

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Avation Medical, Inc.,
Petitioner

v.

EMKinetics, Inc.,
Patent Owner

Case No. PGR2024-00043
U.S. Patent No. 11,844,943

**PETITION FOR POST GRANT REVIEW
OF U.S. PATENT NO. 11,844,943**

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EXHIBIT LIST

Exhibit No.	Description
1001	U.S. Patent No. 11,844,943 (“’943 patent”)
1002	File History of U.S. Patent No. 11,844,943 (“’943 patent file history”)
1003	Declaration of Dr. Brett Wingeier in Support of Petition for Post Grant Review of U.S. Patent No. 11,844,943 (“Wingeier Decl.”)
1004	J. Svihra <i>et al.</i> , “Neuromodulative treatment of overactive bladder – noninvasive tibial nerve stimulation,” <i>Bratisl Lek Listy</i> 103(12):480-483 (2002) (“Svihra”)
1005	G. Amarenco <i>et al.</i> , “Urodynamic Effect of Acute Transcutaneous Posterior Tibial Nerve Stimulation in Overactive Bladder,” <i>J. Urology</i> 169: 2210-2215 (2003) (“Amarenco”)
1006	U.S. Patent App. Pub. 2008/0306325 to Burnett <i>et al.</i> (“Burnett”)
1007	Int’l App. Pub. No. WO 2004/108209 to Johnson (“Johnson”)
1008	G. Willy Davila & Minda Neimark, “The Overactive Bladder: Prevalence and Effects on Quality of Life,” <i>Clinical Obstetrics and Gynecology</i> 45(1):173-181 (2002) (“Davila”)
1009	Alan J. Wein & Eric S. Rovner, “Definition and Epidemiology of Overactive Bladder,” <i>Urology</i> 60(Suppl 5A):7-12 (2002) (“Wein”)
1010	Paul Abrams <i>et al.</i> , “Overactive Bladder Significantly Affects Quality of Life,” <i>The American Journal of Managed Care</i> 6(11, Sup.):580-590 (2000) (“Abrams”)
1011	Neeral Kohli & Peter L. Rosenblatt, “Neuromodulation Techniques for the Treatment of the Overactive Bladder,” <i>Clinical Obstetrics and Gynecology</i> 45(1):218-232 (2002) (“Kohli”)
1012	Floor van der Pal <i>et al.</i> , “Current opinion on the working mechanisms of neuromodulation in the treatment of lower urinary tract dysfunction,” <i>Current Opinion in Urology</i> 16(4):261-267 (2006) (“van der Pal”)
1013	Francisco Velasco, “Neuromodulation: An Overview,” <i>Archives of Medical Research</i> 31(3):232-236 (2000) (“Velasco”)

Exhibit No.	Description
1014	J. Groen & J.L.H.R. Bosch, “Neuromodulation techniques in the treatment of the overactive bladder,” 87(8):723-731 (2001) (“Groen”)
1015	Marshall L. Stoller, “Afferent Nerve Stimulation for Pelvic Floor Dysfunction,” <i>Scientific Non Discussion Poster Session</i> 16(257):256 (1999) (“Stoller”)
1016	M. Queralto <i>et al.</i> , “Preliminary results of peripheral transcutaneous neuromodulation in the treatment of idiopathic fecal incontinence,” <i>International Journal of Colorectal Disease</i> 21(2006):670-672 (2006) (“Queralto”)
1017	F. Monti <i>et al.</i> , “Peripheral neuromodulation using surface electrode for treatment of overactive bladder (oab): initial experience,” <i>Clinical Neurophysiology</i> 117(2006):243 (2006) (“Monti”)
1018	U. S. Patent No. 10,786,669 to Rajguru <i>et al.</i> (“‘669 patent”)
1019	U.S. Patent Application No. 15/474,875 to Rajguru (“‘875 application”)
1020	U.S. Patent Application No. 16/732,706 to Rajguru <i>et al.</i> (“‘706 application”)
1021	U.S. Patent No. 11,247,053 to Rajguru (“‘053 patent”)
1022	U.S. Patent No. 6,453,204 to Rhodes (“Rhodes”)
1023	U.S. Patent Application No. 15/084,356 to Rajguru <i>et al.</i> (“‘356 application”)
1024	L. Zhang & D.P. Rabussay, “Clinical evaluation of safety and human tolerance of electrical sensation induced by electric fields with non-invasive electrodes,” <i>Bioelectrochemistry</i> 56(1-2):233-236 (2002) (“Zhang”)
1025	U.S. Patent No. 6,341,236 to Osorio <i>et al.</i> (“‘236 patent”)
1026	U.S. Patent App. Pub. No. 2007/0021803 to Deem <i>et al.</i> (“‘803 application”)
1027	Katherine N. Moore, “Treatment of Urinary Incontinence in Men with Electrical Stimulation: Is Practice Evidence-Based?,” <i>Journal</i>

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	<i>of Wound, Ostomy and Continence Nursing</i> 27(1):20-31 (2000) (“Moore”)
1028	Hermie J. Hermens <i>et al.</i> , “Development of recommendations for SEMG sensors and sensor placement procedures,” <i>Journal of Electromyography and Kinesiology</i> 10(5):361-374 (2000) (“Hermens”)
1029	U.S. Patent No. 8,206,312 to Farquhar (“’312 patent”)
1030	S. Tahseen Hasan <i>et al.</i> , “Transcutaneous Electrical Nerve Stimulation and Temporary S3 Neuromodulation in Idiopathic Detrusor Instability,” <i>The Journal of Urology</i> 155(6):2005-2011 (1996) (“Hasan”)
1031	U.S. Patent App. Pub. No. 2005/0075670 to Bengtsson (“’670 publication”)
1032	U.S. Patent App. Pub. No. 2007/0276449 to Gunter <i>et al.</i> (“’449 publication”)
1033	U.S. Patent No. 7,801,603 to Westlund <i>et al.</i> (“’603 patent”)
1034	U.S. Patent No. 8,712,546 to Kim <i>et al.</i> (“’546 patent”)
1035	Micael A. Crary <i>et al.</i> , “Biomechanical Correlates of Surface Electromyography Signals Obtained During Swallowing by Healthy Adults,” <i>Journal of Speech, Language, and Hearing Research</i> 49(1):186-193 (2006) (“Crary”)
1036	U.S. Patent No. 7,206,630 to Tarler (“’630 patent”)
1037	Stephen A. Koff & Evan J. Kass, “Abdominal Wall Electromyography: A Noninvasive Technique To Improve Pediatric Urodynamic Accuracy,” <i>The Journal of Urology</i> 127(4):736-739 (1982) (“Koff”)
1038	Michael R. van Balken <i>et al.</i> , “Posterior Tibial Nerve Stimulation as Neuromodulative Treatment of Lower Urinary Tract Dysfunction,” <i>The Journal of Urology</i> 166(3):914-918 (2001) (“van Balken”)

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1039	J.L.H. Ruud Bosch, “Electrical neuromodulatory therapy in female voiding dysfunction,” <i>BJU International</i> 98(s1):43-48 (2006) (“Bosch”)
1040	U.S. Patent No. 11,224,742 to Burnett (“‘742 patent”)
1041	Edward J. McGuire <i>et al.</i> , “Treatment of Motor and Sensory Detrusor Instability by Electrical Stimulation,” <i>The Journal of Urology</i> 129(1):78-79 (1983) (“McGuire”)
1042	A.L. Hof, “EMG and Muscle Force: An Introduction,” <i>Human Movement Science</i> 3(1-2):119-153 (1984) (“Hof”)
1043	A Martens De Noordhout <i>et al.</i> , “Percutaneous electrical stimulation of lumbosacral roots in man,” <i>Journal of Neurology, Neurosurgery, and Psychiatry</i> 51(2):174-181 (1988) (“Noordhout”)
1044	U.S. Patent App. Pub. No. 13/840,936 to Rajguru <i>et al.</i> (“‘936 application”)
1045	Int’l App. No. PCT/US2011/052415 (“‘415 application”)
1046	U.S. Provisional App. No. 61/403,680 to Rajguru <i>et al.</i> (‘680 provisional”)
1047	U.S. Patent App. No. 12/508,529 to Burnett <i>et al.</i> (“‘529 application”)
1048	U.S. Patent App. No. 11/866,329 to Burnett <i>et al.</i> (“‘329 application”)
1049	U.S. Provisional App. No. 60/848,720 to Burnett <i>et al.</i> (‘720 provisional”)
1050	File History of U.S. Patent No. 11,224,742 (“‘742 patent”/“‘742 patent file history”)
1051	<i>Avation Medical, Inc. v. EMKinetics, Inc.</i> No. 3:24-cv-01702 (N.D. Cal.) First Amended Complaint, Dkt. No. 5
1052	Notice of Abandonment for U.S. Patent App. No. 12/508,529
1053	Declaration of Todd R. Tucker

PETITIONER’S MANDATORY NOTICES

A. Real Party in Interest (§42.8(b)(1))

Avation Medical, Inc. (“Avation” or Petitioner”) is the real party in interest of this Petition. No other entity is a real party in interest or a privy of Avation for this Petition.

B. Related Proceedings (§42.8(b)(2))

On March 19, 2024, Avation filed a complaint against EMKinetics, Inc. (“EMK” or “PO”) for declaratory judgment of noninfringement of U.S. Patent No. 11,844,943 (“‘943 patent”), U.S. Patent No. 9,002,477 (“‘477 patent”), and U.S. Patent No. 11,224,742 (“‘742 patent”) in the United States District Court for the Northern District of California (“NDCA litigation”). *See Avation Medical, Inc. v. EMKinetics, Inc.*, No. 4:24-cv-01702 (NDCA); Ex.1051. Avation has not filed a civil action challenging the validity of any claim of the ‘943 patent.

C. Lead and Backup Counsel (§42.8(b)(3))

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D. Service Information (§42.8(b)(4))

Petitioner consents to electronic service by email at the email addresses listed above and ipdocket@calfee.com.

I. INTRODUCTION

The '943 patent claims methods of treating overactive bladder ("OAB") or incontinence using well-known transdermal electrical stimulation therapy. The prior art, however, described treatment of OAB and incontinence using noninvasive electrostimulation techniques well before October 2006, the earliest claimed priority date of the '943 patent. Most notably, Svihra—published in 2002 and not considered during the '943 patent's prosecution—describes treating OAB patients using noninvasive electrical stimulation targeting the posterior tibial nerve ("PTN"). Various additional prior art references described similar treatments well before 2006. Moreover, the claims of the '943 patent are also invalid for lack of enablement because the specification teaches against key aspects of the claimed invention. Because the evidence demonstrates that claims 1-39 of the '943 patent ("Challenged Claims") are invalid, the Board should institute post-grant review ("PGR") and find the claims of the '943 patent unpatentable.

II. COMPLIANCE WITH PGR REQUIREMENTS

A. Certification (§42.204(a))

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).

B. Identification of Challenge (§42.204(b))

Petitioner requests cancellation of the Challenged Claims¹ based on the following Grounds:

Ground	Claims	Description
1	1, 3-5	Anticipated by Svihra (Ex.1004)
2	2, 6-13	Obvious over Svihra (Ex.1004) and Knowledge of POSA ²
3	14, 16-18, 27, 29-31	Obvious over Svihra (Ex.1004) and Johnson (Ex.1007)
4	15, 19-26, 28, 32-39	Obvious over Svihra (Ex.1004) and Johnson (Ex.1007) and Knowledge of POSA
5	1-3, 5	Anticipated by Amarenco (Ex.1005)

¹ The Challenged Claims are reproduced in the **Claim Appendix** below.

² See *New World Medical, Inc. v. Microsurgical Tech., Inc.*, IPR2020-01573, Paper 64 at 10 (PTAB March 11, 2022) (analyzing obviousness “is always from the perspective of an ordinarily skilled artisan and one must consider knowledge generally available to one of ordinary skill in the art.”).

