UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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LIVANOVA, INC. and LIVANOVA USA, INC.,
Petitioners

v.

NEURO AND CARDIAC TECHNOLOGIES, LLC,
Patent Owner

Case No. IPR2019-00264
U.S. Patent No. 7,076,307

PATENT OWNER NEURO AND CARDIAC TECHNOLOGIES, LLC'S NOTICE OF APPEAL

Pursuant to 35 U.S.C. §§ 141 and 142, Patent Owner Neuro and Cardiac Technologies, LLC ("Patent Owner") appeals to the United States Court of Appeals for the Federal Circuit from the Final Written Decision of the Patent Trial and Appeal Board entered on May 18, 2020 (Paper No. 32). A copy of the Final Written Decision is attached to this Notice of Appeal.

In accordance with 37 C.F.R. § 90.2(a)(3)(ii), Patent Owner states that the issues on appeal may include, but are not limited to:

(1) the Board's determination that claims 1-5, 7-12, and 18-28 of U.S. Patent No. 7,076,307 ("the '307 patent") are unpatentable under 35 U.S.C. § 103(a) as obvious over the combination of Meadows, Rutecki, and Webster;

(2) the Board's determination that claim 6 of the '307 patent is unpatentable under 35 U.S.C. § 103(a) as obvious over the combination of Meadows, Rutecki, Webster, and Lee;

(3) the Board's claim constructions;

(4) the Board's analysis of secondary considerations of nonobviousness;

(5) any finding or determination by the Board supporting or related to any of the foregoing issues; and

(6) all other issues decided adversely to Patent Owner in any orders, decisions, rulings, and opinions.

In accordance with 37 C.F.R. § 90.2(a)(1), Patent Owner is simultaneously filing copies of this Notice of Appeal with the Patent Trial and Appeal Board and the Director of the United States Patent and Trademark Office. In addition, Patent Owner is filing a copy of this Notice of Appeal with the Clerk of Court of the United States Court of Appeals for the Federal Circuit and paying the requisite filing fee, in accordance with Federal Circuit Rule 15(a)(1) and 37 C.F.R. § 90.2(a)(2).

Date: July 1, 2020

Respectfully Submitted,

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CERTIFICATE OF FILING AND SERVICE

The undersigned hereby certifies that the foregoing was filed electronically with the Board via the PTAB E2E system on July 1, 2020. The undersigned further certifies that a paper copy of the foregoing is being sent via priority mail on July 1, 2020, to the Director of the United States Patent and Trademark Office at the following address:

Office of the General Counsel
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, Virginia 22313-1450

The undersigned also hereby certifies that a true and correct copy of the foregoing is being filed via CM/ECF with the Clerk's Office of the United States Court of Appeals for the Federal Circuit on July 1, 2020, and the required fee is being paid.

Finally, pursuant to 37 C.F.R. § 42.6(e), I hereby certify that on July 1, 2020, a copy of the foregoing was served on counsel for Petitioners at the following e-mail addresses, as authorized in the Petition:

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Dated: July 1, 2020

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Paper 32
Date: May 18, 2020

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LIVANOVA, INC., and LIVANOVA USA, INC.,
Petitioner,

v.

NEURO AND CARDIAC TECHNOLOGIES, LLC,
Patent Owner.

IPR2019-00264
Patent 7,076,307 B2

Before GRACE KARAFFA OBERMANN, SHERIDAN K. SNEDDEN, and ELIZABETH M. ROESEL, *Administrative Patent Judges*.

SNEDDEN, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining All Challenged Claims Unpatentable
35 U.S.C. § 328(a)

I. INTRODUCTION

This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. Petitioner bears the burden of proving unpatentability of the challenged claims, and that burden of persuasion never shifts to Patent Owner. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015). The evidentiary standard is a preponderance of the evidence. *See* 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d).

For the reasons that follow, we determine that Petitioner has established by a preponderance of the evidence that claims 1–12 and 18–28 of Patent No. 7,076,307 B2 (Ex. 1001, "the '307 patent") are unpatentable.

A. Procedural Background

Petitioner filed a Petition requesting *inter partes* review of claims 1–12 and 18–28 ("the challenged claims") of the '307 patent. Paper 1 ("Pet."). Patent Owner filed a Patent Owner Preliminary Response. Paper 6. Upon consideration of the information presented in the Petition and the Preliminary Response, we instituted an *inter partes* review of claims 1–12 and 18–28 of the '307 patent on each ground of unpatentability set forth in the Petition.

Subsequently, Patent Owner filed a Patent Owner Response (Paper 15; "PO Resp."), Petitioner filed a Reply (Paper 20; "Reply"), and Patent Owner filed a Sur-Reply (Paper 25; "Sur-Reply").

The Petition is supported by the Declaration of Richard T. Mihran, Ph.D. Ex. 1003. Patent Owner relies on the Declaration of Shivanand (Nandan) Lad, M.D., Ph.D. (Ex. 2021).

Oral argument was conducted on February 25, 2020. A transcript is entered as Paper 31 ("Tr.").

We address herein the arguments and evidence set forth in the Papers to the extent necessary to resolve the dispute between the parties.

B. The '307 patent (Ex. 1001)

The '307 patent discloses a method and system for neuromodulating vagus nerve(s) to provide therapy for neurological and neuropsychiatric disorders, which comprises implantable and external components. Ex. 1001, Abstract. The claimed subject matter relates to a programmable implantable pulse generator ("IPG"). *Id.* at 32:63–36:34.

Figure 34 of the '307 patent is reproduced below:

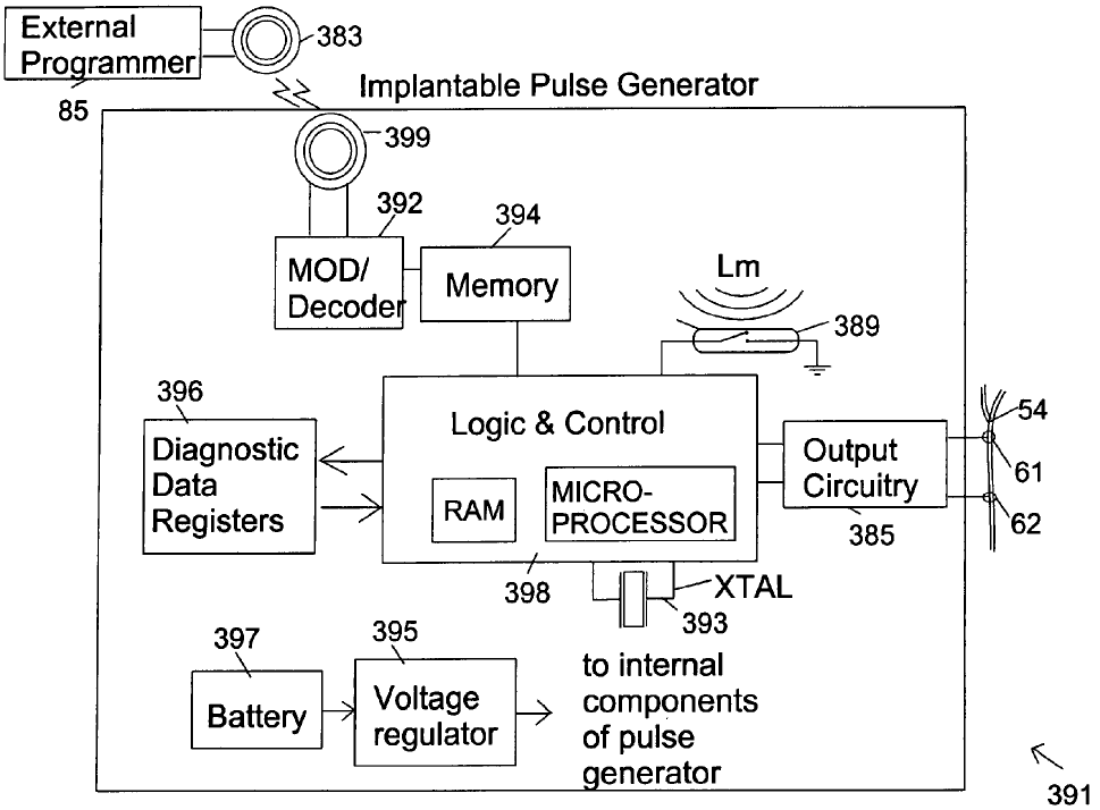

FIG. 34

Figure 34 depicts a "simplified block diagram of the implantable pulse generator." *Id.* at 9:44–45. The '307 patent discloses that the pulse

generator "is preferably a microprocessor based device, where the entire circuitry is encased in a hermetically sealed titanium can." *Id.* at 20:46–48. The system provides "electrical pulses that are delivered to electrodes 61, 62 via a lead 40." *Id.* at 20:51–52. The external programmer 85 communicates with the implanted device via bi-directional inductive telemetry to provide activation, programming, and selection of predetermined/pre-packaged programs. *Id.* at 20:52–57, 25:60–28:23, Figs. 45–52.

The memory contained within the implanted pulse generator stores "pre-determined/pre-packaged" programs for vagus nerve therapy, which "comprise unique combinations of pulse amplitude, pulse width, pulse frequency, ON-time and OFF-time." *Id.* at 20:58–64. Table 4 of the '307 patent is reproduced below.

