

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AVATION MEDICAL, INC.,

Petitioner,

v.

EMKINETICS, INC.,

Patent Owner.

PGR2024-00043

Patent 11,844,943 B2

Before ERICA A. FRANKLIN, JOHN G. NEW, and JASON W. MELVIN,
Administrative Patent Judges.

NEW, *Administrative Patent Judge.*

DECISION

Granting Institution of Post-Grant Review

35 U.S.C. § 324

I. INTRODUCTION

Petitioner Avation Medical, Inc. (“Petitioner”) has filed a Petition (Paper 2, “Pet.”) seeking post-grant review of claims 1–39 of U.S. Patent 11,844,943 B2 (Ex. 1001, the “’943 patent”). Patent Owner EMKinetics, Inc. (“Patent Owner”) timely filed a Preliminary Response. Paper 7 (“Prelim. Resp.”).

Under 35 U.S.C. § 324, the Board “may not authorize a post-grant review to be instituted unless ... the information presented in the petition ... if such information is not rebutted would demonstrate that it is more likely than not that at least 1 of the claims challenged in the petition is unpatentable.” For the reasons we explain below, we institute post-grant review of the ’943 patent.

II. BACKGROUND

A. *Real Parties-in-Interest*

Petitioner identifies Avation Medical, Inc. as the real party-in-interest. Pet. x. Patent Owner identifies EMKinetics, Inc. as the real party-in-interest. Paper 5, 1; Paper 6, 1.

B. *Related Matters*

Petitioner and Patent Owner identify *Avation Medical, Inc. v. EMKinetics, Inc.*, No. 4:24-cv-01702 (N.D. Cal.) (the “California litigation”) as a related matter involving the ’943 patent. Pet. x; Paper 5, 1; Paper 6, 1.

The parties also identify U.S. Patent 9,002,477 (the “’477 patent”) and U.S. Patent 11,224,742 (the “’742 patent”) as being involved in the California litigation. Pet. x; Paper 5, 1; Paper 6, 1. Patent Owner identifies

the '477 patent as being also the subject of IPR2024-01378 and the '742 patent as being also the subject of IPR2024-01375. Paper 6, 1.

C. The Asserted Grounds of Unpatentability

Petitioner contends that claims 1–39 of the '943 patent are unpatentable, based upon the following grounds:

Ground	Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1	1, 3–5	102	Svihra ¹
2	2, 6–13	103	Svihra
3	14, 16–18, 27, 29–31	103	Svihra, Johnson ²
4	15, 19–26, 28, 32–39	103	Svihra, Johnson
5	1–3, 5	102	Amarenco ³
6	4, 6–13	103	Amarenco
7	14–16, 18, 27–29, 31	103	Amarenco, Johnson

¹ J. Svihra et al., *Neuromodulative Treatment of Overactive Bladder—Noninvasive Tibial Nerve Stimulation*, 103(12) BRATISL LEK LISTY 480–83 (2002) (“Svihra”) Ex. 1004.

² Johnson (WO 2004/108209 A1, December 16, 2004) (“Johnson”) Ex. 1007.

³ G. Amarenco et al., *Urodynamic Effect of Acute Transcutaneous Posterior Tibial Nerve Stimulation in Overactive Bladder*, 169 J. UROLOGY 2210–15 (2003) (“Amarenco”) Ex. 1005.

Ground	Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
8	17, 19–26, 30, 32–39	103	Amarenco, Johnson
9	1–3, 5–13	102	Burnett ⁴
10	4, 14–39	103	Burnett, Johnson
11	1–39	112	Lack of enablement

Petitioner also relies upon the Declaration of Dr. Brett Wingeier (the “Wingeier Declaration,” Ex. 1003).

D. The '943 Patent

The '943 patent relates to apparatus and methods for central and peripheral nerve and other tissue modulation or stimulations therapies. Ex. 1001, col. 2, ll. 3–7. According to the '943 patent, these apparatus and methods may be useful in the treatment and prevention of urinary incontinence (UI), overactive bladder (OAB), and other conditions. *Id.* at col. 8, ll. 33–36.

As background, the '943 patent describes neuromodulation for OAB and UI patients by using a posterior tibial nerve stimulator, often referred to as SANS. Ex. 1001, col. 3, ll. 5–7. The '943 patent notes that this treatment is invasive in nature, requiring the insertion of a needle two inches into the patient's ankle region in order to stimulate the posterior tibial nerve. *Id.* at col. 3, ll. 8–11.

⁴ Burnett et al. (US 2008/0306325 A1, December 11, 2008) (“Burnett”) Ex. 1006.

In an exemplary embodiment based on transdermal electrical stimulation therapy, a stimulator electrode may be positioned over a glabrous skin surface to deliver transdermal electrical stimulation through or across the glabrous skin surface to an underlying target nerve, resulting in stimulation of the target nerve. Ex. 1001, col. 3, ll. 32–39; *see also id.* at col. 46, ll. 4–11. According to the '943 patent:

Delivery of electrical stimulation through or across a glabrous surface of the body via an electrode positioned over a glabrous surface, e.g., a glabrous surface on a palmar or plantar surface, unexpectedly allows for the use of a higher frequency and/or higher amplitude electrical pulsation or electrical stimulus to deliver the electrical stimulation than would otherwise be safe and/or tolerable to deliver electrical stimulation through a non-glabrous surface of the body. For example, an electrical stimulus having a frequency of about 5 Hz to about 60 Hz (a range found to be effective for generating motor and/or sensory nerve conduction of the posterior tibial nerve) may be utilized to stimulate a target nerve (to generate motor and/or sensory nerve conduction therein) or tissue through or across a glabrous skin surface (via an electrode positioned over the glabrous skin surface) in a manner that remains safe and tolerable to the patient and avoids burns or injury.

Id. at col. 50, ll. 36–52. The '943 patent explains that using a similar electrical stimulus to stimulate a target nerve or tissue through a non-glabrous skin surface is intolerable and painful, resulting in burns or injury.

Id. at col. 50, ll. 55–61.

In an exemplary embodiment based on an energy based stimulation therapy, an energy emitting device may be positioned in proximity to a skin surface overlying a target nerve, wherein energy may be delivered at a frequency of about 1 Hz to about 30 Hz through the skin surface to the target nerve, thereby generating motor and/or sensory nerve conduction of the

target nerve while remaining safe and tolerable to the subject. Ex. 1001, col. 3, ll. 46–55; *see also id.* at col. 49, ll. 8–25. According to the '943 patent:

[E]nergy delivered transdermally, through, or across a patients skin at about 1 Hz to about 30 Hz, or at less than 10 Hz has unexpectedly been found to stimulate or generate motor and/or sensory nerve conduction of a tibial nerve, where such level of stimulation may be sufficient to treat a patient suffering from urinary incontinence, overactive bladder, fecal incontinence or other conditions. The energy may be delivered through or across a glabrous skin surface or non-glabrous skin surface or any other skin surface (e.g., any skin surface overlying a tibial nerve).

Id. at col. 49, ll. 30–40.

An apparatus for providing electrical stimulation is depicted in Figure 11 of the '943 patent, which is reproduced below:

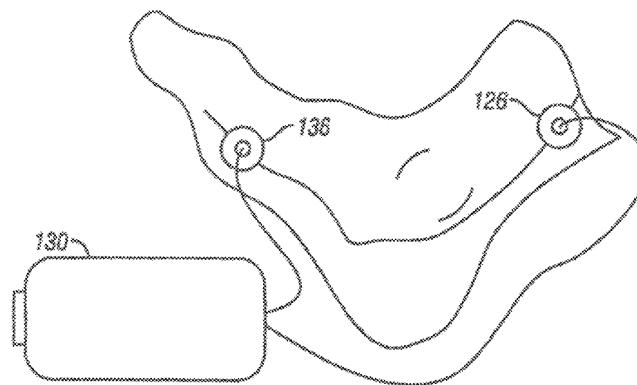


FIG. 11

Figure 11 of the '943 patent depicts an apparatus for providing electrical stimulation

Figure 11 shows a transcutaneous stimulator, such as an electrode 126, that dispenses electrical energy for nerve stimulation. Ex. 1001, col. 17, ll. 9–13. Electrical pulse controller 130 is connected to electrode 126 and to sensor 136. *Id.* at col. 17, ll. 17–20. According to the

'943 patent, "nerve conduction may be detected at a site sufficiently distant from the site of stimulation, so to enable detection of nerve conduction despite the confounding interference from the direct electrical stimuli." *Id.* at col. 17, ll. 20–24.

In an exemplary embodiment based on electromagnetic induction therapy, one or more conductive coils may be configured to generate a magnetic field focused on a target nerve, muscle, or other body tissues in proximity to the coils. Ex. 1001, col. 3, ll. 56–60. One or more sensors may be used to detect electrical conduction in the target nerve, to detect a muscular response caused by an electrical conduction in the target nerve, or to detect stimulation of a nerve, muscle or other body tissues, and to provide feedback about the efficacy of the applied electromagnetic induction therapy. *Id.* at col. 3, ll. 61–66.

An apparatus for magnetic induction therapy is depicted in Figure 1 of the '943 patent, which is reproduced below:

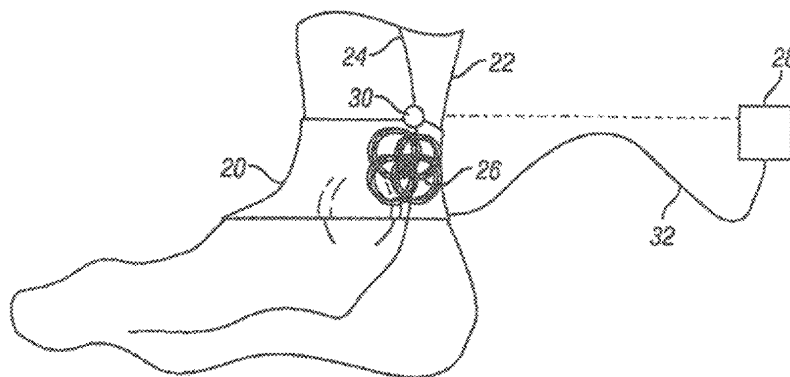


FIG. 1

Figure 1 of the '943 patent depicts an apparatus for magnetic induction therapy

Figure 1 shows a coil wrap 20 disposed over ankle 22 circumferentially to surround a portion of tibial nerve 24. Ex. 1001, col. 10, ll. 21–23.

According to the '943 patent,

Coil wrap **20** contains one or more conductive coils **26** arranged to produce a pulsed magnetic field that will flow across tibial nerve **24** and generate a current that will flow along tibial nerve **24** and spread along the length of tibial nerve **24** all the way to its sacral or pudendal nerve root origins.

Id. at col. 10, ll. 46–51. A programmable logic controller 28 supplies the electrical current that flows through coils 26 and produces the magnetic field. *Id.* at col. 11, ll. 8–11. Figure 1 also shows a sensor 30, whose purpose is “to detect and record the firing of the target nerve and to provide related information to logic controller 28, so to render the intended therapy most effective.” *Id.* at col. 11, ll. 14–18.

E. Representative Claims

Independent claims 1, 14, and 27 of the '943 patent are representative of the challenged claims and recite:

1. A method of treating overactive bladder or incontinence, comprising:
non-invasively positioning a first portion of a patient's body near an ankle relative to an electrical stimulator such that a posterior tibial nerve within the first portion of the body is directly targeted by the electrical stimulator;
passing a current through the electrical stimulator; and
delivering an electrical stimulus from the electrical stimulator to the posterior tibial nerve such that the posterior tibial nerve directly receives the electrical stimulation to treat overactive bladder or incontinence.

14. A method of treating overactive bladder or incontinence, comprising:

non-invasively positioning a first portion of a patient's body near an ankle relative to an electrical stimulator positioned within a sock worn upon a foot of the patient such that a posterior tibial nerve within the first portion of the body is directly targeted by the electrical stimulator;

passing a current through the electrical stimulator; and

delivering an electrical stimulus from the electrical stimulator to the posterior tibial nerve such that the posterior tibial nerve directly receives the electrical stimulation to treat overactive bladder or incontinence.

27. A method of treating overactive bladder or incontinence, comprising:

non-invasively positioning a first portion of a patient's body near an ankle relative to an electrical stimulator positioned upon a strap which is secured over a foot of the patient such that a posterior tibial nerve within the first portion of the body is directly targeted by the electrical stimulator;

passing a current through the electrical stimulator; and

delivering an electrical stimulus from the electrical stimulator to the posterior tibial nerve such that the posterior tibial nerve directly receives the electrical stimulation to treat overactive bladder or incontinence.

