Trials@uspto.gov
571-272-7822

Paper 43
Entered: January 19, 2021

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES PATENT AND TRADEMARK OFFICE

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, *Vice Chief Administrative Patent Judge*,
ROBERT A. POLLOCK, and
JASON W. MELVIN, *Administrative Patent Judges*.

POLLOCK, *Administrative Patent Judge*.

FINAL WRITTEN DECISION

Determining All Challenged Claims Unpatentable
35 U.S.C. § 318(a)

Entering Stipulated Protective Order and
Granting Patent Owner's Motion to Seal
37 C.F.R. §§ 42.1 and 42.54

I. INTRODUCTION

This is a Final Written Decision in an *inter partes* review challenging the patentability of claims 1–18 of U.S. Patent No. 6,381,496 B2 ("the '496 patent," Ex. 1001). We have jurisdiction under 35 U.S.C. § 6.

Petitioner has the burden of proving unpatentability of a claim by a preponderance of the evidence. 35 U.S.C. § 316(e) (2018). Having reviewed the arguments of the parties and the supporting evidence, we determine that Petitioner has demonstrated by a preponderance of the evidence that the challenged claims are unpatentable.

A. Procedural Background

Nevro Corp. ("Petitioner") filed a Petition for an *inter partes* review of claims 1–18 of the '496 patent. Paper 2 ("Pet."). Boston Scientific Neuromodulation Corp. ("Patent Owner") timely filed a Preliminary Response. Paper 6 ("Prelim. Resp."). In view of the then-available, preliminary record, we concluded that Petitioner satisfied the burden, under 35 U.S.C. § 314(a), to show that there was a reasonable likelihood that Petitioner would prevail with respect to at least one of the challenged claims. Accordingly, on behalf of the Director (37 C.F.R. § 42.4(a) (2018)), and in accordance with *SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1353 (2018) and the Office's Guidance on the Impact of SAS on AIA Trial Proceedings (Apr. 26, 2018),[1] we instituted an *inter partes* review of claims 1–18 of the '496 patent on all the asserted grounds. Paper 7 ("Inst. Dec."), 41.

After institution, Patent Owner filed a Response. Paper 23 ("PO Resp."). Petitioner filed a Reply. Paper 33 ("Reply"). Patent Owner filed an

[1] https://www.uspto.gov/patents-application-process/patent-trial-and-appeal-board/trials/guidance-impact-sas-aia-trial.

authorized Sur-reply. Paper 35 ("Sur-reply"). Patent Owner also filed a motion to seal and for entry of stipulated protective order. Paper 22.

On November 10, 2020, the parties presented arguments at oral hearing, the transcript of which is of record. Paper 42 ("Tr.").

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. Asserted Grounds of Unpatentability

The Petition sets forth seven grounds of unpatentability. (Pet. 3–4):

Ground	Claims	Basis	Asserted References
1	1–3, 6	103(a)[2]	Shelton,[3] Nappholz[4]
2	4, 5	103(a)	Shelton, Nappholz, Mumford[5]
3	7	103(a)	Shelton, Nappholz, Barreras '887 (Barreras II)[6]

[2] 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.
[3] U.S. Patent No. 5,387,228, issued Feb. 7, 1995. Ex. 1005.
[4] U.S. Patent No. 5,720,770, issued Feb. 24, 1998. Ex. 1006.
[5] U.S. Patent No. 4,432,360, issued Feb. 21, 1984. Ex. 1009.
[6] U.S. Patent No. 5,735,887, issued Apr. 7, 1998. Ex. 1008.

Ground	Claims	Basis	Asserted References
4	8–13	103(a)	Nappholz
5	14	103(a)	Barreras '217 (Barreras I)[7]
6	15, 16	103(a)	Barreras '217 (Barreras I), Nappholz
7	17, 18	103(a)	Barreras '217 (Barreras I), Nappholz, Mumford

In support of its patentability challenges, Petitioner relies on, *inter alia*, the Declaration of Mark W. Kroll, Ph.D. Ex. 1003. Patent Owner relies, inter alia, the Declaration of Alois A. Langer, Ph.D. Ex. 2006.

E. The '496 Patent and Relevant Background

1. Specification

The '496 patent is directed to "parameter context switching, i.e., defining and/or selecting different operational parameter sets for use by an implant device." Ex. 1001, 5:44–62; *see id.* at Abstract, Title. Elsewhere, the specification expressly defines "context switching" as "changing one set of operational parameters to another." *Id.* at 3:8–10 "[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 '496 patent further states that, "[t]he present invention relates to an implant device, e.g., a spinal cord stimulation (SCS) system or other programmable implant device," and emphasizes the "broad applicability" of the invention to "any other programmable implant system" "including all

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

types of neural stimulators and sensors, deep brain stimulators, cochlear stimulators, drug delivery systems, muscle tissue stimulators, and the like." *Id.* at 1:9–11, 1:16–19, 1:37–45, 5:55–62. 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.

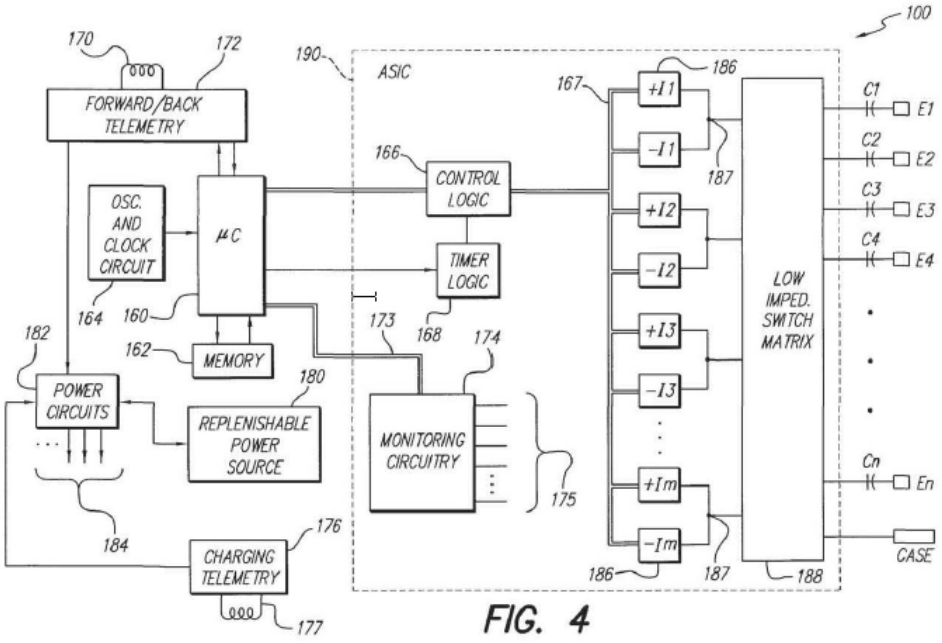


FIG. 4

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.

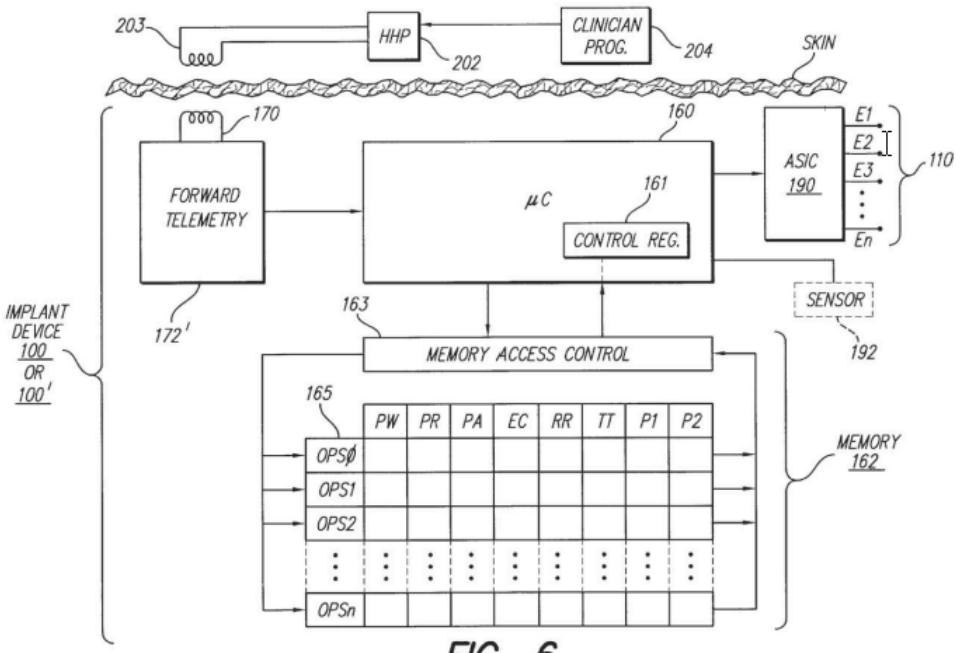


FIG. 6

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. Claims 1, 8, and 14 are independent. Claim 1 is illustrative:

> 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.