TABLE 4

Programmable electrical parameter range

PARAMER	RANGE
Pulse Amplitude	0.1 Volt–10 Volts
Pulse width	20 μS–5 mSec.
Frequency	3 Hz–300 Hz
On-time	5 Secs–24 hours
Off-time	5 Secs–24 hours
Ramp	ON/OFF

Id. at 21:1–12. Table 4 provides an example of parameters that may be included in a predetermined/pre-packaged program, and lists pulse amplitude, pulse width, frequency, ON-time, and OFF-time as such parameters.

Figures 26A and 26B of the '307 patent are reproduced below.

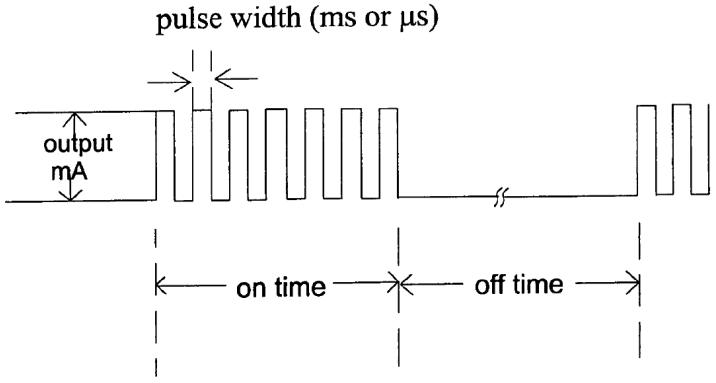

FIG. 26 A

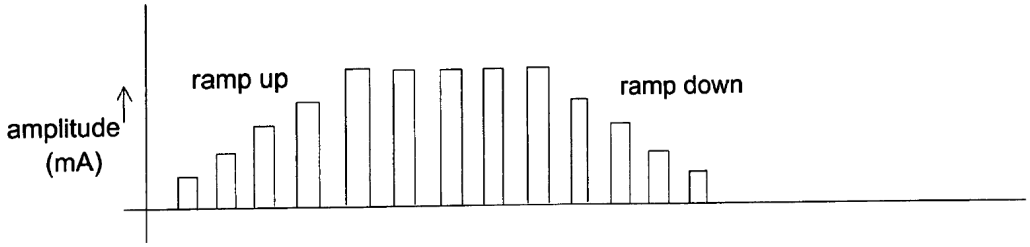

FIG. 26 B

Figures 26A and 26B illustrate aspects of the pulse characteristics, including the "on time" and "off time" parameters. Ex. 1001, 9:23–26, 15:13–17, Figs. 26A, 26B. As discussed in the corresponding text, "on time" and "off time," in the context of vagus nerve stimulation ("VNS") therapy, refer to a therapy procedure wherein the signal is ramped up and ramped down rather than abruptly turned on and off. In particular, the '307 patent provides as follows:

> The pulses delivered to the nerve tissue for stimulation therapy are shown graphically in FIG. 26A. As shown in FIG 26B, for patient comfort when the electrical stimulation is turned on, the electrical stimulation is ramped up and ramped down, instead of abrupt delivery of electrical pulses.

Id. at 15:13–17; *see also id.* at 25:15–20 ("The purpose of the ramping-up is to avoid sudden changes in stimulation, when the pulse train begins.").

Column 19 of the '307 patent discloses several tables providing examples of stimulation parameters used to deliver different stimulation states to the vagus nerves, such as a low or high stimulation state. One such table is reproduced below.

Current output:	0.75 milliAmps.
Pulse width:	0.20 msec.
Pulse frequency:	20 Hz
Cycles:	20 sec. on-time and 2.0 min. off-time in repeating cycles.

Ex. 1001, 19:33–37. The table describes the "on time" and "off time" parameters in the context of repeating cycles. *Id*.

C. Illustrative Claim

Independent claims 1 and 18, reproduced below, are illustrative of the challenged claims:[1]

[1.0] 1. A method of providing electrical pulses to a vagus nerve(s) of a patient for treating or alleviating the symptoms of at least one of neurological, neuropsychiatric, and obesity disorders, comprising the steps of:

[1.1] providing a microprocessor based implanted pulse generator, wherein said pulse generator comprises microprocessor, circuitry, memory, and power source;

[1] In the interest of consistency and clarity, we adopt the Petitioner's annotation to refer to the claim elements of the independent claims. Pet. 46–74.

[1.2] providing at least two predetermined/pre-packaged programs of neuromodulation therapy stored in memory of said implantable pulse generator, wherein said predetermined/pre-packaged programs define neuromodulation parameters of pulse amplitude, pulse-width, pulse frequency, on-time and off-time;

[1.3] providing an implanted lead in electrical contact with said implanted pulse generator; wherein said implanted lead comprising at least one electrode adapted to be in contact with said vagus nerve(s);

[1.4] providing programmer means for activating and/or programming said implanted pulse generator, wherein bi-directional inductive telemetry is used to exchange data with said implanted pulse generator; and

[1.5] selectively choosing between at least two predetermined/pre-packaged program and activating said selected program.

[18.0] 18. A system for providing electrical pulses to a vagus nerve(s) of a patient for treating or alleviating the symptoms of at least one of neurological, neuropsychiatric, and obesity disorders, comprising:

[18.1] an implantable pulse generator comprising microprocessor, circuitry, memory, and power source;

[18.2] at least two predetermined/pre-packaged programs of stimulation therapy stored in said memory to control said electrical pulses emitted by said implantable pulse generator, wherein said predetermined/pre-packaged programs define neuromodulation parameters of pulse amplitude, pulse-width, pulse frequency, on-time and off-time;

[18.3] an implantable lead in electrical contact with said implantable pulse generator wherein said lead comprising at least one electrode adapted to be in contact with said vagus nerve(s); and

[18.4] means for activating and/or programming said implantable pulse generator, wherein bi-directional inductive telemetry is used to exchange data with said implantable pulse generator.

D. Asserted Prior Art

The Petition identifies the following references as prior art in the grounds of unpatentability:

Ex. 1011, John G. Webster, Design of Cardiac Pacemakers, IEEE Press (1995) (selected pages) ("Webster").

Ex. 1013, Michael T. Lee, U.S. Patent No. 6,442,432 B2, issued Aug. 27, 2002 ("Lee").

Ex. 1016, P. Meadows et al., U.S. Patent No. 6,381,496 B1, issued Apr. 30, 2002 ("Meadows").

Ex. 1046, P. Rutecki et al., U.S. Patent No. 5,330,515, issued July 19, 1994 ("Rutecki").

Ex. 1051, Salmons, S. et al., *ASIC or PIC? Implantable stimulators based on semi-custom CMOS technology or low-power microcontroller architecture*, 23 MEDICAL ENGINEERING & PHYSICS 37–43 (2001) ("Salmons").

E. Asserted Grounds of Unpatentability

We instituted review of claims 1–12 and 18–28 of the '307 patent as follows.

Claims	35 U.S.C. §[2]	Reference(s)/Basis
1–5, 7–12, and 18–28	103(a)	Meadows, Rutecki, and Webster
6	103(a)	Meadows, Rutecki, Webster, and Lee
1–5, 7–12, and 18–28	103(a)	Meadows, Rutecki, Webster, and Salmons
6	103(a)	Meadows, Rutecki, Webster, Salmons, and Lee

II. ANALYSIS

A. Person of Ordinary Skill in the Art

Petitioner asserts that a person of ordinary skill in the art

> would have had a bachelor's degree in electrical engineering, biomedical engineering, or similar field, and two to three years of experience in devices and systems utilized for neuro- and/or neuromuscular stimulation, or equivalent. Furthermore, a person with more technical education but less experience could also meet the relevant standard for POSITAs.

Pet. 7.

Patent Owner asserts that a person of ordinary skill in the art

> would have had a bachelor's degree in electrical engineering, biomedical engineering, or a similar field, and two or three years of experience in devices and systems utilized for neuromodulation, or equivalent. Additionally, a person with more technical education but less experience could also meet the relevant standard.

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[2] The Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112-29, 125 Stat. 284, 287–88 (2011), amended 35 U.S.C. §§ 102 and 103. Because the '307 patent was filed before March 16, 2013 (the effective date of the relevant amendment), the pre-AIA version of § 103 applies.

PO Resp. 28–29 (citing Ex. 2021 ¶ 169). Patent Owner contends that its proposed "definition is similar to Petitioner's definition but omits the specific reference to 'neuromuscular' experience." *Id.* at 29.

Having considered the parties' positions and evidence of record, summarized above, we agree with Patent Owner that the claims are directed to methods of neuromodulation and agree that the definition of a person of ordinary skill in the art is likewise appropriately limited to those persons having the relevant education and expertise in devices and systems utilized for neuromodulation, or equivalent. Accordingly, we adopt Patent Owner's definition of a POSA for the purposes of this decision. That said, we discern no appreciable difference in the respective definitions of a POSA as that definition relates to the dispositive issues of this case, discussed below.