Ex. 1001, col. 70, ll. 8–19; *id.* at col. 70, l. 63–col. 71, l. 8; *id.* at col. 71, l. 53–col. 72, l. 9.

F. Priority History of the '943 Patent

The '943 patent issued from U.S. Application Ser. No. 17/568,276 (the “'276 application”), filed on January 4, 2022, and cites the priority

benefit of, *inter alia*, provisional Application Ser. No. 60/848,720, which was filed on October 2, 2006. Ex. 1001, codes (21–22, 60).

Claims 1–39 of the '943 patent were allowed on October 23, 2023, and the patent issued on December 19, 2023. Ex. 1002, 25; Ex. 1001, code (45).

Petitioner contends that the earliest possible effective filing date for the '943 patent claims is September 20, 2010. Pet. 14–17. In contrast, Patent Owner contends that the earliest effective filing date for the '943 patent claims is October 2, 2006. Prelim. Resp. 11–20. We address this issue in Section III.L.4 below.

III. ANALYSIS

A. *Eligibility for Post-Grant Review*

The post-grant review provisions set forth in Section 6(d) of the AIA apply only to patents subject to the first-inventor-to-file provisions of the AIA. *See* AIA § 6(f)(2)(A) (“The amendments made by subsection (d) ... shall apply only to patents described in section 3(n)(1).”). Patents subject to the first-inventor-to-file provisions are those that issue from applications “that contain[] or contained at any time ... a claim to a claimed invention that has an effective filing date as defined in section 100(i) of title 35, United States Code, that is on or after” March 16, 2013. *Id.* § 3(n)(1). Our rules require that each petitioner for post-grant review certify that the challenged patent has an effective filing date that renders the patent available for post-grant review. 37 C.F.R. § 42.204(a) (“The petitioner must certify that the patent for which review is sought is available for post-grant review.”). In addition, “[a] petition for a post-grant review may only be filed not later

than the date that is 9 months after the date of the grant of the patent or of the issuance of a reissue patent (as the case may be).” 35 U.S.C. § 321(c); *see also* 37 C.F.R. § 42.202(a) (accord).

Petitioner contends that the Petition is eligible for post-grant review. Pet. 8–13. Patent Owner does not dispute Petitioner’s contention regarding PGR eligibility. *See generally* Prelim. Resp. For the reasons discussed below, we determine that the Petition is eligible for post-grant review. *See* 35 U.S.C. § 324.

Petitioner states the following:

Petitioner certifies that if the ’943 patent is an AIA patent (*see* § IV.A), it is available for PGR. Petitioner is not barred or estopped from requesting PGR on the Challenged Claims on the grounds below. Petitioner and its privies have not filed a civil action challenging the validity of any claim of the ’943 patent. This petition is timely filed because: (a) Petitioner has not been served with a complaint alleging infringement of the ’943 patent as of this petition’s filing; and (b) it is filed within 9 months of the patent’s issuance (i.e., December 19, 2023).

Pet. 1–2. Petitioner asserts that “the ’943 patent contains a specific reference to patents and/or applications that ‘contain[] or contained at any time’ claims with an effective filing date ‘after the [AIA] effective date,’ i.e., March 16, 2013.” Pet. 9. Petitioner also asserts that “the ’943 patent is also an AIA patent eligible for PGR because it contains claims with an effective filing date after March 16, 2013.” *Id.* at 13. Patent Owner does not contest Petitioner’s assertions regarding PGR eligibility. *See generally* Prelim. Resp.

Furthermore, this Petition was filed on July 1, 2024, which is within nine months subsequent to the December 19, 2023, issue date of the

'943 patent. *Id.* at code (45). On this record, we determine that the '943 patent is an AIA patent and eligible for post-grant review.

B. Claim Construction

The Board applies the same claim construction standard that would be used to construe the claims in a civil action under 35 U.S.C. § 282(b). *See* 37 C.F.R. § 100(b) (2020). Under that standard, claim terms “are generally given their ordinary and customary meaning” as understood by a person of ordinary skill in the art at the time of the invention. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc). “In determining the meaning of the disputed claim limitation, we look principally to the intrinsic evidence of record, examining the claim language itself, the written description, and the prosecution history, if in evidence.” *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 469 F.3d 1005, 1014 (Fed. Cir. 2006) (citing *Phillips*, 415 F.3d at 1312–17). Extrinsic evidence is “less significant than the intrinsic record in determining ‘the legally operative meaning of claim language.’” *Phillips*, 415 F.3d at 1317 (quoting *C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 862 (Fed. Cir. 2004)).

Neither Petitioner nor Patent Owner offers any express construction of any of the claim terms of the '943 patent. *See* Pet. 21; *see also generally* Prelim. Resp.

We determine that no express construction of any claim term beyond the ordinary and customary meaning, as understood by a person of ordinary skill in the art at the time of the invention, is necessary for the purpose of rendering this Decision. *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017).

C. A Person of Ordinary Skill in the Art

Petitioner contends that a person of ordinary skill in the art would have had an undergraduate degree in the field of biomedical engineering or a related discipline, such as electrical engineering, and at least two years of experience in the design and/or analysis of biomedical devices. Pet. 20. Petitioner also proposes that additional work experience could substitute for a formal degree and *vice versa*. *Id.* (citing Wingeier Declaration ¶ 21). Patent Owner does not expressly contest this definition of a person of ordinary skill in the art in its Preliminary Response.

Petitioner’s proposed definition of the level of ordinary skill in the art appears to be consistent with the level of skill presented in the cited prior art. *See, e.g.,* Exs. 1004–1007; *see also Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (the prior art itself may reflect an appropriate level of skill in the art). For the purposes of this Decision, we adopt Petitioner’s proposed definition as defining a person of ordinary skill in the art.

D. Ground 1: Alleged Anticipation of Claims 1 and 3–5 by Svihra

1. Overview of Svihra

Svihra is directed to non-invasive stimulation of the tibial nerve to achieve desired therapeutic effects without introgenic nerve damage using a superficial electrostimulation. Ex. 1004, 480. According to Svihra, the non-invasive stimulation “had improved subjective symptom related to overactive bladder, had no adverse events and was well tolerated.” *Id.*

According to Svihra, the original invasive Stoller’s afferent nerve stimulation (SANS) uses the region of medial ankle for percutaneous tibial nerve stimulation using a needle electrode inserted in the vicinity of the

nerve. Ex. 1004, 481. Svihra aims to produce non-invasive stimulation achieving comparable effect by superficial electrode without iatrogenic damage to the tibial nerve. *Id.* Svihra describes a modified non-invasive stimulation SANS by using surface electrodes for the area of medial ankle and stimulation of tibial nerve with values different from those set by the original SANS stimulator. *Id.* In this method, Svihra describes that:

the electrodes were placed behind the medial ankle of the left lower extremity. Cathode was placed proximally and anode distally. After a control stimulation accompanied by optimization of the electrode position and set intensity of stimulation we had proceeded on with a therapeutic stimulation of tibial nerve. Intensity of the surface SANS was equal to 70 % of intensity, at which the maximal amplitude of response was registered from the abductor hallucis muscle (stimulation by a constant voltage and regulated intensity of direct current). Frequency of stimulation was 1 Hz and duration of square impulse was 0.1 ms. Surface stimulation of 30 minutes duration was repeated once a week for a period of 5 weeks.

Id. According to Svihra, its “results document good tolerance of non-invasive SANS and comparable efficacy with invasive SANS.” *Id.* at 482.

2. Prior Art Status

Petitioner argues that Svihra published in 2002 and is therefore prior art under AIA 35 U.S.C. § 102(a)(1). Pet. 21. Patent Owner argues that “the Petition does not identify any evidence that Svihra was, in fact, publicly accessible before the alleged critical date.” Prelim. Resp. 2.

Specifically, Patent Owner argues that “beyond potentially looking like an article, there is no evidence cited in the Petition that Svihra was publicly accessible at anytime, let alone before the alleged critical date.” Prelim. Resp. 3. Patent Owner notes that the reference does not bear a

copyright notice, and does not include a publication page or an International Standard Book Number (ISBN). *Id.* Patent Owner also notes that Svihra does not bear the name of any known publication, nor does not state that it was published. *Id.* at 3–4. Furthermore, Patent Owner argues, neither the Petition nor the Wingeier Declaration provides or identifies any evidence tending to establish that Svihra was a publicly accessible reference prior to the critical date. *Id.* at 4–5.

Accordingly, argues Patent Owner, Petitioner’s challenge, insofar as it relies on Svihra qualifying as prior art, is based entirely on the document submitted as Exhibit 1004, and the dates listed on Svihra (“2002,” “Received May 30, 2002,” “Accepted December 9, 2002”) are therefore hearsay. Prelim. Resp. 5 (citing *Standard Innovation Corp. v. Lelo, Inc.*, IPR2014-00148, Paper 41, 13–16 (PTAB Apr. 23, 2015)). Furthermore, Patent Owner contends, Svihra states that it was “[r]eceived” and “[a]ccepted” in 2002 in connection with “some entity known as ‘Bratisl Lek Listy,’” but does not expressly state that it was published or otherwise publicly accessible as of the critical date. *Id.* at 5–6 (citing Ex. 1004, 483). Patent Owner therefore contends that Petitioner has failed to carry its burden of identifying, with particularity, “evidence sufficient to establish a reasonable likelihood that Svihra was publicly accessible or that there is a reasonable likelihood that Svihra qualifies as a printed publication.” *Id.* at 6.

It has long been recognized that the touchstone as to whether an asserted reference qualifies as prior art is public accessibility. *See In re Hall*, 781 F.2d 897, 899 (Fed. Cir. 1986). “[A]t the institution stage, the petition must identify, with particularity, evidence sufficient to establish a reasonable likelihood that the reference was publicly accessible before the

critical date of the challenged patent and therefore that there is a reasonable likelihood that it qualifies as a printed publication.” *Hulu, LLC v. Sound View Innovations, LLC*, IPR2018-01039, Paper 29, 13 (PTAB Dec. 20, 2019) (precedential).

We do not find persuasive Patent Owner’s argument that Petitioner has failed to establish that Svihra was not either publicly accessible or a printed publication as of the critical date of September 20, 2010. A cursory internet search reveals that “Bratisl Lek Listy,” which appears on the header of Svihra, is, in fact, an abbreviation for Bratislavské lekárske listy, the Bratislava Medical Journal, an international medical journal founded in 1919, published monthly in English, and currently in its 125th volume. The header of the Svihra reference states, in full: “Bratisl Lek Listy 2002; 103 (12): 480-483,” which we find, based on the current record, that a person of ordinary skill in the art would understand to mean that the Svihra reference appeared as an article appearing in volume 103, number 12, of the Bratislava Medical Journal at pages 480–483, and which was published in December 2002 (i.e., number 12), which antedates the critical date of the ’943 patent. *See Ex. 1004, 480.*

We conclude that, for the purposes of this Decision and on the record as presently developed, the Svihra reference more likely than not exhibits the necessary hallmarks of a printed publication that would have been publicly accessible as of the critical date of the ’943 patent. Indeed, Svihra exhibits many of the same hallmarks of a printed publication as does the Amarenco reference, e.g., journal title and volume number, page numbers, date of acceptance for publication, etc., which Patent Owner does not dispute is a printed publication. *See Ex. 1005.* We consequently conclude

that Petitioner has established the public accessibility of Svihra sufficiently for purposes of institution.

3. Anticipation of claims 1 and 3–5 by Svihra

a. Principles of law

A claim is unpatentable as anticipated under 35 U.S.C. § 102 only when “every element and limitation of the claim was previously described in a single prior art reference, either expressly or inherently, so as to place a person of ordinary skill in possession of the invention.” *Sanofi-Synthelabo v. Apotex, Inc.*, 550 F.3d 1075, 1082 (Fed. Cir. 2008). A reference may inherently anticipate if a claim limitation that is not expressly disclosed “is necessarily present, or inherent, in the single anticipating reference.”