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). We applied this definition in our Institution Decision and Patent Owner adopts it in this proceeding. Inst. Dec. 10–11; PO Resp.

11. As the above definition is both unopposed and consistent with the cited prior art, we apply it here. *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 the challenged claims "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)." *See* 37 C.F.R. § 42.100(b) (2019). Under that standard, we presume that a claim term carries its "ordinary and customary meaning," which "is the meaning that the term would have to a person of ordinary skill in the art in question" at the time of the invention. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007) (quoting *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005)). Any special definition for a claim term must be set forth in the specification with reasonable clarity, deliberateness, and precision. *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994). Limitations, however, may not be read from the specification into the claims (*In re Van Geuns*, 988 F.2d 1181, 1184 (Fed. Cir. 1993)), nor may the Board "construe claims during [an *inter partes* review] so broadly that its constructions are unreasonable under general claim construction principles" (*Microsoft Corp. v. Proxyconn, Inc.*, 789 F.3d 1292, 1298 (Fed. Cir. 2015), *overruled on other grounds by Aqua Products, Inc. v. Matal*, 872 F.3d 1290 (Fed. Cir. 2017)); *see also, 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))).

1. "set of operational parameters"

In our Institution Decision, we addressed Patent Owner's contention that we should construe a "set of operational parameters" as a "combination of more than one type of data defining the stimulation pulses provided by the implant device." Inst. Dec. 7–12 (citing Prelim. Resp. 7–8; Ex. 1001, 17:2–15, Figs. 7–8). At that point in the proceedings, and absent input from Petitioner, we focused primarily on Patent Owner's reference to "stimulation pulses," rather than the number or type of data defining those pulses. *Id.*

In support of its construction, Patent Owner pointed to Figure 6 of the '496 patent, reproduced below. Prelim. Resp. 7–8.

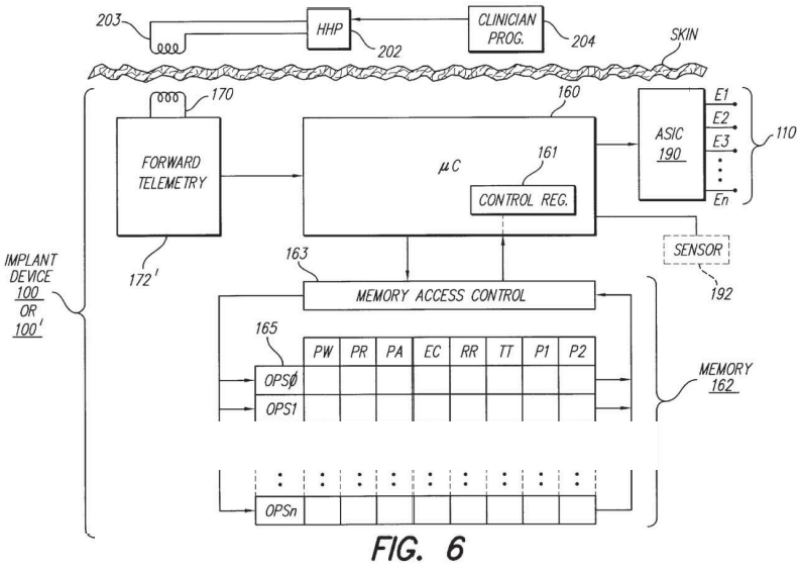


FIG. 6

Figure 6 shows "a block diagram of a portion of the implant device, or IPG 100 or 100', that functionally illustrates one manner that may be used in accordance with the present invention to allow the patient user to select one of a plurality of operational parameter sets (OPSs), for use by the implant device." Ex. 1001, 16:44–49.

In the context of a spinal cord stimulation system (SCS), Figure 6 "functionally illustrates one manner in which different operational parameter sets may be selected for use by the implant device." *Id.* at 5:5–17, 5:23–28, 5:46–50. This includes,

> data that defines operational parameters that are used within the implant device 100 or 100' to control its operation in accordance with an operating program stored in its memory 162. Such data is forwarded to appropriate locations within a memory 162, which specified locations may be considered as a memory table 165.

Id. at 16:63–17:1*; see also* Figs. 7–8 (illustrating memory tables in IPG and hand held programming device, respectively). "[M]emory table 165 includes individual addressable locations wherein various operational parameters may be stored." Ex. 1001, 17:2–4. In this embodiment:

> A first operational parameter 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.

Id. at 17:4–14.

In our Institution Decision, we noted that Patent Owner's first proposed definition was unduly narrow, as it presupposed control of stimulation impulses in an implanted SCS, whereas, "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." Inst. Dec. 13. We further noted that the '496 patent's emphasis on the "broad applicability" of

the invention to "any other programmable implant system" "including all types of neural stimulators and sensors, deep brain stimulators, cochlear stimulators, drug delivery systems, muscle tissue stimulators, and the like." *Id.* at 13–14 (citing 1:16–19, 1:37–45, 5:55–62). Thus, rather than limited to "defining the stimulation pulses" of an SCS system, as indicated in Patent Owner's first proposed construction, we noted that appropriate operational parameters for a drug delivery system may be "related to the type of drug delivery, [or] the drug medication rate of delivery." *Id.* at 14 (citing Ex. 1001, 1:20–29).

Considering the breadth of the '496 disclosure, we found that all of the recited operational parameters were directed to "control[ing] the intended function(s) of some implanted device." Inst. Dec. 14. In particular, we stated that

> 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.

Inst. Dec. 14. Accordingly, we rejected Patent Owner's proposed construction as overly restrictive and provisionally construed "set of operational parameters" as "at least two types of data used by a device to carry out an intended function." *Id.*

Patent Owner now argues that we should construe "set of operational parameters" as "a combination [or collection] of at least two types of data used by a device to carry out an intended function." PO Resp. 12–13 (citing

Ex. 2006 ¶¶ 38–39); Sur-reply 3. Somewhat at odds with its position that the phrase requires "at least two types of data," Patent Owner argues that the claim term "'set' means 'a number of things *of the same kind* that belong or are used together.'" PO Resp. 15–16 (emphasis added) (citing Ex. 2016, 4; 2017, 4; Ex. 2018, 6; Ex. 2019, 7; Ex. 2006 ¶40). In this respect, Petitioner points out that even applying the "colloquial definition of 'set'" referenced by Patent Owner, "a 'set' does not need to have two types of data, irrespective of what 'type of data' means." Reply 4 (citing e.g., Ex. 2016, 4). As noted by Dr. Kroll in the context of claim 8, "each set could have one element." Ex. 2005, 70:16–71:11.

With respect to intrinsic evidence, Patent Owner points to the memory tables in Figures 6–8 of the '496 patent where "OPSs are stored in 'memory tables'" that "include individual addressable locations wherein various operational parameters may be stored." PO Resp. 13–14 (citing Ex. 1001, 17:2–4, 17:38–43, 18:14–17, 19:4–7, 19:20–21, Figs, 6–8, Ex. 2006 ¶¶ 40–42). Patent Owner argues that the figures and related text "make clear . . . that each OPS is a combination of stored data for each of several operational parameters." *Id.* at 14–15 (citing Ex. 1001, 17:4–15, 17:25–32; Ex. 2006 ¶ 40) (emphasis omitted). In particular, "[e]ach operational parameter (or type of data) is found in one column of each row" and, as recited at column 17, lines 4–11 of the '496 patent, may define "pulse rate (PR), pulse amplitude (PA), electrode configuration (EC), ramp rate (RR), treatment times (TT), a first other parameter (P1), and a second other parameter (P2), and the like, associated with a stimulation pulse sequence." *Id.* at 14–15 (citing Ex. 1001, 17:4–15, 17:25–32; Ex. 2006 ¶ 40. Patent Owner emphasizes the '496 Patent's assertion that "[a]ll such data, ***when combined***, thus ***define an operational parameter set (OPS)*** that may be used by the

implant device." *Id.* at 15 (quoting Ex. 1001, 17:4–15) (emphasis added by Patent Owner).