6	4, 6-13	Obvious over Amarenco (Ex.1005) and Knowledge of POSA
7	14-16, 18, 27-29, 31	Obvious over Amarenco (Ex.1005) and Johnson (Ex.1007)
8	17, 19-26, 30, 32-39	Obvious over Amarenco (Ex.1005) and Johnson (Ex.1007) and Knowledge of POSA
9	1-3, 5-13	Anticipated by Burnett (Ex.1006)
10	4, 14-39	Obvious over Burnett (Ex.1006) and Johnson (Ex.1007) and Knowledge of POSA
11	1-39	Lack of enablement under 35 U.S.C. §112

Petitioner's challenges are supported by the testimony of Dr. Brett Wingier, an expert in biomedical engineering and stimulation therapy with over 20 years of experience. Ex.1003, ¶¶6-13.

C. Fee (§42.15(b))

The Director is authorized to charge applicable fees to Deposit Account 03-0172.

D. Service (§42.205)

Proof of service is provided below.

III. BACKGROUND TECHNOLOGY

A. Overactive Bladder (“OAB”) and Incontinence

OAB is a condition that encompasses a range of irritative bladder filling and storage symptoms suggestive of lower urinary tract dysfunction. Ex.1008, 173; Ex.1009, 7. In the early 2000s, OAB was defined as “urgency, with or without urge incontinence, usually with frequency and nocturia.” Ex.1009, 7. “Urgency” refers to a strong desire to void (*i.e.*, urinate), “frequency” refers to a need to urinate on an abnormally frequent basis (including frequent urination at night, referred to as “nocturia”), and “urge incontinence” refers to urine loss preceded by urgency. Ex.1008, 173. In the early 2000’s, it was estimated 17-33 million people in the U.S. were affected by OAB. Ex.1010, 580; Ex.1009, 10; Ex.1003, ¶¶35-36.

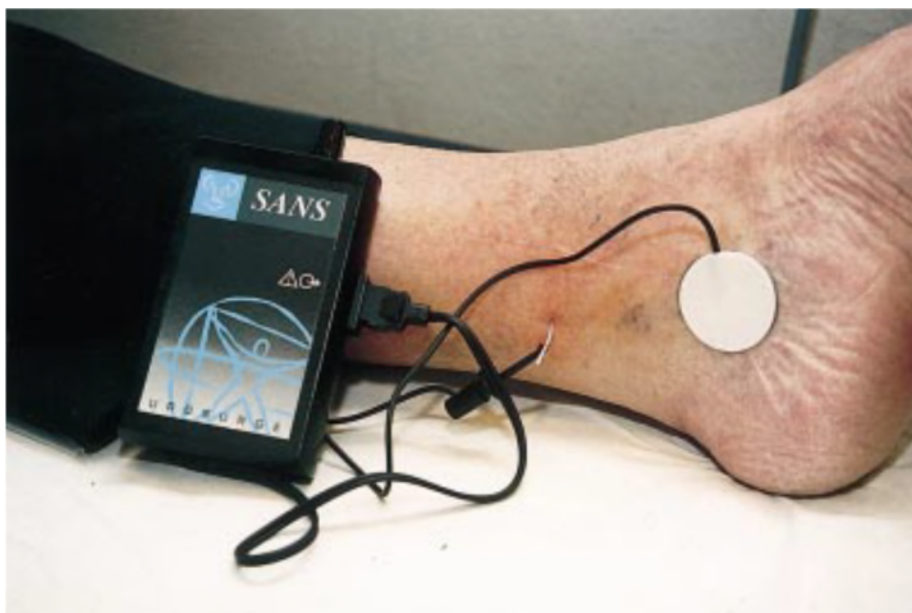
B. Treatment of OAB and UI

Well before 2006, various approaches were used to treat OAB and incontinence, including behavioral modifications, pharmacological therapies, surgery, and neuromodulation. Ex.1011, 219; Ex.1001, 2:35-3:16. Behavioral therapies required adherence to routines, which patients found unattractive. *Id.* Pharmacological interventions often caused unacceptable side effects. *Id.* Surgery was invasive, expensive, and only used when other treatments failed. *Id.* Due to these limitations, neuromodulation techniques were developed to treat OAB and incontinence. Ex.1011, 220; Ex.1003, ¶¶37-38.

Neuromodulation refers to therapeutic techniques involving influencing one neural pathway to modulate activity in another. Ex.1012, 261. By the early 2000's, neuromodulation was used to treat various conditions. Ex.1013, 232. Electrical stimulation was one common form of neuromodulation used to treat OAB and UI. Ex.1003, ¶¶39-40.

Sacral nerve stimulation ("SNS") was a well-known technique for treating OAB and incontinence. Ex.1014, 726. SNS involved implanting a pulse generator and electrode to stimulate nerves emanating from the sacral region of the spinal cord, which communicate with muscles controlling urination. *Id.* While effective, the technique was invasive and costly. *Id.*, 727-28; Ex.1001, 2:62-3:4; Ex.1003, ¶41.

Percutaneous PTN stimulation ("PTNS") (also called Stoller Afferent Nerve Stimulation ("SANS")) was another known electrostimulation technique. Ex.1014, 727; Ex.1001, 3:5-16. A needle connected to an electrical stimulator was inserted near the medial malleolus (*i.e.*, the ankle) to stimulate the PTN. *Id.*



Ex.1014 (Groen), Fig. 4, 728

“Treatment usually takes place weekly for 10-12 weeks over 20-30 min.” *Id.*, 727.

Many studies demonstrated safety and efficacy of SANS. *Id.*, 727-28; Ex.1001, 3:5-16. Stoller, for example, “described an 81% clinical success rate.” Ex.1015, 256. PTNS was, however, invasive given the need to penetrate patients’ skin. Ex.1003, ¶¶42-43.

Noninvasive electrostimulation techniques were also known well before 2006. Ex.1003, ¶44. Transcutaneous electrical nerve stimulation (“TENS”), commonly used to treat various conditions such as pain, was investigated for OAB/incontinence treatment. Ex.1014, 725-26. In TENS, surface electrodes were placed on patients’ skin overlying areas desired for stimulation, including the PTN. *Id.*, 724. Many studies showed positive results in treating OAB/incontinence. *Id.*, 724-25.

For example, McGuire reported on noninvasive PTN electrostimulation in 1983. Ex.1003, ¶45. McGuire’s technique involved applying current via an electrode “applied by a stick-on electrocardiograph-type electrode with a foam backing” to the common peroneal nerve or PTN. Ex.1041, 78-79. McGuire stated “[t]his electrode placement, coupled with a commercially available transcutaneous electrical nerve stimulator used for the control of pain, provides a reasonable method to inhibit detrusor activity.” *Id.*, 79.

In the early 2000’s, studies using similar noninvasive techniques were published. Svihra “tested the effectiveness of modified superficial Stoller’s afferent nerve stimulation (SANS)” in OAB patients. Ex.1004, 480, 481. Svihra attached electrodes “behind the medial ankle of the left lower extremity” and applied electric stimulation targeting the PTN for 30 minutes/week. *Id.* Svihra concluded the technique “is acceptable and safe conservative treatment in case of [OAB].” *Id.*, 480, 482; Ex.1003, ¶46.

Amarenco published a study on “left [PTN] stimulation using a surface self-adhesive electrode on the ankle skin behind the internal malleolus” in patients “presenting with symptoms (urge incontinence and frequency) secondary to [OAB].” Ex.1005, 2210. Amarenco’s results “suggest an objective acute effect of [PTN] stimulation on urodynamic parameters. Improved bladder overactivity is an

encouraging argument to propose [PTN] stimulation as a noninvasive treatment modality in clinical practice.” *Id.*; Ex.1003, ¶47.

Long before 2006, published reports such as McGuire, Svihra, and Amarenco, among many others, demonstrated that noninvasively applying PTN electrostimulation was a well-known and effective OAB/incontinence treatment. *See also* Ex.1016, 670; Ex.1017, 243; Ex.1003, ¶48.

IV. THE ‘943 PATENT

A. AIA Status and Eligibility for PGR

Patents described in AIA §3(n)(1) are eligible for PGR. AIA §6(f)(2)(A), 125 Stat. at 311. According to §3(n)(1), AIA patents include:

any application for patent, and [] any patent issuing thereon, that contains or contained at any time—

(A) 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 the effective date [*i.e.*, March 16, 2013]; or

(B) a specific reference under section 120, 121, or 365(c) of title 35, United States Code, to any patent or application that contains or contained at any time such a claim.

AIA §3(n)(1), 125 Stat. at 293. For multiple reasons, the ‘943 patent is an AIA patent and is eligible for PGR.

First, 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. The ‘943 patent purports to be a continuation of the ‘706 application (issued as ‘053 patent), which is a continuation of the ‘875 application (issued as ‘669 patent). Ex.1001, [63], 1:8-30. The ‘875 application is a CIP of the ‘356 application filed March 29, 2016. *Id.* The ‘356 application is a continuation of the ‘936 application filed March 15, 2013. *Id.* The ‘936 application is a CIP of the ‘415 PCT filed Sept. 20, 2011, which claims priority to the ‘680 provisional filed Sept. 20, 2010. *Id.* The ‘875 application also purports to be a CIP of the ‘529 application filed on July 23, 2009, which is a CIP of the ‘329 application filed Oct. 2, 2007, which claims priority to the ‘720 provisional filed Oct. 2, 2006. *Id.*, [63], 1:8-30. At least several of these patents/applications to which the ‘943 patent contains a specific reference “contain[] or contained at any time” claims with an effective filing date after March 16, 2013.

For example, the ‘669 patent contains claims with an effective filing date no earlier than March 30, 2017, the filing date of the ‘875 application. Claim 1 of the ‘669 patent recites “a method for providing transdermal electrical stimulation therapy to a subject for treating tremors,” including “positioning a stimulator electrode over a skin surface overlying a target nerve or tissue which extends

through a hand of the subject.” Ex.1018, Cl.1. Claim 19, which depends from claim 1 by way of claim 18, further recites “the at least two electrodes are positioned to stimulate an Ulnar or Median nerve.” *Id.*, cls.18-19. There is no written description support or enablement for the features of claims 1 or 19 in any of the applications to which the ‘669 patent claims benefit/priority. If mentioned at all, the prior applications only mentions the term “tremor” once in a list of over 100 “ailments” that purportedly may be treated with the invention. Ex.1023, [0121]; Ex.1044, [0121]; Ex.1045, [0119]; Ex.1047, [0111]; Ex.1048, [0090]; Ex.1049, [0031]. The prior applications never mention the terms “ulnar” or “median” nerve whatsoever, let alone to treat tremors by stimulating the ulnar/median nerves specifically. The first application containing any disclosure even arguably relevant to electrostimulation of the ulnar/median nerves is the ‘875 application filed March 30, 2017, issued as the ‘669 patent. No prior applications to which the ‘669 patent claims benefit/priority supports claims 1 and 19 regarding treatment of tremors by stimulating a nerve extending through the hand or treating tremors by stimulating the ulnar or median nerves.

Moreover, listed below are various additional examples of patents/applications to which the ‘943 patent contains a specific reference that “contain[] or contained at any time” a claim with an effective filing date after March 16, 2013.

- The ‘875 application (which issued as the ‘669 patent) “contained” claims with an effective filing date no earlier than March 30, 2017, the filing date of the ‘875 application itself. The originally-filed claims of the ‘875 application included claim 1 (including the limitations “delivering electrical stimulation . . . to a target nerve or tissue in the hand” and “wherein the pulses generated . . . include pulses of a first amplitude and pulse of a second amplitude, where the first amplitude is different from the second amplitude”) and claim 21 (including the limitation “wherein the pain felt by the subject is migraine pain”).