Verizon Servs. Corp. v. Cox Fibernet Va., Inc., 602 F.3d 1325, 1337 (Fed. Cir. 2010). Thus, the “very essence of inherency is that one of ordinary skill in the art would recognize that a reference *unavoidably* teaches the property in question.” *Agilent Technologies, Inc. v. Affymetrix, Inc.*, 567 F.3d 1366, 1383 (Fed. Cir. 2009) (emphasis added).

b. Petitioner’s arguments

i. Independent claim 1

Petitioner argues that Svihra discloses “us[ing] non-invasive stimulation of the tibial nerve with the intention to achieve desired therapeutic effects” in patients “suffer[ing] from overactive bladder (OAB).” Pet. 21 (citing Ex. 1004, 480). Petitioner contends that those of ordinary skill in the art would understand that “surface electrodes” do not break the skin and that the procedure was therefore non-invasive. *Id.* at 22 (citing

Ex. 1003 ¶ 61). Petitioner points out that Svihra's "surface electrodes" provided "stimulation by a constant voltage and regulated intensity of direct current," and argues that a skilled artisan would understand that providing electrostimulation in this way would necessarily require electrodes connected to an electrical stimulator source. *Id.* (citing Ex. 1004, 481; Ex. 1003 ¶ 62).

Petitioner also contends that a person of ordinary skill in the art would understand that electrodes "placed behind the medial ankle of the left lower extremity" for stimulation of the posterior tibial nerve ("PTN") necessarily indicates a portion of the patients' bodies "near an ankle" were positioned relative to an electrical stimulator, as claimed. Pet. 23 (citing Ex. 1003 ¶ 63). Petitioner notes that Svihra discloses that electrodes were placed "behind the medial ankle" to stimulate the "tibial nerve." *Id.* (citing Ex. 1004, 481). According to Petitioner, the "tibial nerve" is the PTN, and Svihra's electrodes "directly targeted" the patients' PTN. *Id.* (citing Ex. 1003 ¶ 64).

Petitioner additionally argues that Svihra's "therapeutic stimulation of tibial nerve" involved "stimulation by a constant voltage and regulated intensity of direct current" *via* "surface electrodes" placed behind the patients' medial ankle. Pet. 23 (citing Ex. 1004, 481). Petitioner asserts that, for electrical stimulation to be applied through "surface electrodes," the electrodes necessarily would have been connected to an electrical stimulator source through which current was passed. *Id.* (Ex. 1003 ¶ 66).

Petitioner also contends that Svihra discloses that "[a]fter a control stimulation accompanied by optimization of the electrode position and set intensity of stimulation we had proceeded on with a therapeutic stimulation

of tibial nerve,” which involved “stimulation by a constant voltage and regulated intensity of direct current.” Pet. 24 (citing Ex. 1004, 481). Petitioner states that Svihra therefore delivered electrical stimulus from an electrical stimulator through the electrodes to the PTN, as recited in claim 1, to “patients with overactive bladder (OAB) without bladder outlet obstruction.” *Id.* (citing Ex. 1003 ¶ 67).

ii. Dependent claims 3–5

Claim 3 of the ’943 patent recites “[t]he method of claim 1 further comprising detecting a muscular response caused by an electrical conduction or stimulation of the posterior tibial nerve.” Ex. 1001, col. 70, ll. 24–26. Petitioner argues that Svihra discloses using an electromyographic (“EMG”) device, which measures the electrical muscle response resulting from stimulation of muscle by nerves. Pet. 24 (citing Ex. 1004, 481; Ex. 1003 ¶ 69). Petitioner notes that Svihra discloses that the “[i]ntensity of the surface SANS was equal to 70% of intensity, at which the maximal amplitude of response was registered from the abductor hallucis muscle.” *Id.* (citing Ex. 1004, 481).

Dependent claim 4 recites “wherein delivering the electrical stimulus comprises activating the electrical stimulator for a duration of about 30 minutes per week to treat the patient.” Ex. 1001, col. 70, ll. 27–29. Petitioner contends that Svihra expressly discloses “[s]urface stimulation of 30 minutes duration was repeated once a week for a period of 5 weeks.” Pet. 25 (citing Ex. 1003 ¶ 71).

Dependent claim 5 recites “[t]he method of claim 1 further comprising displaying physiological parameters detected from the patient.” Ex. 1001,

col. 70, ll. 30–31. Petitioner argues that Svihra discloses the use of an EMG device, which measures electrical activity and muscle response resulting from stimulation of muscle by nerves. Pet. 25 (citing Ex. 1004, 481 (“electromyographic device Nicolet Viking II E”); Ex. 1003 ¶ 72).

Petitioner notes that Svihra discloses that “the maximal amplitude of response was registered from the abductor hallucis muscle,” by which it refers to the maximum electrical signal from the patients’ muscle as a result of stimulation therapy. *Id.* (citing Ex. 1004, 481; Ex. 1003 ¶ 73). Petitioner argues that a person of ordinary skill in the art would understand that because Svihra determined the “maximal amplitude of response,” the results were necessarily displayed to the operator, who would be otherwise unable to determine the maximum electrical signal, i.e., the “maximal amplitude.” *Id.*

c. Patent Owner’s arguments

Patent Owner does not dispute the teachings of Svihra or the merits of Petitioner’s arguments, arguing instead, as we explain in Section III.D.2 above, that Petitioner has failed to demonstrate that Svihra is a prior art printed publication. *See* Prelim. Resp. 2–6.

d. Analysis

We agree with Petitioner that, for the purposes of this Decision, Svihra more likely than not anticipates challenged claims 1 and 3–5 of the ’943 patent. With respect to claim 1, Svihra discloses “the superficial stimulation of tibial nerve was used, which tested the effectiveness of modified superficial Stoller’s afferent nerve stimulation (SANS)” in the

treatment of patients with “overactive bladder (OAB) without bladder outlet obstruction.” Ex. 1004, 481. Svihra discloses that “[w]hen using the modified non-invasive stimulation SANS it is necessary to use surface electrodes for the area of medial ankle and stimulation of tibial nerve with different values” and that the non-invasive surface electrodes “were placed behind the medial ankle of the left lower extremity.” *Id.*

Claim 1 further recites “passing a current through the electrical stimulator; and delivering an electrical stimulus from the electrical stimulator to the posterior tibial nerve such that the posterior tibial nerve directly receives the electrical stimulation to treat overactive bladder or incontinence.” Ex. 1001, col. 70, ll. 15–19. Svihra discloses that “when using the modified non-invasive stimulation SANS it is necessary to use surface electrodes for the area of medial ankle and stimulation of tibial nerve with different values, which cannot be set by the original SANS stimulator. We have used an electromyographic device Nicolet Viking II E.” Ex. 1004, 481. Svihra thus teaches the use of a Nicolet Viking II E as an electrical stimulator to deliver current to the non-invasive surface electrodes, thereby electrically stimulating the PTN.

We consequently conclude that, based upon the record as presently developed, Petitioner has sufficiently demonstrated, for the purpose of this Decision, that it is more likely than not that Svihra anticipates challenged claim 1 of the ’943 patent.

e. Dependent claims 3–5

We similarly agree with Petitioner, for the reasons stated by Petitioner, and for the purposes of this Decision, that Svihra more likely than

not anticipates dependent claims 3–5. With respect to claim 3, Svihra expressly discloses “[i]ntensity of the surface SANS was equal to 70% of intensity, at which the maximal amplitude of response was registered from the abductor hallucis muscle.” Ex. 1004, 481.

With respect to claim 4, Svihra expressly discloses that “[s]urface stimulation of 30 minutes duration was repeated once a week for a period of 5 weeks.” Ex. 1004, 481.

With respect to claim 5, Svihra discloses that “*the maximal amplitude of response was registered* from the abductor hallucis muscle (stimulation by a constant voltage and regulated intensity of direct current.” Ex. 1004, 481 (emphasis added). Svihra also teaches that electrical stimulation was delivered to the electrodes *via* a Nicolet Viking IIE EMG device. *Id.* We agree with Petitioner that such a device is capable of measuring the electromyographic response of the contraction of the abductor hallucis muscle of the foot and displaying it. Indeed, and as Petitioner argues, we find, based on the current record, that the device must *necessarily* have displayed such a response for the operator to have been able to determine the maximal amplitude of response of the muscle contraction.

Based upon the record presently before us, we conclude that Petitioner has sufficiently demonstrated that it is more likely than not that Svihra anticipates challenged claims 3–5 of the ’943 patent.

f. Summary

Based upon the record presently before us, we conclude that Petitioner has established that Svihra more likely than not anticipates challenged claims 1 and 3–5 of the '943 patent that are challenged upon Ground 1.

Furthermore, because we determine that Petitioner has demonstrated that it is more likely than not that at least one claim is unpatentable on at least one of the stated Grounds, we institute post-grant review of all challenged claims of the '943 patent, based on all of the remaining grounds identified in the Petition. *See* 37 C.F.R. § 42.208(a); *SAS Inst., Inc. v. Iancu*, 584 U.S. 357, 371 (2018); *PGS Geophysical AS v. Iancu*, 891 F.3d 1354, 1360 (Fed. Cir. 2018) (interpreting the statute to require “a simple yes-or-no institution choice respecting a petition, embracing all challenges included in the petition”). Nevertheless, we provide our preliminary views with respect to remaining Grounds 2–11 below, based upon the parties’ arguments and the evidence of record as presently developed.

E. Ground 2: Alleged obviousness of claims 2 and 6–13 over Svihra

1. Principles of law

A patent claim is unpatentable under 35 U.S.C. § 103 if “the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention 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 determining obviousness when all elements of a claim are found in various pieces of prior art, “the factfinder must further consider the factual questions of whether a person of ordinary skill in the art would be motivated to combine those references, and whether in making that combination, a person of ordinary skill would have had a reasonable expectation of success.” *Dome Patent L.P. v. Lee*, 799 F.3d 1372, 1380 (Fed. Cir. 2015); *see also WMS Gaming, Inc. v. Int’l Game Tech.*, 184 F.3d 1339, 1355 (Fed. Cir. 1999) (“When an obviousness determination relies on the combination of two or more references, there must be some suggestion or motivation to combine the references.”). “Both the suggestion and the expectation of success must be founded in the prior art, not in the applicant’s disclosure.” *In re Dow Chemical Co.*, 837 F.2d 469, 473 (Fed. Cir. 1988); *see also In re Magnum Oil Tools Int’l, Ltd.*, 829 F.3d 1364, 1381 (Fed. Circ. 2016) (finding 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”) (internal quotations and citations omitted).

An obviousness analysis “need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” *KSR*, 550 U.S. at 418; *see In re Translogic Tech*,

Inc., 504 F.3d 1249, 1259 (Fed. Cir. 2007). In *KSR*, the Supreme Court also stated that an invention may be found obvious if trying a course of conduct would have been obvious to a person of ordinary skill in the art:

When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103.

550 U.S. at 421. “*KSR* affirmed the logical inverse of this statement by stating that § 103 bars patentability unless ‘the improvement is more than the predictable use of prior art elements according to their established functions.’” *In re Kubin*, 561 F.3d 1351, 1359–60 (Fed. Cir. 2009) (citing *KSR*, 550 U.S. at 417).

Claims 2 and 6–13 depend, directly or indirectly, from independent claim 1. Petitioner argues that these dependent claims are obvious variations of the allegedly anticipated independent claim 1.

2. Petitioner’s arguments

a. Dependent claims 2 and 6–13

i. Claim 2

Claim 2 depends from claim 1 and recites “wherein non-invasively positioning comprises positioning an electrode patch in communication with the electrical stimulator near an ankle of the patient.” Ex. 1001, col. 70, ll. 20–23.

Petitioner argues that Svihra discloses the use of “surface electrodes” in the electrostimulation procedure, which a skilled artisan would have

interpreted as referring to an “electrode patch,” which was well known in the art. Pet. 26 (citing Ex. 1004, 481; Ex. 1003 ¶ 76; Ex. 1024, 234; Ex. 1025; Ex. 1026; Ex. 1027, 24; Ex. 1003 ¶ 77). Petitioner alternatively argues that it would have been obvious to try to use known “electrode patches” given the finite number of types of electrodes that could be used in electrical stimulation procedures. *Id.* at 27 (citing Ex. 1003 ¶ 78).

ii. Claim 6

Claim 6 recites “detecting for a lack of presence of electrical conduction at a second portion of the patient’s body distant from the first portion as an indicator of electrode migration from the first portion.” Ex. 1001, col. 70, ll. 36–38. Petitioner argues that a person of ordinary skill in the art would have interpreted claim 6 to encompass detecting for the presence or lack of presence of electrical conduction using techniques such as EMG based on the claim language and Specification. Pet. 27 (citing Ex. 1003 ¶ 79). Petitioner contends that detecting for the presence or lack of presence of electrical conduction, as recited in claim 6, therefore refers to detection techniques such as EMG. *Id.* (citing Ex. 1003 ¶ 79–80).