Petitioner, by contrast, proposes that we construe "set of operational parameters" as "the set of data used by a device to carry out an intended function." Reply 2–8. Petitioner contends that, whereas dictionary definitions of "set" (including those submitted by Patent Owner) encompass a wide variety of meanings, in the context of the '496 patent we should look to its technical or mathematical meaning of a collection of objects encompassing any number of members, including one and zero, i.e., a "null set." Reply 3–5 (citing Ex. 1024, 155 (defining "empty set" as having zero elements), 334 (defining "null set" as an empty set), 432 (defining set as, *inter alia*, "[a] well-defined collection of objects."), 441 (defining "singleton" as "[a] set containing just one element"); Ex. 1022, 88:14–89:6; Ex. 2016–2019); *see* PO Resp. 15–16; Reply 3–4 (addressing dictionary definitions).

Patent Owner responds that "Petitioner's reliance on the 'technical (i.e., mathematical)' definition of 'set' to include zero and single member sets . . . ignores the context of the '496 patent—which is directed to medical devices, not mathematics." Sur-reply 3. In this respect, we cannot agree with Patent Owner. Of course, the '496 patent generally, and the disputed claim term in particular, are directed to the electronic control of medical devices. Indeed, Figures 6–8 and the related text upon which Patent Owner relies, feature a block diagram of circuitry including memory for controlling a representative device. *See*, *e.g.*, Ex. 1001, 17:14–24 (describing circuitry and control logic for generating stimulation impulses). Such technical pursuits, however, inescapably embody the application of mathematical principles and, as the '496 patent does not expressly define this term to the contrary,

we agree with Petitioner that one of ordinary skill in the art (as defined in section II.F, above) would have understood it in the mathematical/technical sense.

We also, however, note Patent Owner's salient observation that "Petitioner never explains how a device can use a set of data having zero members to carry out an intended function." Sur-reply 3. Petitioner neither points to, nor do we discern, any evidence that "set" in the context of the '496 patent describes or suggests the execution of any intended function based on a null set. Absent such explanation or evidence, we determine that any definition for "set of operational parameters" must include at least one operational parameter.[8]

Petitioner also argues that the '496 patent does not "*require* at least two types of data." And although Patent Owner's arguments rely on the SCS embodiment, the '496 patent itself asserts "broad applicability," and may be used with many other types of implant devices and/or systems. Reply 5 (citing Ex. 1001, 5:55–62). Petitioner argues, for example, that the '496 patent is applicable to controlling an implant device such as an insulin pump described by Irsigler[9] where the single parameter is flow rate. *Id.* (citing Ex. 1023, 1072, Fig. 1; Ex. 1001, 1:38–45 (asserting applicability to "drug

[8] We view the plural "parameters" in this phrase as merely a linguistic convention encompassing sets having more than one parameter (as shown, for example, in the SCS-based examples of the '496 patent).
[9] Irsigler, K., et al., "Long Term Continuous Intraperitoneal Insulin Infusion with an Implanted Remote-Controlled Insulin Infusion Device," Diabetes, 30(12):1072-1075, (December 1981), Ex. 1023.

delivery systems"); Ex. 1022, 91:17–92:12 (Patent Owner's expert noting that early pacemakers used a single operational parameter)).[10]

Patent Owner contends that the insulin pump Petitioner refers to is irrelevant as outmoded technology. Sur-reply 4. We are unpersuaded by Patent Owner's attorney argument in light of the '496 patent's asserted "broad applicably" to SCS systems "or any other programmable implant system," "including all types of . . . drug delivery systems. . . regardless of whether such systems incorporate implantable or external components." Ex. 1001, 1:16–19, 1:34–45, 5:55–62.

In sum, we agree with Petitioner, that "set of operational parameters" does not require at least two types of data. And to the extent Patent Owner's reference to "a combination," or even "a collection," might be read to infer such a requirement, we are unpersuaded they should be included in the construction for the reasons stated. Accordingly, we modify our initial construction as Petitioner proposes, and construe "set of operational parameters" as "set of data used by a device to carry out an intended function."

2. "parameter context switching." (Claim 14)

The preamble to claim 14 recites: "An implant system that permits parameter context switching." In our Institution Decision, we noted that the Specification provides an express definition of "parameter context switching" as "defining and/or selecting different operational parameter sets

[10] Patent Owner's counsel also contends that the Irsigler insulin pump "uses at least three types of data." Sur-reply 4 (citing Ex. 1023, 1072). But as we understand the reference, Irsigler indicates that although the pump may be programmed to respond to different biological conditions, this reduces to different levels for a single parameter—flow rate.

for use by an implant device," and provisionally adopted that term to the extent construction was required. Inst. Dec. 15–16 (citing Ex. 1001, 5:44–47). To the extent necessary, we apply that definition here.

The parties presently agree that the express definition of the "parameter context switching" applies, but disagree as to whether the preamble is limiting and, thus, whether the term should be accorded patentable weight. PO Resp. 17, 56–60; Reply 8, 22; Sur-reply 23.

Patent Owner contends that, despite its sole recitation in the preamble, "'parameter context switching' is a substantive limitation of claim 14 and its dependents," because it is "a focus" of the '496 patent highlighted in the title, abstract, and specification, and because it discloses steps that are essential to the invention. PO Resp. 56–60 (citations omitted). Patent Owner points to *On Demand Mach. Corp. v. Ingram Indus., Inc.*, 442 F.3d 1331, 1343–44 (Fed. Cir. 2006), as instructive, where recitation of "high speed manufacture" in the preamble was "limiting because this concept was 'fundamental' to the invention and the 'entirety of the claim implements the preamble's high speed manufacture of a single copy' of a book." *Id.* at 59–60. Patent Owner argues that, as in *On Demand*,

> the entirety of claim 14 implements the '496 patent's fundamental concept of parameter context switching, yet the concept is only stated in the preamble. Without its preamble, claim 14 recites only standard features of implantable devices—*e.g.*, "a first memory element" for storing a "set of operational parameters" and "control data" that defines a single "set of operational parameters." (EX1001 at 20:65-21:21.) Only with the framework provided by the preamble's "parameter context switching" does claim 14 align with the stated purpose and invention of the '496 patent.

Id. at 60.

Patent Owner's argument has some merit. It is not, however, dispositive because we are not guided solely by the specification. "Whether 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." *Deere & Co. v. Bush Hog, LLC*, 703 F.3d 1349, 1357 (Fed. Cir. 2012) (internal quotation marks omitted). Although we agree with Patent Owner that the Specification of the '496 patent highlights context switching as an important aspect, Patent Owner does not cite any case law requiring the Applicant to seek protection for a highlighted element in every claim. Nor does Patent Owner argue that the case law requires that any element highlighted in the specification must be read into every claim where it is not recited.

We also 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). Here, the preamble to claim 14 recites "[a]n implant system that permits parameter context switching." As Petitioner points out, the "permits" element of the preamble indicates the permissive nature of claim 14 and describes a purpose of the implant system to *permit* parameter context switching. Reply 22. The body of the claim, however, neither references nor describes the concept of parameter context switching.[11] Rather, it describes a structurally

[11] In this respect, we decline to read the word "permit" in the preamble as "describ[ing] a device that ***practices*** parameter context switching," as Patent Owner proposes. *See* Sur-reply 24; *SuperGuide Corp. v. DirecTV Enters.,*

complete invention comprising an implant device, an external control device, and an external charging device. Ex. 1001, 20:65–21:22. 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." *Pitney Bowes* at 1305.

Accordingly, we are persuaded that the preamble to claim 14 should not be read as limiting.

D. Overview of Asserted References

1. Shelton (Ex. 1005)

Shelton is directed to "implantable medical devices capable of generating output stimulating pulses at selectable energy levels" and more specifically, implantable cardiac pacemakers having programmable stimulating pulse amplitudes selectable by means of an external programming unit. Ex. 1005, code (57), 1:6–9. 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

Inc., 358 F.3d 870, 875 (Fed. Cir. 2004). ("Though understanding the claim language may be aided by the explanations contained in the written description, it is important not to import into a claim limitations that are not a part of the claim.")

