *Id.* at 9:22–27.

Figure 6 of the '496 patent is reproduced below.



Figure 6 depicts a functional block diagram of the IPG of Figure 4, and functionally illustrates a method for selecting different operational parameters sets. *Id.* at 5:14–18.

The '496 patent's Specification describes memory 162 storing memory table 165 which “includes individual addressable locations wherein various operational parameters may be stored.” *Id.* at 17:2–4. The Specification explains:

A first operational parameter, for example, may comprise data that defines the pulse width (PW) of a stimulation pulse. Yet other operational parameter data may define the pulse rate (PR), pulse amplitude (PA), electrode configuration (EC), ramp rate (RR), treatment times (TI), a first other parameter (P1), and a second other parameter (P2), and the like, associated with a stimulation pulse sequence. All such data, when combined, thus define an operational parameter set (OPS) that may be used by the implant device 100 or 100' as it provides stimulation pulses through selected electrodes E1, E2, . . . En of the electrode array 110.

Id. at 17:4–15. Memory 162 may store “a plurality of different operational parameter sets, e.g., OPS0, OPS1, OPS2, . . . OPSn.” *Id.* at 17:26–32. The patient user may then manually select a different OPS from each OPS stored within memory 162. *Id.* at 17:32–45.

2. *Challenged Claims*

The '496 patent includes 18 claims. Petitioner challenges claims 1–18. Pet. 2. Of these, we list independent claims 1, 8, and 14 below.

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.
8. A method of changing the operational parameters used to control an implant device, comprising:
 - 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;
 - storing the plurality of sets of operational parameters;

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

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.

14. An implant system that permits parameter context switching comprising:

an implant device comprising:

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

a first memory element wherein the set of operational parameters is stored,

a replenishable power source that provides operating power for the implant device,

a first telemetry circuit that receives control data from an external source, and

a second telemetry circuit that receives power to replenish the replenishable power source;

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

an external charging device comprising:

a power source, and

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.

Ex. 1001, 19:47–22:35.

3. *Relevant Prosecution History*

The Examiner allowed claims 1–18 without rejection or comment. Ex. 1002, 40–46. None of the references recited in Petitioner’s Grounds were before the Examiner. *See* Ex. 1001, code (56).

II. ANALYSIS

A. *Legal Standards*

“In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable.” *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016) (citing 35 U.S.C. § 312(a)(3) (requiring *inter partes* review petitions to identify “with particularity . . . the evidence that supports the grounds for the challenge to each claim”)). This burden of persuasion never shifts to Patent Owner. *See Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015) (discussing the burden of proof in *inter partes* review).

A claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which that subject matter pertains. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) objective evidence of nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

In analyzing the obviousness of a combination of prior art elements, it can be important to identify a reason that would have prompted one of skill in the art “to combine . . . known elements in the fashion claimed by the patent at issue.” *KSR*, 550 U.S. at 418. A precise teaching directed to the specific subject matter of a challenged claim is not necessary to establish obviousness. *Id.* Rather, “any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed.” *Id.* at 420. Accordingly, a party that petitions the Board for a determination of unpatentability based on obviousness must show that “a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so.” *In re Magnum Oil Tools Int’l, Ltd.*, 829 F.3d 1364, 1381 (Fed. Cir. 2016) (internal quotations and citations omitted).

B. Level of Ordinary Skill in the Art

In determining the level of skill in the art, we consider the type of problems encountered in the art, the prior art solutions to those problems, the rapidity with which innovations are made, the sophistication of the technology, and the educational level of active workers in the field. *Custom Accessories, Inc. v. Jeffrey-Allan Indus. Inc.*, 807 F.2d 955, 962 (Fed. Cir. 1986); *Orthopedic Equip. Co. v. United States*, 702 F.2d 1005, 1011 (Fed. Cir. 1983).

Petitioner contends that a person of ordinary skill in the art as of the relevant date “would have had general knowledge of implantable medical devices and various related technologies,” as well as “(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.” Pet. 11 (citing Ex. 1003 ¶¶ 15–18). Patent Owner does not presently dispute Petitioner's proposed definition of the skilled artisan. Prelim. Resp. 6. And as Petitioner's proposed definition is not inconsistent with the cited prior art, we adopt it for the purposes of this Decision. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (explaining that specific findings regarding ordinary skill level are not required “where the prior art itself reflects an appropriate level and a need for testimony is not shown” (quoting *Litton Indus. Prods., Inc. v. Solid State Sys. Corp.*, 755 F.2d 158, 163 (Fed. Cir. 1985))).

C. Claim Construction

We interpret a claim “using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. 282(b).” 37 C.F.R. § 42.100(b) (2019). Under this standard, we construe the claim “in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent.” *Id.* Furthermore, at this stage in the proceeding, we need only construe the claims to the extent necessary to determine whether to institute *inter partes* review. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (“[W]e need only construe terms ‘that are in controversy, and only to the extent necessary to resolve the controversy.’” (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999))).

Petitioner proposes constructions for several claim phrases under 35 U.S.C. § 112, sixth paragraph as means-plus-function limitations. Pet. 12–15. In particular, Petitioner proposes constructions for “selection means,” “memory access control means,” “memory means,” “telemetry means,” “change means,” and “means for selecting one of a plurality of sets of operational parameters,” which it presents in tabular format. *Id.* Patent Owner does not contest Petitioner’s proposed constructions of means-plus-function limitations. *See* Prelim. Resp. 6. Because Petitioner’s presently uncontested definitions are not unreasonable, we apply them for the purposes of this Decision.

Patent Owner proposes constructions for the claim phrases “set of operational parameters,” and “parameter context switching.” *See* Prelim. Resp. 7–9. We address each of these in turn below.

1. “set of operational parameters”

Patent Owner argues the ’496 patent’s Specification “clearly defines a ‘set of operational parameters’ or an operational parameter set (‘OPS’).” *Id.* at 7. In particular, Patent Owner refers to memory table 165 of Figure 6, and the Specification’s discussion thereof, to construe “set of operational parameters” as a “combination of more than one type of data defining the stimulation pulses provided by the implant device.” *Id.* at 7–8 (citing Ex. 1001, 17:2–15). According to the Specification, “FIG. 6 depicts a functional block diagram of a portion of an implant device, e.g., the IPG of FIG. 4 or FIG. 5, and functionally illustrates one manner in which different operational parameter sets may be selected for use by the implant device.” *Id.* at 5:23–28. And with reference to Figure 6, “memory table 165 includes

individual addressable locations wherein various operational parameters may be stored.” Ex. 1001, 17:2–4. In the embodiment set forth in Figure 6, these

may comprise data that defines the pulse width (PW) of a stimulation pulse. . . . pulse rate (PR), pulse amplitude (PA), electrode configuration (EC), ramp rate (RR), treatment times (TI), . . . and the like, associated with a stimulation pulse sequence. All such data, when combined, thus define an operational parameter set (OPS) that may be used by the [IPG] as it provides stimulation pulses through selected electrodes.