Petitioner argues that Svihra discloses the use of an EMG device to measure the amplitude of response from the muscle. Pet. 30 (citing Ex. 1004, 481). According to Petitioner, even if Svihra did not expressly state the EMG results were used to detect for the presence or lack of presence of electrical conduction, a person of ordinary skill in the art would have found it obvious based on the knowledge in the art of EMG to modify Svihra’s procedure to detect for the presence or lack of presence of electrical conduction at a second portion of a patient’s body as an indicator of

electrode migration, electrode malfunction, and proper electrode placement.
Id. (citing Ex. 1003 ¶¶ 85, 90).

iii. Claim 7

Claim 7 recites “wherein detecting for the presence of electrical conduction comprises detecting via an electrode patch positioned upon the second portion.” Ex. 1001, col. 70, ll. 36–38.

Petitioner argues that claim 7 does not cover a novel or nonobvious feature of the alleged invention. Pet. 31. Petitioner points out that the ’943 patent expressly states that sensors can be used to detect for the presence of electrical conduction and that any known sensor can be used in the claimed method. *Id.* (citing Ex. 1001, col. 25, ll. 5–8, col 26, ll. 61–64; Ex. 1003 ¶ 91).

Petitioner notes that Svihra discloses the use of EMG to measure “the maximal amplitude of response [] registered from the abductor hallucis muscle.” Pet. 31 (quoting Ex. 1004, 481). Petitioner also contends that the ’943 patent discloses that various sensors/electrodes, including “electrode patches,” could be used for EMG. *Id.* (citing, e.g., Ex. 1003 ¶¶ 92–93; Ex. 1035, 188; Ex. 1036, col. 5, ll. 33–50; Ex. 1037, 736).

Alternatively, Petitioner argues, those of ordinary skill in the art would have found it obvious to modify Svihra’s procedure to use an “electrode patch” for detecting the presence of electrical conduction, which would have involved nothing more than simple substitution of known elements (i.e., substituting EMG electrodes for known “electrode patches”) or the predictable use of prior art elements according to established functions

(using known “electrode patches” as EMG electrodes). Pet. 32 (citing Ex. 1003 ¶ 94).

iv. Claim 8

Claim 8 recites “detecting for a lack of presence of electrical conduction at a second portion of the patient’s body distant from the first portion as an indicator of electrode malfunction from the first portion.” Ex. 1001, col. 70, ll. 39–42.

Petitioner notes that claim 8 is nearly identical to claim 6, except that it recites “an indicator of electrode malfunction” in place of “an indicator of electrode migration.” Pet. 32. Petitioner again argues that modifying Svihra to detect a lack of electrical conduction at a second portion of a patient’s body, via EMG, as an indicator of electrode migration, electrode malfunction, and proper electrode placement would have been obvious to a person of ordinary skill in the art. *Id.* at 33.

v. Claim 9

Claim 9 recites “wherein detecting for the presence of electrical conduction comprises detecting via an electrode patch positioned upon the second portion.” Ex. 1001, col. 70, ll. 43–45. Petitioner notes that claim 9 is nearly identical to claim 7, and would have been obvious to a skilled artisan for the same reasons. Pet. 33.

vi. Claim 10

Claim 10 recites “detecting for a lack of presence of electrical conduction at a second portion of the patient’s body distant from the first

portion as an indicator of proper electrode placement upon the first portion.”
Ex. 1001, col. 70, ll. 46–50. Petitioner argues that claim 10 is nearly identical to claim 6, and would have therefore been obvious to a skilled artisan for the same reasons. Pet. 33.

vii. Claim 11

Claim 11 recites “wherein detecting for the presence of electrical conduction comprises detecting via an electrode patch positioned upon the second portion.” Ex. 1001, col. 70, ll. 51–53. Petitioner argues that claim 11 is nearly identical to claim 7, and would have therefore been obvious to a skilled artisan for the same reasons. Pet. 34.

viii. Claim 12

Claim 12 recites “detecting for a lack of presence of electrical conduction through tissue at a second portion of the patient’s body distant from the first portion as an indicator of electrode placement upon the first portion.” Ex. 1001, col. 70, ll. 54–58. Petitioner argues that claim 12 is nearly identical to claim 6, and would have therefore been obvious to a skilled artisan for the same reasons. Pet. 34.

ix. Claim 13

Claim 13 recites “detecting for the presence of electrical conduction through tissue comprises detecting via an electrode patch positioned upon the second portion.” Ex. 1001, col. 70, ll. 54–58. Petitioner argues that claim 13 is nearly identical to claim 7, and would have therefore been obvious to a skilled artisan for the same reasons. Pet. 34.

3. Patent Owner's arguments

Patent Owner does not dispute the teachings of Svihra or the merits of Petitioner's arguments, arguing instead, as we explain in Section III.D.2 above, that Petitioner has failed to demonstrate that Svihra is a prior art printed publication. *See* Prelim. Resp. 2–6.

4. Analysis

We find persuasive, based upon the record as presently developed, Petitioner's arguments that claims 2 and 6–13 likely would have been obvious over Svihra. We consequently conclude that, in our preliminary view, and on the record as presently developed, Petitioner has demonstrated, for the purpose of this Decision, that it is more likely than not that Svihra renders obvious challenged claims 2 and 6–13 of the '943 patent.

F. Ground 3: Alleged obviousness of claims 14, 16–18, 27, and 29–31 over Svihra and Johnson

1. Overview of Johnson

Johnson relates to “a pulsed electrical stimulator for direct attachment onto a garment electrode, for providing electrical stimulation to nerve, muscle, skin, circulatory and/or other tissue of a human or animal subject.” Ex. 1007, 1. According to Johnson, the electrical stimulator is “adapted for direct attachment onto a garment electrode worn by the wearer, thereby eliminating the need for long wire leads extending from a belt-worn stimulator to a remote electrode position.” *Id.* at 3. Johnson teaches that “[t]he electrode may for example be a garment electrode such as a stocking, sleeve, wrap, glove, or other type of garment to be worn over one or more body parts of a human or animal subject.” *Id.*

The electrical stimulator and therapeutic garment connection system is depicted in Figure 1 of Johnson, which is reproduced below:

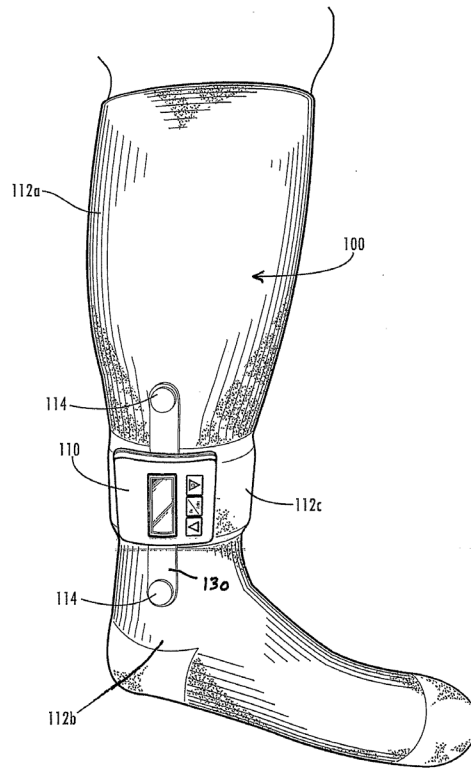


Fig. 1

Figure 1 of Johnson depicts the electrical stimulator and therapeutic garment connection system

Figure 1 shows a garment electrode 100, depicted as a stocking, having an electrical stimulator 110 directly attached thereto by a connector strap.

Ex. 1007, 6. According to Johnson:

[T]he garment electrode 100 preferably comprises a first conductive region 112a to apply therapeutic energy having a first electrical polarity, and a second conductive region 112b to apply energy with a second electrical polarity opposite the first polarity; with the first and second conductive regions 112a, 112b separated by a non-conductive region 112c.

Id. at 7.

2. Petitioner's arguments

a. Independent claim 14

Petitioner argues that Svihra teaches nearly all of the limitations of claim 14, with the exception that Svihra does not teach or suggest the limitation of claim 14 reciting “non-invasively positioning a first portion of a patient’s body near an ankle relative to an electrical stimulator positioned within a sock worn upon a foot of the patient.” Pet. 35. However, argues Petitioner, Johnson discloses electric stimulators and garment systems including electric stimulators “for direct attachment onto a garment electrode,” including socks, stockings, sleeves, wraps, gloves, or other types of garments. *Id.* at 37 (quoting Ex. 1007, 3, claim 4). Petitioner contends that Johnson also teaches attachment of electrodes *via* a “connector strap.” *Id.* at 37–38 (quoting Ex. 1007, 6; Ex. 1022, 4 (disclosing socks that “position electrically conductive patches correctly relative to the nerves to which electrical connection is made”)); Ex. 1003 ¶ 113).

b. Dependent claims 16–18, 27, and 29–31

i. Dependent claims 16–18

Petitioner argues that Svihra and Johnson teach or suggest all of the limitations of claim 14, and that, for the reasons provided above, Svihra teaches the additional limitations of claims 16–18. Pet. 36–37.

ii. Independent claim 27

Petitioner argues, as with independent claim 14, that Svihra teaches or suggests all of the limitations of claim 27, except the limitation reciting “non-invasively positioning a first portion of a patient’s body near an ankle

relative to an electrical stimulator *positioned upon a strap which is secured over a foot of the patient.*” Pet. 37–38 (emphasis added). As with claim 14, Petitioner argues that Johnson expressly teaches the use of a strap to secure the electrodes in position. *Id.* at 37–38 (citing Ex. 1007, 6; Ex. 1022, 4).

iii. Dependent claims 29–31

Petitioner argues that Svihra and Johnson teach or suggest all of the limitations of claim 27, and that, for the reasons provided above in Section III.E.2.a.iv, Svihra teaches the additional limitations of claims 29–31. Pet. 39.

3. Patent Owner’s arguments

Patent Owner does not dispute the teachings of Svihra or the merits of Petitioner’s arguments, arguing instead, as we explain in Section III.D.2 above, that Petitioner has failed to demonstrate that Svihra is a prior art printed publication. *See* Prelim. Resp. 2–6.

4. Analysis

We find, in our preliminary view, and on the record as presently developed, Petitioner’s arguments that claims 14, 16–18, 27, and 29–31 would have been obvious over the combination of Svihra and Johnson. We consequently conclude that Petitioner has demonstrated, for the purpose of this Decision, that it is more likely than not that Svihra and Johnson render obvious challenged claims 14, 16–18, 27, and 29–31 of the ’943 patent.

G. Ground 4: Alleged obviousness of claims 15, 19–26, 28, and 32–39 over Svihra, Johnson

1. Petitioner’s arguments

Petitioner argues that Svihra and Johnson, together with the knowledge of a person of ordinary skill in the art, teach or suggest all of the limitations of these dependent claims for the same reasons provided above with respect to dependent claims 2, 6, and 7, as shown in the Table below:

Claim(s)	For the reasons provided above for claim
15, 28	2
19, 21, 23, 25, 32, 34, 36, 38	6
20, 22, 24, 26, 33, 35, 37, 39	7

2. Patent Owner’s arguments

Patent Owner does not dispute the teachings of Svihra or the merits of Petitioner’s arguments, arguing instead, as we explain in Section III.D.2 above, that Petitioner has failed to demonstrate that Svihra is a prior art printed publication. *See* Prelim. Resp. 2–6.

3. Analysis

Because we find persuasive, based upon the record as presently developed, Petitioner’s arguments presented above with respect to claims 2, 6, and 7, we similarly conclude that dependent claims 15, 19–26, 28, and

32–39 likely would have been obvious over the combination of Svihra and Johnson and the knowledge of those of ordinary skill in the art. We consequently conclude that Petitioner has demonstrated, for the purpose of this Decision, that it is more likely than not that Svihra and Johnson render obvious challenged claims 15, 19–26, 28, and 32–39 of the '943 patent.