Furthermore, in view of the above definition, and based on their statements of experience and qualifications, we find that Dr. Mihran and Dr. Lad both are qualified to opine about the perspective of a person of ordinary skill in the art at the time of the invention. *See* Ex. 1004 (Dr. Mihran's curriculum vitae); Ex. 2022 (Dr. Lad's curriculum vitae).

B. Claim Construction

For petitions filed before November 13, 2018, such as the case here,[3] we interpret the claims of an unexpired patent that will not expire before

[3] The Petition was filed on November 12, 2018. The Final Rule changing the claim construction standard does not apply here, as the Petition was filed before the effective date of the Final Rule, November 13, 2018. *See* Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board, 83 Fed. Reg. 51,340, 51,340, 51,344 (Oct. 11, 2018).

issuance of a final written decision using the broadest reasonable interpretation in light of the specification. *See* 37 C.F.R. § 42.100(b) (2018); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016). Under the broadest reasonable construction standard, claim terms are presumed to have their ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech., Inc*., 504 F.3d 1249, 1257 (Fed. Cir. 2007). Any special definitions for claim terms must be set forth with reasonable clarity, deliberateness, and precision. *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

Only terms that are in controversy need to be construed, and then only to the extent necessary to resolve the controversy. *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc*., 200 F.3d 795, 803 (Fed. Cir. 1999); *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co*., 868 F.3d 1013, 1017 (Fed. Cir. 2017) (applying *Vivid Techs.* in the context of an *inter partes* review).

1. "on-time and off-time"

Each of independent claims 1 and 18 recite "at least two predetermined/pre-packaged programs" and provide that the "predetermined/pre-packaged programs define neuromodulation parameters of pulse amplitude, pulse-width, pulse frequency, on-time and off-time." In the Petition, Petitioner does not offer a construction for "on-time and off-time." Pet. 18–29.

In its Response, Patent Owner contends that, "when properly construed, the meaning of 'on-time and off-time' in the challenged claims is critical to a full understanding of the invention and helps explain why a POSITA would not combine *Meadows* and *Rutecki* as Petitioner proposes."

PO Resp. 27. To that point, Patent Owner contends that the Specification discloses that "'on-time and off-time' in the context of VNS therapy refer to a duty cycle within a prolonged, intermittent therapy procedure, wherein the signal is ramped up and ramped down rather than abruptly turned on and off." *Id.* To support that contention, Patent Owner directs us to the following disclosure in the Specification:

> The pulses delivered to the nerve tissue for stimulation therapy are shown graphically in FIG. **26**A. As shown in FIG **26**B, for patient comfort when the electrical stimulation is turned on, the electrical stimulation is ramped up and ramped down, instead of abrupt delivery of electrical pulses.

Id. (quoting Ex. 1001, 15:13–17). Thus, according to Patent Owner, "the plain and ordinary meaning of 'on-time and off-time' in the challenged claims is a duty cycle within a prolonged, intermittent therapy procedure, wherein the signal is ramped up and ramped down rather than abruptly turned on and off." *Id.* at 28.

In its Reply, Petitioner responds that "there is a relevant embodiment in the '307 Patent that differentiates a ramping parameter from 'on-time' and 'off-time' and illustrates ramping as a programmable variable that can be set to 'off,' or no ramping." Reply 5 (citing Ex. 1001, 21:1–13 (Table 4)). Table 4 is reproduced (with highlighting added) below:

TABLE 4

Programmable electrical parameter range

PARAMER	RANGE
Pulse Amplitude	0.1 Volt–10 Volts
Pulse width	20 μS–5 mSec.
Frequency	3 Hz–300 Hz
On-time	5 Secs–24 hours
Off-time	5 Secs–24 hours
Ramp	ON/OFF

Table 4 is entitled "Programmable Implantable Pulse Generator (IPG)" and is described in the Specification as follows:

> These pre-packaged/pre-determined programs comprise unique combinations of pulse amplitude, pulse width, pulse frequency, ON-time and OFF-time.
>
> . . . The range of programmable electrical stimulation parameters are shown in table 4 below."

Ex. 1001, 20:62–67. Thus, according to Petitioner, the Specification discloses "On-time" and "Off-time" parameters and, additionally, an optional independent "Ramp" parameter that may be set to "ON/OFF." Reply 6–7 (citing Ex. 1055, 223:23–224:23).

Furthermore, Petitioner contends that the claims do not require a "duty cycle" because

> the claim terms "on-time and off-time" refer to parameters in a "program," and ranges of those parameters are illustrated in Table 4 as having values up to 24 hours each. "On-time" and "off-time" refer to no more than time intervals in a given measurement period (e.g., one day) and do not impliedly require a repeating cycle within a 24-hour period.

Id. at 9. Thus, according to Petitioner, the terms "on-time and off-time" do not require "a duty cycle within a prolonged, intermittent therapy procedure." *Id.* at 7.

In its Sur-Reply, Patent Owner contends as follows with regard to the meaning of "on-time and off-time" in the context of the '307 patent:

> [W]hile the specification suggests a limited situation where ramping might optionally be turned off, the testimony of Dr. Lad was that a POSITA would understand that the "on-time and off-time" of the '307 Patent claims would typically include the ramping functionality. *See* Exhibit 2021 at ¶¶ 88–93, 115–16, 136–44.

Sur-Reply 4.

Patent Owner acknowledges that the term "duty cycle" is not used in the Specification, but contends that:

> Regardless of the specific terminology used in the '307 Patent specification, the concept of repeating cycles of on-time and off-time within a treatment session, which is what duty cycle is, is certainly taught in the '307 Patent. *See, e.g.*, '307 Patent at 19:30–65, Figures 26A and 42. . . . Petitioner's argument that the claims do not literally recite a "duty cycle" is unavailing, as the therapy procedures disclosed in the specification are recited as VNS therapy procedures, which operate according to a duty cycle (as described in the '307 Patent).

Sur-Reply 4 (citing Exhibit 2021 ¶¶ 89–90, 136–44).

Having considered the parties positions and evidence of record, summarized above, we determine as follows. First, we agree with Petitioner that the Specification does not support Patent Owner's contention that the terms "on-time" and "off-time" encompass the concept of a ramp, wherein "the signal is ramped up and ramped down rather than abruptly turned on and off." PO Resp. 27. The Specification expressly discloses a "ramp" as a

parameter that is distinct from on-time and off-time parameters. Reply 5 (citing Ex. 1001, 21:1–13 (Table 4)).

Second, we determine that the recited "on-time" and "off-time" parameters, together, may define a repeatable treatment period within a prolonged, intermittent therapy procedure, or, in other words, a "duty cycle." PO Resp. 27–28. That is, in the context of the '307 patent, "on-time" and "off-time" refer to time intervals within a given treatment period, and the presence of both an "on-time" and "off-time" implies a repeatable cycle within any given therapy procedure. In this regard, we note that the Specification describes various parameters, such as on-time and off-time, for VNS therapy for the treatment of neurological and neuropsychiatric disorders. Ex. 1001, 20:58–64, Figures 26A–26B. For example, Table 4 shows that the "on-time" and "off-time" parameters can take values between 5 seconds and 24 hours, thereby describing VNS treatments as including repeating cycles of on-time and off-time. Ex. 1001, 21:1–13 (Table 4); *see also*, Ex. 1001, 19:30–39 ("20 sec. on-time and 2.0 min. off-time in repeating cycles."), 19:40–47 ("1.5 min. on-time and 20.0 min. off-time in repeating cycles."), 19:48–56 ("1.5 min. on-time and 20.0 min. off-time in repeating cycles."), 19:58–65 ("2.0 min. on-time and 20.0 min. off-time in repeating cycles.").

The preambles of claims 1 and 18 recite "providing electrical pulses to a vagus nerve(s) of a patient for treating or alleviating the symptoms of at least one of neurological, neuropsychiatric, and obesity disorders," demonstrating that VNS therapy is the appropriate context for defining "on-time and off-time." Ex. 1001, 32:64–67, 35:6–9. On this point, we credit Dr. Lad's testimony that the concept of duty cycle is important in VNS

therapy, the focus of the '307 patent, because it provides "a cumulative therapy whose effects are felt over time rather than immediately, and because prolonged excitation of the vagus nerve without an off time will damage the nerve." Ex. 2021 ¶¶ 88–89.

Thus, the evidence of record supports a determination that "on-time" and "off-time" are expressly recited parameters that require a non-zero value to ensure the effective delivery of VNS therapy and, therefore, together, define a duty cycle. To the extent further discussion of the meaning of this term is necessary to our decision, we provide that discussion below in our analysis of the asserted grounds of unpatentability.

2. Other Recited Claim Terms/Phrases

Petitioner advances proposed constructions for the following phrases recited in the claims: "providing programmer means for activating and/or programming said implanted pulse generator, wherein bi-directional inductive telemetry is used to exchange data with said implanted pulse generator" (claim 1); "means for activating and/or programming said implantable pulse generator, wherein bi-directional inductive telemetry is used to exchange data with said implantable pulse generator" (claim 18); "telemetry means for remote device interrogation and/or programming over a wide area network" (claim 6); and "telemetry means to remotely control said predetermined program(s)" (claim 21). Pet. 19–29.

Patent Owner does not challenge those proposed constructions in its Preliminary Response. *See* PO Resp. 26 ("Patent Owner agrees to the claim constructions for those four terms proposed in the Petition.").