Ex.1019, 101-03. None of the applications to which the ‘875 application claims benefit/priority provides written description support or enablement for delivering electrical stimulation at pulses of a first amplitude and a different second amplitude, or of treating pain caused by a migraine by electrically stimulating nerves/tissues within the hand.
- The ‘706 application (which issued as the ‘053 patent) “contained” claims with an effective filing date no earlier than March 30, 2017, the filing date of the ‘875 application. The originally-filed claims of the ‘706 application included claim 1 (which included limitations “wherein the pulses generated . . . include pulses of a first amplitude

and pulse of a second amplitude, where the first amplitude is different from the second amplitude,” “a pulse width of 200 microseconds,” and “five pulses at the first amplitude followed by five pulses at the second amplitude”), claim 11 (which specified positioning the electrode “in proximity to an ulnar nerve”), and claim 12 (which specified positioning the electrode “in proximity to a median nerve”).

Ex.1020, 101-02. None of the applications to which the ‘706 application claims benefit/priority prior to the ‘875 application provides written description support or enablement for any of the specific pulse-parameter limitations of original claim 1, or for positioning an electrode in proximity to an ulnar or median nerve as specified in original claims 11-12.

- The ‘053 patent “contains” claims with an effective filing date no earlier than March 30, 2017, the filing date of the ‘875 application. The issued claims of the ‘053 patent include claim 1 (which specifies treating migraines by positioning an electrode over a skin surface overlying a target nerve or tissue extending through a subject’s hand).

Ex.1021, cl.1. As discussed above regarding the originally-filed claims of the ‘875 application, none of the applications to which the ‘053 patent claims benefit/priority prior to the ‘875 application

provides written description support or enablement for treating pain caused by migraines by electrically stimulating nerves and tissues within the hand.

Accordingly, because the ‘943 patent contains a “specific reference” to the patents/applications discussed above that “contain or contained” claims with an effective filing date after March 16, 2013, the ‘943 patent is a patent described in AIA §3(n)(1) and is eligible for PGR. *See* AIA §3(n)(1), 125 Stat. at 293.

Second, the ‘943 patent is also an AIA patent eligible for PGR because it contains claims with an effective filing date after March 16, 2013. As explained below, the ‘943 patent’s claims are unpatentable under 35 U.S.C. §112 because the specification does not enable “positioning a first portion of a patient's body ***near an ankle*** relative to an electrical stimulator.” *See infra*, §VI.K. If the claims are not invalid for lack of enablement, the earliest effective filing date for the claims is January 4, 2022 (*i.e.*, the ‘943 patent’s filing date), as none of the applications to which it claims priority/benefit enable the claimed subject matter for the same reasons discussed below regarding the ‘943 patent itself. *See id.* Accordingly, the ‘943 patent is an AIA patent and is eligible for PGR. *See* AIA §3(n)(1), 125 Stat. at 293.

B. Effective Filing Date

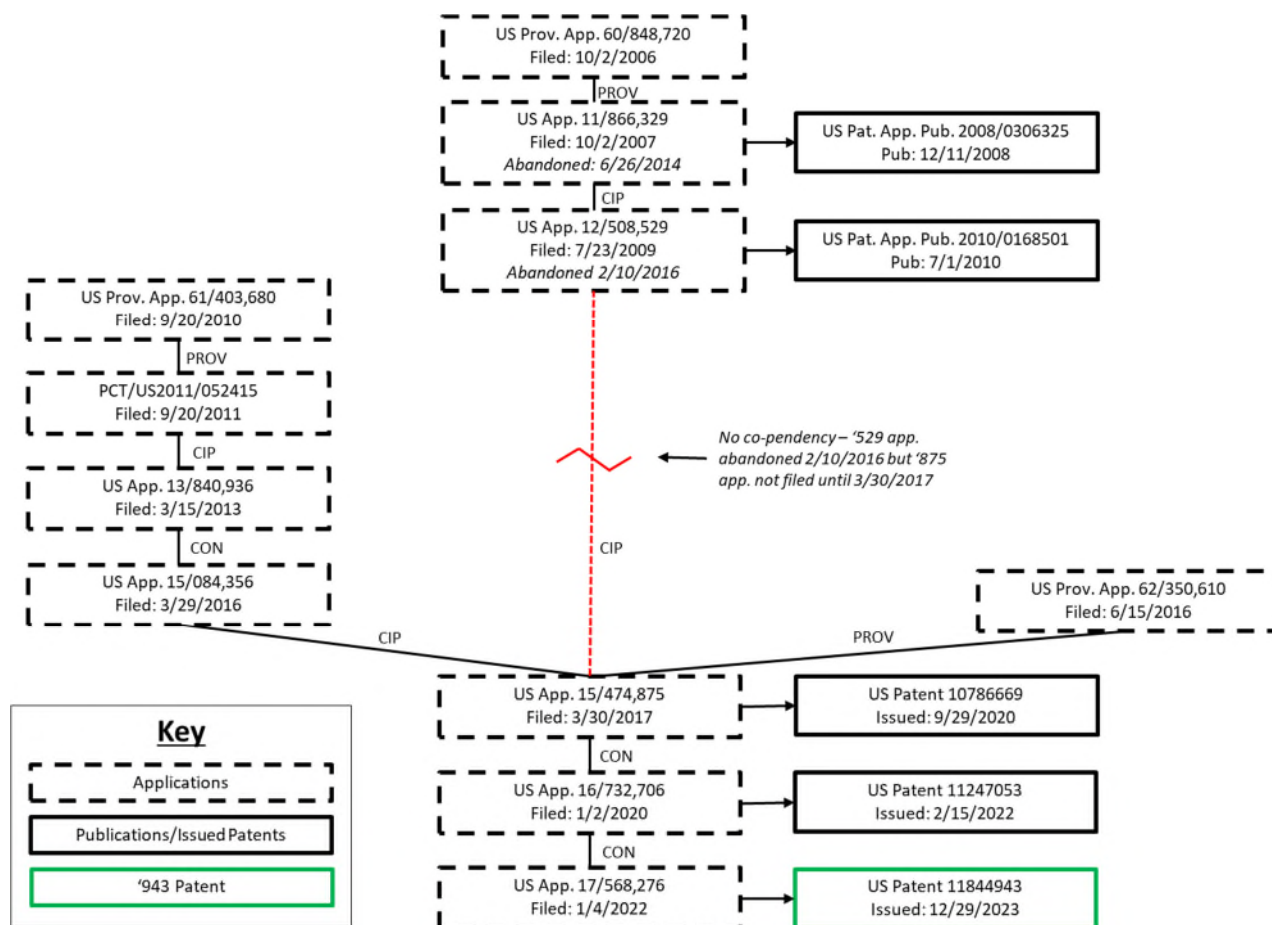
Due to enablement issues, a convoluted family tree, and defects in the ‘943 patent’s priority chain, determining the effective filing date of the claims of the ‘943 patent is complicated. As explained above, for purposes of PGR eligibility, Petitioner contends the earliest effective filing date of the claims of the ‘943 patent is the filing date of the ‘943 patent itself. *Supra*, §IV.A. However, because the prior art relied upon by Petitioner was published well before that date, for simplicity Petitioner need not rely on that date for purposes of unpatentability. Rather, for purposes of this proceeding other than PGR eligibility, Petitioner contends the earliest effective filing date of the ‘943 patent is September 20, 2010. *See infra*, §IV.B.1. Even if, however, the Board determines the ‘943 patent is entitled to the earliest claimed priority date of October 2, 2006 (*i.e.*, the filing date of the ‘720 provisional), the claims of the ‘943 patent are invalid as anticipated and/or obvious. *See infra*, §IV.B.2.

1. The ‘943 Patent’s Earliest Possible Effective Filing Date Is September 20, 2010

Due to defects in the ‘943 patent’s priority chain, the earliest possible effective filing date for the patent is September 20, 2010 (*i.e.*, the filing date of the ‘680 provisional). The ‘943 patent’s benefit/priority claim is convoluted and includes three branches. As shown below, the patent claims priority through two

different sets of continuation/CIP applications and separately to one provisional.

Ex.1001, [63], 1:8-30.



The '610 provisional was filed in 2016 and is not relevant to this analysis. Defects exist in the other two branches.

First, as shown above, the '943 patent claims benefit to the '706 application filed January 2, 2020, which is a continuation of the '875 application filed March 30, 2017. Ex.1001, 1:8-30. The '875 application is a CIP of the '356 application filed on March 29, 2016, which is a continuation of the '936 application filed on March 15, 2013. *Id.* The '936 application is a CIP of the '415 PCT application

filed on September 20, 2011. *Id.* Finally, the '415 PCT application claims priority to the '680 provisional filed on September 20, 2010. *Id.* Thus, based on the first branch, the '943 patent is at best entitled to a priority date of September 20, 2010.³

Second, the '943 patent separately claims benefit as a continuation of the '706 application filed January 2, 2020, which is a continuation of the '875 application filed March 30, 2017. *Id.* The '875 application is allegedly a CIP of the '529 application filed July 23, 2009. PO abandoned the '529 application, however, by February 10, 2016. Ex.1052, 1-2. Because PO did not file the application that led to the '875 application until March 30, 2017, there was no co-pendency between the '875 application and the '529 application. *See* 35 U.S.C. §120. Thus, PO's benefit claim to the '529 application is ineffective. Accordingly, the earliest effective filing date of the '943 patent based on the second branch is the filing date of the '875 application, *i.e.*, March 30, 2017.

³ Benefit/priority claims to earlier-filed applications in either of the '356 or '936 applications that are not enumerated in the '943 patent cannot be relied on to give the '943 patent an earlier effective filing date. *See Droplets, Inc. v. E*TRADE Bank*, 887 F.3d 1309, 1317 (Fed. Cir. 2018). Nor can the '943 patent obtain an earlier effective filing date by incorporating earlier-filed applications by reference. *Id.* at 1320.

Given the break in co-pendency, patent application publications that published from the '529 and/or '329 applications constitute prior art to the claims of the '943 patent. Indeed, the '329 application published as Burnett on December 11, 2008, which is more than one year before the earliest priority date of the '943 patent (*i.e.*, September 20, 2010). *See* Ex.1006. Burnett thus constitutes prior art under AIA 35 U.S.C. §102(a)(1).

2. Even if the '943 Patent's Priority Date Is October 2, 2006, the Prior Art Still Invalidates the Patent

Even if the Board determines the '943 patent is entitled to the earliest claimed priority date of October 2, 2006 (*i.e.*, the filing date of the '720 provisional), ***all references relied on by Petitioner herein other than Burnett*** were published before that date and thus qualify as prior art under AIA §102(a)(1) or (2).

C. '943 Patent Overview

The '943 patent relates generally to stimulation therapy. Ex.1001, 2:3-7. The patent states “[r]ecent data highlights the beneficial effects of invasive, needle-based electrostimulation (ES) of the [PTN] in individuals with OAB and UI. ES has been found to modulate bladder dysfunction through its action on the pudendal nerve and the sacral plexus which provides the major excitatory input to the bladder.” *Id.*, 2:29-34. The patent indicates known treatments for OAB/incontinence include neuromodulation (*e.g.*, SNS and PTNS/SANS), and that

while “an abundance of published peer-reviewed clinical trials demonstrate the safety and efficacy of the SANS therapy,” both treatments are invasive. *Id.*, 2:62-3:16; Ex.1003, ¶¶49-52.

The patent discloses apparatuses and methods for providing magnetic or electrostimulation therapy for treatment of OAB/incontinence. Ex.1001, 8:26-36. While much of the patent relates to electromagnetic therapy and microneedle-based electrostimulation, the patent discusses electrostimulation therapy “variations” that use an electrical pulse controller 130, electrode 126, and sensor 136. *Id.*, 17:9-30, Fig. 11 (below); Ex.1003, ¶53.