H. Ground 5: Alleged Anticipation of Claims 1–3 and 5 by Amarenco

1. Overview of Amarenco

Amarenco relates to urodynamic changes during acute posterior tibial nerve stimulation. Ex. 1005, 2210. In view of the result of improved bladder overactivity, Amarenco proposes posterior tibial nerve stimulation as a noninvasive treatment modality in clinical practice. *Id.*

Amarenco describes posterior tibial nerve stimulation used in the study as follows:

Stimulation was done using a self-adhesive surface stimulation electrode without an implanted needle electrode. Contact electrodes were placed with electrode gel on the ankle skin with the negative electrode behind the internal malleolus and the positive electrode 10 cm. above the negative electrode. The correct position of the negative electrode was determined by visualization of rhythmic flexion of the toes secondary to plantar muscle contraction during stimulation delivered at 1 hz. The intensity level was then chosen as the intensity immediately under the threshold determining motor contraction. In addition, no pain was to be noted during the stimulation procedure, which necessarily had to be comfortable for the patient. Stimulation frequency during cystometry was then applied at 10 Hz. and a pulse width of 200 milliseconds in continuous mode.

Ex. 1005, 2211. Amarenco concludes that posterior tibial nerve stimulation is a minimally invasive technique that can suppress detrusor instability or

hyperreflexia and the finding of improved bladder capacity further supports its use as a noninvasive treatment modality in clinical practice. *Id.* at 2214.

2. Petitioner's arguments

a. Claim 1

Petitioner asserts that Amarenco is directed to “acute tibial nerve stimulation in a population presenting with symptoms (urge incontinence and frequency) secondary to [OAB].” Pet. 44 (quoting Ex. 1005, 2210; Ex. 1003 ¶ 140). Petitioner argues that Amarenco discloses the use of “left [PTN] stimulation using a surface self-adhesive electrode on the ankle skin behind the internal malleolus with shocks in continuous mode at 10Hz. frequency and 200 milliseconds wide” and expressly states that the procedure was “non-invasive.” *Id.* at 44–45 (quoting Ex. 1005, 2210, 2214). Petitioner also contends that those of ordinary skill in the art would understand that the stimulation regime disclosed by Amarenco would necessarily require that the electrodes be connected to an electrical stimulator source. *Id.*

Petitioner further notes that Amarenco discloses that “[s]timulation frequency during cystometry was then applied at 10 Hz. and a pulse width of 200 milliseconds in continuous mode. This second cystometry during [PTN] stimulation was started immediately after determining the chosen stimulation.” Pet. 46 (citing Ex. 1005, 2211). Petitioner asserts that Amarenco therefore discloses delivery of electrical stimulus from an electrical stimulator through the electrodes to the PTN. *Id.* (citing Ex. 1003 ¶ 145).

b. Claim 2

Petitioner argues that Amarenco discloses the use of a “self-adhesive surface stimulation electrode” that was placed “on the ankle skin with the negative electrode behind the internal malleolus and the positive electrode 10 cm. above the negative electrode.” Pet. 47 (quoting Ex. 1005, 2211). Petitioner contends that a “self-adhesive surface stimulation electrode” is an “electrode patch,” as recited in claim 2. *Id.* (citing Ex. 1003 ¶ 147).

c. Claim 3

Petitioner argues that Amarenco discloses that “[t]he correct position of the negative electrode was determined by visualization of rhythmic flexion of the toes secondary to plantar muscle contraction during stimulation delivered at 1 hz.” Pet. 47 (quoting Ex. 1005, 2211). Petitioner contends that “flexion of the toes” and “muscle contractions” are muscular responses caused by Amarenco’s stimulation of the PTN. *Id.* (citing Ex. 1003 ¶ 148).

d. Claim 5

Petitioner argues that Amarenco discloses performing cystometry before and after PTN stimulation “with computerized analysis of results.” Pet. 47 (citing Ex. 1005, 2211). Petitioner points to Figures 3 and 4 of Amarenco, which depict EMGs, i.e., the measured and recorded electrical activity in response to muscle stimulation by a nerve. *Id.* at 48 (citing Ex. 1003 ¶ 149). Petitioner maintains that cystometry and EMG are “physiological parameters” detected from Amarenco’s patients and displayed, as shown in these Figures. *Id.* (citing Ex. 1003 ¶ 149).

3. Patent Owner's arguments

Patent Owner urges us, with respect to Grounds 5–8, to exercise our discretion under 35 U.S.C. § 325(d) to deny institution because:

“(i) Amarenco was previously presented and considered during prosecution of the ’943 Patent; (ii) Johnson was previously presented and considered during prosecution of the ’943 Patent; and (iii) the combination of Amarenco and Johnson was previously presented and considering during the prosecution of the ’943 Patent.” Prelim. Resp. 7. Patent Owner asserts that “Amarenco and Johnson—as well as the proposed combination thereof—were each presented to the Examiner during original prosecution through a Third-Party Submission under 37 C.F.R. § 1.290, which included a concise description of the relevance of Amarenco and Johnson.” *Id.* at 8 (citing Ex. 1002 at 148–153).

Briefly, Patent Owner argues that on May 15, 2023, during prosecution of the application that subsequently issued as the ’943 patent, the Office received a Third-Party Submission identifying Amarenco, Johnson, and one other reference not presently at issue.⁵ Prelim. Resp. 8 (citing Ex. 1002, 148). According to Patent Owner, the Third-Party Submission was made anonymously through a registered patent practitioner, but Patent Owner notes that Petitioner does not deny having been the real party-in-interest behind such submission. *Id.*

Patent Owner argues that Grounds 5–8 of the Petition duplicate the Third-Party Submission previously presented during prosecution. Prelim. Resp. 8. Patent Owner notes that the Third-Party Submission includes a

⁵ Rhodes (US 6,453,204 B1, September 17, 2002) (“Rhodes”) Ex. 1022.

claim chart identifying the same portions of Amarenco as Grounds 5–6 of the Petition, and a second claim chart identifying the same portions of the proposed Amarenco/Johnson combination as Grounds 7–8 in the Petition. *Id.* (comparing Pet. 44–47 with Ex. 1002, 149–150, also comparing Pet. 58–60 with Ex. 1002, 151–53).

The Examiner signed the acknowledgment entering the Third-Party Submission, indicating that “all documents listed above have been considered.” Ex. 1002, 16. Shortly thereafter, the claims were allowed on November 22, 2023 by the Examiner, and the ’943 patent issued on December 19, 2023 without any intervening Office Actions or further discussion of the Third-Party Submission.⁶ Ex. 1002, 5–10; Ex. 1001, code (45).

Patent Owner argues that there can be no genuine dispute, on this record, that “the same or substantially the same prior art or arguments previously were presented to the Office” as Grounds 5–8 of the Petition, within the meaning of 35 U.S.C. § 325(d), or that the Examiner merely overlooked the Third-Party Submission. Prelim. Resp. 9 (citing *Monolithic*

⁶ In the Allowance, the Examiner stated the following reasons for allowing the claims:

Regarding independent claims 1, 14, and 27, for a method non-invasively positioning a first portion of a patient’s body near an ankle relative to an electrical stimulator such that a posterior tibial nerve within the first portion of the body is directly targeted by the electrical stimulator, delivering electric stimulus to treat overactive bladder or incontinence has not been suggested or disclosed in the prior art when combined with the rest of the claim limitations of independent claim 1 and 14.

Ex. 1002, 30.

Power Sys., Inc. v. Volterra Semiconductor LLC, IPR2020-01348, Paper 19, 12 (PTAB Mar. 4, 2021)). Patent Owner therefore urges us to exercise our discretion and deny institution of Grounds 5–8 under 35 U.S.C. § 325(d).

4. Analysis

We agree with Petitioner that, based upon the record as currently developed, Amarenco likely anticipates challenged claims 1 and 3–5 of the '943 patent, for the reasons given by Petitioner.

Amarenco notes that “posterior tibial nerve stimulation has been used as a chronic treatment to improve urge incontinence and frequency” and is directed to a study of “detrusor activity modifications during acute tibial nerve stimulation in a population presenting with symptoms (urge incontinence and frequency) secondary to overactive bladder.”

Ex. 1005, 2210.

Amarenco discloses:

Stimulation was done using a self-adhesive surface stimulation electrode without an implanted needle electrode. Contact electrodes were placed with electrode gel on the ankle skin with the negative electrode behind the internal malleolus and the positive electrode 10 cm. above the negative electrode. The correct position of the negative electrode was determined by visualization of rhythmic flexion of the toes secondary to plantar muscle contraction during stimulation delivered at 1 hz. The intensity level was then chosen as the intensity immediately under the threshold determining motor contraction.... Stimulation frequency during cystometry was then applied at 10 Hz. and a pulse width of 200 milliseconds in continuous mode.

Ex. 1005, 2211.

We conclude that, based upon the record as presently developed, Petitioner has sufficiently demonstrated, for the purpose of this Decision,

that it is more likely than not that Amarenco anticipates challenged claim 1 of the '943 patent.

Patent Owner's request that we exercise our discretion under § 325(d) is not tenable. In deciding whether to exercise our discretion under § 325(d) in situations where only some of the challenges fall within its scope, we evaluate the challenges and determine whether § 325(d) is sufficiently implicated that its statutory purpose would be undermined by instituting on all challenges. If so, the panel will evaluate whether the entire petition should be denied." *See* USPTO, *SAS Q&As* (June 5, 2018) at D1, *available at*: https://www.uspto.gov/sites/default/files/documents/sas_qas_20180605.pdf; *see also* *Kansas State Univ. Res. Found.*, PGR2022-00021, Paper 11 at 7–8 & n.3 (Vidal Feb. 24, 2023) (holding that “the Board will further evaluate ... whether § 325(d) is sufficiently implicated that its statutory purpose would be undermined by instituting review on all challenges presented in the Petition”).

We having instituted post grant review based at least upon claim 1 of Ground 1 of the Petition. Even if the panel agreed with Patent Owner that Grounds 5–8 present “the same or substantially the same prior art or arguments” previously presented to the Office, § 325(d) would not be “sufficiently implicated” due to the 7 other asserted grounds. We therefore do not proceed with the § 325(d) analysis established in *Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 at 8 (PTAB Feb. 13, 2020) (precedential) and decline to exercise our discretion to deny the petition on that basis.

5. Summary

Based upon the record presently before us, we conclude that Petitioner has demonstrated that it is more likely than not that Amarenco anticipates challenged claims 1–3 and 5 of the '943 patent that are challenged upon Ground 5.

I. Ground 6: Alleged obviousness of claims 4 and 6–13 over Amarenco

Claims 4 and 6–13 depend, directly or indirectly, from independent claim 1. Petitioner argues that these dependent claims are obvious variations of the allegedly anticipated independent claim 1.

1. Petitioner's arguments

a. Claim 4

Petitioner argues that application of electrostimulation for 30 minutes per week for the treatment of OAB/incontinence was known in the art. Pet. 49 (citing Ex. 1004, 481; Ex. 1038, 915; Ex. 1039, 44; Ex. 1003 ¶¶ 151–152). Petitioner argues that although Amarenco does not expressly disclose multiple treatment sessions, it would have been obvious to modify Amarenco's teachings to apply electrical stimulation in 30 minute, weekly treatment sessions. *Id.* (citing Ex. 1003 ¶ 153).

b. Claim 6

Petitioner argues that a skilled artisan would have interpreted claim 6 to encompass detecting for the presence or lack of presence of electrical conduction using techniques such as EMG based on the claim language and specification. Pet. 49 (citing Ex. 1003 ¶¶ 154–159). Petitioner argues

further that EMG was a conventional technique for detecting the presence or lack of presence of electrical conduction at a second portion of a patient's body, and was commonly used during electrical stimulation procedures. *Id.* at 50 (citing Ex. 1003 ¶ 161; Ex. 1041, 119; Ex. 1028, 361; Ex. 1029, col. 1, ll. 45–63). Petitioner contends that Amarengo discloses the use of EMGs to measure the electrical activity and muscle response from patients. *Id.* at 51 (citing Ex. 1005, Figs. 3–4; Ex. 1003 ¶ 160).

c. Claim 7

Petitioner argues that Amarengo discloses the performance of EMG measurements. Pet. 52 (citing Ex. 1005, Figs. 3–4). Furthermore, Petitioner notes, and as the '943 patent acknowledges, prior art discloses various sensors/electrodes, including “electrode patches,” could be used for EMG. *Id.* (citing, e.g., Ex. 1003 ¶¶ 167–168; Ex. 1035, 188; Ex. 1036, col. 5, ll. 33–50; Ex. 1037, 736).

d. Claims 8, 10, and 12

Petitioner notes that claims 8, 10, and 12 are almost identical to claim 6, and advances the same arguments in support of the contention that claim 8 also would have been obvious for those reasons. Pet. 53–55.

e. Claims 9, 11, and 13

Petitioner argues that claims 9, 11, and 13 are almost identical to claim 7, and advances the same arguments in support of the contention that claims 9, 11, and 13 also would have been obvious for those reasons. Pet. 54–55.