For the purposes of this decision, we adopt Petitioner's claim constructions for the above-mentioned phrases recited in the challenged

claims because those constructions are not disputed and are supported by the Specification as well as the plain language of the claims.

C. Petitioner's Patentability Challenges

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 said 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 skill in the art; and (4) objective evidence of nonobviousness, i.e., secondary considerations. *See Graham v. John Deere Co*., 383 U.S. 1, 17–18 (1966).

We analyze the instituted grounds of unpatentability in accordance with the above-stated principles.

1. Ground 1: Obviousness of Claims 1–5, 7–12, and 18–28 over the Combination of Meadows, Rutecki, and Webster

a. Summary of References Relied Upon

i. Meadows

Meadows discloses a spinal cord stimulation ("SCS") system or other programmable implant device. Ex. 1016, 1:12–15. The SCS of Meadows "includes several components, ranging from implantable and external components, surgical tools, and software." *Id.* at 1:14–16.

Figure 1 of Meadows is reproduced below.

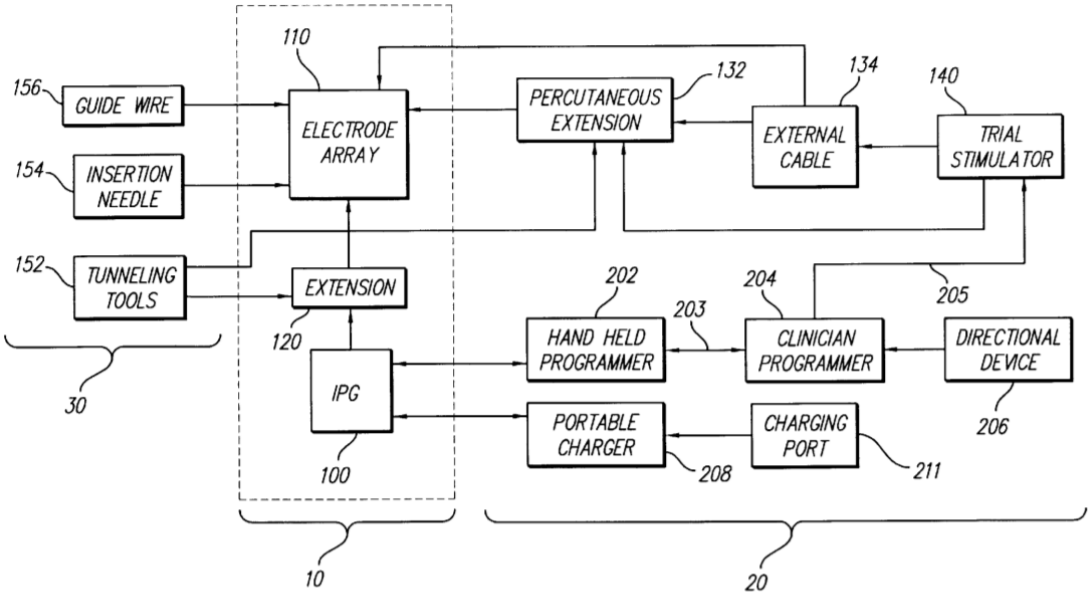

FIG. 1

Ex. 1016, Fig. 1. Figure 1 is a block diagram that illustrates the various implantable, external, and surgical components of a representative SCS system of Meadows. *Id.* at 4:60–65. In that embodiment, the components of the invention are subdivided into three broad categories: "(1) implantable components 10, (2) external components 20, and (3) surgical components 30." *Id*. at 6:2–4 (emphasis omitted). The implantable components 10 include implantable pulse generator (IPG) 100, electrode array 110, and extension 120. *Id.* at 6:5–8. Extension 120 is used to electrically connect electrode array 110 to IPG 100. *Id.*

Meadows discloses that the SCS "treats chronic pain by providing electrical stimulation pulses from an electrode array placed epidurally near a patient's spinal cord." Ex. 1016, 1:12–15. The "electrode array" is described as a series of up to sixteen separate electrodes for connection to

various locations along the spinal cord. *Id.* at 6:31–62. The separate electrodes provide simultaneous treatment to a number of locations along the spinal cord. *Id.* at 17:11–15. Meadows discloses that "providing multiple stimulation channels" allows the system "to address variable stimulation parameter requirements and multiple sites of electrical stimulation signal delivery." *Id.* at 2:25–28. In contrast, Meadows discloses that existing SCS systems had "only a single stimulation channel, which must be multiplexed in a fixed pattern to up to four electrode contacts," or had "only one voltage source, and hence only a single stimulation channel, for delivery of the current stimulus to multiple electrodes through a multiplexer." *Id.* at 2:35–37, 2:41–44.

Meadows also discusses the need "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." Ex. 1016, 2:65–3:1. In that regard, Meadows discloses that the SCS system has the ability to perform "context switching," which is defined in Meadows as "changing one set of operational parameters to another" for the multiple spinal cord electrodes. *Id.* at 3:8–10. Moreover, Meadows discloses that the operational parameter sets (OPSs) may be selected by a patient. *Id*. at 1:9–20; *see also id.* at Abstract ("The patient may swap the current set of operational parameters with another set of operational parameters."). The ability to change the operational parameter set may be achieved by including memory circuitry within the implant device wherein a plurality of OPSs are stored. *Id.* at Abstract. Meadows discloses that "[w]hen the patient wishes to change the OPS, he manually activates the appropriate controls on the hand-held programming device, and

such activation causes the new OPS to be telemetered to the implant device, where it replaces the current OPS." *Id.*

Figure 6 of Meadows is reproduced below:

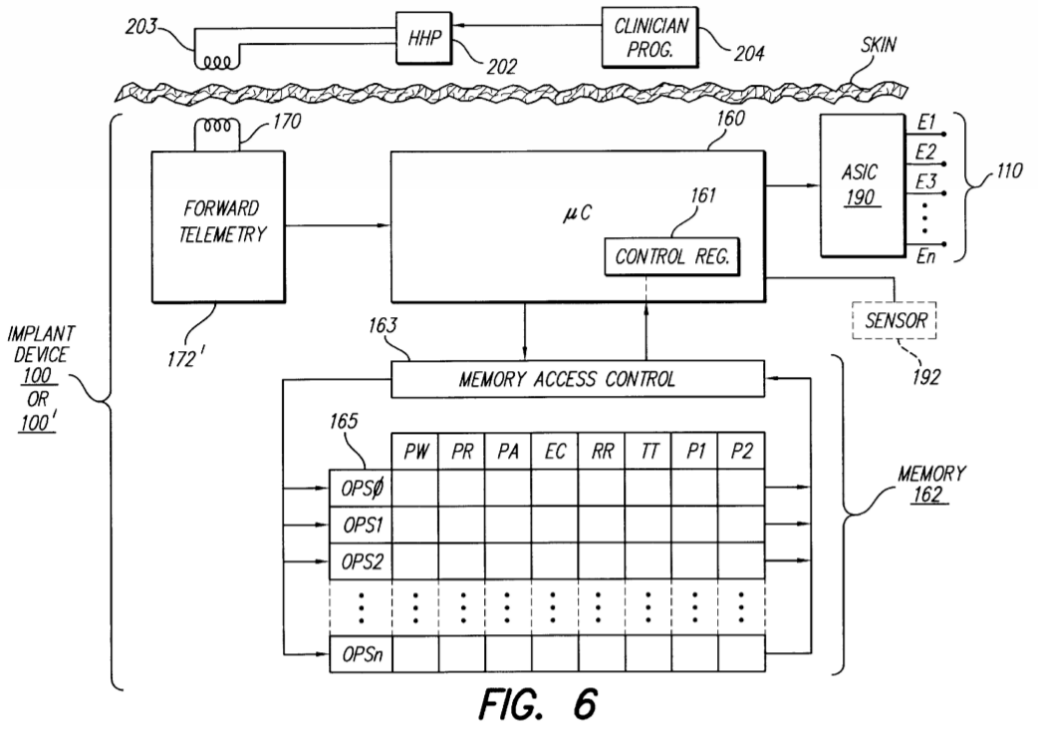

FIG. 6

Figure 6 "depicts a functional block diagram of a portion of an implant device . . . and functionally illustrates one manner in which different operational parameter sets may be selected for use by the implant device." *Id.* at 5:16–18. As shown in Figure 6, the "operational parameters" of Meadows may include "pulse width (PW) . . . 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)." *Id.* at 17:6–10.

ii. Rutecki

Rutecki is directed to "techniques for treating painful syndromes in patients by selective electrical stimulation of vagus nerve afferent fiber activity with an implanted neurostimulating device." Ex. 1046, 1:11–15; *see also id.* at 6:26–29 (The neurostimulator is "preferably but not necessarily implantable in the patient."). Specifically, Rutecki discloses as follows:

> Selective stimulation of the vagal afferents for treating and controlling pain according to the invention is performed using a neurostimulator, which is preferably but not necessarily implantable in the patient. The therapy is delivered from a pulse generator of the neurostimulator to a nerve electrode array implanted on the patient's vagus nerve to appropriately modulate the electrical activity of the nerve. The neurostimulator is programmed by the attending physician to provide the desired therapeutic modality for that purpose.