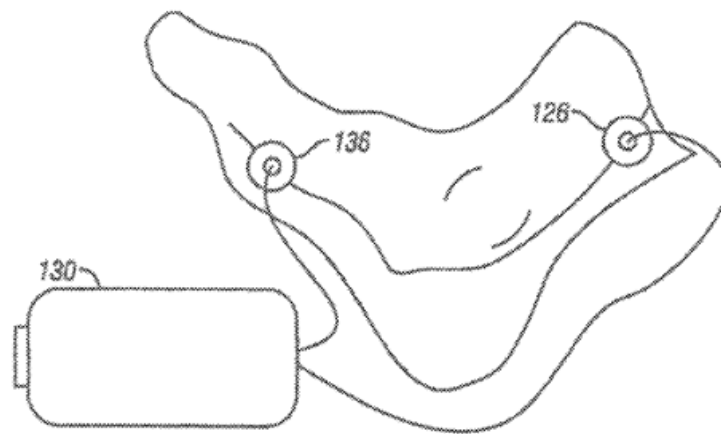


FIG. 11

Notably, the patent explicitly states that using an electrical stimulus 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.***” Ex.1001, 50:55-61 (emphasis added). Further, the patent indicates “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.***” *Id.*, 50:62-51:3 (emphasis added). The medial malleolus refers to the ankle on the inside of the foot, while the abductor hallucis longus is a muscle that abducts and flexes the big toe. Ex.1003, ¶54. The patent further states that “[w]hile 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, 50:62-51:3 (emphasis added). The patent thus clearly states electrostimulation therapy targeting nerves near the ankle, such as the PTN, should not be used because it is “intolerable,” “painful,” “impractical,” and “not feasible.” *Id.*, 50:55-51:3. This explicit teaching against targeting nerves near the ankle is directly contrary to the claim language, which requires positioning an electrical stimulator “near an ankle” of the patient. *Id.*, cls. 1, 14, 27. This express teaching against the claimed invention renders the claims invalid for lack of enablement. Ex.1003, ¶55; *infra*, §VI.K.

D. Prosecution History

The ‘943 patent issued on December 19, 2023 from the ‘276 application, which was filed on January 4, 2022. The ‘276 application was filed with 39 claims, which are identical to those issued in the ‘943 patent. Ex.1002, 301-05. On May 15, 2023, a third-party submission was filed citing Amarenco (Ex.1005), Rhodes (Ex.1022), and Johnson (Ex.1007). *Id.*, 142-47. On October 23, 2023, a notice of allowance was issued. *Id.*, 25.

Despite that over 450 references were cited during prosecution (Ex.1001, [56] and a third-party submission was filed, the Examiner did not substantively discuss the submission or references cited, or issue any anticipation/obviousness rejections over these or any other references.

E. Person of Ordinary Skill in the Art (“POSA”)

A POSA at the time of the claimed invention 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. Additional work experience could substitute for a formal degree and vice versa. Ex.1003, ¶21.

V. CLAIM CONSTRUCTION

Patent claims are construed under the standard used in civil actions under 35 U.S.C. §282(b). 37 C.F.R. §42.200(b). Except as noted below, no terms require construction for purposes of this Petition.⁴

VI. EXPLANATION OF UNPATENTABILITY

A. Ground 1: Svihra (Ex.1004) Anticipates Claims 1-3 and 5

Svihra published in 2002 and is therefore prior art under AIA 35 U.S.C. §102(a)(1). Svihra was not cited or considered during prosecution of the ‘943 patent.

1. Claim 1:

a. Element [1.p]

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).” Ex.1004, 480. Svihra states “[n]oninvasive stimulation

⁴ Nothing herein is a waiver of challenge, or agreement that the requirements of 35 U.S.C. §112 are met for any claim.

had improved subjective symptom related to overactive bladder, had no adverse events and was well tolerated.” *Id.*; Ex.1003, ¶59.⁵

b. Element [1.a]

Svihra performed “non-invasive stimulation of the tibial nerve” via “electrode[s] attached behind the medial ankle of the left lower extremity.” Ex.1004, 480; *see also id.*, 481. Svihra’s stated goal was to test a modified version of Stoller’s minimally-invasive, percutaneous procedure by instead using “non-invasive” surface electrodes. *Id.*; Ex.1003, ¶¶60-61.

Svihra explicitly states the procedure was “non-invasive.” Ex.1004, 480, 481, 482. A POSA would understand “surface electrodes” do not break the skin and thus the procedure was non-invasive. Ex.1003, ¶61. Svihra’s “surface electrodes” provided “stimulation by a constant voltage and regulated intensity of direct current.” Ex.1004, 481. A POSA would appreciate providing electrostimulation in this way would necessarily require electrodes connected to an electrical stimulator source. Ex.1003, ¶62. Thus, the “surface electrodes” and/or the electrical stimulator source are an “electrical stimulator,” as claimed. *Id.* Additionally, a POSA would understand electrodes “placed behind the medial

⁵ Prior art need only disclose treating overactive bladder **or** incontinence, not both, to anticipate. *See, e.g., Brown v. 3M*, 265 F.3d 1349, 1352 (Fed. Cir. 2001).

ankle of the left lower extremity” for stimulation of the PTN necessarily indicates a portion of the patients’ bodies “near an ankle” were positioned relative to an electrical stimulator, as claimed. *Id.*, ¶63.

Svihra indicates electrodes were placed “behind the medial ankle” to stimulate the “tibial nerve.” Ex.1004, 481. The “tibial nerve” is the PTN. Ex.1003, ¶64. Further, Svihra’s electrodes “directly targeted” the patients’ PTN. The ‘943 patent does not explain how a nerve is “directly targeted” or distinguish “directly targeting” a nerve from simply “targeting” a nerve; rather, the patent merely discloses placing stimulation devices in the vicinity of portions of the body. *Id.*, ¶65. Svihra “directly targeted” the patients’ PTN in the same way by placing electrodes “behind the medial ankle” and providing electrical stimulation to the patients’ PTN. *Id.*

c. Element [1.b]

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. Ex.1004, 481. In order 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. Ex.1003, ¶66.

d. Element [1.c]

Svihra states “[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.” Ex.1004, 481 (emphasis added). Thus, Svihra delivered electrical stimulus from an electrical stimulator through the electrodes to the PTN. Ex.1003, ¶67. Moreover, Svihra’s study included “patients with overactive bladder (OAB) without bladder outlet obstruction.” Ex.1004, 481. Svihra states “[n]oninvasive stimulation had improved subjective symptom related to [OAB], had no adverse events and was well tolerated.” *Id.*, 480. Svihra explained “[t]he group with SANS stimulation achieved statistically significant differences after the treatment,” and over half the patients had “significant improvement of OAB symptoms.” *Id.*, 481-82; Ex.1003, ¶68.

2. Claim 3

Svihra anticipates claim 1. *Supra*, §VI.A.1. Further, Svihra used an electromyographic (“EMG”) device, which measures electrical activity and muscle response resulting from stimulation of muscle by nerves. Ex.1004, 481; Ex.1003, ¶69. Svihra states “[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*** (stimulation by a constant voltage and regulated intensity of direct

current).” Ex.1004, 481 (emphasis added). In other words, Svihra measured the electrical signal emanating from the muscle as a result of electrical stimulation, which is “detecting a muscular response.” Ex.1003, ¶70.

3. Claim 4

Svihra anticipates claim 1. *Supra*, §VI.A.1. Further, Svihra explicitly states stimulation was applied once per week for 30 minutes. Ex.1004, 481 (“[s]urface stimulation of 30 minutes duration was repeated once a week for a period of 5 weeks.”); Ex.1003, ¶71.

4. Claim 5

Svihra anticipates claim 1. *Supra*, §VI.A.1. Further, Svihra used an EMG device, which measures electrical activity and muscle response resulting from stimulation of muscle by nerves. Ex.1004, 481 (“electromyographic device Nicolet Viking II E”); Ex.1003, ¶72. Svihra states “the maximal amplitude of response was registered from the abductor hallucis muscle,” Ex.1004, 481, which refers to the maximum electrical signal from the patients’ muscle as a result of stimulation therapy. Ex.1003, ¶73. Measurement of electrical signals from patients are “physiological parameter[s] detected from the patient,” and a POSA would understand that because Svihra determined the “maximal amplitude of response” the results were necessarily displayed to Svihra (or Svihra could not have known the maximum electrical signal, *i.e.*, “maximal amplitude”)). *Id.*

B. Ground 2: Svihra (Ex.1004) in View of the Knowledge of a POSA Renders Obvious Claims 2, 6-13

1. Claim 2

Svihra anticipates claim 1. *Supra*, §VI.A.1. Further, claim 2 does not cover a novel or nonobvious features of the alleged invention. The patent explicitly states that any type of electrode, including known TENS patches, can be used in the claimed method. Ex.1001, 46:28-39 (“[v]arious types of electrodes may be utilized as a stimulator electrode, *e.g.*, a surface electrode, microneedle electrode, a TENS (transcutaneous electrical nerve stimulation) patch or other electrode that may be positioned over or on the skin surface.”); Ex.1003, ¶75.

Setting that aside, Svihra used “surface electrodes” in the electrostimulation procedure, which a POSA would interpret as likely referring to an “electrode patch.” Ex.1004, 481; Ex.1003, ¶76. Moreover, as the patent acknowledges, “electrode patches” for electrostimulation were known in the art. *E.g.*, Ex.1024, 234 (“electrode patches”); Ex.1025 (“electrode patch” for electrostimulation of vagus nerve); Ex.1026 (“dermal patch” for nerve stimulation); Ex.1027, 24 (“self-adhesive patch eletrodes” for TENS treatment of incontinence); Ex.1003, ¶77.

Even if Svihra’s surface electrodes are not an “electrode patch,” modifying Svihra to “position[] an electrode patch in communication with the electrical stimulator” would have been obvious. Using an “electrode patch” in place of Svihra’s “surface electrodes” would have involved nothing more than simple

substitution of known elements (substituting “surface electrodes” for known “electrode patches”) or predictable use of prior art elements according to established functions (using known “electrode patches” to provide electrostimulation). *Id.*, ¶78. Additionally, it would have been obvious to try use of known “electrode patches” given the finite number of types of electrodes that could be used in electrical stimulation procedures. *Id.* A POSA would have expected success modifying Svihra’s procedure in this manner and the results would have been predictable given the widespread, successful use of “electrode patches” throughout the art in similar procedures. *Id.*

2. Claim 6

Svihra anticipates claim 1. *Supra*, §VI.A.1. Further, a POSA 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. Ex.1003, ¶79.

EMG is a measure of muscle response and electrical activity in response to stimulation of muscle by a nerve. *Id.*, ¶80; Ex.1042, 120-21; Ex.1043, 174. When a nerve activates a muscle, EMG measures the presence or lack of presence of electrical conduction of the nerve impulse between the stimulation site and the muscle. *Id.* Detecting for the presence or lack of presence of electrical conduction, as recited in claim 6, thus refers to detection techniques such as EMG. Ex.1003,

¶¶79-80. The claim also refers to detecting conduction “at a second portion of the patient’s body distant from the first portion,” which is typical of EMG procedures in which EMG electrodes are typically placed at locations distant from a stimulation site. *Id.*, ¶81; Ex.1028, 367; Ex.1030, 10. Moreover, the claim requires detecting “for a lack of **presence** of electrical conduction,” which a POSA would have understood refers to EMG. EMG measurements showing presence/lack of presence of electrical activity indicate there is/is not electrical conduction in the muscle, and necessarily indicate the **presence** (or lack of presence) of electrical conduction in the nerve that stimulates the muscle. Ex.1003, ¶82. This interpretation is further supported by the specification, which indicates sensors (including known EMG electrodes that provide feedback regarding electrical conduction such as F or M waves) can be used to detect the presence or lack of presence of electrical conduction at a second portion of a patient’s body as an indicator of electrode migration, malfunction, or placement. *Id.*, ¶83; Ex.1001, 4:66-5:7, 17:9-30, 57:23-36, 57:53-58:3, 58:39-50, 58:66-59:5, 61:13-14, 65:35-62, 67:14-59. The patent further indicates sensors for detecting electrical conduction such as EMG electrodes were known, and thus claim 6 does not cover any new or nonobvious features of the alleged invention. Ex.1001, ¶20:54-62, 25:6-8, 26:61-64, 36:15-27; Ex.1003, ¶84. In any event, the claim language and specification indicate claim 6 encompasses detection techniques such as EMG.