2. Patent Owner's arguments

Patent Owner does not dispute the teachings of Amarenco or the merits of Petitioner's arguments, urging us instead, as we explained above in Section III.H.2.b, to exercise our discretion not to institute under 35 U.S.C. § 325(d). *See* Prelim. Resp. 7–11.

3. Analysis

We find persuasive, based upon the record as presently developed, Petitioner's arguments that claims 4 and 6–13 would have been obvious over Amarenco. We have also explained above why we are unable to grant Patent Owner's request to discretionarily deny institution of post-grant review under 35 U.S.C. § 325(d). We consequently conclude that Petitioner has demonstrated, for the purpose of this Decision, that it is more likely than not that Amarenco and the knowledge of a person of ordinary skill in the art likely render obvious challenged claims 4 and 6–13 of the '943 patent.

J. Ground 7: Alleged obviousness of claims 14–16, 18, 27–29, and 31 over Amarenco and Johnson

1. Petitioner's arguments

Petitioner's arguments mirror those presented by Petitioner with respect to Ground 3 in Sections III.F.2 and III.G.1 (for claim 15) above, i.e., that Amarenco discloses all of the limitations of independent claims 14 and 27 with the exception of the limitations reciting an electrical stimulator “positioned within a sock worn upon a foot of the patient” and “positioned upon a strap which is secured over a foot of the patient” in independent

claims 14 and 17, respectively. Pet. 57–60. And, as in Section III.F.2., Petitioner relies upon Johnson to cure these alleged deficiencies. *Id.*

With respect to dependent claims 15, 16, 18, 28, 29, and 31, Petitioner relies upon essentially the same arguments. Pet. 58, 60.

2. Patent Owner’s arguments

Patent Owner does not dispute the teachings of Amarenco and Johnson or the merits of Petitioner’s arguments, urging us instead, as we explained above in Section III.H.2.b, to exercise our discretion not to institute under 35 U.S.C. § 325(d). *See* Prelim. Resp. 7–11.

3. Analysis

We find persuasive, based upon the record as presently developed, Petitioner’s arguments that claims 14–16, 18, 27–29, and 31 would have been obvious over the combination of Amarenco and Johnson. We have also explained above why we are unable to grant Patent Owner’s request to discretionarily deny institution of post-grant review under 35 U.S.C. § 325(d). We consequently conclude that Petitioner has demonstrated, for the purpose of this Decision, that it is more likely than not that Amarenco and Johnson likely render obvious challenged claims 14–16, 18, 27–29, and 31 of the ’943 patent.

K. Ground 8: Alleged obviousness of claims 17, 19–26, 30, and 32–39 over Amarenco, and Johnson

1. Petitioner’s arguments

Petitioner’s arguments mirror those presented by Petitioner with respect to Ground 4 in Sections III.G.1 and III.F.2 (for claim 17) above.

Petitioner argues that Amerenco teaches the same limitations of the claims as Svihra, and that the combination of Amarenco and Johnson teaches all of the limitations of claims 19–26, 30, and 32–39. Pet. 61–65. With respect to claim 17, Petitioner argues that Svihra and the knowledge of a person of ordinary skill in the art would have rendered this claim obvious for the same reasons regarding claim 4. Pet. 61 (citing Ex.1003 ¶ 196; *see* Section III.I.1.a. above).

2. Patent Owner’s arguments

Patent Owner does not dispute the teachings of Amarenco and Johnson or the merits of Petitioner’s arguments, urging us instead, as we explained above in Section III.H.2.b, to exercise our discretion not to institute under 35 U.S.C. § 325(d). *See* Prelim. Resp. 7–11.

3. Analysis

We find persuasive, based upon the record as presently developed, Petitioner’s arguments that challenged claims 17, 19–26, 30, and 32–39 would have been obvious over the combination of Amarenco, Johnson, and the knowledge of those of ordinary skill in the art. We have also explained above why we are unable to grant Patent Owner’s request to discretionarily deny institution of post-grant review under 35 U.S.C. § 325(d). We consequently conclude that Petitioner has demonstrated, for the purpose of this Decision, that it is more likely than not that Amarenco, Johnson, and the knowledge of a person of ordinary skill in the art likely render obvious challenged claims 17, 19–26, 30, and 32–39 of the ’943 patent.

L. Ground 9: Alleged Anticipation of Claims 1–3 and 5–13 by Burnett

1. Overview of Burnett

Burnett⁷ relates to energy emitting apparatus and methods for providing a medical therapy. Ex. 1006 ¶ 2. Burnett is a published U.S. application related to the application from which the '943 patent issued. *Compare id.* at codes (21), (60), *with* Ex. 1001, codes (63), (60).

Burnett describes neuromodulation for OAB and UI patients by using a posterior tibial nerve stimulator, often referred to as SANS. Ex. 1006 ¶ 28. Burnett notes that this treatment is invasive in its nature, requiring the insertion of a needle five centimeters into the patient's ankle region in order to stimulate the posterior tibial nerve. *Id.*

Burnett discloses “apparatus and methods for treating a variety of ailments by providing energy to a target nerve, for example magnetic energy, electrical energy or ultrasound energy, at a location and in an amount optimized by detecting conduction in the target nerve.” Ex. 1006 ¶ 31. Burnett discloses:

[A]n energy emitting apparatus for delivering a medical therapy that includes one or more energy generators, a logic controller electrically connected to the one or more energy generators, and one or more sensors for detecting electric conduction in a target nerve, which are connected to the logic controller. The one or more energy generators produce energy focused on the target nerve upon receiving a signal from the logic controller, and the applied energy is varied by the logic controller according to an input provided by the one or more sensors based on electric conduction in the target nerve. The feedback provided by the sensors to the logic controller about the efficacy of the applied

⁷ Daniel R. Burnett is listed as an inventor on both Burnett and the '943 patent. *See* Ex. 1006, code (75); Ex. 1001, code (72).

treatment causes the logic controller to modulate the current transmitted to the coils.

Id. ¶ 32. Burnett also describes a device that “provides a targeted and precise stimulation of the posterior tibial nerve, or of other peripheral nerves, in a non-invasive manner by employing an ergonomic wrap or cradle that specifically targets the posterior tibial nerve in a consistent and repeatable manner.” *Id.* ¶ 89. This therapy does not require a major surgery to implant a permanent nerve stimulation device. *Id.* ¶ 90.

An apparatus for magnetic induction therapy is depicted in Figure 1 of Burnett, which is reproduced below:

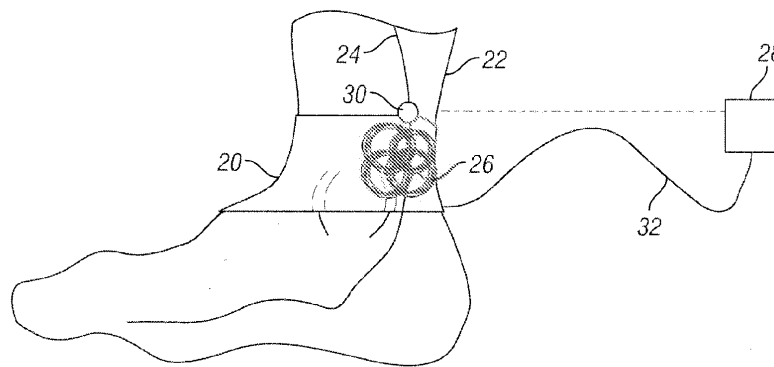


FIG. 1

Figure 1 of Burnett depicts an apparatus for magnetic induction therapy

Figure 1 shows a coil wrap 20 disposed over ankle 22 circumferentially to surround a portion of tibial nerve 24. Ex. 1006 ¶ 49. According to Burnett:

Coil wrap 20 contains one or more conductive coils 26 arranged to produce a pulsed magnetic field that will flow across tibial nerve 24 and generate a current that will flow along tibial nerve 24 and spread along the length of tibial nerve 24 all the way to its sacral or pudendal nerve root origins.

Id. ¶ 51. A programmable logic controller 28 supplies the electrical current that flows through coils 26 and produces the magnetic field. *Id.* ¶ 53.

Figure 1 also shows a sensor 30, whose purpose is “to detect and record the firing of the target nerve and to provide related information to logic controller 28, so to render the intended therapy most effective.” *Id.*

An apparatus for providing electrical energy for nerve stimulation is depicted in Figure 11 of Burnett, which is reproduced below:

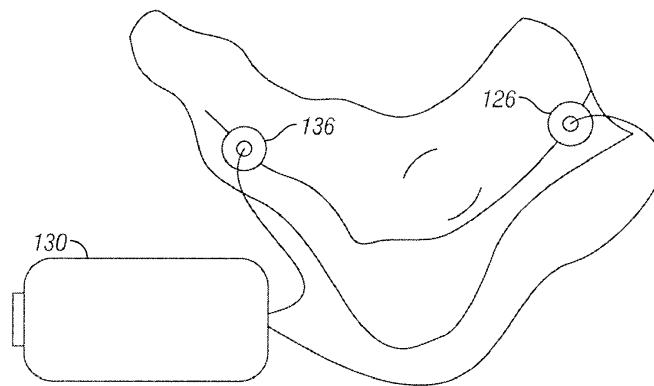


FIG. 11

Figure 11 of Burnett depicts an apparatus for providing electrical energy for nerve stimulation

Figure 11 shows a transcutaneous stimulator, such as an electrode 126, that dispenses electrical energy for nerve stimulation. Ex. 1006 ¶ 88. Electrical pulse controller 130 is connected to electrode 126 and to sensor 136. *Id.* According to Burnett, “nerve conduction may be detected at a site sufficiently distant from the site of stimulation, so to enable detection of nerve conduction despite the confounding interference from the direct electrical stimuli.” *Id.*

2. Petitioner's arguments

a. Claim 1

Petitioner argues that Burnett discloses treating OAB/urinary incontinence using “energy emitting apparatuses and methods.” Pet. 65 (citing Ex. 1006 ¶¶ 2, 89–90; Ex. 1003 ¶ 215). Specifically, Petitioner contends, Burnett discloses that “the source of energy for nerve stimulation is electrical energy that is dispensed through ... a transcutaneous stimulator, such as an electrode 126.” Pet. 66 (quoting Ex. 1006 ¶ 88). The energy emitting apparatus disclosed by Burnett is positioned “over ankle 22 ... to surround a portion of tibial nerve 24.” *Id.* (quoting Ex. 1006 ¶ 49; Ex. 1003 ¶ 216).

Petitioner further asserts that Burnett discloses:

[A]n electrical pulse controller **128** is electrically connected both to percutaneous needle **124** and to sensor **134**, to provide the desired feedback and modulate the power to percutaneous needle **134**. In the embodiment of FIG. **11**, electrical pulse controller **130** is connected both to electrode **126** and to sensor **136**, and performs a function similar to that of electrical pulse controller **128**.

Pet. 66 (quoting Ex. 1006 ¶ 88; citing Ex. 1003 ¶ 217). Petitioner states that Burnett also discloses that its invention “provides a targeted and precise stimulation of the posterior tibial nerve, or of other peripheral nerves, in a non-invasive manner by employing an ergonomic wrap or cradle that specifically targets the posterior tibial nerve in a consistent and repeatable manner.” *Id.* (quoting Ex. 1006 ¶ 89; citing Ex. 1003 ¶ 218).

b. Claim 2

Petitioner argues that Burnett discloses that “the source of energy for nerve stimulation is electrical energy that is dispensed through ... a transcutaneous stimulator, such as an electrode 126.” Pet. 67 (quoting Ex. 1006 ¶ 88; Ex. 1003 ¶ 219).

c. Claim 3

Petitioner argues that Burnett discloses that “detection of muscle contraction may also confirm that the target nerve is being stimulated and provide an indication to the patient or to a healthcare provider as to whether stimulation has been applied at an excessive level in view of the anatomical and physiological characteristics of the patient.” Pet. 67 (quoting Ex. 1006 ¶¶ 58, 35; citing Ex. 1003 ¶ 220).

d. Claims 5, 8, 10, and 12

Petitioner argues that Burnett discloses that its devices “detect a variety of physiologic changes, including neural impulses, muscular contraction, twitching, etc. that may occur with neural or muscular stimulation.” Pet. 67 (citing Ex. 1006 ¶ 80, 82). Petitioner argues that a skilled artisan would understand that Burnett’s sensors measure physiological parameters of a patient, and that the results would have been displayed in order to be useful to provide “the correct level of stimulation.” *Id.* (citing Ex. 1003 ¶ 221).

e. Claims 6, 9, 11, and 13

Petitioner argues that Burnett discloses that:

[T]he source of energy for nerve stimulation may be electrical energy and nerve conduction may be detected at a site sufficiently distant from the site of stimulation, so to enable detection of nerve conduction despite the confounding interference from the direct electrical stimuli. In these embodiments, direct electrical stimulation of nerve and muscle may be tailored to provide optimal therapy and, in the case of electrode migration or other electrode malfunction, to report lack of stimulation of the bodily tissues.