Id. at 6:26–35. Stimulation is delivered to the vagus nerve "above the point where the pain sensation is most pronounced to the patient." *Id.* at 7:1–5. In particular, treatment is performed "by selectively applying a pulse wave form to a lead/electrode implanted on the patient's cervical vagus nerve or other site preferably above the location of the pain to stimulate afferent fibers for activating a descending anti-nociceptive pathway and thereby blocking incoming pain signals." *Id.* at Abstract.

Rutecki discloses that the pulse waveform has programmable functions, which include "output current or voltage, output signal frequency, output signal pulse width, output signal on-time, output signal off-time, daily treatment time for continuous or periodic modulation of vagal activity, and output signal-start delay time." *Id.* at Abstract, 10:32–38. "The programmed pulse sequences are applied to the implanted electrode either on a continuous basis, or only during the period the patient is normally

awake, or is initiated by the patient or automatically in response to the onset of pain." *Id.* at Abstract.

iii. Webster

Webster, a textbook, is relied on by Petitioner for general teachings related to the implementation of programmable pacemakers. Ex. 1011, 33. Webster describes a "programmer" as "an external device which communicates programming and telemetry information with the pacemaker." *Id.* Webster further discloses that

> a bidirectional communications link can . . . be used to relay data collected from sensors in the patient or pacemaker. This process is called *telemetry*. Although programming and telemetry are different pacemaker functions—putting data in versus getting data out—they share much of their hardware and theory of operation.

Id.

b. Petitioner's Challenge

Petitioner asserts that claims 1–5, 7–12, and 18–28 are unpatentable under 35 U.S.C. § 103 as obvious over the combination of Meadows, Rutecki, and Webster. Pet. 32–74. In support of its assertion that the combination of Meadows, Rutecki, and Webster renders those challenged claims obvious, Petitioner provides a detailed discussion explaining how each claim limitation is disclosed in the combination of Meadows, Rutecki, and Webster. *Id.* As for the recitation of "on-time and off-time," Petitioner identifies Meadows' disclosure of "treatment times (TT)" and "treatment (stimulation) time, and the like" and "auto-run time." *Id.* at 51. Petitioner further contends that, "to the extent that it is argued that *Meadows* does not explicitly disclose the operational parameters of on-time and off-time, a

POSITA would look to *Rutecki* for other applicable parameters (e.g., that would fall under the category of "and the like" contemplated by Meadows) when using the IPG of Meadows for VNS." *Id.* at 52.

In combining Meadows and Rutecki, Petitioner contends that the "IPGs used in the neurostimulation systems of *Rutecki* and *Meadows* each utilize neuromodulation to address the same problem of chronic neuropathic pain, i.e., the same neurological disorder." *Id.* at 38 (citing Ex. 1003 ¶¶ 279–81). Petitioner contends that Meadows discloses that the use of multiple unique OSPs is applicable to "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 37 (quoting Ex. 1016, 1:41–45) (emphasis omitted). Petitioner further contends that the IPG of Rutecki was one of the well-known "types of neural stimulators" and that a person of ordinary skill in the art would have recognized that the improvements disclosed in Meadows directed to storing multiple parameter sets in the memory of an IPG and making these selectable by a patient would have benefited the systems of Rutecki. *Id.* (citing Ex. 1003 ¶ 265). In particular, Petitioner contends that Meadows explains the desirability of providing patients a convenient way to change operating parameters, e.g., to avoid having to "schedule an appointment" to see a physician. *Id.* at 36 (citing Ex. 1016, 2:48–3:1). In this regard, Petitioner directs our attention to the following disclosure in Meadows:

> Often, the changes needed by the patient are relatively benign (insofar as the safety of the altered treatment is concerned), and could easily be made by the patient himself or herself if only the implant device provided such capability. . . .

> Thus, 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 36 (citing Ex. 1016, 2:55–3:1). Thus, according to Petitioner, a person of ordinary skill in the art would have been "motivated to apply the broad teachings of *Meadows* for managing multiple sets of unique programmable therapy parameters in implantable neurostimulators to the application of stimulation of the vagus nerve to alleviate pain, as disclosed in *Rutecki*, to yield the predictable and beneficial result of giving patients some limited control to choose different stimulation parameter sets without having to visit a physician or other clinician each time a change is desirable." *Id.* at 39 (citing Ex. 1003 ¶ 275).

With regard to whether, and why, an ordinarily skilled artisan would have combined Meadows and Rutecki with Webster, Petitioner contends that:

> While the *Webster* programming system is described in the context of a bidirectional telemetry of an IPG used for stimulating cardiac tissue, i.e., a pacemaker, IPGs used for VNS (e.g., *Meadows* as modified by *Rutecki*) are physically and functionally very similar to a traditional programmable pacemaker, and in each case, external programmers are used to modify programmable stimulation parameters in the IPG along with receiving status and diagnostic information from the IPG. [Ex. 1003] ¶ 299.

Id. at 44.

c. Patent Owner's Response

Patent Owner sets forth several arguments to support its position that Petitioner fails to establish that claims 1–5, 7–12, and 18–28 of the '307 patent would have been obvious over the combination of Meadows, Rutecki,

and Webster. PO Resp. 41–54. First, Patent Owner contends that Petitioner failed to establish a motivation to combine Meadows and Rutecki. *Id.* at 41–46. Patent Owner contends that "Petitioner's suggestion that SCS and VNS systems are interchangeable and can be combined with each other for the purpose of rendering the claims obvious is an improper use of hindsight." *Id.* at 45. According to Patent Owner, Meadows discloses an SCS device that relies on electrode arrays to deliver pulses along the spinal column for treatment of pain, which "is a vastly different system than afferent VNS therapy for neurological and neuropsychiatric disorders." *Id.* at 41.

Second, Patent Owner contends that the combined disclosure of Meadows and Rutecki fails to disclose elements [1.2] and [18.2]. *Id.* at 46–51. In particular, Patent Owner contends that the OPSs of Meadows are not "predetermined/pre-packaged programs of neuromodulation therapy" as described in the '307 patent because they are designed for spinal cord stimulation and do not define neuromodulation parameters such as on-time and off-time. *Id.* at 47. Patent Owner contends that the treatment times and auto-run times in Meadows are not the same as the recited on-time and off-time parameters, which, according to Patent Owner, refer to the duty cycle within an intermittent therapy program. *Id.*

Third, Patent Owner contends that "*Rutecki* distinguishes itself from dorsal column stimulation systems (like *Meadows*), thus expressly teaching away from such a combination." *Id.* at 42 (citing Ex. 1046, 8:9–27).

Fourth, Patent Owner contends that "nothing in Meadows teaches or suggests the concept of a duty cycle (as the '307 Patent and VNS therapy in general), rendering its teachings (and SCS) not only unsuitable for application to VNS therapy but dangerous, as well." *Id.* at 42. According to

Patent Owner, the multiple electrodes of Meadows are not suitable for VNS therapy because the OPSs of Meadows manage direct therapy applied to different locations of the spinal cord, and not different stimulation programs to a single area as required by the VNS system recited in the claims. *Id.* at 50 (Ex. 2021 ¶¶ 194, 212). Patent Owner acknowledges that Rutecki discloses a VNS system, but contends that Rutecki expressly distinguishes itself from dorsal column stimulation systems (like Meadows), and therefore, for the reasons discussed by Rutecki, the systems are not interchangeable. *Id.* at 45–46 (citing Ex. 2021 ¶¶ 181–83). In particular, Rutecki discloses as follows:

> The [disclosed VNS systems are] distinguished from the pain suppression performed by the prior art [transcutaneous electrical nerve stimulation (TENS)] and dorsal column stimulation techniques. Vagal stimulation performed according to the invention is stimulation of the nerve itself, in contrast to the activation of receptors by TENS units. Dorsal column stimulation is also at the cord level, and, like TENS therapy, is thought to work in accordance with the gate theory of pain described earlier herein. In fact, the pain associated with many neuropathies may result from loss of large fiber function and consequent inability of the large fiber sensory pathways to inhibit the incoming pain signals from small diameter pain fibers. *With vagal stimulation, it does not appear to be an activation of somatic large fiber sensory nerves, but rather, an activation of brain stem centers which in turn activate a descending pathway to inhibit incoming pain signals*. Thus, vagal stimulation is more akin to brain stem stimulation for pain control, but is much less invasive.

Ex. 1046, 8:9–27 (emphasis added). Thus, according to Patent Owner,

> combining the teachings of *Meadows* and *Rutecki* would require modifications of one or both references that would not only change their fundamental operation but render them unsuitable for their intended purposes. *See* MPEP § 2143.01 (citing *In re*

> *Ratti*, 270 F.2d 810, 813 (C.C.P.A. 1959)). Neither Petitioner nor Dr. Mihran explains how combining *Meadows* and *Rutecki* would preserve the operation of either one, maintaining its suitability for its intended purpose. In contrast, as Dr. Lad explains, combining the VNS therapy procedures of *Rutecki* with the SCS procedure of *Meadows* would endanger the patient and would require a change in the principle operation of one or both references. *See* [Ex. 2021] ¶¶ 100–01, 181–83.

PO Resp. 45–46.