Id. at 17:4–14.

Patent Owner’s definition is consistent with “the implanted pulse generator (IPG) and hand-held programmer (HHP) of a spinal cord stimulation (SCS) system,” used to exemplify parameter context switching in Figure 6 of the ’496 Specification. *See, e.g., id.* at 5:44–53. On the record before us, however, we find Patent Owner’s proposed definition unduly narrow.

As an initial matter, we note that none of the challenged claims recite a spinal cord stimulation system or any other type of implanted pulse generator that might require a set of operational parameters to direct the implanted device to deliver “stimulation pulses” as Patent Owner’s proposed construction suggests. Moreover, the ’496 Specification emphasizes 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.” *Id.* at 1:16–49 (emphasis added). Accordingly, it states:

While the invention will be described in the context and background of a spinal cord stimulation system, it is to be understood that the invention has applicability, and can be used with, numerous different types of implant devices and systems, including all types of neural stimulators and sensors, deep brain

stimulators, cochlear stimulators, drug delivery systems, muscle tissue stimulators, and the like.

Id. at 1:37–45. The Specification likewise emphasizes that the invention “has broad applicability, and may be used with numerous different types of implant devices and/or systems” other than implanted pulse generators. *Id.* at 5:55–62. Thus, for example, whereas “[f]or a pulse generator system, e.g., an SCS system, [operational] parameters might include: stimulation pulse amplitudes, pulse durations, channel frequencies, electrode configurations ramp rates and treatment times, and the like,” for a drug delivery system, appropriate operational parameters may be “related to the type of drug delivery, [or] the drug medication rate of delivery.” *Id.* at 1:20–29.

We understand all of the above parameters to control the intended function(s) of some implanted device. In particular, irrespective of the type of device or system, the Specification explains that “[t]he present invention relates to the manner in which these operational parameters, used by the implant system as it carries out its intended function, are changed and managed.” *Id.* at 1:34–37. “When it is necessary to change the operation of such an implanted device, it is necessary to modify the parameters used by the device as it carries out its intended function, e.g., delivering stimulation pulses, delivering drug medication, sensing physiological activity, or the like.” *Id.* at 1:29–34.

In view of the above, we reject Patent Owner’s proposed definition as overly restrictive, and provisionally construe “set of operational parameters” as “at least two types of data used by a device to carry out an intended function.”

2. “*parameter context switching*.”

The Specification provides an express definition of “parameter context switching” as “defining and/or selecting different operational parameter sets for use by an implant device.” Ex. 1001, 5:44–47. Pointing to the Specification’s definition of the similar term, “context switching,” Patent Owner suggests instead that we construe this term as “changing one set of operational parameters to another.” Prelim. Resp. 8–9 (citing Ex. 1001, 3:8–10). To the extent these terms may have different meanings—and to the extent “parameter context switching” need be construed in this proceeding—we provisionally adopt the Specification’s express definition of this term as “defining and/or selecting different operational parameter sets for use by an implant device.”

Among all of the ’496 patent claims, term “parameter context switching” appears only in the preamble of independent claim 14. Patent Owner contends that, as used therein, the term “is a substantive limitation of the claim.” Prelim. Resp. 26–27. In particular, Patent Owner argues that “the preamble should be considered a substantive limitation of Claim 14 because, as is clear from a review of the entire specification, ‘context switching’ is the focus of the patent and essential to an understanding of the invention.” *Id.* at 27 (citations omitted).

Patent Owner points out that “[w]hether to treat a preamble as a limitation is determined on the facts of each case in light of the overall form of the claim, and the invention as described in the specification.” *Id.* (quoting *Deere & Co. v. Bush Hog, LLC*, 703 F.3d 1349, 1357 (Fed. Cir. 2012) (internal quotation marks omitted)). Although we do not disagree that the ’496 patent teaches context switching, we take particular note of the overall form of the claim. “If the claim preamble, when read in the context

of the entire claim, recites limitations of the claim, or, if the claim preamble is ‘necessary to give life, meaning, and vitality’ to the claim, then the claim preamble should be construed as if in the balance of the claim.” *Pitney Bowes, Inc. v. Hewlett Packard Co.*, 182 F.3d 1298, 1305 (Fed. Cir. 1999) (citations omitted).

Claim 14 recites an implant system comprising an implant device, an external control device, and an external charging device. Ex. 1001, 20:65–21:22. The preamble recites the purpose of the invention, i.e., providing “[a]n implant system that permits parameter context switching.” Because “the body of the claim fully and intrinsically sets forth the complete invention, including all of its limitations, and the preamble offers no distinct definition of any of the claimed invention’s limitations, but rather merely states, for example, the purpose or intended use of the invention, [] the preamble is of no significance to claim construction because it cannot be said to constitute or explain a claim limitation.” *Id.*

In view of the above, we do not view the preamble of claim 14 as limiting. The parties are, nevertheless, welcome to further discuss the construction of “parameter context switching” and other claim terms at trial.

D. Ground 1: Obviousness over the combined teachings of Shelton and Nappholz

As Ground 1, Petitioner challenges claims 1–3 and 6 as obvious over Shelton and Nappholz. Pet. 20–37. Petitioner’s challenge includes a detailed mapping of the teachings of these references to each limitation of the claims. *See id.* We begin our analysis with an overview of the references asserted under Ground 1.

1. Overview of Shelton (Ex. 1005)

Shelton is directed to an implantable cardiac pacemaker having programmable stimulating pulse amplitudes selectable by means of an external programming unit. Ex. 1005, code (57). Shelton discloses that “state-of the art implantable medical devices are vastly more sophisticated and complex than early pacemakers, and are capable of performing significantly more complex functions.” *Id.* at 1:20–23. For example, incorporating digital circuits in implantable devices allows for programming and reprogramming to alter one or more operating parameters. *Id.* at 3:13–24. Shelton discloses that because “digital technology has made it possible to program numerous non-invasively programmable parameters in implantable devices, it is now relatively common for pacemakers to provide for a plurality of different stimulating pulse amplitude settings.” *Id.* at 3:32–36.