Pet. 68 (quoting Ex. 1006 ¶ 36; also citing *id.* ¶ 88; Ex. 1003 ¶ 222).

f. Claim 7

Petitioner contends that Burnett discloses that:

[S]ensor **54** may include a conductive electrode patch that provides a feedback to logic controller **56** for adjusting, if necessary, the stimulation parameters of coils **52**. Alternatively, sensor **54** may be a sensor patch that is either applied to the skin of the patient or is incorporated within the structure of cradle **48**.

Pet. 68–69 (quoting Ex. 1003 ¶ 67; Ex. 1003 ¶ 223).

3. Patent Owner’s arguments

Patent Owner simultaneously opposes Petitioner’s arguments with respect to both Grounds 9 and 10. Patent Owner challenges whether Burnett, which was published on December 11, 2008, is prior art under AIA 35 U.S.C. § 102(a)(1). Prelim. Resp. 11. Patent Owner argues that the earliest effective filing date of the ’943 patent claims is October 2, 2006, and therefore, Burnett is not prior art to the ’943 patent claims. *Id.*

Patent Owner disputes Petitioner’s assertion that “for purposes of this proceeding other than PGR eligibility, ... the earliest effective filing date of

the '943 Patent is September 20, 2010.” Prelim Resp. 12; *see* Pet. 14. Specifically, Patent Owner argues that the '943 patent, in its priority claims under 35 U.S.C. § 120, specifically and explicitly identifies the application (U.S. Application Ser. No. 11/866,329), that was later published as Burnett. Prelim. Resp. 11 (citing Ex. 1006, code (53)). Patent Owner points out that, in the same priority claims under 35 U.S.C. § 120, the '943 patent specifically and explicitly identifies, by serial number and filing date, several other applications that establish a continuous claim of priority to October 2, 2006. *Id.* (citing Ex. 1001, code (63)).

Patent Owner argues that Petitioner failed to note that U.S. Patent Application Ser. No. 13/840,936 (the “'936 Application”), in the chain of applications, also claims priority to several other applications. Prelim. Resp. 13. Specifically, Patent Owner argues that the '936 Application claims priority, through two intervening continuation-in-part applications (including the Burnett reference), to a provisional patent application filed October 2, 2006, as shown in the following reproduction of the first paragraph of the '936 Application as filed. *Id.*

According to Patent Owner, U.S. Provisional Patent Application Ser. No. 60/848,720 (the “'720 provisional application”) was filed October 2, 2006. Prelim. Resp 13 (citing Ex. 1044, 1). One year later, U.S. Patent Application Ser. No. 11/866,329 (the “'329 application”⁸) was filed on October 2, 2007, explicitly claiming priority benefit of the '720 provisional application in its first paragraph. *Id.* (citing Ex. 1048 ¶ 1). Patent Owner argues that, while the '329 application was still pending, U.S. Patent

⁸ The '329 application eventually issued as the Burnett reference. *See* Ex. 1006, code (21).

Application Ser. No. 12/508,529 (the “’529 application”) was filed July 23, 2009, expressly claiming priority to both the ’329 application and the ’720 provisional application. Prelim. Resp. 14 (citing Ex. 1047 ¶ 1).

Patent Owner contends that the ’720 provisional application, as well as each intervening application, which establish a continuous chain of priority to the ’720 provisional application, are specifically listed in both the ’943 patent and in its parent application. Prelim. Resp. 14. Therefore, argues Patent Owner, the ’943 patent “contains . . . a specific reference to the earliest filed application[s]” to which priority is claimed, as required by 35 U.S.C. § 120. *Id.* at 15. Patent Owner therefore contends that the earliest effective filing date of the claims is October 2, 2006. *Id.*

4. Analysis

a. Effective filing date

As an initial matter, we turn to the question of whether the Burnett reference is prior art under 35 U.S.C. § 102(a)(1) to the ’943 patent. Based on the current record, we disagree with Patent Owner’s position that the ’943 patent is entitled to claim the priority benefit of the October 2, 2006 filing date of the ’720 provisional application. To assist the reader, we reproduce below the following diagram from page 15 of the Petition.

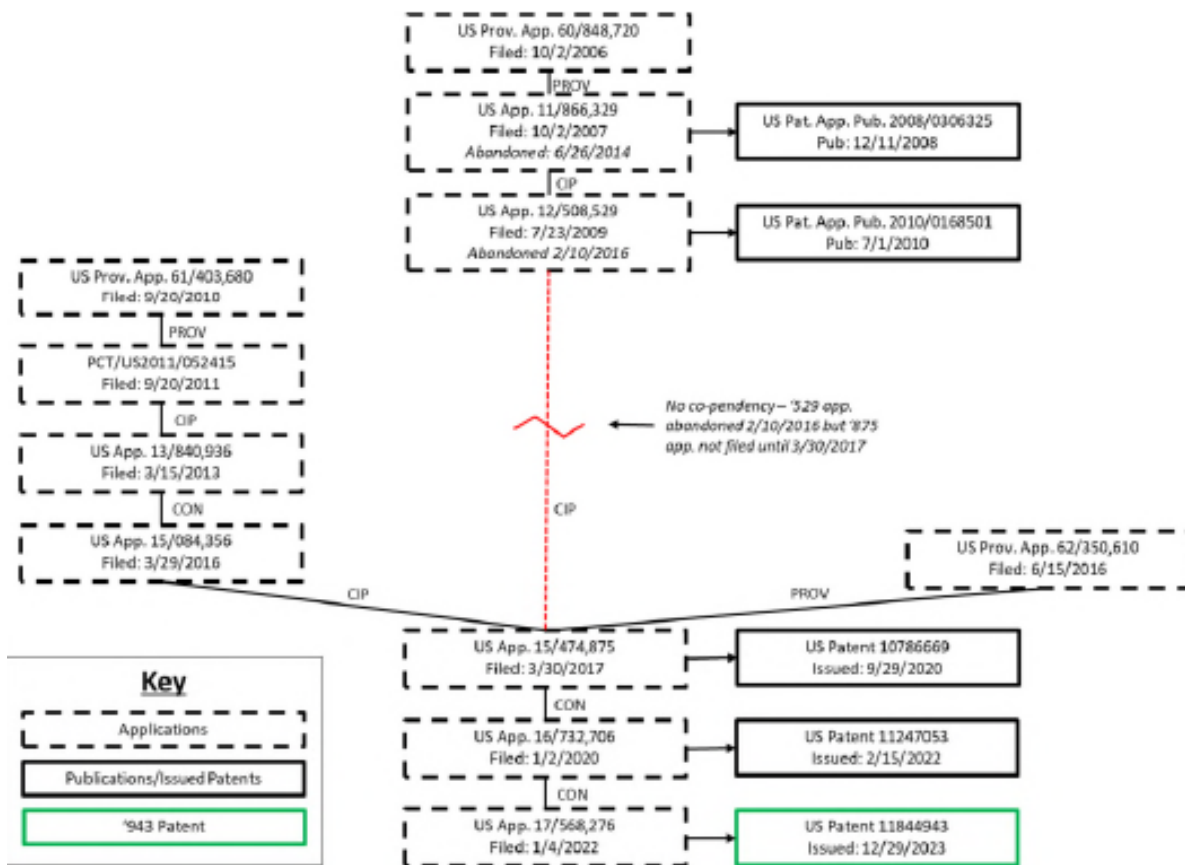


Diagram illustrating the “family tree” of the ’943 patent (depicted at lower right)

We agree with Patent Owner that the ’943 patent expressly claims the priority benefit of the ’720 provisional application (at top center). *See* Ex. 1001, code (60) (listing “provisional application No. 5,995,873, filed on Oct. 2, 2006”). However, simply to claim the priority benefit of an earlier application is not necessarily to receive it. *See In re NTP, Inc.*, 654 F.3d 1268, 1276 (Fed. Cir. 2011) (holding that “a patent’s claims are not entitled to an earlier priority date merely because the patentee claims priority.... Rather, for a patent’s claims to be entitled to an earlier priority date, the patentee must demonstrate that the claims meet the requirements of 35 U.S.C. § 120.”). As the diagram shows (and as we have verified), the ’529 application was a continuation-in-part of the preceding ’329 application. *See*

Ex. 1001, code (63). However, the '529 application was abandoned on February 10, 2016 (*See* Ex. 1052), and the succeeding application, U.S. Patent Application Ser. No. 15,474,875 (the "'875 application") which is listed in the '943 patent as being a continuation-in-part of the '529 application, was not filed until March 30, 2017. *See* Ex. 1001, code (63) (stating that "said application No. 15/474,875 is a continuation-in-part of application No. 12/508,529"). Put simply, the '875 application was not filed until over a year after the '529 application was abandoned.

As 35 U.S.C. § 120 states, in relevant part:

An application for patent for an invention disclosed in the manner provided by section 112(a) (other than the requirement to disclose the best mode) in an application previously filed in the United States, or as provided by section 363 or 385, which names an inventor or joint inventor in the previously filed application shall have the same effect, as to such invention, as though filed on the date of the prior application, *if filed before the patenting or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the filing date of the first application* and if it contains or is amended to contain a specific reference to the earlier filed application.

(emphasis added). In other words, if there is a "break in the chain" of priority caused by the abandonment or termination of an application claiming priority prior to filing of a subsequent application, the subsequent application loses the priority benefit of the abandoned or terminated application, as well as the priority benefit of all applications that antedate that abandoned or terminated application.

Such is the case presently before us. Based on the current record, we are persuaded that the abandonment of the '529 application prior to filing of the continuation-in-part '875 application broke the priority chain leading to

the '720 provisional application, and the '943 patent cannot, therefore, claim the priority benefit of the '720 provisional application's October 2, 2006 filing date.

Consequently, the earliest date of which the '943 patent could possibly claim the priority benefit is that of U.S. Patent Provisional Application Ser. No. 61/403,680 (the "'680 provisional application") (located at the top of the left branch of the "family tree" depicted above), which has a filing date of September 20, 2010. *See* Ex. 1001, code (60). Burnett (i.e., the '329 application) was filed on October 2, 2007 and thus antedates the '680 provisional application. Consequently, Patent Owner's argument fails based on the current record, and Burnett is prior art to the '943 patent.

Having established sufficiently, for the purpose of this Decision, that Burnett is prior art to the '943 patent, we next turn to the question of whether Petitioner has met its burden of showing that Burnett more likely than not anticipates challenged claims 1–3 and 5–13 of the '943 patent.

b. Anticipation

We find persuasive, based upon the record as presently developed, Petitioner's arguments that challenged claims 1–3 and 5–13 are likely anticipated by Burnett. We consequently conclude that Petitioner has demonstrated, for the purpose of this Decision, that it is more likely than not that Burnett anticipates claims 1–3 and 5–13 of the '943 patent.

M. Ground 10: Alleged obviousness of claims 4 and 14–39 over Burnett, Johnson

Challenged claims 14 and 27 are independent. Challenged claim 4 depends from independent claim 1; challenged claims 15–26 depend, directly or indirectly, from independent claim 14; and challenged claims 28–31 depend, directly or indirectly, from independent claim 27.

1. *Petitioner’s arguments*

a. Independent claims 14 and 27

Petitioner’s arguments are substantially the same as those presented for Grounds 3 and 7 above. Petitioner argues that Burnett, like Svihra and Amarenco, teaches all of the limitations of claim 1. Pet. 70. Petitioner argues that Burnett teaches “[t]he inductive magnetic pulses continue for an appropriate duration of use, for example, for 15–30 minutes, and notes that application of electrostimulation for 30 minutes per week for the treatment of OAB/incontinence was known in the art. *Id.* (citing Ex. 1006 ¶ 102; Ex. 1004, 481; Ex. 1038, 915; Ex. 1039, 44; Ex. 1003 ¶¶ 231–32”).