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 via telemetry using a commercially available external programming unit such as the Medtronic Model 9760 programmer. *Id.* at 8:22–43. An embodiment of Shelton's pacemaker is shown in Figure 1, reproduced below.

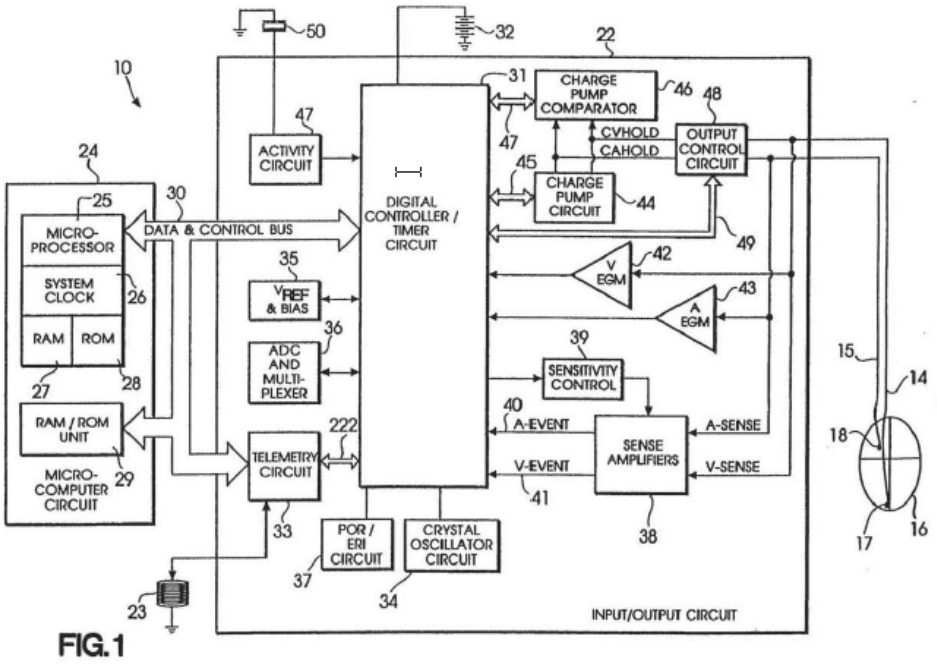


FIG.1

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, 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.

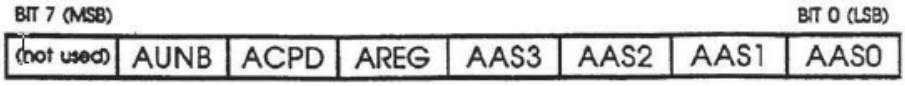


FIG.2

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, 13–15, Tables 1, 2. 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. 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.

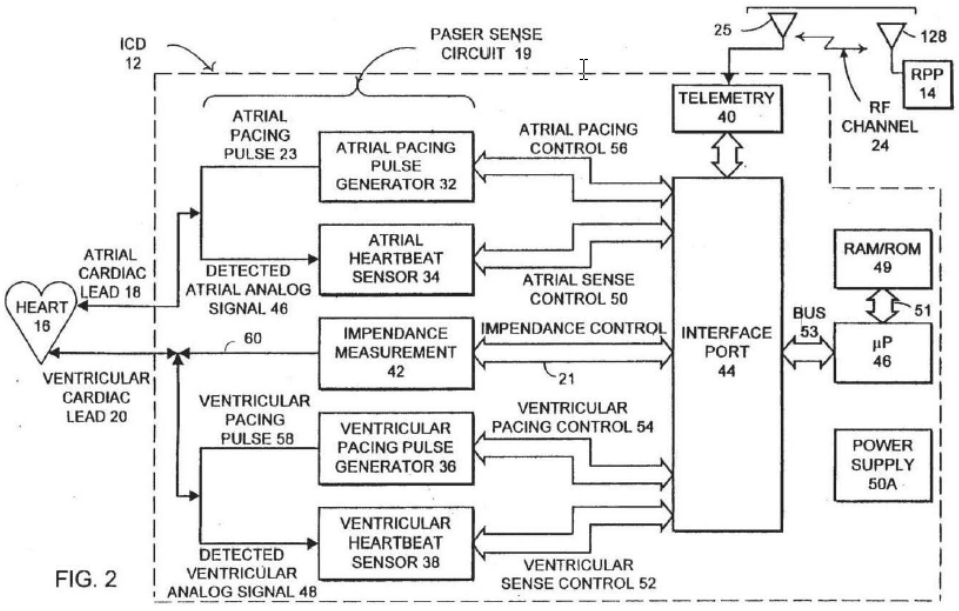


Figure 2 depicts a block diagram of an implantable cardiac device.

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:

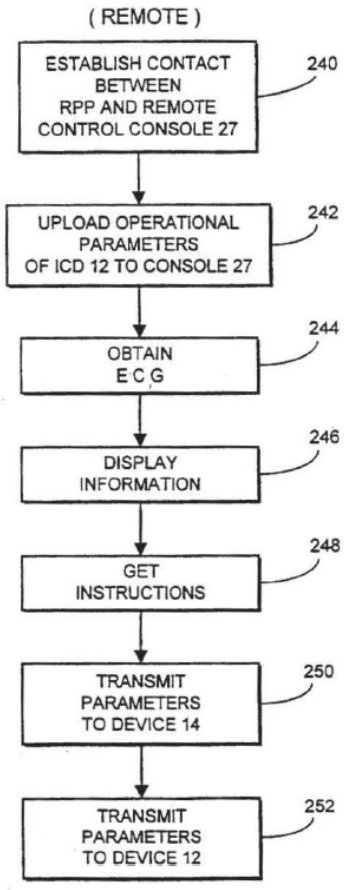


FIG. 6

Figure 6 depicts a flow chart for remotely changing the operational parameters of an implantable cardiac device via the RPP. *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:

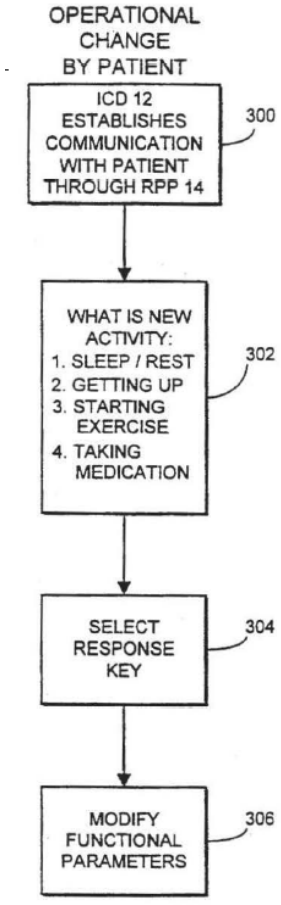


FIG. 7

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. Mumford (Ex. 1009)

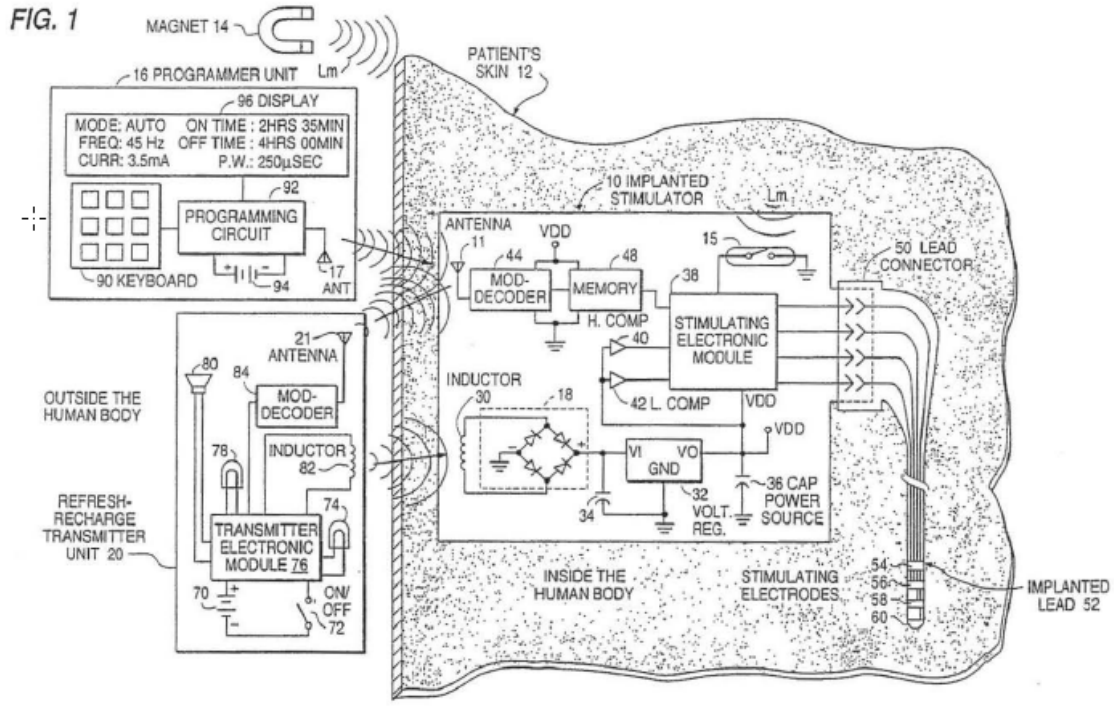
Mumford is directed to a computer-controlled programmer designed to control the parameters of a wide variety of implantable devices, e.g., cardiac pacers and neural stimulators, with different programming requirements. Ex. 1009, code (57), 1:30–38. Mumford discloses "[t]he programmer automatically changes 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.