Well before 2006, 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. Ex.1003, ¶86; Ex.1041, 119; Ex.1028, 361; Ex.1029, 1:45-63. EMG electrodes were typically placed at a second portion of a patient's body away from the stimulation site, Ex.1003, ¶86; Ex.1030, 10; Ex.1028, 367, and a variety of types of EMG electrodes including surface electrodes that measure electrical activity through skin tissue were used. Ex.1003, ¶86; Ex.1030, 3, 10; Ex.1028, 362. It was also known well before 2006 that electrodes could be improperly positioned, migrate, and/or malfunction during electric stimulation procedures. Ex.1003, ¶87; Ex.1001, 3:2-4; Ex.1031, [0024]; Ex.1032, [0005]; Ex.1033, 1:41-48. EMG was thus used to detect improper electrode placement, migration, and malfunction. Ex.1003, ¶88; Ex.1030, 7 (EMG "confirmed satisfactory positioning of the electrode" during electrostimulation for treatment of OAB), 10 (EMG used to "confirm [electrodes] continued optimum position"); Ex.1034, 12:28-45 (EMG used to confirm electrode placement). Given the teachings in the prior art to use EMG for these purposes and the conventional use of EMG, a POSA would have found it obvious to use EMG to detect improper electrode placement, migration, and/or malfunction. Ex.1003, ¶89. Indeed, it was well known that EMG measures electrical conduction (or lack of conduction) in muscle stimulated by a nerve and

of a nerve impulse between a stimulation site and muscle. *Id.*; Ex.1042, 120-21. A POSA would thus recognize that a lack of EMG signal from a muscle corresponding to a nerve that was electrically stimulated necessarily means there is an issue with the patients' nerve or an issue with the stimulator electrode, such as improper placement, migration, or malfunction. Ex.1003, ¶89.

As discussed above, Svihra used an EMG device to measure the amplitude of response from the muscle. Ex.1004, 481. Even if Svihra did not explicitly state the EMG results were used to detect for the presence or lack of presence of electrical conduction, a POSA would have found it obvious based on the above-described knowledge in the art 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. Ex.1003, ¶¶85, 90. Modifying Svihra's procedure (which already involves measuring EMG, Ex.1004, 481) in this way would have involved nothing more than using prior art elements in accordance with their known functions (*i.e.*, using Svihra's EMG measurement to determine electrode parameters, including improper electrode placement, migration, and/or malfunction, and therapeutic efficacy) and/or applying known techniques to improve a known process (*i.e.*, improving Svihra's procedure by using EMG signals in known ways, including indicating proper electrode placement, electrode

migration, or electrode malfunction). Ex.1003, ¶90. A POSA would understand the results would be predictable, given the conventional nature of EMG and the use of EMG for similar reasons in the art. *Id.*; Ex.1030, 7, 10; Ex.1034, 12:28-45.

Moreover, a POSA would have also been motivated to modify Svihra in this manner based on the teachings of the art itself, including to “confirm satisfactory positioning of the electrode” (proper electrode placement) or confirm the electrode’s “continued optimum position” (electrode migration). Ex.1030, 7, 10; Ex.1003, ¶90.

3. Claim 7

Svihra and the knowledge of a POSA would have rendered obvious claim 6. *Supra*, §VI.B.2. Further, claim 7 does not cover a novel or nonobvious features of the alleged invention. The patent explicitly 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. Ex.1001, 25:5-8 (“the sensor may [be] a sensor type known in the art (*e.g.*, EKG sensor)”), 26:61-64 (sensors “known to persons of ordinary skill in the art” can be used); Ex.1003, ¶91.

Setting that aside, Svihra used EMG to measure “the maximal amplitude of response [] registered from the abductor hallucis muscle.” Ex.1004, 481.

Moreover, as the patent acknowledges, various sensors/electrodes, including “electrode patches,” could be used for EMG. *E.g.*, Ex. 1003, ¶¶92-93; Ex.1035,

188 (electrode “patch” for surface EMG); Ex.1036, 5:33-50 (“electrode patch” for detecting physiological signal such as EMG); Ex.1037, 736 (“sticky surface patch electrodes” for EMG).

Even if Svihra does not explicitly disclose the specific type of EMG sensor/electrode used in the EMG measurements conducted in his procedure, a POSA would have found it obvious to modify Svihra’s procedure to use an “electrode patch” for detecting the presence of electrical conduction. Ex.1003, ¶94. Using an “electrode patch” in place of Svihra’s EMG sensor/electrode would have involved nothing more than simple substitution of known elements (substituting EMG electrodes for known “electrode patches”) or predictable use of prior art elements according to established functions (using known “electrode patches” for EMG). *Id.* Additionally, it would have been obvious to try use of known “electrode patches” for EMG given the finite number of types of sensors/electrodes that could be used in EMG procedures. *Id.* A POSA would have expected success modifying Svihra’s procedure in this manner and the results would have been predictable given the widespread, successful use of EMG “electrode patches” throughout the art in similar procedures. *Id.*

4. Claim 8

Svihra anticipates claim 1. *Supra*, §VI.A.1. Claim 8 is nearly identical to claim 6 except stating “an indicator of electrode malfunction.” As discussed above,

modifying Svihra to detect a 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 would have been obvious. *Supra*, §VI.B.2. Thus, claim 8 is obvious for the same reasons regarding claim 6. *Id.*; Ex.1003, ¶95.

5. Claim 9

Svihra and the knowledge of a POSA render obvious claim 8. *Supra*, §VI.B.4. Claim 9 is nearly identical to claim 7. As discussed above, modifying Svihra to use “electrode patch[es]” for detecting electrical conduction would have been obvious. *Supra*, §VI.B.3. Thus, claim 9 is obvious for the same reasons regarding claim 7. *Id.*; Ex.1003, ¶96.

6. Claim 10

Svihra anticipates claim 1. *Supra*, §VI.A.1. Claim 10 is nearly identical to claim 6 except stating “an indicator of proper electrode placement.” As discussed above, modifying Svihra to detect a 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 would have been obvious. *Supra*, §VI.B.2. Thus, claim 10 is obvious for the same reasons regarding claim 6. *Id.*; Ex.1003, ¶97.

7. Claim 11

Svihra and the knowledge of a POSA render obvious claim 10. *Supra*, §VI.B.6. Claim 11 is nearly identical to claim 7. As discussed above, modifying Svihra to use an “electrode patch” for detecting electrical conduction would have been obvious. *Supra*, §VI.B.3. Thus, claim 11 is obvious for the same reasons regarding claim 7. *Id.*; Ex.1003, ¶98.

8. Claim 12

Svihra anticipates claim 1. *Supra*, §VI.A.1. Claim 12 is nearly identical to claim 6 except stating detecting for conduction “through tissue” and “as an indicator of electrode placement.” As discussed above, modifying Svihra to detect a lack of presence of electrical conduction (including using surface EMG electrodes that detect through skin tissue) at a second portion of a patient’s body as an indicator of electrode migration, electrode malfunction, and proper electrode placement would have been obvious. *Supra*, §VI.B.2. Thus, claim 12 is obvious for the same reasons regarding claim 6. *Id.*; Ex.1003, ¶99.

9. Claim 13

Svihra and the knowledge of a POSA render obvious claim 12. *Supra*, §VI.B.8. Claim 13 is nearly identical to claim 7. As discussed above, modifying Svihra to use an “electrode patch” for detecting the presence of electrical conduction would have been obvious. *Supra*, §VI.B.3. Thus, claim 13 is obvious for the same reasons regarding claim 7. *Id.*; Ex.1003, ¶100.

C. Ground 3: Svihra (Ex.1004) in View of Johnson (Ex.1007) Renders Obvious Claims 14, 16-18, 27, and 29-31

1. Claim 14:

a. Element [14.p]

Svihra discloses this limitation. *Supra*, §VI.A.1.a; Ex.1003, ¶102.

b. Element [14.a]

Svihra discloses nearly all elements of this limitation. *Supra*, §VI.A.1.b.

Svihra uses “surface electrodes” placed on the patients’ skin. Ex.1004, 481. Other types of electrodes and electrode placements were also well known before 2006.

Ex.1003, ¶¶103-04. Johnson, for example, discloses electric stimulators and garment systems. Ex.1007, 1:11-15. Johnson sought to improve on prior electric stimulators, which were large, inconvenient, and uncomfortable. *Id.*, 2:9-20.

Johnson thus discloses electric stimulators “for direct attachment onto a garment electrode,” including socks, stockings, sleeves, wraps, gloves, or other types of garments, *id.*, 3:2-15, 3:26-28, cl.4, as well as attachment via a “connector strap.” *Id.*, 6:18-20. *See also* Ex.1022, 4:25-51 (disclosing socks that “position electrically conductive patches correctly relative to the nerves to which electrical connection is made”); Ex.1003, ¶104.

Even if Svihra does not disclose positioning an electrical stimulator within a sock worn upon a foot of the patient, a POSA would have found it obvious to modify Svihra’s teachings to position the electrical stimulator within a sock. *Id.*,

¶105. Positioning Svihra’s electrodes within a sock would have involved nothing more than simple substitution of known elements (substituting “surface electrodes” for Johnson’s sock/garment electrodes) or combining prior art elements according to known methods (combining Svihra’s electrodes with Johnson’s sock/garment electrodes). *Id.* Additionally, it would have been obvious to try use of Johnson’s sock/garment electrodes given the finite number of types of stimulator electrodes that could be used in stimulation procedures and the finite number of ways to position electrodes on a user’s body. *Id.* A POSA would have expected success modifying Svihra’s procedure in this manner and the results would have been predictable given the use such electrodes in the prior art such as in Johnson. *Id.* Moreover, a POSA would have also been motivated to modify Svihra in this manner based on the teachings of the art itself, including to improve user comfort and convenience, as disclosed by Johnson. Ex.1007, 2:9-20; Ex.1003, ¶105.

c. Element [14.b]

Svihra discloses this limitation. *Supra*, §VI.A.1.c; Ex.1003, ¶106.

d. Element [14.c]

Svihra discloses this limitation. *Supra*, §VI.A.1.d; Ex.1003, ¶107.

2. Claim 16

Svihra and Johnson would have rendered obvious claim 14. *Supra*, §VI.C.1. Further, Svihra discloses the additional limitations of this claim. *Supra*, §VI.A.2; Ex.1003, ¶108.

3. Claim 17

Svihra and Johnson would have rendered obvious claim 14. *Supra*, §VI.C.1. Further, Svihra discloses the additional limitations of this claim. *Supra*, §VI.A.3; Ex.1003, ¶109.

4. Claim 18

Svihra and Johnson would have rendered obvious claim 14. *Supra*, §VI.C.1. Further, Svihra discloses the additional limitations of this claim. *Supra*, §VI.A.4; Ex.1003, ¶110.

5. Claim 27:

a. Element [27.p]

Svihra discloses this limitation. *Supra*, §VI.A.1.a; Ex.1003, ¶111.

b. Element [27.a]

Svihra discloses nearly all elements of this limitation. *Supra*, §VI.A.1.b. Svihra uses “surface electrodes” placed on the patients’ skin. Ex.1004, 481. Other types of electrodes and electrode placements were also well known before 2006. Ex.1003, ¶¶112-13. Johnson, for example, discloses electric stimulators and garment systems. Ex.1007, 1:11-15. Johnson sought to improve on prior electric stimulators, which were large, inconvenient, and uncomfortable. *Id.*, 2:9-20. Johnson thus discloses electric stimulators “for direct attachment onto a garment electrode,” including socks, stockings, sleeves, wraps, gloves, or other types of garments, *id.*, 3:2-15, 3:26-28, cl.4, as well as attachment via a “connector strap.”