Petitioner argues that Burnett further teaches all of the limitations of independent claims 14 and 27, except for the limitations reciting that the stimulating electrodes are “positioned within a sock worn upon a foot of the patient” (claim 14) or “positioned upon a strap which is secured over a foot of the patient” (claim 27). *See* Pet. 70–72, 75–76. As above, Petitioner argues that Johnson, and the knowledge of those of ordinary skill in the art, cure these alleged deficiencies, and that a skilled artisan would have been motivated to combine the teachings of the references with a reasonable expectation of success. *Id.*

b. Dependent claim 4

Petitioner argues that Burnett teaches “[t]he inductive magnetic pulses continue for an appropriate duration of use, for example, for 15–30 minutes.” Pet. 70 (citing Ex. 1006 ¶ 102). Petitioner also asserts that the application of electrostimulation for 30 minutes per week for the treatment of OAB/UI was well known in the art. *Id.* (citing Ex. 1004, 481; Ex. 1038, 915; Ex. 1039, 44; Ex. 1003 ¶¶ 231–232). Petitioner therefore argues that it would have been obvious to modify Burnett’s teachings to apply electrical stimulation in 30-minute, weekly treatment sessions. *Id.* (citing Ex. 1003 ¶ 223).

c. Dependent claims 15–26 and 28–39

Petitioner asserts that, for the same reasons asserted in the previous Grounds of the Petition, the combination of Burnett and Johnson and the knowledge of those of ordinary skill in the art renders these dependent claims obvious. Pet. 72–74, 76–79. Petitioner argues that Burnett, like Svihra and Amarenco, discloses the additional limitations of these claims. *Id.*

2. Patent Owner’s arguments

Patent Owner does not dispute the teachings of Amarenco and Johnson or the merits of Petitioner’s arguments, urging us instead, as we explained above in Section III.H.2.b, to exercise our discretion not to institute under 35 U.S.C. § 325(d). *See* Prelim. Resp. 7–11.

3. Analysis

For the same reasons set forth with respect to Grounds 2–4 and 6–8 above, and based upon the record as presently developed, we agree with Petitioner that claims 4 and 14–39 would more likely than not have been obvious over Burnett and Johnson. We consequently conclude that, based upon the record as presently developed, Petitioner has sufficiently demonstrated, for the purpose of this Decision, that it is more likely than not that Burnett, Johnson and the knowledge of a person of ordinary skill in the art render obvious challenged claims 4 and 14–39 of the '943 patent.

N. Ground 11: Claims 1–39 Lack of Enablement

1. Petitioner's arguments

Petitioner argues that the claims of the '943 patent “lack enablement because the specification teaches against a key aspect of all the claims—positioning an electrical stimulator ‘near an ankle’ of the patient.” Pet. 80. Specifically, Petitioner contends that, although the '943 patent Specification indicates that electrical stimulation can be safely applied across a “glabrous surface” (such as the palm of the hand or bottom of the foot), the patent clearly indicates that applying electrical stimulation to a “non-glabrous surface” (such as the “medial malleolus” or inner ankle) is painful, impractical, and not feasible. *Id.* (citing Ex. 1001, cols. 50–51, ll. 35–3; Ex. 1003 ¶ 271).

According to Petitioner, the '943 patent's express statements that electric stimulation should not be applied at non-glabrous surfaces such as a patient's ankle teaches against the claimed invention. Pet. 81 (citing Ex. 1003 ¶¶ 272–73). Petitioner contends that the claims require “non-

invasively positioning a first portion of a patient's body near an ankle relative to an electrical stimulator.” *Id.* (citing, e.g., Ex. 1001, claims 1, 14, 27). However, argues Petitioner, the disclosures of the '943 patent Specification warning that electrically stimulating a non-glabrous skin surface, e.g., a site near a patient's ankle, discourages experimentation with electrical stimulation at such sites on a patient's body. *Id.* (citing *AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1244 (Fed. Cir. 2003)). Therefore, Petitioner contends, because a significant, undue amount of experimentation would have been required to practice the claimed invention, the claims of the '943 patent are more likely than not unpatentable for lack of enablement. *Id.* (citing Ex. 1003 ¶¶ 272–273).

2. Patent Owner's arguments

Patent Owner responds that Petitioner's enablement challenge fails because Petitioner has not shown, as required, that practicing the claimed inventions would require “undue experimentation.” Prelim. Resp. 20 (citing *In re Vaeck*, 947 F.2d 488, 495 (Fed. Cir. 1991)).

Patent Owner argues that Petitioner focuses exclusively on portions of the '943 patent Specification that Petitioner argues discourage utilizing purely electrical stimuli within a certain frequency range (e.g., “about 5 Hz to about 60 Hz or greater”) to stimulate nerves through certain skin surfaces (e.g., “non-glabrous skin surfaces”). Prelim. Rep. 20–21. Patent Owner contends that no claim of the '943 patent recites particular frequency ranges or particular types of skin surfaces and, furthermore, that the '943 patent claims, on their face and absent any claim construction, do not preclude the application of electromagnetic stimuli, which the Specification explicitly

contemplates as being acceptable within and with these frequencies and skin types. *Id.*

Patent Owner contends that neither Petitioner nor Petitioner's declarant attempts to show that undue experimentation would be required to practice the challenged claims. Prelim. Resp. 21. Patent Owner notes that there is no genuine dispute that a person of ordinary skill in the art could, based on the '943 patent Specification, practice the claimed inventions, even the embodiments that Petitioner asserts are inadvisable. *Id.* Patent Owner points out, by way of example, that Petitioner's declarant does not state that he tried, but failed, to practice the claims with the frequencies and skin types supposedly discouraged in the Specification. *Id.* at 22.

According to Patent Owner, this is a case in which a patent claims methods of treatment that do not recite particular frequency ranges or skin types and may therefore be practiced with various frequency ranges and with various skin types, all of which are disclosed in the Specification. Prelim. Resp. 22. Patent Owner contends that, at most, certain frequency ranges and skin types that could be used to practice the invention are discouraged in the Specification. *Id.* Patent Owner notes that the record suggests that the inventors of the '943 patent were the first to recognize the advantages and disadvantages of certain frequency ranges for certain stimuli as applied to certain skin types, an assertion not contradicted by Petitioner or its declarant. *Id.* Patent Owner asserts that, although Petitioner reads portions of the Specification of the '943 patent to discourage certain embodiments, Petitioner never shows that undue experimentation would be required to practice such embodiments, even if discouraged. *Id.* at 22–23.

3. Analysis

Section 112 requires that the patent specification enable “those skilled in the art how to make and use the full scope of the claimed invention without ‘undue experimentation’” in order to extract meaningful disclosure of the invention and, by this disclosure, advance the technical arts.

Invitrogen Corp. v. Clontech Laboratories, Inc., 429 F.3d 1052, 1070 (Fed. Cir. 2005) (citing *Koito Mfg. Co., Ltd. v. Turn-Key-Tech, LLC*, 381 F.3d 1142, 1155 (Fed. Cir. 2004) (quoting *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1365 (Fed. Cir. 1997))). Furthermore:

The scope of [patent] claims must be less than or equal to the scope of the enablement. The scope of enablement, in turn, is that which is disclosed in the specification plus the scope of what would be known to one of ordinary skill in the art without undue experimentation.

Nat’l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc., 166 F.3d 1190, 1196 (Fed. Cir. 1996); *see also In re Goodman*, 11 F.3d 1046, 1050 (Fed. Cir. 1993) (holding that “the specification must teach those of skill in the art ‘how to make and how to use the invention as broadly as it is claimed’”). Furthermore, “the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art.” *In re Fisher*, 427 F.2d 833, 839 (C.C.P.A. 1970).

Based upon the evidence of record, as presently developed, we are not persuaded that Petitioner has sufficiently demonstrated that it is more likely than not that the challenged claims of the ’943 patent are not enabled by the disclosures of the Specification. We agree with Petitioner that, in certain passages, the Specification expressly discourages the presentation of

electrical stimuli, at certain intensities and frequencies, upon non-glabrous (i.e., hairy) skin:

In contrast, utilizing an electrical stimulus having a frequency of about 5 Hz to about 60 Hz or greater to stimulate a target nerve or tissue through a non-glabrous skin surface (via an electrode positioned over the non-glabrous skin surface) is intolerable and painful, resulting in burns or injury, and thus making such a procedure impractical and not feasible.

For example, delivering electrical stimulation through a non-glabrous surface of the body, for example, by stimulating a site overlying a nerve near the medial malleolus to elicit a motor response of the abductor hallucis longus, generates a painful shock to the patient. While at a single pulse, such as in the use for EMG diagnostics, such electrical stimulation may be tolerable, as the frequency increases, the shocking sensation builds and quickly becomes painful and intolerable.

Ex. 1001, cols. 50–51, ll. 35–3.

Nevertheless, in other disclosures, the '943 patent Specification teaches:

Energy delivered transdermally, through, or across a patient's skin at a frequency from about 1 Hz to about 30 Hz, or at a frequency of less than 10 Hz has unexpectedly been found to stimulate or generate motor and/or sensory conduction in a target nerve. For example, energy delivered transdermally, through, or across a patient's skin at about 1 Hz to about 30 Hz, or at less than 10 Hz has unexpectedly been found to stimulate or generate motor and/or sensory nerve conduction of a tibial nerve, where such level of stimulation may be sufficient to treat a patient suffering from urinary incontinence, overactive bladder, fecal incontinence or other conditions. *The energy may be delivered through or across a glabrous skin surface or non-glabrous skin surface or any other skin surface (e.g., any skin surface overlying a tibial nerve).*

Ex. 1001, col. 49, ll. 26–40 (emphasis added). The source of the “energy” recited in the preceding passage is described by the ’943 patent Specification as:

An energy emitting device may be positioned in proximity to or over a skin surface overlying a target nerve or tissue. The energy emitting device may include any of the devices, systems or applicators described herein and/or illustrated in any of the various FIGS. 1–49, e.g., an electrode or applicator for delivering electrical stimulation or an applicator for providing electromagnetic or magnetic stimulation or induction therapy.

Id. at col. 49, ll. 10–17.

The ’943 patent Specification thus discloses that electrical, electromagnetic, or magnetic stimulation or induction therapy can be safely applied at frequencies of less than 10 Hz and can be safely delivered transdermally across either glabrous or non-glabrous skin in the vicinity of PTN near the ankle of a patient.

Against these disclosures, and on the record as presently developed, we find that, for the purpose of this Decision, Petitioner’s argument that the Specification does not teach those skilled in the art how to make and use the full scope of the claimed inventions without undue experimentation would likely not be persuasive at trial. We consequently conclude that, on the evidence of record at this stage of the proceeding, Petitioner has failed to establish that it is more likely than not that any claim in Ground 11 is unpatentable for lack of enablement. Nevertheless, because we find that Petitioner has sufficiently demonstrated that at least one of the challenged claims of the ’943 patent would more likely than not be unpatentable, we institute post-grant review. *See SAS*, 584 U.S. at 371; *see also PGS*, 891 F.3d at 1360; 37 C.F.R. § 42.208(a).

IV. CONCLUSION

For the reasons we have explained, we conclude that Petitioner has established a sufficiently persuasive showing that it is more likely than not the cited prior art references anticipate or render obvious at least one claim of the '943 patent, as set forth in at least one of the asserted Grounds 1–10. 35 U.S.C. § 324. We consequently institute post-grant review of the challenged claims of the '943 patent on all Grounds set forth in the Petition.

V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED, pursuant to 35 U.S.C. § 324(a), that the Petition for post-grant review of the challenged claims of U.S. Patent 11,844,943 B2 is GRANTED with respect to all grounds in the Petition; and

FURTHER ORDERED that post-grant review is instituted.

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Patent 11,844,943 B2

For PETITIONER:

Todd Tucker
Kyle Deighan
CALFEE, HALTER & GRISWOLD LLP
ttucker@calfee.com
kdeighan@calfee.com

For PATENT OWNER:

David Gerasimow
The Law Offices of David A. Gerasimow, P.C.
dave@gerasimowlaw.com

Eran Steinberg
venture@erasteinberg.com