4. Barreras '217 (Barreras I, Ex. 1007)

Barreras I 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).[12] With respect to such devices, Barreras I 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 I 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 Barreras I's implantable stimulator system is illustrated in Figure 1, reproduced below.



[12] Barreras I 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 pulses. *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 I 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.*

5. Barreras '887 (Barreras II, Ex. 1008)

Barreras II 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 II 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.

E. Obviousness in view of Shelton and Nappholz (Ground 1)

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.* In opposing the Petition, Patent Owner contends that the Petition fails to establish that the following language from claim 1 is rendered obvious under Ground 1: "a plurality of sets of operational parameters," "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," and "whereby the operation of the implant device may be changed through selection of a different set of operational parameters." PO Resp. 25–50; Sur-reply 5–23. Patent Owner further challenges Petitioner's assertions with respect to the "memory circuity" and "memory means external to the implant device wherein the plurality of sets of operational parameters are stored" recited in claims 2 and 3, respectively. PO Resp. 47–50; Sur-reply 22.

We have reviewed Petitioner's contentions regarding Ground 1 and conclude that Petitioner has established by a preponderance of the evidence that the undisputed limitations are taught or suggested by the prior art for the reasons disclosed in the Petition. We address the disputed elements below.

1. Petitioner's contentions regarding disputed elements of Claim 1

Claim 1 recites "electronic circuitry including a control register wherein a control set of operational parameters is stored." As stated on page 24 of the Petition, "Shelton discloses loading data to control the implanted pacemaker into an eight-bit atrial output control register that resides in digital controller/timer circuit," illustrated in Figure 2, reproduced below. Pet. 24.

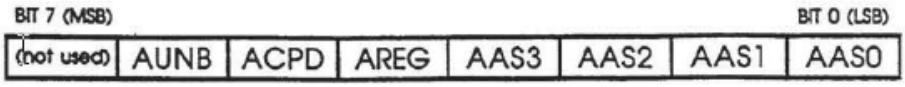


FIG.2

Figure 2 shows the eight-bit atrial control register referenced by Petitioner. Ex. 1005, 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. According to Petitioner, "Shelton also loads data to control the implanted pacemaker into a ventricular output control register." Pet. 24 (citing Ex. 1005, 14:1–10. The controller retrieves the data from the control register to control the operation of the pacemaker. *Id.* (citing Ex. 1005, 12:6-24; Ex. 1003 ¶ 66).

Claim 1 further recites "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." With respect to this element, Petitioner relies on Shelton's teaching that "digital controller/timer circuit 31 uses the data in the atrial output control register to control various aspects of atrial pacing by pacemaker 10." (Pet. 25 (citing Ex. 1005, 12:20–23; Ex. 1003 ¶ 74)). Petitioner points to the data in the atrial output register, for example, as a control set of operating parameters. *Id.* (citing Ex. 1005, 12:20-23; Ex. 1003 ¶¶ 74–75).

With respect to "a plurality of sets of operational parameters," Petitioner states 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." Pet. 25 (citing Ex. 1005, 23:33–42, 24:28–32). Petitioner, however, argues that this element is disclosed by Nappholz. *Id.* (citing Ex. 1003 ¶ 76). In particular, 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; *see id.* at 45–48. Petitioner asserts that when the patient selects a new mode of operation, Nappholz's device reconfigures or modifies the operation parameters, wherein each mode of operation

corresponds to a different set of operational parameters. *Id.* (citing Ex. 1006, 9:17–29, Fig. 7; Ex. 1003 ¶¶ 76–78) Accordingly, Petitioner contends, "it would have been obvious to a POSA that a physician or a patient should have the capability to define respective characteristics associated with the operation of the implant device." *Id.* at 26 (citing ¶¶ 76–79); *see also id*. at 49 ("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") (citing e.g., Ex. 1003 166–168).

Petitioner relies on Nappholz and Shelton with respect to the means plus function limitation, "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." Referencing the action of microcontroller 160 of the '496 patent, Petitioner contends that Shelton's Figure 1 illustrates a similar structure performing the same function. Pet. 26–28 (citations omitted); Ex. 1003 ¶¶ 81–90.

Petitioner further relies on Nappholz as disclosing selection means, stating that with Nappholz's RPP, "a user can change the mode of operation of Nappholz's implant device by making a selection of a new level of activity" where "each mode of operation corresponds with a different set of operational parameters." *Id.* at 28 (citing Ex 1006, 9:17–29, Fig 7; Ex. 1003 ¶ 91).

Petitioner concludes that one of skill in the art reading Shelton in view of Nappholz,

> 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.

Pet. 28–29 (citing Ex. 1003 ¶¶ 81-92).

Further addressing the "selection means," Petitioner points to Shelton's description of external programming devices, such as the Medtronic Model 9760, that can communicate with an implanted device and select a set of operational parameters for controlling an implanted device. *Id.* at 29 (citing Ex. 1005, 8:14–50; Ex. 1010 ¶¶ 83–86). Petitioner further contends that Nappholz's RPP 14 could also perform this function. *Id.* (citing Ex. 1006, Fig. 7, 9:17–29; Ex. 1003 ¶ 93). Petitioner concludes that, in light of Shelton and Nappholz, one of ordinary skill in the art would have known that "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." *Id.* (citing Ex. 1003 ¶ 94).

Petitioner similarly addresses the claim language, "whereby the operation of the implant device may be changed through selection of a different set of operational parameters," asserting that "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." Pet. 30 (citing Ex. 1006, 9:17–29). Accordingly, Petitioner contends, "Shelton in view of Nappholz . . . describes changing the operation of the implant device through selection of a different set of operational parameters." *Id.* (citing Ex. 1003 ¶¶ 96–97).

2. Patent Owner's Response

Patent Owner contends that Shelton alone does not disclose a plurality of sets of operational control parameters, pointing out that even Petitioner admits that this element is not expressly disclosed in Shelton. PO Resp. 26 (citing Pet. 20, 25; Ex. 1003 ¶¶ 60, 76). Rather, Patent Owner contends Shelton's Figure 2 illustrates the disclosure of "at best, only a singular 'control set of operational parameter'—an additional limitation of the '496 patent that is separate and distinct from a 'plurality of operational parameter sets.'" *Id.* at 27–28 (citing Ex. 1005, 12:20–24). As we understand this argument, Patent Owner contends that although Shelton discloses ten pulse amplitude settings programmable with an external controller, these settings are not concurrently stored in memory. *See* PO Resp. 29 (citing Ex. 2005, 71:20–72:3, 72:5–73:3, 77:23–78:23). Thus, according to Patent Owner's expert, "Shelton discloses a plurality of programmable—not selectable—settings for a single parameter—i.e., a single type of data for example pulse amplitude . . . . . Shelton does not even hint at defining, storing, or selecting from a 'plurality of operational parameter sets' . . . ." *Id.* (citing Ex. 2006 ¶¶ 3–9, 48). We are persuaded that Petitioner's position is correct.