Shelton discloses an implantable pacemaker that may be non-invasively programmed using a telemetry system, as shown in Figure 1, reproduced below.

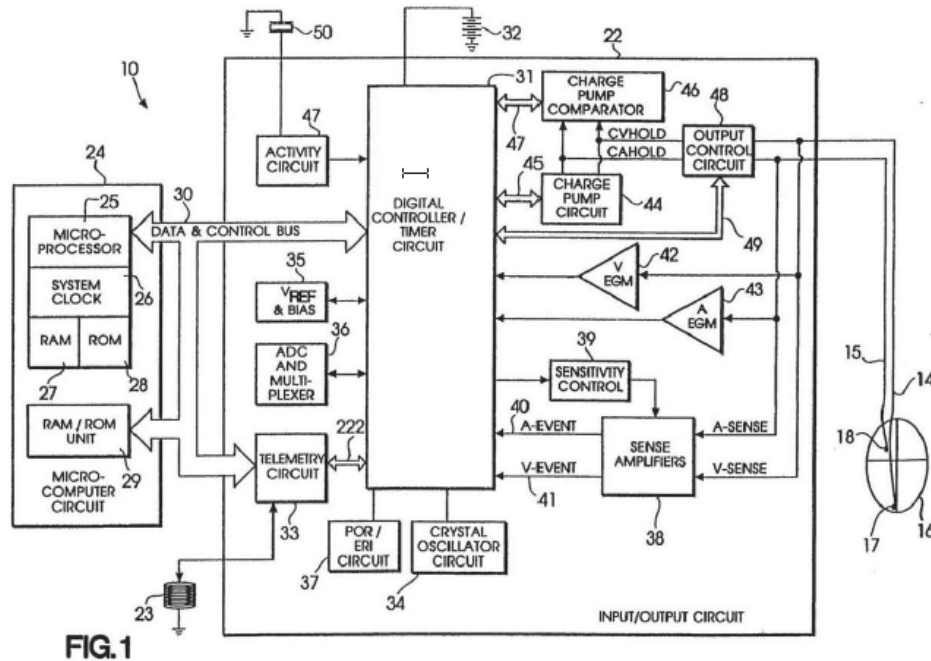


Figure 1 depicts a block diagram of implantable pacemaker 10. *Id.* at 7:21–22.

Implantable pacemaker 10 includes “activity sensor 50 [] bonded to the inside of the pacemaker’s outer, protective shield.” *Id.* at 9:12–15. Activity sensor 50 is coupled to input/output circuit 22, which includes microcomputer circuit 24. *Id.* at 15–23. Microcomputer circuit 24 includes microprocessor 25 and on-board random access memory (“RAM”) 27 and read only memory (“ROM”) 28, which are each coupled to digital controller/timer circuit 31. *Id.* at 9:24–34. Input/output circuit 22 is also connected to antenna 23 through radio frequency (“RF”) telemetry circuit 33, which may be coupled directly to microcomputer circuit 24. *Id.* at 9:46–54.

Digital controller/timer circuit 31 “includes certain registers for storing digital data used in the control of pacemaker functions.” *Id.* at 12:6–8. For programmable functions, “the digital data representing selected values for programmable parameters are downloaded from an external

programming device to pacemaker 10 via the telemetry link.” *Id.* at 12:9–12. Figure 2, reproduced below, shows a diagram of an eight-bit atrial output control register.

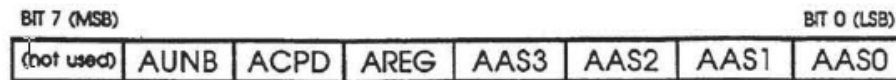


FIG.2

Figure 2 depicts the format of an eight-bit atrial control register in the digital controller/timer circuit from Figure 1. *Id.* at 7:23–25. The register includes several bit positions, including AUNB, which identifies unipolar or bipolar atrial pacing; ACPD, which enables and disables the atrial portion of charge pump circuit 44; AREG, which enables and disables charge pump comparator 46, and AAS3–AAS0, which determine the amplitude of atrial stimulating pulses. *See id.* at 12:25–67. Figure 3 depicts a similar ventricular output control register. *Id.* at 13:50–52.

Shelton discloses that “for each chamber there are sixteen possible amplitude settings.” *Id.* at 15:29–32. “[D]igital controller/timer circuit 31 implements a pacing algorithm and at various times takes steps to initiate delivery of atrial and/or ventricular stimulating pulses.” *Id.* at 15:54–57. The resulting operation of pacemaker 10 “offers ten programmable pacing pulse amplitude settings.” *Id.* at 23:33–36. Shelton discloses “some of the programmable amplitudes are implemented as ‘regulated’ settings for which charge pump comparator 46 is used to ensure that output pulses are generated at the desired amplitude.” *Id.* at 23:39–42.

2. Overview of Nappholz (Ex. 1006)

Nappholz is directed to cardiac stimulation system including an implanted device in communication with an external device. Ex. 1006, code

(57). The implantable device may be a cardiac monitoring and/or stimulation device, and the external device may be a repeater programmer and telephone (“RPP”). *Id.* at 3:61–65. The system including implantable cardiac device (“ICD”) 12 and RPP 14 is shown in Figure 2, reproduced below.