Id., 6:18-20. *See also* Ex.1022, 4:25-51 (disclosing socks that “position electrically conductive patches correctly relative to the nerves to which electrical connection is made”); Ex.1003, ¶113.

Even if Svihra does not disclose positioning an electrical stimulator upon a strap secured over a foot of the patient, a POSA would have found it obvious to modify Svihra’s teachings to position the electrical stimulator upon a strap. *Id.*, ¶114. Positioning Svihra’s electrodes upon a strap would have involved nothing more than simple substitution of known elements (substituting “surface electrodes” for Johnson’s electrical stimulator/strap) or combining prior art elements according to known methods (combining Svihra’s electrodes with Johnson’s stimulator/strap). *Id.* Additionally, it would have been obvious to try use of Johnson’s stimulator/strap given the finite number of types of stimulator electrodes that could be used in stimulation procedures and the finite number of ways to position electrodes on a user’s body. *Id.* A POSA would have expected success modifying Svihra’s procedure in this manner and the results would have been predictable given the use such electrodes in the prior art such as in Johnson. *Id.* Moreover, a POSA would have also been motivated to modify Svihra in this manner based on the teachings of the art itself, including to improve user comfort and convenience, as disclosed by Johnson. Ex.1007, 2:9-20; Ex.1003, ¶114.

c. Element [27.b]

Svihra discloses this limitation. *Supra*, §VI.A.1.c; Ex.1003, ¶115.

d. Element [27.c]

Svihra discloses this limitation. *Supra*, §VI.A.1.d; Ex.1003, ¶116..

6. Claim 29

Svihra and Johnson would have rendered obvious claim 27. *Supra*, §VI.C.5.
Further, Svihra discloses the additional limitations of this claim. *Supra*, §VI.A.2;
Ex.1003, ¶117.

7. Claim 30

Svihra and Johnson would have rendered obvious claim 27. *Supra*, §VI.C.5.
Further, Svihra discloses the additional limitations of this claim. *Supra*, §VI.A.3;
Ex.1003, ¶118.

8. Claim 31

Svihra and Johnson would have rendered obvious claim 27. *Supra*, §VI.C.5.
Further, Svihra discloses the additional limitations of this claim. *Supra*, §VI.A.4;
Ex.1003, ¶119.

D. Ground 4: Svihra (Ex.1004) in View of Johnson (Ex.1077) and the Knowledge of a POSA Renders Obvious Claims 15, 19-26, 28, and 32-39

1. Claim 15

Svihra and Johnson would have rendered obvious claim 14. *Supra*, §VI.C.1. Further, Svihra and the knowledge of a POSA would have rendered obvious this claim for the reasons regarding claim 2. *Supra*, §IV.B.1; Ex.1003, ¶121.

2. Claim 19

Svihra and Johnson would have rendered obvious claim 14. *Supra*, §VI.C.1. Further, Svihra and the knowledge of a POSA would have rendered this claim obvious for the reasons regarding claim 6. *Supra*, §IV.B.2; Ex.1003, ¶122.

3. Claim 20

Svihra and Johnson and the knowledge of a POSA would have rendered obvious claim 19. *Supra*, §VI.D.2. Further, Svihra and the knowledge of a POSA would have rendered this claim obvious for the reasons regarding claim 7. *Supra*, §IV.B.3; Ex.1003, ¶123.

4. Claim 21

Svihra and Johnson would have rendered obvious claim 14. *Supra*, §VI.C.1. Further, Svihra and the knowledge of a POSA would have rendered this claim obvious for the reasons regarding claim 6. *Supra*, §IV.B.2; Ex.1003, ¶124.

5. Claim 22

Svihra and Johnson and the knowledge of a POSA would have rendered obvious claim 21. *Supra*, §VI.D.4. Further, Svihra and the knowledge of a POSA would have rendered this claim obvious for the reasons regarding claim 7. *Supra*, §IV.B.3; Ex.1003, ¶125.

6. Claim 23

Svihra and Johnson would have rendered obvious claim 14. *Supra*, §VI.C.1. Further, Svihra and the knowledge of a POSA would have rendered this claim obvious for the reasons regarding claim 6. *Supra*, §IV.B.2; Ex.1003, ¶126.

7. Claim 24

Svihra and Johnson and the knowledge of a POSA would have rendered obvious claim 23. *Supra*, §VI.D.6. Further, Svihra and the knowledge of a POSA would have rendered this claim obvious for the reasons regarding claim 7. *Supra*, §IV.B.3; Ex.1003, ¶127.

8. Claim 25

Svihra and Johnson would have rendered obvious claim 14. *Supra*, §VI.C.1. Further, Svihra and the knowledge of a POSA would have rendered this claim obvious for the reasons regarding claim 6. *Supra*, §IV.B.2; Ex.1003, ¶128.

9. Claim 26

Svihra and Johnson and the knowledge of a POSA would have rendered obvious claim 25. *Supra*, §VI.D.8. Further, Svihra and the knowledge of a POSA

would have rendered this claim obvious for the reasons regarding claim 7. *Supra*, §IV.B.3; Ex.1003, ¶129.

10. Claim 28

Svihra and Johnson would have rendered obvious claim 27. *Supra*, §VI.C.5. Further, Svihra and the knowledge of a POSA would have rendered this claim obvious for the reasons regarding claim 2. *Supra*, §IV.B.1; Ex.1003, ¶130.

11. Claim 32

Svihra and Johnson would have rendered obvious claim 27. *Supra*, §VI.C.5. Further, Svihra and the knowledge of a POSA would have rendered this claim obvious for the reasons regarding claim 6. *Supra*, §IV.B.2; Ex.1003, ¶131.

12. Claim 33

Svihra and Johnson and the knowledge of a POSA would have rendered obvious claim 32. *Supra*, §VI.D.11. Further, Svihra and the knowledge of a POSA would have rendered this claim obvious for the reasons regarding claim 7. *Supra*, §IV.B.3; Ex.1003, ¶132.

13. Claim 34

Svihra and Johnson would have rendered obvious claim 27. *Supra*, §VI.C.5. Further, Svihra and the knowledge of a POSA would have rendered this claim obvious for the reasons regarding claim 6. *Supra*, §IV.B.2; Ex.1003, ¶133.

14. Claim 35

Svihra and Johnson and the knowledge of a POSA would have rendered obvious claim 34. *Supra*, §VI.D.13. Further, Svihra and the knowledge of a POSA would have rendered this claim obvious for the reasons regarding claim 7. *Supra*, §IV.B.3; Ex.1003, ¶134.

15. Claim 36

Svihra and Johnson would have rendered obvious claim 27. *Supra*, §VI.C.5. Further, Svihra and the knowledge of a POSA would have rendered this claim obvious for the reasons regarding claim 6. *Supra*, §IV.B.2; Ex.1003, ¶135.

16. Claim 37

Svihra and Johnson and the knowledge of a POSA would have rendered obvious claim 36. *Supra*, §VI.D.15. Further, Svihra and the knowledge of a POSA would have rendered this claim obvious for the reasons regarding claim 7. *Supra*, §IV.B.3; Ex.1003, ¶136.

17. Claim 38

Svihra and Johnson would have rendered obvious claim 27. *Supra*, §VI.C.5. Further, Svihra and the knowledge of a POSA would have rendered this claim obvious for the reasons regarding claim 6. *Supra*, §IV.B.2; Ex.1003, ¶137.

18. Claim 39

Svihra and Johnson and the knowledge of a POSA would have rendered obvious claim 38. *Supra*, §VI.D.17. Further, Svihra and the knowledge of a POSA

would have rendered this claim obvious for the reasons regarding claim 7. *Supra*, §IV.B.3; Ex.1003, ¶138.

E. Ground 5: Amarenco (Ex.1005) Anticipates Claims 1-3 and 5

Amarenco published in 2003 and is therefore prior art under AIA 35 U.S.C. §102(a)(1). While Amarenco was cited during prosecution of the ‘943 patent, it was not substantively considered and did not form the basis of any rejections. The Board should not exercise discretion to deny institution under §325(d) based on Amarenco. *Infra*, §VII.B.

1. Claim 1:

a. Element [1.p]

Amarenco studied “acute tibial nerve stimulation in a population presenting with symptoms (urge incontinence and frequency) secondary to [OAB].” Ex.1005, 2210; Ex.1003, ¶140.

b. Element [1.a]

Amarenco’s procedure involved “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.” Ex.1005, 2210. Amarenco states “[s]timulation 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.” Id., 2211 (emphasis added).

Amarenco explicitly states the procedure was “non-invasive.” Ex.1005, 2214. A POSA would also understand “self-adhesive surface stimulation electrode[s]” do not break the skin and thus the procedure was non-invasive. Ex.1003, ¶¶141-42. Amarenco’s electrodes provided stimulation at “10 Hz. and a pulse width of 200 milliseconds in continuous mode.” Ex.1005, 2211. A POSA would appreciate providing electrostimulation in this way would necessarily require electrodes connected to an electrical stimulator source. Ex.1003, ¶142. Thus, the electrodes and/or the electrical stimulator source are an “electrical stimulator,” as claimed. *Id.* Additionally, a POSA would understand electrodes “on the ankle skin with the negative electrode behind the internal malleolus and the positive electrode 10 cm. above the negative electrode” for stimulation of the PTN necessarily indicates a portion of the patients’ bodies “near an ankle” were positioned relative to an electrical stimulator, as claimed. Ex.1005, 2211; Ex.1003, ¶142.

Amarenco indicates “surface self-adhesive electrodes on the ankle skin behind the internal malleolus” were used to stimulate the “left [PTN].” Ex.1005, 2210. Further, Amarenco’s electrodes “directly targeted” the patients’ PTN. The ‘943 patent does not explain how a nerve is “directly targeted” or distinguish

“directly targeting” a nerve from simply “targeting” a nerve; rather, the patent merely discloses placing stimulation devices in the vicinity of portions of the body. Amarenco “directly targeted” the patients’ PTN in the same way by placing electrodes “on the ankle skin behind the internal malleolus” and providing electrical stimulation to the patients’ PTN. Ex.1003, ¶143.

c. Element [1.b]

Amarenco applied stimulation via “surface self-adhesive electrode[s]” “at 10 Hz. and a pulse width of 200 milliseconds in continuous mode.” Ex.1005, 2211. In order for electrical stimulation to be applied through the electrodes, the electrodes necessarily would have been connected to an electrical stimulator source through which current was passed. Ex.1003, ¶144.

d. Element [1.c]

Amarenco states “[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.” Ex.1005, 2211. Thus, Amarenco delivered electrical stimulus from an electrical stimulator through the electrodes to the PTN. Ex.1003, ¶145. Moreover, Amarenco’s study included patients “presenting with symptoms (urge incontinence and frequency) secondary to overactive bladder.”

Ex.1005, 2210-11. Amarenco reported successful results, including suppressing detrusor instability and improved bladder capacity. *Id.*, 2214; Ex.1003, ¶146.

2. Claim 2

Amarenco anticipates claim 1. *Supra*, §VI.E.1. Further, claim 2 does not cover a novel or nonobvious features of the alleged invention. *Supra*, §VI.B.1. Setting that aside, Amarenco used 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.”

Ex.1005, 2211. A “self-adhesive surface stimulation electrode” is an “electrode patch.” Ex.1003, ¶147.

3. Claim 3

Amarenco anticipates claim 1. *Supra*, §VI.E.1. Further, Amarenco states “[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.” Ex.1005, 2211. “Flexion of the toes” and “muscle contractions” are muscular responses caused by Amarenco’s stimulation of the PTN. Ex.1003, ¶148.

4. Claim 5

Amarenco anticipates claim 1. *Supra*, §VI.E.1. Further, Amarenco performed cystometry before and after PTN stimulation “with computerized analysis of results.” Ex.1005, 2211. As shown in Figs.3-4, Amarenco also

performed EMG, which measures electrical activity and response to muscle stimulation by a nerve. *Id.*, Figs.3-4 (below); Ex.1003, ¶149.