With regard to Webster, Patent Owner contends that nothing in Webster cures the deficiencies related to the improper combination of Meadows and Rutecki. *Id.* at 52.

Patent Owner further contends that the nonobviousness of the subject matter of the challenged claims is supported by "the long-felt need for and failure of others to realize the inventions claimed in the '307 Patent counsel against a finding of obviousness." *Id.* at 62. In particular, Patent Owner contends as follows:

> Cyberonics—predecessor in interest to Petitioner and the applicant and owner of *Rutecki*—filed the *Rutecki* application on June 17, 1992. *See* [Ex. 1046] at [22]. Cyberonics filed *Baker* on November 18, 1991. *See* [Ex. 1012] at [22]. But Petitioner did not introduce the first implantable VNS device incorporating multiple predetermined/pre-packaged programs until 2017. And Petitioner's first patents describing multiple therapy programs in an implanted pulse generator were filed in 2005. *See* Exhibit 2019 (filing date October 27, 2005). Thus, it took Petitioner years to realize the benefit of combining implantable VNS technology with multiple programs. Moreover, Petitioner's use of the technology claimed in the '307 Patent has resulted in overwhelming commercial success.

Id. at 63.

d. Petitioner's Reply

In its Reply, Petitioner contends that

> Even under PO's proposed construction, Meadows discloses parameters that define "on-time and off-time." For example, regarding the "duty cycle" aspect, Meadows discloses that "the patient can schedule auto-run times for **IPG operation** at **certain times of the day** . . . . The auto-run time continues for a set time period, e.g., several hours, or **for only a few minutes**." Ex. 1016 at 12:45–52 (emphases added). Thus, Meadows discloses this as an example of a duty cycle by scheduling IPG auto-run times to deliver therapy (signal "on-time") at "certain times of the day" (intermittent therapy) thereby defining sequences of "on-time" and "off-time" throughout the day (a prolonged procedure). *See e.g.* Ex. 1003 ¶ 177, 327-333, 374.

Reply 12–13. Furthermore, according to Petitioner, Meadows has the necessary hardware features to accept vagal nerve programming parameters identified in Rutecki. *Id.* at 15 (citing Pet. 40–41; Ex. 1054, 48:13–23; Ex. 1003 ¶¶ 284–87). Thus, according to Petitioner, "Meadows discloses the ability to be programmed with parameters, such as those in Rutecki, defining 'on-time and off-time' under [Patent Owner's] more narrow interpretation." *Id.* at 13–14 (citing Ex. 1003 ¶¶ 264–69, 276–87). Moreover, Petitioner contends that "[a] POSITA, utilizing ordinary creativity and the teachings of the references, would readily program the parameters of the Meadows IPG to define safe stimulation on-times and stimulation off-time times." *Id.* at 17 (citing Ex. 1003 ¶¶ 328–29; Pet. at 51).

Regarding Patent Owner's teaching away and motivation to combine arguments, Petitioner contends that "Rutecki does not disparage storing multiple therapy programs," but rather "contribut[es] to the motivation to

utilize Meadows' teachings with Rutecki's VNS application." *Id.* at 19. In particular, Petitioner contends as follows:

> Rutecki's disclosure of an alternative to the more convenient storage of multiple therapy programs to provide some control by the patient (per Meadows) does not constitute a teaching away . . . . Instead, Rutecki recognizes the benefit of having an additional program available for patient activation as an alternative to an initial program stored in memory. [Ex. 1016,] 13:4–9. The device of Meadows provides the benefit of allowing the additional program of Rutecki to be programmed in memory as an alternative OPS, rather than requiring the patient to return to a physician for re-programming of the device.
>
> . . . Moreover, with respect to the technical aspects of an SCS IPG, PO's expert agrees with Dr. Mihran that internal components of VNS IPGs and SCS IPGs have the same components and include overlapping parameters. *E.g.,* Ex. 1055 at 110:15–129:17. Thus, PO fails to establish that Rutecki teaches away from a combination with the IPG of Meadows.

Id. at 19–20.

Petitioner also contends that Patent Owner's secondary considerations arguments are conclusory and insufficient to demonstrate the requisite nexus between the claimed invention and secondary considerations of non-obviousness. *Id.* at 21–24.

e. Patent Owner's Sur-Reply

In its Sur-Reply, Patent Owner argues that the argument that "there is no support in the references for combining them in this way, and nothing in the references overcomes Dr. Lad's opinion that a POSITA would not combine the therapies discussed in *Meadows* and *Rutecki* as Petitioner has done." Sur-Reply 10. In particular, Patent Owner contends as follows:

> Although *Rutecki* discloses on-times and off-times of 1 minute and 59 minutes, respectively, there is nothing in Meadows that

> suggests such a repeating pattern of treatment times. In fact, Dr. Lad testified at his deposition that repeating patter[n]s (or what he referred to as "bursts") were not explored in the context of SCS therapy until just recently—years after the invention date of the '307 Patent—further confirming the non-obviousness of Petitioner's proposed combination. *See*, *e.g.*, Exhibit 1055 at 125:13–126:21, 183:8–24.

Id. at 10–11.

Patent Owner contends that the claims are directed to VNS treatments requiring repeating cycles of on-time and off-time, or duty cycles. In particular, Patent Owner contends as follows:

> Petitioner also argues that the '307 Patent discloses tonic stimulation (like Meadows) because Table 4 shows that the "on-time" and "off-time" parameters can take values between 5 seconds and 24 hours. *See* Reply at 24. But Table 4 merely shows the "range of programmable electrical stimulation parameters." *See* '307 Patent at 20:65–67, Table 4. Thus, it shows the *technical "programming" capability* of the IPG. But the *technical capability* of the described IPG must be read in the context of the specification, which describes VNS treatments as including repeating cycles of on-time and off-time. Nothing in the specification states that any particular combination of the values shown in Table 4 constitutes a specific (or appropriate) therapy program for VNS therapy—and certainly not a 24-hour on-time and 24-hour off-time treatment. On the contrary, the more relevant examples of predetermined/prepackaged program parameter values are shown in the '307 Patent specification in Column 19. *See, e.g.*, '307 Patent at 19:30–39 ("20 sec. on-time and 2.0 min. off-time in repeating cycles."), 19:40–47 ("1.5 min. on-time and 20.0 min. off-time in repeating cycles."), 19:48–56 ("1.5 min. on-time and 20.0 min. off-time in repeating cycles."), 19:58–65 ("2.0 min. on-time and 20.0 min. off-time in repeating cycles.").

Id. at 13. Here, Patent Owner directs our attention to Dr. Lad's declaration explaining why the types and manner of therapy procedures are different

between SCS and VNS systems, regardless of the fact that the hardware components are similar. *Id.* at 12 (citing Ex. 2021 ¶ 191 ("The cumulative therapy system of the '307 Patent relies on multiple, selectable, and complete therapy programs[, which] differs from the conventional wisdom at the time, which was vagal tuning . . . .")).

Patent Owner contends that Petitioner failed to successfully rebut Patent Owner's evidence of teaching away. *Id.* at 14–17 (citing Reply 20). In particular, Patent Owner argues that

> *Rutecki* teaches away from multiple programs because it explicitly says that the parameters are applied until reprogrammed. *See* Response at 51 (quoting *Rutecki* at 10:67–11:4). Petitioner argues that *Meadows* improves on this point, so *Rutecki* does not teach away. But, as Patent Owner has pointed out, *Meadows*'s operational parameter sets are not "predetermined/prepackaged programs" as defined in the claims. *See, e.g.,* Response at 46–51; Exhibit 2021 at ¶¶ 189–212. Petitioner's argument that *Rutecki* merely discloses an "alternative to the more convenient storage of multiple therapy programs" is misplaced and finds no support in *Rutecki*. That argument trivializes the inventive aspect of using multiple predetermine/prepackaged programs rather than tuning the system for each patient at a particular time.

Id. at 14.

f. Analysis

i. Whether the Combination of Meadows and Rutecki Teach or Suggest the Claimed "at least two predetermined/pre-packaged programs" having the recited "on-time" and "off-time" parameters

As noted by Patent Owner, there are certain differences between the scope and content of the prior art that a person of ordinary skill in the art would have to contemplate prior to combining the teachings to arrive at the

claimed subject matter, such as differences between SCS therapy and VNS therapy. PO Resp. 25, 39–41. In this regard, the dispute between the parties concerns whether the combination of Meadows and Rutecki teaches or suggests an IPG having "at least two predetermined/pre-packaged programs" of neuromodulation therapy as required by the claims, and, in particular, the on-time and off-time parameters of elements [1.2] and [18.2]. Pet. 35–39, 49–52, 67; PO Resp. 47–51. Having considered the parties' positions and evidence of record, summarized above, we determine that Petitioner has established that Meadows combined with Rutecki suggests the elements of [1.2] and [18.2]. Pet. 49–52.

To begin, Meadows discloses an implantable pulse generator (Ex. 1016, 9:7–18) that is programmed with a "plurality" of OPSs (*id.* at 3:54–58). Each OPS "includes parameter values that define, e.g., pulse amplitude, pulse width (duration), channel frequency, electrode configuration, ramp rate, treatment (stimulation) time, and the like" (*id.* at 9:18–22) and, additionally, "treatment times" (*id.* at 17:2–13) and "auto-run times" (*id.* at 12:41–56). The parties dispute whether the disclosed treatment times and auto-run times in Meadows are the same as the recited "on-time" and "off-time" parameters.