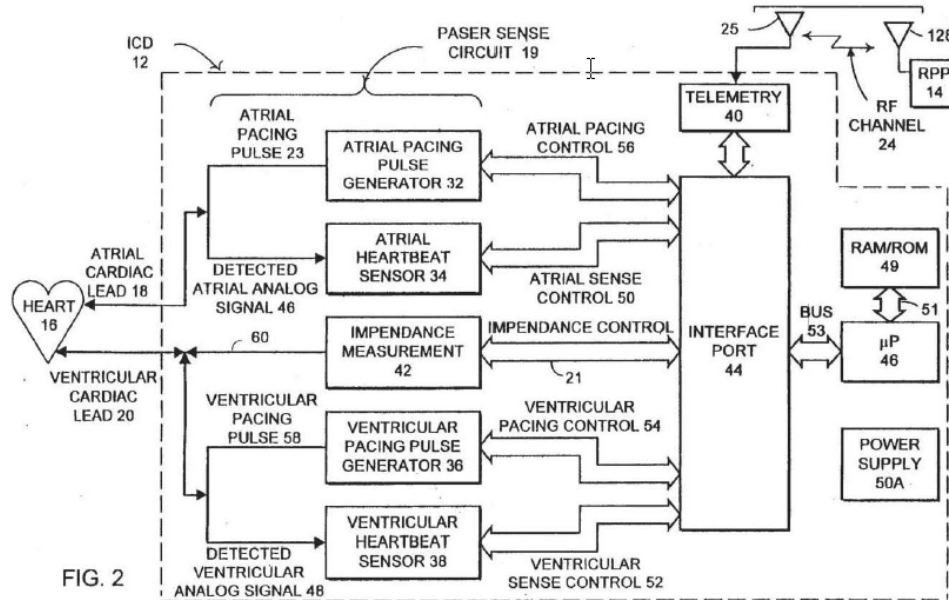


Figure 2 depicts a block diagram of an implantable cardiac device.

The implantable cardiac device 12 may include microprocessor 46 connected to RAM/ROM unit 49. *Id.* at 4:30–52. The external device, e.g., RPP 14, may also include a microprocessor connected to an external memory used to store programming data. *Id.* at 5:56–60; *see* Figure 3. The programming data may include “a complete set of operational parameters, and allowable ranges for these parameters and other programmable options.” *See id.* at 6:64–67. RPP 14 may further communicate with a remote control console located in a physician’s office. *Id.* at 4:11–13.

Nappholz discloses remotely modifying operation of the implantable cardiac device in Figure 6, reproduced below:

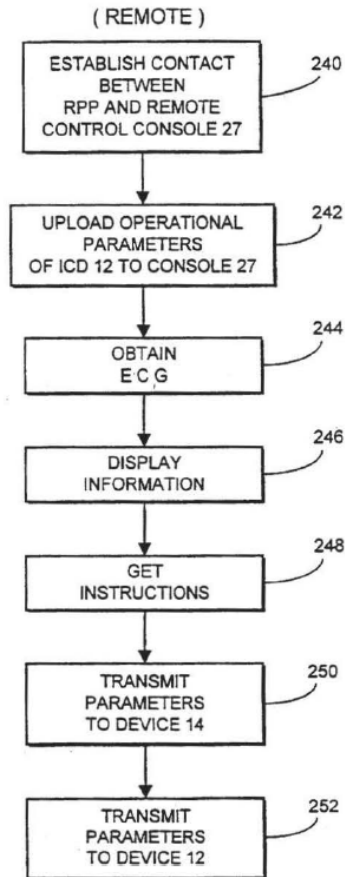


FIG. 6

Figure 6 depicts a flow chart for remotely changing the operational parameters of an implantable cardiac device. *Id.* at 3:35–37.

“At implantation, [] device 12 is programmed in a conventional manner.” *Id.* at 7:8–9. To remotely modify operation of the implantable device, “the physician enters instructions for the initializing or changing of the functional parameters.” *Id.* at 7:59–60. The functional parameters are then downloaded from the remote console to the RPP and then to the implantable cardiac device. *Id.* at 7:60–65.

Nappholz discloses that “the cardiac stimulation device must be adaptable to various physiological or pathological conditions and to vary the

therapy applied to the patient accordingly.” *Id.* at 8:60–66. A method for varying therapy is shown in Figure 7, reproduced below:

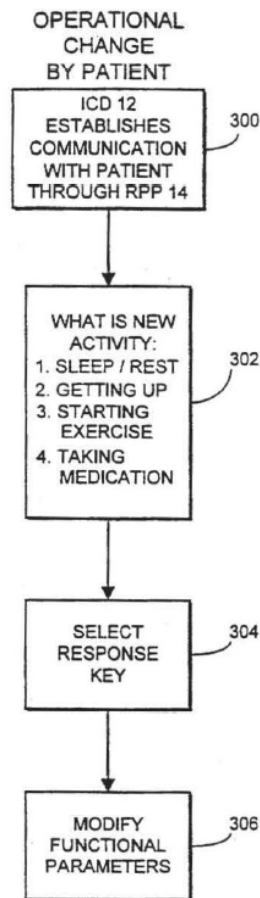


FIG. 7

Figure 7 depicts a flow chart for changing the operation of the device by the patient. *Id.* at 3:38–39.

The implantable cardiac device communicates with the external device to request information from the patient when it “detects a change which may require a different mode of operation.” *Id.* at 9:19–24. The patient may then select a response from a menu of activities displayed by the external device. *Id.* at 9:24–29. Based on that selection, the implantable cardiac device “reconfigures or modifies its operational parameters, in Step

306.” *Id.* Upon this modification, the implantable cardiac device may also alert the patient of a change in its mode of operation. *Id.* at 9:39–40.

3. *Analysis*

Petitioner argues that claims 1–3 and 6 are obvious over Shelton and Nappholz. Pet. 20–37. Petitioner’s challenge includes a detailed mapping of the teachings of these references to each limitation of the claims. *See id.* Patent Owner opposes. Prelim. Resp. 19–23. Because Patent Owner does not separately argue the merits of claims 2, 3 and 6, and the Petition appears to sufficiently address those claims, we address in this section the elements of independent claim 1 only. *See id.* at 23.

i. “An implantable device comprising”

Petitioner asserts Shelton discloses an implantable device. Pet. 22. Patent Owner does not dispute Petitioner’s assertion regarding this limitation.

ii. “an implantable case”

Petitioner asserts Shelton discloses a pacemaker housed in a protective shield. Pet. 23.

Patent Owner does not dispute Petitioner’s assertion regarding this limitation.

iii. “electronic circuitry housed within said implantable case for performing a prescribed function”

Petitioner asserts Shelton discloses an implantable pacemaker including input/output circuit 22 that “performs the application of stimulating pulses to the heart and other prescribed algorithms.” Pet. 23–24.

Patent Owner does not dispute Petitioner's assertion regarding this limitation.

- iv. *“the electronic circuitry including a control register wherein a control set of operational parameters is stored”*

Petitioner asserts Shelton discloses a controller including an atrial control register and a ventricular output control register. Pet. 24.