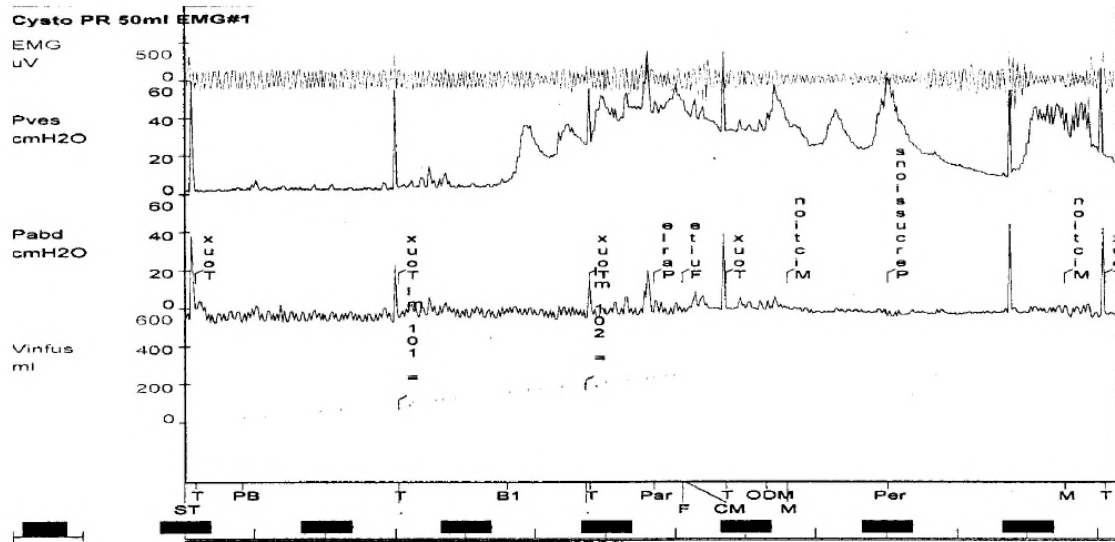


FIG. 3. Standard cystometry in 42-year-old patient with multiple sclerosis presenting with urge incontinence, frequency and urgency shows overactive bladder with noninhibited detrusor contraction.

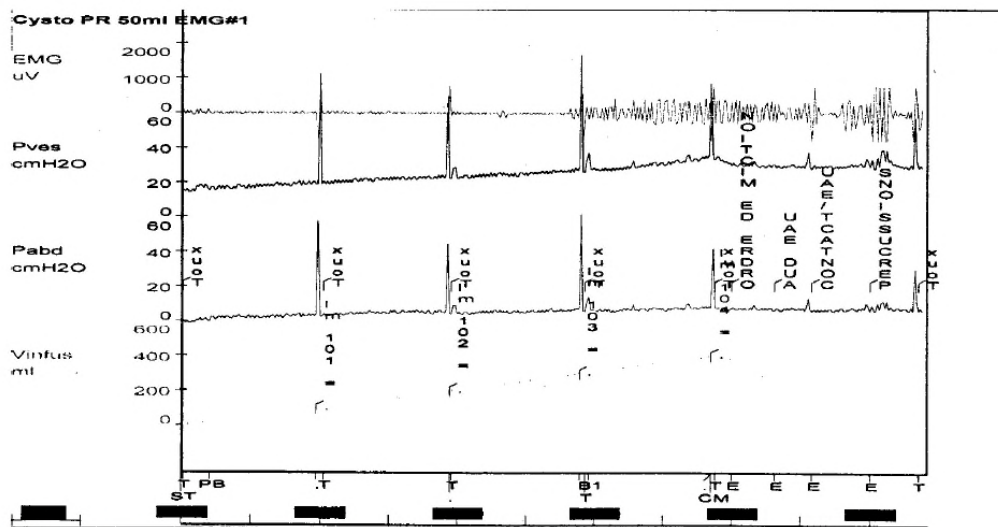


FIG. 4. Cystometry following surface stimulation with 10 Hz. of posterior tibial nerve at ankle demonstrates improvement in urodynamic parameters with suppression of involuntary detrusor contractions.

Cystometry and EMG are “physiological parameters” detected from Amarenco’s patients and displayed, as shown in the figures. Ex.1003, ¶149.

F. Ground 6: Amarenco (Ex.1005) in View of the Knowledge of a POSA Renders Obvious Claims 4 and 6-13

1. Claim 4

Amarenco anticipates claim 1. *Supra*, §VI.E.1. Further, application of electrostimulation for 30 minutes per week for the treatment of OAB/incontinence was known in the art. Ex.1004, 481; Ex.1038, 915; Ex.1039, 44; Ex.1003, ¶¶151-52. While Amarenco did not disclose multiple treatment sessions, it would have been obvious to modify Amarenco's teachings to apply electrical stimulation in 30 minute, weekly treatment sessions. Ex.1003, ¶153. Modifying Amarenco in this manner would have involved applying known techniques to improve known processes and/or combining prior art elements to known methods—namely, applying known, successful weekly 30-minute treatment sessions to Amarenco's method. *Id.* A POSA would have found results to be predictable based on the knowledge of the art, in which this precise treatment duration and frequency was known and used successfully to treat OAB/incontinence. *Id.*

2. Claim 6

Amarenco anticipates claim 1. *Supra*, §VI.E.1. Further, as discussed above, a POSA 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. *Supra*, §VI.B.2; Ex.1003, ¶¶154-59.

Further, as discussed above, 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. Ex.1003, ¶161; Ex.1041, 119; Ex.1028, 361; Ex.1029, 1:45-63. EMG electrodes were typically placed at a second portion of a patient's body away from the stimulation site, Ex.1003, ¶161; Ex.1030, 10; Ex.1028, 367, and a variety of types of EMG electrodes including surface electrodes that measure electrical activity through skin tissue were used. Ex.1003, ¶161; Ex.1030, 3, 10; Ex.1028, 362. It was also known well before 2006 that electrodes could be improperly positioned, migrate, and/or malfunction during electric stimulation procedures. Ex.1003, ¶162; Ex.1001, 3:2-4; Ex.1031, [0024]; Ex.1032, [0005]; Ex.1033, 1:41-48. EMG was thus used to detect improper electrode placement, migration, and malfunction. Ex.1003, ¶163; Ex.1030, 7 (EMG "confirmed satisfactory positioning of the electrode" during electrostimulation for treatment of OAB), 10 (EMG used to "confirm [electrodes] continued optimum position"); Ex.1034, 12:28-45 (EMG used to confirm electrode placement). Given the teachings in the prior art to use EMG for these purposes and the conventional use of EMG, a POSA would have found it obvious to use EMG to detect improper electrode placement, migration, and/or malfunction. Ex.1003, ¶164. Indeed, it was well known that EMG measures electrical conduction (or lack of conduction) in muscle stimulated by a nerve and

of a nerve impulse between a stimulation site and muscle. *Id.*; Ex.1042, 120-21. A POSA would thus recognize that a lack of EMG signal from a muscle corresponding to a nerve that was electrically stimulated necessarily means there is an issue with the patients' nerve or an issue with the stimulator electrode, such as improper placement, migration, or malfunction. Ex.1003, ¶164.

As discussed above, Amarenco used EMG to measure the electrical activity and muscle response from patients. Ex.1005, Figs.3-4; Ex.1003, ¶160. Even if Amarenco did not explicitly state the EMG results were used to detect for the presence or lack of presence of electrical conduction, a POSA would have found it obvious based on the above-described knowledge in the art to modify Amarenco'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. Ex.1003, ¶¶160, 165. Modifying Amarenco's procedure (which already involves measuring EMG, Ex.1005, Figs.3-4) in this way would have involved nothing more than using prior art elements in accordance with their known functions (*i.e.*, using Amarenco's EMG measurement to determine electrode parameters, including improper electrode placement, migration, and/or malfunction, and therapeutic efficacy) and/or applying known techniques to improve a known process (*i.e.*, improving Amarenco's procedure by using EMG signals in known ways, including indicating

proper electrode placement, electrode migration, or electrode malfunction). Ex.1003, ¶165. A POSA would understand the results would be predictable, given the conventional nature of EMG and the use of EMG for similar reasons in the art. *Id.*; Ex.1030, 7, 10; Ex.1034, 12:28-45. Moreover, a POSA would have also been motivated to modify Amarenco in this manner based on the teachings of the art itself, including to “confirm satisfactory positioning of the electrode” (proper electrode placement) or confirm the electrode’s “continued optimum position” (electrode migration). Ex.1030, 7, 10; Ex.1003, ¶165.

3. Claim 7

Amarenco and the knowledge of a POSA would have rendered obvious claim 6. *Supra*, §VI.F.2. Further, claim 7 does not cover a novel or nonobvious features of the alleged invention. The patent explicitly 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. Ex.1001, 25:5-8 (“the sensor may [be] a sensor type known in the art (*e.g.*, EKG sensor)”), 26:61-64 (sensors “known to persons of ordinary skill in the art” can be used); Ex.1003, ¶166.

Setting that aside, Amarenco performed EMG measurements. Ex.1005, Figs.3-4. Moreover, as the patent acknowledges, various sensors/electrodes, including “electrode patches,” could be used for EMG. *E.g.*, Ex. 1003, ¶¶167-68; Ex.1035, 188 (electrode “patch” for surface EMG); Ex.1036, 5:33-50 (“electrode

patch” for detecting physiological signal such as EMG); Ex.1037, 736 (“sticky surface patch electrodes” for EMG).

Even if Amarenco does not explicitly disclose the specific type of EMG sensor/electrode used in the EMG measurements conducted in the procedure, a POSA would have found it obvious to modify Amarenco’s procedure to use an “electrode patch” for detecting the presence of electrical conduction. Ex.1003, ¶169. Using an “electrode patch” in place of Amarenco’s EMG sensor/electrode would have involved nothing more than simple substitution of known elements (substituting EMG electrodes for known “electrode patches”) or predictable use of prior art elements according to established functions (using known “electrode patches” for EMG). *Id.* Additionally, it would have been obvious to try use of known “electrode patches” for EMG given the finite number of types of sensors/electrodes that could be used in EMG procedures. *Id.* A POSA would have expected success modifying Amarenco’s procedure in this manner and the results would have been predictable given the widespread, successful use of EMG “electrode patches” throughout the art in similar procedures. *Id.*

4. Claim 8

Amarenco anticipates claim 1. *Supra*, §VI.E.1. Claim 8 is nearly identical to claim 6 except stating “an indicator of electrode malfunction.” As discussed above, modifying Amarenco to detect a 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 would have been obvious. *Supra*, §VI.F.2. Thus, claim 8 is obvious for the same reasons regarding claim 6. *Id.*; Ex.1003, ¶170.

5. Claim 9

Amarenco and the knowledge of a POSA would have rendered obvious claim 8. *Supra*, §VI.F.4. Claim 9 is nearly identical to claim 7. As discussed above, modifying Amarenco to use an "electrode patch" for detecting the presence of electrical conduction would have been obvious. *Supra*, §VI.F.3. Thus, claim 9 is obvious for the same reasons regarding claim 7. *Id.*; Ex.1003, ¶171.

6. Claim 10

Amarenco anticipates claim 1. *Supra*, §VI.E.1. Claim 10 is nearly identical to claim 6 except stating "an indicator of proper electrode placement." As discussed above, modifying Amarenco to detect a 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 would have been obvious. *Supra*, §VI.F.2. Thus, claim 10 is obvious for the same reasons regarding claim 6. *Id.*; Ex.1003, ¶172.

7. Claim 11

Amarenco and the knowledge of a POSA would have rendered obvious claim 10. *Supra*, §VI.F.6. Claim 11 is nearly identical to claim 7. As discussed

above, modifying Amarenco to use an “electrode patch” for detecting the presence of electrical conduction would have been obvious. *Supra*, §VI.F.3. Thus, claim 11 is obvious for the same reasons regarding claim 7. *Id.*; Ex.1003, ¶173.