In that regard, Meadows discloses that the patient can schedule auto-run times for the disclosed IPG at certain times of day, meaning the time that therapy automatically turns on and runs for a specified period of time. Specifically, Meadows discloses as follows:

> [T]he patient can schedule auto-run times for IPG operation at certain times of the day. . . . The auto-run time continues for a set time period, e.g., several hours, or for only a few minutes. Advantageously, the auto-run time is defined by the current OPS.

Ex. 1016, 12:41–56; *see also*, (Ex. 1016) at 17:2-13 ("operational parameter data may define . . . treatment times (TT)"); Pet. 51; Ex. 1003 ¶¶ 327, 329. Having considered the parties positions and evidence of record, however, we do not understand the parameters defining "treatment times (TT)" and "auto-run time" as necessarily disclosing both on-time and off-time parameters. While an "auto-run time" may result in the same practical effect, a period of on-time and a period of off-time, we find insufficient evidence supporting a determination that the OPSs disclosed in Meadows include an off-time parameter. Rather, the off-time in Meadows is merely determined as a consequence of the device not having an on-time. Consequently, we agree with Patent Owner that Petitioner fails to establish that Meadows discloses the recited off-time parameter.

There is no dispute, however, that Rutecki discloses an implanted neurostimulating device that may be programed with each of the claimed parameters, including "output signal on-time, [and] output signal and off-time," which have the same meaning of the recited on-time and off-time parameters. Pet. 52; Ex. 1046, 1:11–15, 10:32–38; Ex. 1003 ¶¶ 309–333; PO Resp. 50–51. Thus, the evidence of record supports the conclusion that Rutecki discloses on-time and off-time parameters as recited in the challenged claims. Ex. 1046, 1:11–15, 10:32–38; Ex. 1003 ¶¶ 309–333; Pet. 52; PO Resp. 50–51. Accordingly, taken together, we determine that the combination of Meadows and Rutecki discloses the disputed elements of the recited predetermined/pre-packaged programs of neuromodulation therapy as required by the challenged claims. *See In re Merck & Co. Inc*., 800 F.2d 1091, 1097 (Fed. Cir. 1986) ("Non-obviousness cannot be established by attacking references individually where the rejection is based

upon the teachings of a combination of references. . . . [The reference] must be read, not in isolation, but for what it fairly teaches in combination with the prior art as a whole.").

ii. Whether a Person of Ordinary Skill in the Art Would Have Had Reason to Combine the SCS System of Meadows with the VNS System of Rutecki

A critical issue in this case is whether a person of ordinary skill in the art would have had reason to combine the SCS system of Meadows with the VNS system of Rutecki to achieve a system or method of providing electrical pulses to a vagus nerve using an IPG having "at least two predetermined/pre-packaged programs" of neuromodulation therapy stored in its memory. Whether there was a motivation to combine prior art references is a question of fact. *Arctic Cat Inc. v. Bombardier Recreational Prods. Inc*., 876 F.3d 1350, 1359 (Fed. Cir. 2017). An invention is not obvious simply because all of the claimed limitations were known in the prior art at the time of the invention. Instead, we ask "whether there is a reason, suggestion, or motivation in the prior art that would lead one of ordinary skill in the art to combine the references, and that would also suggest a reasonable likelihood of success." *Smiths Indus. Med. Sys., Inc. v. Vital Signs, Inc*., 183 F.3d 1347, 1356 (Fed. Cir. 1999). The motivation "can be found explicitly or implicitly in the prior art references themselves, in market forces, in design incentives, or in 'any need or problem known in the field of endeavor at the time of invention and addressed by the patent.'" *Arctic Cat*, 876 F.3d at 1359 (quoting *KSR*, 550 U.S. at 420–21). Having considered the parties' positions and evidence of record, summarized above, we determine that a preponderance of evidence supports a determination that

a person of ordinary skill in the art would have been motivated to combine the disclosures of Meadows, Rutecki, and Webster to achieve an implantable VNS device according to the challenged claims.

To begin, we note that both Meadows and Rutecki are related to using neuromodulation to treat "the same neurological disorder" (Ex. 1003 ¶ 278)—that is, chronic neuropathic pain (Ex. 1016, 1:12–15; Ex. 1046, Abstract). Pet. 37. Rutecki, in particular, "relates generally to methods and apparatus for treating . . . neurological disorders by application of modulating electrical signals to a selected nerve or nerve bundle of the patient" (Ex. 1046, 1:6–10), such as "the vagus nerve . . . to inhibit the sensation of pain" (*id.* at 4:55–62). The therapy described by Rutecki "is delivered from a pulse generator of the neurostimulator to a nerve electrode array implanted on the patient's vagus nerve to appropriately modulate the electrical activity of the nerve." *Id.* at 6:29–3. An implantable version of the device is disclosed (*id.* at 9:55–58), and Rutecki expressly teaches that the device may be programmed with each of the claimed parameters of elements [1.b] and [18.b], including "output signal on-time [and] output signal off-time" (*id.* at 10:32-38, 12:24–59), as discussed above.

For its part, Meadows discloses an IPG having the elements of [1.1] and [18.1]. Pet. 47–48 (citing Ex. 1016, 9:7-18, 9:49-51, Fig. 4; Ex. 1003 ¶¶ 309–15). Although Meadows does not explicitly disclose stimulating a vagus nerve, Meadows is widely applicable to "all types of neural stimulators." Ex. 1016, 1:38–45. Additionally, Meadows discloses a similar, and, as discussed above, functionally equivalent set of stimulation parameters within the disclosed OPSs that are used to define stimulation therapy programs. *See id.* at 9:18–22 ("The operational parameter set for an

IPG 100 . . . includes parameter values that define, e.g., pulse amplitude, pulse width (duration), channel frequency, electrode configuration, ramp rate, treatment (stimulation) time, and the like."). Regarding elements [1.2] and [18.2], Meadows discloses that a plurality of predetermined OPSs (example "programs" of "neuromodulation therapy," as recited in elements [1.2] and [18.2]) are stored in the memory of the IPG. Ex. 1016, 3:11–15, 3:54–58 (disclosing a plurality of OPSs programably stored in memory circuitry of implant device). Given the strong similarities of the devices and methods disclosed in Meadows and Rutecki, we agree with Petitioner that a person of ordinary skill in the art would have been motivated to combine the advances in IPG technology disclosed in Meadows and Webster (providing general guidance on the advances of IPG technology, summarized above) to the VNS stimulation methods and parameter sets disclosed by Rutecki (e.g., to avoid having to go to see a physician each time the parameter set is desired to be changed), thereby achieving the subject matter of the challenged claims. Pet. 35–45.

We have considered Patent Owner's contentions that combining the SCS system of Meadows with the VNS system of Rutecki would render the neurostimulation system of Meadows unsatisfactory for the disclosed intended purposes, but we are instead persuaded by Petitioner's arguments and evidence. In this regard, we note that combinations that change the "basic principles under which the [prior art] was designed to operate," *In re Ratti*, 270 F.2d 810, 813 (CCPA 1959), or that render the prior art "inoperable for its intended purpose," *In re Gordon*, 733 F.2d 900, 902 (Fed. Cir. 1984), may fail to support a conclusion of obviousness. However, the preponderance of evidence on this record does not support a conclusion that

the systems of Meadows and Rutecki are incompatible. Rather, a preponderance of the evidence supports a determination that the system of Meadows could have been used to run the stimulation programs of Rutecki with few modifications. For example, the VNS stimulator disclosed in Rutecki requires only a single pair of bipolar electrodes, representing a single channel, which is contemplated by Meadows. Ex. 1016, 7:56–57 ("[T]he present invention may also be used in single-channel systems. . . ."); *see also*, Ex. 1003 ¶ 285 ("The requirement of only a single channel of stimulation for VNS simplifies the combination and decreases demands on IPG memory, since the multiple sets of operating parameters need only be stored with respect to one channel of stimulation, rather than multiple discrete channels, as is common in SCS."). Pet. 52–53.

Furthermore, we credit Dr. Mihran's testimony that Meadow's leads require only routine modification to apply Meadow's device to VNS:

> And as I testified earlier, really the only thing that would require any modification whatsoever or particular form would be just having a correct lead that was appropriate for the particular morphology or anatomy of the vagus nerve itself as compared to other possible targeted nerve structures. And beyond that, all of the parameter values, all of the parameter ranges, and all of the programmability that is part of the IPG of Meadows would serve to function as the vagus nerve stimulator with the appropriate electrode attached.

Ex. 1054, 48:13–23; *see also* Ex. 1003 ¶¶ 284–87 ("IPGs used for VNS are physically and functionally very similar to IPGs used for SCS, both of which had in turn, commonly evolved from programmable cardiac pacemaker technologies") (citing Ex. 1046, 11:26–12:2, Figs. 2–3; Ex. 1016, 7:56–57).