Patent Owner does not dispute Petitioner's assertion regarding this limitation.

- v. *“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”*

Petitioner asserts Shelton's digital controller/timer circuit uses data in the atrial control register to control various aspects of atrial pacing by the pacemaker. Pet. 25.

Patent Owner does not dispute Petitioner's assertion regarding this limitation.

- vi. *“a plurality of sets of operational parameters” and “whereby the operation of the implant device may be changed through selection of a different set of operational parameters.”*

Petitioner contends that “[w]hile Shelton discloses a pacemaker having a selectable output amplitudes . . . it may not expressly disclose a plurality of sets of operational control parameters. Nappholz discloses this useful feature for simplifying use by a patient.” Pet. 25. In particular, Petitioner asserts “Nappholz describes changing the operation of the implant device by selecting a new level of activity using Nappholz's [external

controller], which can select a set of operational parameters for controlling an implanted device.” *Id.* at 30 (citing Ex. 1006, 9:17-29).

Petitioner asserts that Nappholz discloses different modes of operation corresponding to different levels of activity for a patient, e.g., sleep/rest, getting up, exercise, and taking medication. *Id.* at 25. Petitioner asserts that when the patient selects a new mode of operation, Nappholz discloses reconfiguring or modifying the operation parameters, wherein each mode of operation corresponds to a different set of operational parameters. *Id.* (citing Ex. 1003 ¶¶ 76–78). Petitioner further asserts that “Nappholz describes changing the operation of the implant device by selecting a new level of activity using Nappholz’s [external controller], which can select a set of operational parameters for controlling an implanted device.” *Id.* at 30 (citing Ex. 1006, 9:17-29).

Petitioner contends “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.” *Id.* at 26 (citing Ex. 1003 ¶¶ 76-79).

Patent Owner responds that “Nappholz does not disclose a ‘plurality of sets of operational parameters,’ or ‘swapping one set of operational parameters for another.’” Prelim. Resp. 13. Rather, Nappholz’s pacemaker merely “requests information from the [patient] about his level of activity,” and thereafter “simply reconfigures or modifies the pacing algorithm.” Prelim. Resp. 14 (citing Ex. 1006, 9:17–29). Thus, Patent Owner contends, although “the Nappholz pacemaker detects conditions in the heart and uses that input to modify the pacing algorithm, dynamically modifying pacing algorithms in response to sensed cardiac events and input from the user

regarding his or her activity level is not the same as switching between preexisting sets of operational parameters.” *Id.* at 14.

As noted in section II(C)(1), above, we define a “set of operational parameters” as “at least two types of data used by a device to carry out an intended function.” We also understand Patent Owner’s statements regarding “switching” parameters to refer to claim 1’s requirement that “the operation of the implant device may be changed through selection of a different set of operational parameters.” Considering our construction of “set of operational parameters,” this latter element would be satisfied by changing one or more of the “at least two types of data used by a device to carry out an intended function.”

Patent Owner’s interpretation of Nappholz as modifying an algorithm rather than an operational parameter, per se, is not unreasonable on its face. This interpretation, however, is not plainly evident from our present reading of the reference, nor supported by the evidence of how one of ordinary skill in the art would have understood Nappholz’s disclosure. Rather, it is possible to view Nappholz’s algorithm as either one of the operational parameters controlling an implanted device, or part of the means by which a patient reconfigures or modifies its operational parameters. Accordingly, at this stage of the proceedings, and for the reasons set forth on pages 25 and 30 of the Petition and paragraphs 76–78, 96, and 97 of Dr. Kroll’s declaration,⁷ Petitioner has satisfied its burden of demonstrating a reasonable

⁷ The Kroll Declaration provides sworn testimony by Dr. Kroll, a person that appears on this record to meet the definition of a person of ordinary skill in the art as of October 1999. *See* Ex. 1003 ¶¶ 3–10, 15–18; Ex. 1004; Pet. 11. Patent Owner does not presently challenge Dr. Kroll’s qualifications nor the definition of a person of ordinary skill in the art. *See* Prelim. Resp. 6. Although we recognize that some of the statements by Dr. Kroll are the

likelihood that one of ordinary skill in the art would have read Nappholz as disclosing “a plurality of sets of operational parameters” and that “the operation of the implant device may be changed through selection of a different set of operational parameters.” Patent Owner is welcome to provide further argument and evidence in support of its position at trial.

vii. *“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”*

Petitioner asserts “the ‘selection means’ of claim 1 would have been obvious over Shelton in view of Nappholz. Pet. 29 (citing Ex. 1003 ¶¶ 81–95).

Patent Owner does not dispute Petitioner’s assertion regarding this limitation.

4. *Conclusion*

For the reasons set forth above, Petitioner has established a reasonable likelihood of prevailing in demonstrating that claim 1 unpatentable under Ground 1. Having reviewed the contentions with respect to claims 2, 3, and 6, we similarly find that Petitioner has established a reasonable likelihood of prevailing with respect to those claims. We, nevertheless, look forward to any expert testimony and other countervailing evidence supporting Patent Owner’s contentions.

same or substantially the same as those made in the Petition, and some of those statements may not include evidentiary support beyond that provided in the Petition, we find in this case that the un rebutted testimony of Dr. Kroll is entitled to some weight at this stage of the proceeding. Patent Owner may challenge Dr. Kroll’s testimony during trial through cross-examination and/or a declaration by a witness for Patent Owner.

E. Ground 2: Obviousness over the combination of Shelton, Nappholz, and Mumford

As Ground 2, Petitioner challenges claims 4 and 5 as obvious over Shelton, Nappholz, and Mumford. Pet. 37–42. Petitioner’s challenge includes a detailed mapping of the teachings of these references to each limitation of the claims. *See id.* We begin our analysis with an overview of Mumford, first asserted under Ground 2.

1. Overview of Mumford

Mumford is directed to a computer-controlled programmer designed to control the parameters of a wide variety of implantable devices, e.g., cardiac pacers and neural stimulators, with different programming requirements. Ex. 1009, code (57); 1:30–38. Mumford discloses “[t]he programmer automatically changes programming options in response to . . . selection of certain modes and lead configurations. The programmer software is designed to limit access to certain ranges of values of parameters and certain parameters themselves, which require the attendance of an authorized physician.” *Id.* at 2:66–3:5. Mumford teaches an access control digital lock used to control the level of access to the programmer. *Id.* at 5:55–56. Entering the correct combination permits full access mode to the programmer, as opposed to the limited access mode. *Id.* at 5:59–66.