As construed in section II.C.1, above, "set of operational parameters" means "set of data used by a device to carry out an intended function." Shelton Figure 2 shows eight bit positions, four of which (AAS3, AAS2, AAS1, and AAS0) determine the amplitude of atrial stimulating pulses. Ex. 1005, 12:25–67, 13–15 Tables 1, 2. Data at these positions comprise a set of operational parameters and, in particular, "the control set of operational parameters that is stored in the control register," set forth in claim 1. Shelton discloses a "selection means," i.e., an external programmer like the Medtronic Model 9760, which can be used to select pulse amplitude

settings and communicate them to the implanted device. Patent Owner's expert states that, "Shelton discloses a plurality of programmable—not selectable—settings for a single parameter—i.e., a single type of data for example pulse amplitude." Ex. 2006, ¶48; Reply 9. But Petitioner points out that the Medtronic Model 9760 allows a user to save at least one set of operational parameters and to later select that saved set of operational parameters. Reply 9–10 (citing Ex. 1022, 111:18–112:7). In this light, we agree with Petitioner that "Shelton alone discloses a plurality of *selectable* sets of operational parameters that govern stimulation amplitudes" and, therefore, satisfies the disputed claim elements under our construction. *See* Reply 10 (citing Ex. 1005, 13–15, Tables 1, 2).

Patent Owner also argues that Shelton fails to disclose "set[s] of operational parameters" because cardiac stimulation devices employ sophisticated algorithms to dynamically adjust therapy incrementally, or not at all. PO Resp. 30. But to the extent the pulse amplitude selected in Shelton is fed into an algorithm, it nevertheless, is still a "set of data used by the device to carry out an intended function." *See* section II.C.1, above.

Patent Owner further argues that Sheldon fails to disclose "set[s] of operational parameters" because its device cannot be programmed by a patient, but requires physician input to change amplitude settings. PO Resp. 5–9, 31–24; Sur-reply 8–10. We are persuaded Petitioner is correct for the reasons set forth on pages 10–11 of the Reply. In short, although patient accessibility is one of the benefits touted in the specification of the '496 patent, this is not an element of claim 1. To the contrary, claim 1 is agnostic as to the user, if any. *See* Ex. 1022, 72:3–14 (Dr. Langer admitting that claim 1 does not require a patient to manually select an operational parameter nor preclude selection by clinician or physician users).

We further note that the only reference to patient control of operating parameters is found in claim 17 (not challenged under Ground 1), which includes "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." In this respect, claim differentiation suggests that the remaining claims do not require a means for patient user control. Accordingly, the claims encompass physician-only programming and, indeed, automatic adjustments based on the patient's physiology or behavior.

To the extent Shelton alone does not satisfy the disputed elements, Petitioner further relies on Nappholz. Patent Owner contends "[l]ike Shelton, Nappholz also fails to disclose a plurality of 'sets of operational parameters under any claim construction." PO Resp. 35 (emphasis omitted). In particular, Patent Owner points to Nappholz as describing an operational program "including ***a complete set*** of operational parameters, and allowable ranges for these parameters and other programmable options [] stored in the external console 27 or RPP." *Id.* at 35–36 (citing Ex. 1006, 6:64:67, 7:8–9, 7:50–8:2; Ex. 2006 ¶¶ 52, 53, 64). Accordingly, Patent Owner argues, Nappholz's device is implanted with "a single set of operational parameters that will allow it to operate properly under all possible conditions." *Id.* (citing, e.g., Ex. 2006 ¶¶ 53, 64).

We are persuaded that Petitioner's position is correct. Indeed, in this respect, the arrangement Patent Owner describes in Nappholz is comparable to memory table 165 of the '496 patent, which comprises "individual addressable locations wherein various operational parameters may be stored," and where "most of these operational parameters, if not all, are initially defined by the clinician using the clinician programmer." Ex. 1001, 17:2–4, 17:45–55; *see also id.* at 17:25–45 (describing retrieval of

operational parameters stored in memory). Consistent with Patent Owner's description, Nappholz describes that a physician can preprogram the entirety of this information into the device at the time of implantation, such that it contains all possible sets of operational parameters available to a particular patient. Ex. 1006, 6:64–67 (operating program having "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), *see also* Reply 12–13 (discussing additional evidence that Nappholz's operational parameters are preprogrammed for a particular patient and selectable as illustrated in Figure 7).

Moreover, and illustrative of "selection means for switching between multiple operational parameters," Nappholz's claim 27 recites, "means for generating first and second electrical stimulation signals for said heart to provide selectively one of a corresponding first therapy and a second therapy, means for switching between said first and second therapies in response to data from said patient indicative of a change in a condition of the patient." Ex. 1006, 17:12–22. Accordingly, Patent Owner's distinction between the multiple operational parameters of claim 1 exemplified in memory table 165 of the '496 patent, and Nappholz's description of the entirety of its programming options as a complete set of operational parameters (i.e., comprising all sets of operational parameters that can be deployed as control sets), is a matter of semantics with no patentable significance.[13] Both systems comprise a defined number of operational

[13] Accordingly, we see no contradiction in Dr. Kroll's testimony that "if we're going to make a selection between multiple choices [i.e., between more than one operational parameter], those choices have to exist somewhere" because Nappholz's device is pre-programmed with all of the

parameters, albeit accessed in different manners. Those of memory table 165 are addressable by the location of the group, whereas those in Nappholz are addressable by the location of individual elements comprising the group. Irrespective of how their data are structured and accessed, they are both a "set of operational parameters," in that each is a "set of data used by a device to carry out an intended function."

As set forth in the Petition and illustrated in Figure 7, Nappholz discloses that, in response to a query from the device, a patient may change the mode of operation using a remote communication console. For example,

> when the device 12 detects a change which may require a different mode of operation, it establishes communication via a routine handshake. The device 14 then requests information from the pat[i]ent about his level of activity. Various levels of activity are displayed, as shown in Step 302. This is accomplished by showing a menu of *2S* activities on display (Step 302). In Step 304, the patient selects a key on unit 14 corresponding to his level of activity, the device 12 then reconfigures or modifies its operational parameters.

Ex. 1006, 9:17–29; *see also* claim 27. Patent Owner contends that Nappholz fails to satisfy the disputed claim elements because the above "passage makes clear that the device—not the patient. . . initiates the selection process when it 'detects a change which may require a different mode of operation.'" PO Resp. 37.

Patent Owner's position does not prevail for at least the reasons set forth on pages 11–13 of the Reply, which we adopt. As discussed above, we emphasize that claim 1 does not require that *the patient* select a different operational parameter set and, accordingly, the claim is met from selection

---

sets of operational parameters available for treating a particular patient. *See* Ex. 2005, 67:4 –76:4.

by a physician, the device itself, or a digital algorithm. Indeed, even Patent Owner's expert conceded "that the selection means in Claim 1, in addition to the hand-held programmer, would enable automatic selection of an operational parameter set without the intervention of either a patient user or a physician user or a clinician user." Ex. 1022, 71:4–12, 72:3–8.

Moreover, and contrary to Patent Owner's interpretation, Nappholz does discloses patient selection of operational parameters, as is illustrated in Nappholz's Figure 7. That a patient's input may be prompted by Nappholz's system, and that the precise set of operational parameters selected may be interpreted and refined by the system's algorithm is not contrary to the challenged claims. *See* Sur-reply 19–20 (distinguishing use of algorithm to provide incremental changes and as-need "dynamic" therapy from "swap[ping] one entire set of operational parameters for another.").

We are similarly persuaded that the modes of operation disclosed in Nappholz are operational parameter sets. PO Resp. 40–44. Although Patent Owner argues that "'mode' has a very specific meaning in the pacemaker art . . . . [that] does not carry over to spinal stimulators," the claims at issue are not limited to spinal simulators. *See id.* at 41–42; Ex. 1022, 72:17–20.

Patent Owner further argues that "Nappholz does not perform a context switch as defined in the '496 patent" because it "'reconfigures or modifies its operational parameters' rather than swapping in a complete new set." PO Resp. 42–44. As an initial matter, we note that "parameter context switching" is specific to the preamble of claim 14. *See* section II.C.2, above. We, nevertheless, credit Petitioner's argument that Nappholz's device is configured to change the set of operational parameters within a given mode. Reply 15–16 (citing, e.g., Ex. 2006 ¶¶ 63–64; Ex. 1006 (based on patient input, "device 12 reconfigures or modifies its operational parameters")).