Dr. Lad's testimony is consistent with Dr. Mihran's on this point. Specifically, Dr. Lad testified that the components of many IPGs share

common components and each could be programmed with stimulation therapy parameters. Ex. 1055, 116:16–120:12, 128:7–129:17. Dr. Lad also testified that IPGs for VNS and SCS have similar abilities in terms of delivering packets of energy (*id.* at 127:16–128:5) and that the leads tend to be interoperable between the IPGs (*id.* at 129:5–17). Dr. Lad testified that electrode arrays of SCS IPGs evolved from monopolar and bi-polar arrays and that it would have been technically possible to reduce the number of electrodes on a SCS IPG to a number suitable for VNS therapy. *Id.* at 231:14–17. Thus, while we understand that the SCS therapy programs of Meadows, or the use of a multitude of leads as in Meadows, may endanger a patient receiving VNS therapy, a preponderance of the evidence of record supports a conclusion that a POSA could have modified the IPG hardware of Meadows to make use of a single lead and programmed with the VNS treatment programs disclosed by Rutecki and would have been motivated to do so to obtain the benefit of patient control, as disclosed in Meadows. Pet. 35–41; Ex. 1003 ¶¶ 264–287.

We have also considered Patent Owner's arguments that Rutecki teaches away from the use of "at least two predetermined/pre-packaged neuromodulation therapy programs" (elements [1.2], [18.2]) and/or "selectively choosing between" at least two programs parameters (element [1.5]). PO Resp. 41, 46, 51, 52. We recognize that one "may rebut a prima facie case of obviousness by showing that the prior art teaches away from the claimed invention in any material respect." *In re Peterson*, 315 F.3d 1325, 1331 (Fed. Cir. 2003); citing *In re Geisler*, 116 F.3d 1465, 1469 (Fed. Cir. 1997). However, for a reference to teach away, it must state more than a general preference for an alternative invention. It must "criticize,

discredit, or otherwise discourage" investigation into the invention claimed. *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc*., 567 F.3d 1314, 1327 (Fed. Cir. 2009) (quoting *In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004)). The most that can be said about Rutecki is that it discloses certain VNS devices and methods that are distinguishable from other known neurostimulators and methods involving, for example, direct brain stimulation or dorsal column stimulation. Ex. 1046, 8:9–27. We discern no disclosure in Rutecki that rises to the level of criticism guiding a person of ordinary skill in the art away from combining, for example, SCS or other IPG hardware components and the systems disclosed by Rutecki and, therefore, we are persuaded that Petitioner has established a motivation to combine, notwithstanding Patent Owner's arguments to the contrary.

As to the dependent claims, the dispute between the parties similarly concerns whether the combination of Meadows and Rutecki fails to disclose an "on-time and off-time" parameters as set forth in the challenged claims. PO Resp. 53–54. For the reasons set forth above, we resolve that dispute in favor of Petitioner.

iii. Secondary Considerations

Before we can determine that Petitioner demonstrates the obviousness of the challenged claims, we must consider the evidence of obviousness anew in light of any evidence of secondary considerations of nonobviousness presented by Patent Owner. *See Graham*, 383 U.S. at 17-18 ("Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be

patented. As indicia of obviousness or nonobviousness, these inquiries may have relevancy."); *Transocean Offshore Deepwater Drilling, Inc. v. Maersk Drilling USA, Inc*., 699 F.3d 1340, 1349 (Fed. Cir. 2012) ("This objective evidence must be "considered as part of all the evidence, not just when the decision maker remains in doubt after reviewing the art." (quoting *Stratoflex, Inc. v. Aeroquip Corp*., 713 F.2d 1530, 1538-39 (Fed. Cir. 1983))).

Among the secondary considerations that must be considered is the existence of a long-felt but unsolved need. *Graham*, 383 U.S. at 17–18. Patent Owner, however, does not present any actual evidence of long-felt need, only argument, which we find insufficient to rebut evidence of record establishing a motivation to apply the advances in IPG technology disclosed in Meadows and Webster to the VNS stimulation methods disclosed by Rutecki so as to avoid having to go to see a physician each time the parameter set is desired to be changed, as discussed above. PO Resp. 62–65. As such, Patent Owner has failed, on the current record, to establish a long-felt need. *See Tex. Instruments v. U.S. Int'l Trade Comm'n*, 988 F.2d 1165, 1178 (Fed. Cir. 1993) ("[L]ong-felt need is analyzed as of the date of an articulated identified problem and evidence of efforts to solve that problem."); *Iron Grip Barbell Co., Inc. v. USA Sports, Inc*., 392 F.3d 1317, 1325 (Fed. Cir. 2004)("Absent a showing of long-felt need or the failure of others, the mere passage of time without the claimed invention is not

evidence of nonobviousness."); *accord In re Wright*, 569 F.2d 1124, 1127 (CCPA 1977).[4]

g. Conclusion

In conclusion, we are persuaded by Petitioner's arguments, as they are supported by the cited evidence, notwithstanding Patent Owner's arguments, addressed above. Accordingly, we determine that Petitioner has demonstrated by a preponderance of the evidence that claims 1–5, 7–12, and 18–28 of the '307 patent are unpatentable under 35 U.S.C. § 103(a) as obvious over the combination of Meadows, Rutecki, and Webster.

2. Ground 2: Obviousness of Claim 6 over the Combination of Meadows, Rutecki, Webster, and Lee

Petitioner contends that Claim 6 is unpatentable under 35 U.S.C. § 103 over the combination of Meadows, Rutecki and Webster further in view of Lee. Pet. 75–79. Claim 6 depends from claim 1 and further requires "wherein said implanted pulse generator may further comprise a telemetry means for remote device interrogation and/or programming over a wide area network." Ex. 1001, 33:37–40. For that element, Petitioner relies on Lee, which is generally directed to "providing real-time communication between the [implantable medical devices ("IMDs")], medical instruments associated

[4] We acknowledge Patent Owner's assertion that "Petitioner's use of the technology claimed in the '307 Patent has resulted in overwhelming commercial success," but note that such attorney argument is not the equivalent of evidence of commercial success. PO Resp. 63. Thus, even assuming a nexus between the Patent Owner's assertion of commercial success and a patent claim, we determine that the record lacks sufficient evidence to support a finding of commercial success sufficient to overcome the evidence of obviousness set forth in the Petition.

with or compatible with the IMDs, and a specialized remote expert data center, a central IMD support information network, or other remote collaborators." Ex. 1013, 1:13-18; Ex. 1003 ¶ 425. Lee also discloses that its implantable medical device may be "a pacemaker, defibrillator, drug pump, [or] neurological stimulator." Ex. 1013, 10:46-50.

Patent Owner's arguments, as to this ground, for the most part refer back to the discussion with respect to ground 1, which we discuss above. PO Resp. 54–68.

Having considered the parties' positions and evidence of record, we agree, for the reasons set forth in the Petition, which we adopt (Pet. 75–79; Ex. 1003, ¶¶ 426, 437–40), that Lee discloses the element of claim 6 and that a person of ordinary skill in the art would have been motivated to apply the general technological advances disclosed in Lee to the neurostimulators of Meadows and Rutecki. Accordingly, we determine that Petitioner has demonstrated by a preponderance of the evidence that claim 6 of the '307 patent is unpatentable under 35 U.S.C. § 103(a) as obvious over the combination of Meadows, Rutecki, Webster, and Lee.

3. Grounds 3 and 4

Because the obviousness grounds over the combination of Meadows, Rutecki, Webster, and Lee are dispositive as to claims 1–12 and 18–28, we need not reach the obviousness grounds over the combination of Meadows, Rutecki, Salmons, and Webster (ground 3) and combination of Meadows, Rutecki, Salmons, Webster, and Lee (ground 4). *See SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1359 (2018) (holding a petitioner "is entitled to a final written decision addressing all of the claims it has challenged").

III. CONCLUSION

In summary, we make the following conclusions.[5]

Claims	35 U.S.C. §	Reference(s)/ Basis	Claims Shown Unpatentable	Claims Not Shown Unpatentable
1–5, 7–12, 18–28	103(a)	Meadows, Rutecki, Webster	1–5, 7–12, 18–28	
6	103(a)	Meadows, Rutecki, Webster, Lee	6	
1–5, 7–12, 18–28	103(a)[6]	Meadows, Rutecki, Salmons, Webster		

[5] Should Patent Owner wish to pursue amendment of the challenged claims in a reissue or reexamination proceeding subsequent to the issuance of this decision, we draw Patent Owner's attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding*, 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. *See* 37 C.F.R. § 42.8(a)(3), (b)(2).

[6] As explained above in Section II.C.3, we do not reach Petitioner's challenge to claims 1–5, 7–12, and 18–28 as obvious over the combination of Meadows, Rutecki, Salmons, and Webster.

Claims	35 U.S.C. §	Reference(s)/ Basis	Claims Shown Unpatentable	Claims Not Shown Unpatentable
6	103(a)[7]	Meadows, Rutecki, Salmons, Webster, Lee		

IV. ORDER

Accordingly, it is

ORDERED that claims 1–12 and 18–28 of the '307 patent are unpatentable; 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.

[7] As explained above in Section II.C.3, we do not reach Petitioner's challenge to claim 6 as obvious over the combination of Meadows, Rutecki, Salmons, Webster, and Lee.

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