2. Analysis and Conclusion

Patent Owner argues that Petitioner relies on Mumford “to satisfy limitations having nothing to do with ‘a plurality of sets of operational parameters,’” and challenges Ground 2 by relying solely on its arguments with respect to Ground 1. Prelim. Resp. 23–24. Accordingly, we institute trial on claims 4 and 5 for the reasons set forth with respect to Ground 1.

F. Ground 3: Obviousness over the combination of Shelton, Nappholz, and Barreras '887

As Ground 3, Petitioner challenges claim 7 as obvious over Shelton, Nappholz, and Barreras '887 (Barreras II). Pet. 42–44. Petitioner's challenge includes a detailed mapping of the teachings of these references to each limitation of the claims. *See id.* We begin our analysis with an overview of Barreras '887, first asserted under Ground 3.

1. Overview of Barreras '887 (Ex. 1008)

Barreras '887 is directed to a RF coupled neural stimulator system including a subcutaneous receiver. Ex. 1008, 8:48–64. Barreras '887 discloses the subcutaneous receiver is capable of: 1) memorizing data defining all stimulation values in a non-volatile memory, 2) using the memorized values to autonomously regulate “all stimulation functions such as amplitude, rate, pulse width, amplitude ramp-up time at the start of stimulation, amplitude ramp-down time when stimulation ceases, and electrode polarity.” *Id.* at 8:53–56. The stimulation values are stored in appropriate memory locations. *Id.* at 8:60–61.

Barreras '887 further discloses that a microcontroller associated with the subcutaneous receiver receives specific data definition stimulation values, electrode selection and polarity, all of which are programmed into an erasable/reprogrammable non-volatile memory. *Id.* at 11:34–40. The device then regulates the output voltage and on/off duration of a D/A converter. *Id.* at 11:40–42.

2. Analysis and Conclusion

Patent Owner argues that Petitioner relies on Barreras '887 “to satisfy limitations having nothing to do with ‘a plurality of sets of operational

parameters,”” and challenges Ground 3 by relying solely on its arguments with respect to Ground 1. Prelim. Resp. 23–24. Accordingly, for the reasons set forth with respect to Ground 1, we institute trial on claim 7.

G. Ground 4: Obviousness over Nappholz

As Ground 3, Petitioner challenges claims 8–13 as obvious over Nappholz. Pet. 44–57. Petitioner’s challenge includes a detailed mapping of the teachings of these references to each limitation of the claims. *See id.* Patent Owner opposes. Prelim. Resp. 25–26. Because Patent Owner does not separately argue the merits of claims 9–13, and the Petition appears to sufficiently address those claims, we address below only the elements of independent claim 8. *See id.* at 26.

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

Petitioner asserts that Nappholz discloses using repeater programmer and telephone (RPP) to change the operation parameters of an implant device. Pet. 44.

Patent Owner does not respond to this limitation.

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”

Petitioner asserts that Nappholz discloses an implant device having different modes of operation. Pet. 45. Petitioner contends “[a] physician enters instructions for initializing or changing the modes—the operational parameter sets—of the implant device” as shown in Figure 6. *Id.* Petitioner asserts that Nappholz customizes different modes corresponding to different levels of activity, wherein selecting a new mode of operation “reconfigures

or modifies the operational parameters.” *Id.* at 46–47. Petitioner asserts “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.” *Id.* at 47–48 (citing Ex. 1003 ¶¶ 160-162).

Patent Owner repeats the argument set forth with respect to claim 1 that “Nappholz fails to disclose ‘a plurality of sets of operational parameters’ or a device wherein one set of operational parameters can be selected and swapped for another.” Prelim. Resp. 26. For the reasons set forth in section II(D)(3)(vi), we do not find Patent Owner’s arguments persuasive.

i. “storing the plurality of sets of operational parameters”

Petitioner asserts that “Nappholz discloses the implanted device downloading functional parameters that make up an operational parameter set of the implanted device from the RPP.” Pet. 48. Petitioner asserts that Nappholz saves the operational parameters corresponding to various modes of operation into the memory of the implanted device. *Id.*

Patent Owner repeats the argument as to a plurality of sets of operational parameters. Prelim. Resp. 26. For the reasons set forth in section II(D)(3)(vi), above, we do not find Patent Owner’s argument persuasive.

ii. “selecting one of the stored sets of operational parameters as a control set of operational parameters”

Petitioner contends that Nappholz discloses different modes of operation, “wherein each mode of operation is a different functional parameter set.” Pet. 49 (citing Ex. 1003 ¶ 167). Petitioner contends that

Nappholz disclosure of a patient selecting a different mode of operation results in selecting a control set of operational parameters. *Id.* at 49.

Patent Owner repeats the argument as to a plurality of sets of operational parameters. Prelim. Resp. 26.

3. “*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*”

Petitioner contends Nappholz discloses a physician may define functional parameters for the implant device which are downloaded to the device. Pet. 50. The downloaded parameters then control the operation of the implanted device in the form of different modes of operation. *Id.*

Patent Owner does not respond to this limitation.

4. *Conclusion*

For the reasons set forth above, Petitioner has established a reasonable likelihood of prevailing in demonstrating that claims 8 is unpatentable under Ground 4. Considering the record before us, we similarly find that Petitioner has established a reasonable likelihood of prevailing with respect to claims 9–13.

H. Ground 5: Obviousness over Barreras '217

As Ground 5, Petitioner challenges claim 14 as obvious over Barreras '217 (Barreras I). Pet. 57–62. Petitioner's challenge includes a detailed mapping of the teachings of that reference to each limitation of the claim. *See id.* We begin our analysis with an overview of the asserted reference.

1. Overview of Barreras '217 (Ex. 1007)

Barreras '217 is generally directed to implantable devices, and in particular, to an implantable stimulator that delivers electrical stimulation pulses to a targeted tissue. Ex. 1007, code (57).⁸ With respect to such devices, Barreras '217 states that, “it is important that the physician or medical technician be permitted to change the pulse current frequency, pulse width and ON time of the electric stimulation impulses.” *Id.* at 7:51–54. Accordingly, Barreras '217 discloses “[a] system for delivering electric stimulation pulses . . . comprising an implantable stimulator . . . [and] means for programming said implantable stimulator such that said stimulator delivers electric stimulation pulses to [a] targeted tissue in a manner dependent upon the stimulation program.” *See id.* at 14:14–19 (claim 25 as it depends from claim 16).