Although the '496 patent discloses embodiments in which a first set of operational parameters stored in first location is replaced with a second set stored in a second location, we do not read this as a requirement of the challenged claims. We find it sufficient that Nappholz discloses modifying a set of operational parameters to create a second set of operational parameters. Once modified, the new set of operational parameters serve as the control set of operational parameters, irrespective of whether the modification involved replacing a single parameter or the entirety of the original set, and irrespective of how, or how often, that process occurs.

Patent Owner further argues that Nappholz fails to disclose selecting from a plurality of sets of operational parameters, and that Petitioner improperly relies on the same feature to satisfy both the "defining" element of claim 12, and "selecting" elements of claims 1 and 8. PO Resp. 44–45. Petitioner's position is more persuasive. As we understand the reference, the parameters programmed into Nappholz's device by a physician define the universe of possible sets of operational parameters available to the device, individual sets of which may be selected as the control set of operational parameters by the algorithm, and with input from the patient. We additionally credit Petitioner's argument that the defining and selecting elements are satisfied because Nappholz's external console or RPP includes a complete set of operational parameters, and because the physician must customize the implanted device for the particular patient and the patient's condition. Reply 18 (citing Ex. 1006, 6:56–67). Accordingly, "the physician . . . enters instructions for initializing or changing the functional parameters of the implant device." *Id.* (citing Pet., 54).

Patent Owner further argues that one of ordinary skill in the art would not have understood Nappholz or Shelton to disclose defining, storing, or

selecting from a plurality of sets of operational parameters, because they "would not consider it necessary or safe to allow a patient the ability to make wholesale changes to the operational parameters of such a system." PO Resp. 46; Sur-reply 21–22. We disagree with Patent Owner for the reasons set forth at pages 18–20 of the Reply, which we adopt. *See also id* at 45–49 (similar arguments in context of Claim 8). In short, we do not read the challenged claims to require a patient unfettered access to a device's operational parameters. Yet, as Petitioner points out, "Nappholz's express disclosure belies the safety argument because it unambiguously allows a user to select an activity level, and thus"—with the assistance of the devices internal programming—a set of operational parameters. Reply 19.

3. Disputed elements of claims 2 and 3

With respect to claim 2, Petitioner points to Shelton's RAM/ROM unit 29 within microcomputer circuit 24, and/or Nappholz's RAM 49 as "electronic circuitry . . . includ[ing] memory circuitry wherein the plurality of sets of operational parameters are stored." Pet. 30 (citing Ex. 1005, 9:27–34, 9:24–34; Ex. 1006, Fig. 2; Ex. 1003 ¶¶ 100–101). With respect to claim 3, Petitioner points to memory 106 in Nappholz's RPP/external console as disclosing "memory means external to the implant device wherein the plurality of sets of operational parameters are stored." Pet. 34 (citing Ex. 1006, 3:1–10, 5:57–60, 7:59–64; Ex. 1003 ¶¶ 113–117. As summarized in Patent Owner's Sur-reply, Patent Owner argues that claims 2 and 3 refer to where "the ***plurality*** of sets of operational parameters are ***stored,***" but

> [t]he passages of Nappholz on which Petitioner relies do not disclose the storage of a plurality of OPSs; they disclose only that the initial "functional parameters are downloaded to external RPP 14" (EX1006 at 7:61-62) and then "are downloaded from

> RPP 14 to the cardiac stimulating device 12." (EX1006 at 7:63-64.) These passages thus relate to the initial programming of one set of operational parameters—not to the storage of a ***plurality*** of sets of operational parameters. (EX2006 ¶¶ 52-53, 74, 77-78.)

Sur-reply 21–22; *see* PO Resp. 47–50.

We agree with Petitioner here, at least with respect to Nappholz. Nappholz discloses an operational program having "a complete set of operational parameters, and allowable ranges for these parameters and other programmable options [] stored in the external console 27 or RPP," which we equate to the memory table 165 of the '496 patent (comprising "individual addressable locations wherein various operational parameters may be stored") and, the storage location for a plurality of sets of operational parameters. *See* section II.D.2, above; Ex. 1001, 17:2–4. Ex. 1006, 6:64–67. In addition, Petitioner points to Nappholz's Figure 6 and corresponding text stating that: "In step 250 the functional parameters are downloaded to external RPP 14. In step 252, the functional parameters are downloaded from RPP 14 to the cardiac stimulating device 12." Reply 20 (quoting Ex. 1006, 7:59–64). Petitioner, thus, reasons that Step 252 stores the operational parameters on Nappholz's implant device, and that the operational parameters are also loaded on Nappholz's implant device using Nappholz's external programming device. *Id.* Petitioner notes, as do we, that the operational parameters loaded onto the Nappholz's implant device include a plurality of sets of operational parameters that correspond to the patient's selection of an activity level. *Id.* at 20–21.

4. Weight of Expert Opinions

Patent Owner contends that we should accord little or no weight to Dr. Kroll's opinions. PO Resp. 21–25; Sur-reply 25–26. Patent Owner,

however, neither challenges Dr. Kroll's credentials nor moves to exclude his testimony. Patent Owner's primary complaint appears to be that more than 140 paragraphs of Dr. Kroll's 265-paragraph declaration are essentially identical to the Petition such that it "merely repeats arguments from the Petitioner verbatim." PO Resp. 22–23. Patent Owner also points to three instances at Dr. Kroll's deposition (Ex. 2005, 71:7–11, 101:11–102:5, 105:22–106:9) and two in his declaration (Ex. 1003 ¶¶ 76, 167) where it contends Dr. Kroll provided opinions unsupported by credible evidence. PO Resp. 24; Sur-reply 26.

Although it is often helpful to the Board for an expert declaration to further explicate or support a party's assertions, we have not been apprised of requirement that they do so. Irrespective of the precise relationship between the declaration and a party's assertions, we consider the clarity of the expert's opinions, whether those opinions are supported in the record, the expert's experience and qualifications, and the reputation the witness puts on the line with every submission to, and deposition before, this body. In the present case, we do not find Dr. Kroll's testimony as a whole so wanting as to be given little or no weight. We, nevertheless, take Patent Owner's arguments into account in considering Dr. Kroll's testimony, and draw our conclusions based on the entirety of the record.

5. Conclusion as to Ground 1

Patent Owner makes no additional arguments with respect to claim 6, relying instead on its arguments with respect to claim 1. PO Resp. 23. For the reasons set forth above, Petitioner has established by a preponderance of the evidence that claims 1–3, and 6 are obvious in view of Shelton and Nappholz.

F. Grounds 2–4: Obviousness over one or more of Shelton, Nappholz, Mumford, and Barreras ’887

As Ground 2, Petitioner challenges claims 4 and 5 as obvious over Shelton, Nappholz, and Mumford. Pet. 37–42. As Ground 3, Petitioner challenges claim 7 as obvious over Shelton, Nappholz, and Barreras ’887 (Barreras II). Pet. 42–44. As Ground 4, Petitioner challenges claims 8–13 as obvious over Nappholz. Pet. 44–57. For each ground, Petitioner challenge includes a detailed mapping of the teachings of these references to each limitation of the claims.

For each of Grounds 2–4, Patent Owner relies solely on its arguments with respect to Ground 1. PO Resp. 50–51 (arguing that “Mumford does not disclose ‘a plurality of sets of operational parameters’ and Petitioner does not suggest that it does”), 52–53 (arguing that “Barreras II does not disclose ‘a plurality of sets of operational parameters’ or selecting from such a plurality and Petitioner does not suggest that it does”), 53–55 (restating prior argument that although Nappholz discloses “***an*** initial set of operational parameters, this does not amount to a ***plurality*** of combinations of operational parameters”); Sur-reply 23 (referencing “the same reasons discussed above in regards to Ground 1”). We have addressed Petitioner’s arguments regarding Ground 1 in section II.E, above. We have reviewed Petitioner’s contentions regarding Grounds 2–4 and conclude that Petitioner has established by a preponderance of the evidence that claims 4, 5, and 7–13 are obvious over the combinations set forth in Grounds 2–4.

G. Ground 5: Obviousness over Barreras ’217 (Barreras I)

As Ground 5, Petitioner challenges claim 14 as obvious over Barreras ’217 (Barreras I). Pet. 57–62; Reply 23. Petitioner’s challenge includes a detailed mapping of the teachings of that reference to each

limitation of the claim. *See id*. Claim 14 recites, as preamble, "[a] implant system that permits parameter context switching." As discussed in section II.C.2, above, we do not treat the preamble as limiting. As Patent Owner's arguments with respect to Ground 5 are based on this non-limiting language, we are persuaded Petitioner prevails here. *See* PO Resp. 56–62; Sur-reply 23–25.