One embodiment of the Barerras '217's implantable stimulator system is illustrated in Figure 1, reproduced below.

⁸ Barreras '217 makes clear that the disclosed invention is not limited to an implantable stimulator, but encompasses other devices, such as implantable drug delivery systems, pacemakers, and diagnostic units. *See id.* at 4:20–23, 6:22–28, 10:51–59.

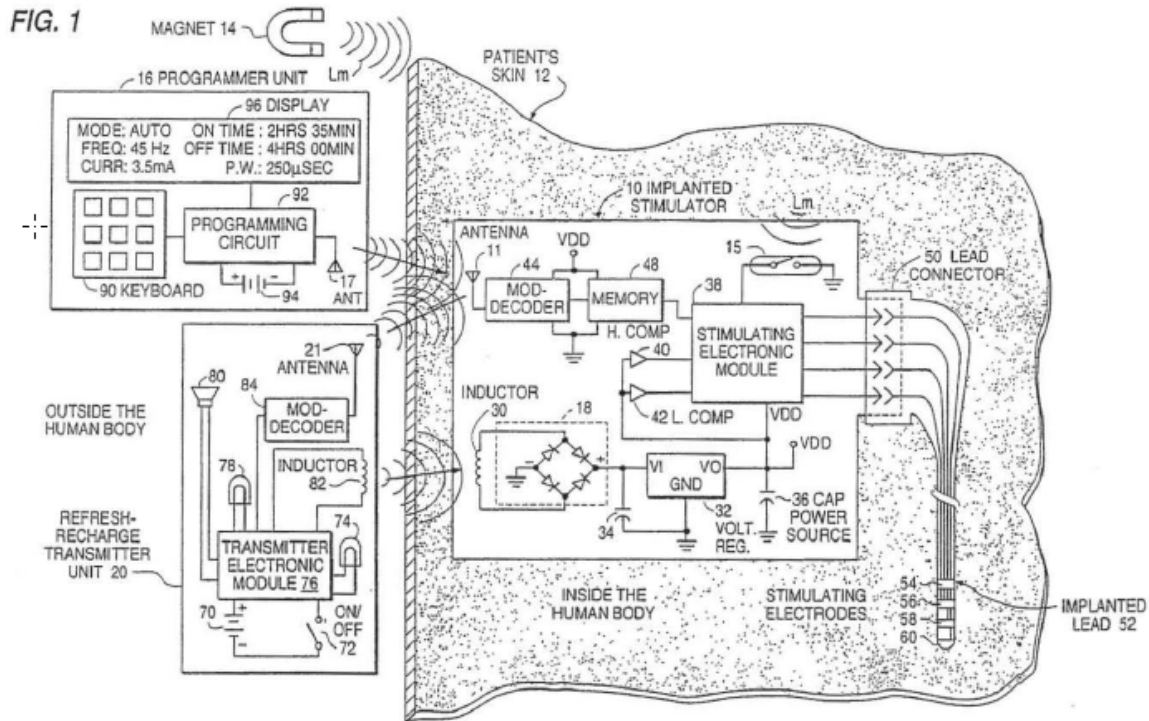


Figure 1 depicts an implantable stimulator 10, hand held magnet 14, programmer unit 16, and refresh-recharge transmitter unit 20. *Id.* at 4:61–64.

Implantable stimulator 10 includes modulator/demodulator and decoder circuit 44 and memory unit 48. *Id.* at 6:12–14. Memory 48 “stores information regarding the pulse width, pulse amplitude and stimulating frequency, for the delivery of substantially continual stimulation doses. *Id.* at 7:42–46. Implantable stimulator 10 also includes capacitive energy power supply and source 36 to provide source power for stimulating electronic module 38. *Id.* at 6:7–11. Barreras ’217 discloses implantable stimulator 10 includes antenna 11 for receiving RF telemetric data from programmer unit 16 and refresh-recharge transmitter 20. *Id.* at 5:56–6:2.

Programmer unit 16 includes programming circuit 92 and antenna 17. *Id.* at 8:3–11. A physician or medical technician programs programming unit 16 with frequency, pulse width, and ON time, etc. via keyboard 90, and

the resulting program data is stored programming circuit 92. *Id.* Programmer unit 16 “transfer[s] the commands and programming information from antenna 17 to antenna 11. Upon 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.” *Id.* at 8:8–15.

Refresh-recharge transmitter unit 20 includes primary battery 70 and inductor coil 82 that emits RF waves which are received by inductor 30 of the implantable stimulator. *Id.* at 6:34–46. Transmitter electronic module 76 sends out command signals via antenna 21 to antenna 11 in the implanted stimulator. *Id.* at 6:47–54. “These received command signals are demodulated by decoder 44 and replied and responded to based on a program in memory 48. Memory 48 then activates the proper control and the inductor receiver coil 30 [accepts] the RF coupled power from inductor 82.” *Id.*

2. Analysis

Petitioner argues claim 14 is obvious over Barreras ’217. We address each element of the claim below.

a) An implant system that permits parameter context switching comprising”

Petitioner asserts Barreras ’217 discloses an implanted stimulator that receives programming information including operating parameters such as frequency, pulse, width, and ON time. Pet. 57. Petitioner contends “Barreras’s programming information allows the stimulating electronic module to change operational parameters,” and thus discloses an implant system that permits parameter context switching. *Id.* at 57–58 (citing Ex. 1003 ¶¶ 194–195).

Patent Owner responds that “context switching” is expressly defined in the specification as “changing one set of operational parameters to another” whereas Barreras ’217 “merely discloses modifying individual operational parameters.” Prelim. Resp. 28. In the alternative, Patent Owner argues that “even if ‘Barreras’s programming information allows the stimulating electronic module to change operational parameters,’ . . . that does not constitute ‘changing one set of operational parameters to another’ and, therefore, does not satisfy the ‘context switching’ limitation.” *Id.*

We do not find Patent Owner’s arguments persuasive on the present record. As discussed in section II(C)(2), above, we do not construe “parameter context switching” in the preamble of claim 14 as a limitation of the system described in that claim. Nevertheless, to the extent we were to accord weight to the preamble, the Specification expressly defines the term as “defining and/or selecting different operational parameter sets for use by an implant device.” In this respect, Barreras ’217 discloses an implantable stimulator system including a programmer unit, with which a physician can program various operational parameters such as frequency, pulse width, and ON time. *See* section II(H)(1), above. The programmer unit transmits this information as command signals to the memory of the implanted device, which thereby controls its operation. *See id.* Barreras ’217 claims this process as a “means for programming [an] implantable stimulator such that said stimulator delivers electric stimulation pulses to [a] targeted tissue in a manner dependent upon the stimulation program.” Ex. 1007, 14:14–19.

We further note that Barreras ’217 discloses at least three operational parameters (frequency, pulse width, and ON time), the data for which is stored in memory unit 48. *See* section II(H)(1), above. We perceive this collection of operational parameters as a “set” of operational parameters.

When a physician reprograms an implanted device to change one or more of the operational parameters, this changes the set of operational parameters controlling the device's intended function.

In view of the above, and based on the record before us, Barreras '217 discloses means for "defining and/or selecting different operational parameter sets for use by an implant device," and, thus, permits parameter context switching as set forth in claim 14.

b) *"an implant device comprising"*

Petitioner contends Barreras '217 discloses an implanted device.

Patent Owner does not dispute Petitioner's assertion regarding this limitation.

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

Petitioner contends Barreras '217 discloses an implanted device with electronic circuitry that process digital programming information. Pet. 58–59.

Patent Owner does not dispute Petitioner's assertion regarding this limitation.

(2) *"a first memory element wherein the set of operational parameters is stored"*

Petitioner contends that Barreras '217 discloses memory 48 that stores information regarding pulse width, pulse amplitude, and stimulating frequency, which "enable a set of operating parameters." Pet. 59 (citing Ex. 1003 ¶¶ 200–201).

Patent Owner contends that Barreras '217 discloses modifying individual operating parameters as opposed to a "set of operational parameters." Prelim. Resp. 28 (emphasis in original).

We do not find Patent Owner's argument persuasive for the reasons set forth in section II(H)(2)(a), above.

(3) *“a replenishable power source that provides operating power for the implant device”*

Petitioner contends that Barreras '217 discloses replenishable capacitive power source 36 that provides power to the implant device. Pet. 59.

Patent Owner does not dispute Petitioner's assertion regarding this limitation.

(4) *“a first telemetry circuit that receives control data from an external source”*

Petitioner contends that Barreras '217 discloses decoder 44 coupled to antenna 11 for receiving programming commands sent via telemetry. Pet. 60.

Patent Owner does not dispute Petitioner's assertion regarding this limitation.

(5) *“a second telemetry circuit that receives power to replenish the replenishable power source”*

Petitioner contends that Barreras '217 discloses inductor 30 configured to receive power signals from refresh-recharge transmitter unit 20 via antenna 11 to charge the replenishable power supply. Pet. 60.

Patent Owner does not dispute Petitioner's assertion regarding this limitation.

c) *“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”

Petitioner contends that Barreras ’217 discloses external programming unit 16 including programming circuit 92 for transmitting programming information through antenna 17 to the implanted device. Pet. 61.

Patent Owner does not dispute Petitioner’s assertion regarding this limitation.

(1) *“an external charging device comprising”*

Petitioner contends that Barreras ’217 discloses external refresh-replenish transmitter unit 20. Pet. 61–62.

Patent Owner does not dispute Petitioner’s assertion regarding this limitation.

(2) *“a power source”*

Petitioner contends that Barreras ’217 discloses rechargeable battery 70 in refresh-replenish transmitter unit 20. Pet. 62.

Patent Owner does not dispute Petitioner’s assertion regarding this limitation.

(3) *“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”*

Petitioner contends that Barreras ’217 discloses refresh-replenish transmitter unit 20 includes inductor coil 82 to provide power to inductor coil 20 of implant stimulator 10. Pet. 62.

Patent Owner does not dispute Petitioner’s assertion regarding this limitation.

3. Conclusion

For the reasons set forth above, Petitioner has established a reasonable likelihood of prevailing in demonstrating that claim 14 is unpatentable under Ground 5.

I. Ground 6: Obviousness over the combination of Barreras '217 and Nappholz

As Ground 6, Petitioner challenges claims 15 and 16 as obvious over the combination of Barreras '217 and Nappholz. Pet. 62–69. Petitioner's challenge includes a detailed mapping of the teachings of these references to each limitation of the claims. *See id.* In disputing Petitioner's challenge under Ground 6, Patent Owner relies on its earlier arguments with respect to Barreras '217 and Nappholz, which we have discussed above. *See* Prelim. Resp. 28–29.

For the reasons set forth in sections II(G) and II(H), above, Petitioner has demonstrated a reasonable likelihood that claims 15 and 16 are unpatentable over the combination of Barreras '217 and Nappholz.

J. Ground 7: Obviousness over the combination of Barreras '217, Nappholz, and Mumford

As Ground 7, Petitioner challenges claims 17 and 18 as obvious over the combination of Barreras '217, Nappholz, and Mumford. Pet. 69–76. Petitioner's challenge includes a detailed mapping of the teachings of these references to each limitation of the claims. *See id.* In disputing Petitioner's challenge under Ground 7, Patent Owner relies on its earlier arguments with respect to Barreras '217 and Nappholz, which we have discussed above. *See* Prelim. Resp. 30–31. Accordingly, on the present record, Petitioner has

demonstrated a reasonable likelihood that claims 17 and 18 are unpatentable under Ground 7.

III. CONCLUSION

On the present record, we find Petitioner has made a sufficiently persuasive showing that the cited references would have taught or suggested each element of claims 1–18, and set forth a sufficient rationale for why a person of ordinary skill would have been motivated to combine these teachings and suggestions to arrive at the invention recited in claims 1–18. Petitioner has established a reasonable likelihood of prevailing in demonstrating that claims 1–18 would have been obvious over the prior art.

IV. ORDER

ORDERED, pursuant to 35 U.S.C. § 314(a), that an *inter partes* review of claims 1–18 of the '496 Patent is instituted with respect to all grounds set forth in the Petition; and

FURTHER ORDERED, pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4(b), that the *inter partes* review of the '496 patent shall commence on the entry date of this Order, and notice is hereby given of the institution of a trial.

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Patent 6,381,496 B1

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