To the extent the preamble is limiting, parameter context switching means "changing one set of operational parameters to another." Ex. 1001, 5, 44–47; section II.C.2, above. Pointing to Barreras I's disclosure of an implanted stimulator that receives programming information, including operating parameters such as frequency, pulse, width, and ON time, 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. Pet. 57–58 (citing; Ex. 1007, 5:48–49, 8:3–6, 8:11–16, Fig. 1; Ex. 1003 ¶¶ 194–195).

Patent Owner responds that Barreras I comprises an implantable stimulator programmed via an external programmer. PO Resp. 60–61. According to Patent Owner,

> Once programmed, the operational parameter values that were not chosen during programming are not stored in the device's memory or selectable by the physician or patient. There is also no suggestion that any operational parameters are arranged as combinations—*i.e.*, sets of operational parameters. Thus, Barreras I does not disclose defining, storing, or selecting from a plurality of operational parameter sets.

PO Resp. 61 (citing Ex. 2006 ¶ 66); *see also id.* at 62 (quoting Petitioner's acknowledgement that "Barreras I does not specifically disclose transferring *a plurality* of sets [of] operational parameters to the implanted device"); Sur-

reply 24–25 (Barreras I . . . discloses transmitting ***only one*** OPS—the control set of operational parameters common to every implantable device—which does not satisfy the '496 patent's limitation s of defining, storing, and selecting from ***a plurality*** of OPSs").

Patent Owner's arguments are misplaced. Claim 14 does not recite the limitations Patent Owner seeks to impose and contains no requirement for defining or storing multiple sets of operational parameters. To the contrary, claim 14 refers to only a single defined set of operational parameters stored in memory. In particular, claim 14 refers to transferred "control data . . . that defines the set of operational parameters stored in the first memory element of the implant device," and which control "electronic circuity that performs a prescribed function."

Thus, were we to accord the preamble patentable weight as Patent Owner urges, claim 14 would instead require "changing one set of operational parameters to another." Barreras I satisfies this element. In particular, Barreras I discloses an implantable stimulator system including a programmer unit, with which a physician can program a set of operational parameters (frequency, pulse width, and ON time), the data for which is stored in memory unit 48. *See* section II.D.4, above. The programmer unit transmits this information as command signals to the memory of the implanted device, which thereby controls its operation. *See id.* 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. Barreras I 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. Thus, as articulated by Petitioner,

> Barreras I discloses transmitting at least one set of operational parameters to the implant device from a programming unit 16 to the implant device using the programming circuit 92 and antenna 17. EX1007, Barreras I, 8:3-15. Barreras I's programming unit may thus be used to define other sets of operational parameters as well.

Reply 23.

In view of the above, we persuaded that Barreras I 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. Patent Owner does not challenge Ground 5 on any basis not discussed above. We have reviewed Petitioner's contentions regarding Ground 5 and conclude that Petitioner has established by a preponderance of the evidence that claim 14 is obvious in view Barreras I.

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

As Ground 6, Petitioner challenges claims 15 and 16 as obvious over the combination of Barreras I 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 I and Nappholz, which we have discussed above in sections II.G and II.E, respectively. *See* PO Resp. 62–63; Sur-reply 25. For the reasons advanced by Petitioner (*see* Pet. 62–69), and for the reasons set forth in sections II(G) and II(E), above, Petitioner has established by a preponderance of the evidence that claims 15 and 16 are unpatentable over the combination of Barreras I and Nappholz.

I. Ground 7: Obviousness over the combination of Barreras I, Nappholz, and Mumford

As Ground 7, Petitioner challenges claims 17 and 18 as obvious over the combination of Barreras I, 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 I and Nappholz, which we address in the previous section. *See* PO Resp. 63–64; Sur-reply 25. We have reviewed Petitioner's contentions regarding Ground 7 and conclude that Petitioner has established by a preponderance of the evidence that claims 17 and 18 are unpatentable under Ground 7.

J. Stipulated Protective Order and Patent Owner's motion to seal

In Paper 22, Patent Owner submits a Stipulated Protective Order based on our Default Protective Order but having modifications regarding in-house counsel access and expert certifications. Petitioner does not oppose (*id.* at 1) and we determine the proposed modifications are acceptable. Accordingly, the Stipulated Protective Order (Attachment A to Paper 22) shall apply to the confidentiality of documents submitted in this proceeding.

Also in Paper 22, Patent Owner moves to seal Exhibits 2007–2009, 2011, and portions of its Patent Owner Response containing data taken from those exhibits. *Id.* at 4. Petitioner does not oppose the motion.

According to Patent Owner, Exhibit 2008 is a confidential physician survey relating to the SCS market; Exhibit 2009 is confidential internal presentation relating to SCS devices; and Exhibit 2011 is an internal SCS market analysis. *Id.* at 2. According to Patent Owner, public disclosure of

this information would result in competitive harm to Patent Owner. *Id.* at 2–4.

"There is a strong public policy for making all information filed in a quasi-judicial administrative proceeding open to the public, especially in an *inter partes* review which determines the patentability of claims in an issued patent and therefore affects the rights of the public." *Garmin Int'l v. Cuozzo Speed Techs., LLC*, IPR2012-00001, Paper 34 (PTAB Mar. 14, 2013), 1–2. For this reason, except as otherwise ordered, the record of an *inter partes* review shall be made available to the public. 35 U.S.C. § 316(a)(1); 37 C.F.R. § 42.14.

The standard for granting a motion to seal is "for good cause." 37 C.F.R. § 42.54(a). That standard includes a showing that

> (1) the information sought to be sealed is truly confidential, (2) a concrete harm would result upon public disclosure, (3) there exists a genuine need to rely in the trial on the specific information sought to be sealed, and (4) on balance, an interest in maintaining confidentiality outweighs the strong public interest in having an open record.

Argentum Pharms. LLC v. Alcon Research, Ltd., IPR2017-01053, Paper 27 (PTAB Jan. 19, 2018) (informative), 3–4. The moving party bears the burden of showing that the relief requested should be granted. 37 C.F.R. § 42.20(c).

Patent Owner has set forth a reasonable case that good cause exists to seal the identified information. Because our Decision does not rely on any of the material sought to be protected we are satisfied that Patent Owner has provided sufficient justification for keeping this information confidential, which outweighs the heightened public interest in understanding the basis

for our decision on patentability. Accordingly, we grant Patent Owner's motion to seal.

III. CONCLUSION

On the present record, we find Petitioner has established by a preponderance of the evidence that the cited references would have taught or suggested each element of claims 1–18 of the '496 patent, 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 those claims. Accordingly, and for the foregoing reasons, Petitioner has met its burden of showing, by a preponderance of the evidence, that claims 1–18 of the '496 patent are unpatentable, as summarized in the following table:

Claims	35 U.S.C §	Reference(s)/ Basis	Claims Shown Unpatentable	Claims Not Shown Unpatentable
1–3, 6	103(a)	Shelton, Nappholz	1–3, 6	
4, 5	103(a)	Shelton, Nappholz, Mumford	4, 5	
7	103(a)	Shelton, Nappholz, Barreras '887	7	
8–13	103(a)	Nappholz	8–13	

14	103(a)	Barreras ’217	14	
15, 16		Barreras ’217, Nappholz	15, 16	
17, 18		Barreras ’217, Nappholz, Mumford	17, 18	
Overall Outcome			1–18	

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claims 1–18 of U.S. Patent No. 6,381,496 B1 are determined to be unpatentable;

ORDERED that the Stipulated Protective Order (Attachment A to Paper 22) applies to this proceeding;

ORDERED that Patent Owner’s Motion to Seal is Granted; and

FURTHER ORDERED that, because this is a final written decision, parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

For PETITIONER:

Jon Wright
Ian Soule
STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.
Jwright-ptab@sternekessler.com
Isoule-ptab@sternekessler.com

Ching-Lee Fukuda
Thomas Broughan
Sharon Lee
SIDLEY AUSTIN
clfukuda@sidley.com
tbroughan@sidley.com
Sharon.lee@sidley.com

For PATENT OWNER:

David Caine
Wallace Wu
ARONLD & PORTER KAYE SCHOLER LLP
David.caine@apks.com
Wallace.wu@apks.com