8. Claim 12

Amarenco anticipates claim 1. *Supra*, §VI.E.1. Claim 12 is nearly identical to claim 6 except stating conduction is “through tissue” and is “an indicator of electrode placement.” As discussed above, modifying Amarenco to detect a lack of presence of electrical conduction through tissue at a second portion of a patient’s body as an indicator of electrode migration, electrode malfunction, and proper electrode placement would have been obvious. *Supra*, §VI.F.2. Thus, claim 10 is obvious for the same reasons regarding claim 6. *Id.*; Ex.1003, ¶174.

9. Claim 13

Amarenco and the knowledge of a POSA would have rendered obvious claim 12. *Supra*, §VI.F.8. Claim 13 is nearly identical to claim 7. As discussed above, modifying Amarenco to use an “electrode patch” for detecting the presence of electrical conduction would have been obvious. *Supra*, §VI.F.3. Thus, claim 13 is obvious for the same reasons regarding claim 7. *Id.*; Ex.1003, ¶175.

G. Ground 7: Amarenco (Ex.1005) in View of Johnson (Ex.1007) Renders Obvious Claims 14-16, 18, 27-29, and 31

1. Claim 14:

a. Element [14.p]

Amarenco discloses this limitation. *Supra*, §VI.E.1.a; Ex.1003, ¶177.

b. Element [14.a]

Amarenco discloses nearly all elements of this limitation. *Supra*, §VI.E.1.b. Amarenco uses “surface self-adhesive electrodes” placed on the patients’ skin. Ex.1005, 2211. Other types of electrodes and electrode placements were also well known before 2006. Ex.1003, ¶¶178-79. Johnson, for example, discloses electric stimulators and garment systems. Ex.1007, 1:11-15. Johnson sought to improve on prior electric stimulators, which were large, inconvenient, and uncomfortable. *Id.*, 2:9-20. Johnson thus discloses electric stimulators “for direct attachment onto a garment electrode,” including socks, stockings, sleeves, wraps, gloves, or other types of garments, *id.*, 3:2-15, 3:26-28, cl.4, as well as attachment via a “connector strap.” *Id.*, 6:18-20. *See also* Ex.1022, 4:25-51 (disclosing socks that “position electrically conductive patches correctly relative to the nerves to which electrical connection is made”); Ex.1003, ¶179.

Even if Amarenco does not disclose positioning an electrical stimulator within a sock worn upon a foot of the patient, a POSA would have found it obvious to modify Amarenco’s teachings to position the electrical stimulator within a sock.

Ex.1003, ¶180. Positioning Amarenco's electrodes within a sock would have involved nothing more than simple substitution of known elements (substituting Amarenco's electrodes for Johnson's sock/garment electrodes) or combining prior art elements according to known methods (combining Amarenco's electrodes with Johnson's sock/garment electrodes). *Id.* Additionally, it would have been obvious to try use of Johnson's sock/garment electrodes given the finite number of types of stimulator electrodes that could be used in stimulation procedures and the finite number of ways to position electrodes on a user's body. *Id.* A POSA would have expected success modifying Amarenco's procedure in this manner and the results would have been predictable given the use such electrodes in the prior art such as in Johnson. *Id.* Moreover, a POSA would have also been motivated to modify Amarenco in this manner based on the teachings of the art itself, including to improve user comfort and convenience, as disclosed by Johnson. Ex.1007, 2:9-20; Ex.1003, ¶180.

c. Element [14.b]

Amarenco discloses this limitation. *Supra*, §VI.E.1.c; Ex.1003, ¶181.

d. Element [14.c]

Amarenco discloses this limitation. *Supra*, §VI.E.1.d; Ex.1003, ¶182.

2. Claim 15

Amarenco and Johnson would have rendered obvious claim 14. *Supra*, §VI.G.1. Further, Amarenco discloses the additional limitations of this claim. *Supra*, §VI.E.2; ; Ex.1003, ¶183.

3. Claim 16

Amarenco and Johnson would have rendered obvious claim 14. *Supra*, §VI.G.1. Further, Amarenco discloses the additional limitations of this claim. *Supra*, §VI.E.3; Ex.1003, ¶184.

4. Claim 18

Amarenco and Johnson would have rendered obvious claim 14. *Supra*, §VI.G.1. Further, Amarenco discloses the additional limitations of this claim. *Supra*, §VI.E.4; Ex.1003, ¶185.

5. Claim 27:

a. Element [27.p]

Amarenco discloses this limitation. *Supra*, §VI.E.1.a; Ex.1003, ¶186.

b. Element [27.a]

Amarenco discloses nearly all elements of this limitation. *Supra*, §VI.E.1.b. Amarenco uses “surface self-adhesive electrodes” placed on the patients’ skin. Ex.1005, 2211. Other types of electrodes and electrode placements were also well known before 2006. Ex.1003, ¶¶187-88. Johnson, for example, discloses electric stimulators and garment systems. Ex.1007, 1:11-15. Johnson sought to improve on

prior electric stimulators, which were large, inconvenient, and uncomfortable. *Id.*, 2:9-20. Johnson thus discloses electric stimulators “for direct attachment onto a garment electrode,” including socks, stockings, sleeves, wraps, gloves, or other types of garments, *id.*, 3:2-15, 3:26-28, cl.4, as well as attachment via a “connector strap.” *Id.*, 6:18-20. *See also* Ex.1022, 4:25-51 (disclosing socks that “position electrically conductive patches correctly relative to the nerves to which electrical connection is made”); Ex.1003, ¶188.

Even if Amarenco does not disclose positioning an electrical stimulator upon a strap secured over a foot of the patient, a POSA would have found it obvious to modify Amarenco’s teachings to position the electrical stimulator upon a strap. *Id.*, ¶189. Positioning Amarenco’s electrodes upon a strap would have involved nothing more than simple substitution of known elements (substituting Amarenco’s electrodes for Johnson’s electrical stimulator/strap) or combining prior art elements according to known methods (combining Amarenco’s electrodes with Johnson’s stimulator/strap). *Id.* Additionally, it would have been obvious to try use of Johnson’s stimulator/strap given the finite number of types of stimulator electrodes that could be used in stimulation procedures and the finite number of ways to position electrodes on a user’s body. *Id.* A POSA would have expected success modifying Amarenco’s procedure in this manner and the results would have been predictable given the use such electrodes in the prior art such as in Johnson. *Id.*

Moreover, a POSA would have also been motivated to modify Amarenco in this manner based on the teachings of the art itself, including to improve user comfort and convenience, as disclosed by Johnson. Ex.1007, 2:9-20; Ex.1003, ¶189.

c. Element [27.b]

Amarenco discloses this limitation. *Supra*, §VI.E.1.c; Ex.1003, ¶190.

d. Element [27.c]

Amarenco discloses this limitation. *Supra*, §VI.E.1.d; Ex.1003, ¶191.

6. Claim 28

Amarenco and Johnson would have rendered obvious claim 27. *Supra*, §VI.G.5. Further, Amarenco discloses the additional limitations of this claim. *Supra*, §VI.E.2; Ex.1003, ¶192.

7. Claim 29

Amarenco and Johnson would have rendered obvious claim 27. *Supra*, §VI.G.5. Further, Amarenco discloses the additional limitations of this claim. *Supra*, §VI.E.3; Ex.1003, ¶193.

8. Claim 31

Amarenco and Johnson would have rendered obvious claim 27. *Supra*, §VI.G.5. Further, Amarenco discloses the additional limitations of this claim. *Supra*, §VI.E.4; Ex.1003, ¶194.

H. Ground 8: Amarenco (Ex.1005) in View of Johnson (Ex.1007) and the Knowledge of a POSA Renders Obvious Claims 17, 19-26, 30, and 32-39

1. Claim 17

Amarenco and Johnson would have rendered obvious claim 14. *Supra*, §VI.G.1. Further, Svihra and the knowledge of a POSA would have rendered this claim obvious for the reasons regarding claim 4. *Supra*, §IV.F.1; Ex.1003, ¶196.

2. Claim 19

Amarenco and Johnson would have rendered obvious claim 14. *Supra*, §VI.G.1. Further, Amarenco and the knowledge of a POSA would have rendered this claim obvious for the reasons regarding claim 6. *Supra*, §IV.F.2; Ex.1003, ¶197.

3. Claim 20

Amarenco and Johnson and the knowledge of a POSA would have rendered obvious claim 19. *Supra*, §VI.H.2. Further, Amarenco and the knowledge of a POSA would have rendered this claim obvious for the reasons regarding claim 7. *Supra*, §IV.F.3; ; Ex.1003, ¶198.

4. Claim 21

Amarenco and Johnson would have rendered obvious claim 14. *Supra*, §VI.G.1. Further, Amarenco and the knowledge of a POSA would have rendered this claim obvious for the reasons regarding claim 6. *Supra*, §IV.F.2; Ex.1003, ¶199.

5. Claim 22

Amarenco and Johnson and the knowledge of a POSA would have rendered obvious claim 21. *Supra*, §VI.H.4. Further, Amarenco and the knowledge of a POSA would have rendered this claim obvious for the reasons regarding claim 7. *Supra*, §IV.F.3; Ex.1003, ¶200.

6. Claim 23

Amarenco and Johnson would have rendered obvious claim 14. *Supra*, §VI.G.1. Further, Amarenco and the knowledge of a POSA would have rendered this claim obvious for the reasons regarding claim 6. *Supra*, §IV.F.2; Ex.1003, ¶201.

7. Claim 24

Amarenco and Johnson and the knowledge of a POSA would have rendered obvious claim 23. *Supra*, §VI.H.6. Further, Amarenco and the knowledge of a POSA would have rendered this claim obvious for the reasons regarding claim 7. *Supra*, §IV.F.3 ; Ex.1003, ¶202.

8. Claim 25

Amarenco and Johnson would have rendered obvious claim 14. *Supra*, §VI.G.1. Further, Amarenco and the knowledge of a POSA would have rendered this claim obvious for the reasons regarding claim 6. *Supra*, §IV.F.2; Ex.1003, ¶203.

9. Claim 26

Amarenco and Johnson and the knowledge of a POSA would have rendered obvious claim 25. *Supra*, §VI.H.8. Further, Amarenco and the knowledge of a POSA would have rendered this claim obvious for the reasons regarding claim 7. *Supra*, §IV.F.3; Ex.1003, ¶204.

10. Claim 30

Amarenco and Johnson would have rendered obvious claim 27. *Supra*, §VI.G.5. Further, Amarenco and the knowledge of a POSA would have rendered this claim obvious for the reasons regarding claim 4. *Supra*, §IV.F.1; Ex.1003, ¶205.

11. Claim 32

Amarenco and Johnson would have rendered obvious claim 27. *Supra*, §VI.G.5. Further, Amarenco and the knowledge of a POSA would have rendered this claim obvious for the reasons regarding claim 6. *Supra*, §IV.F.2; Ex.1003, ¶206.

12. Claim 33

Amarenco and Johnson and the knowledge of a POSA would have rendered obvious claim 32. *Supra*, §VI.H.11. Further, Amarenco and the knowledge of a POSA would have rendered this claim obvious for the reasons regarding claim 7. *Supra*, §IV.F.3; Ex.1003, ¶207.

13. Claim 34

Amarenco and Johnson would have rendered obvious claim 27. *Supra*, §VI.G.5. Further, Amarenco and the knowledge of a POSA would have rendered this claim obvious for the reasons regarding claim 6. *Supra*, §IV.F.2; Ex.1003, ¶208.

14. Claim 35

Amarenco and Johnson and the knowledge of a POSA would have rendered obvious claim 34. *Supra*, §VI.H.13. Further, Amarenco and the knowledge of a POSA would have rendered this claim obvious for the reasons regarding claim 7. *Supra*, §IV.F.3; Ex.1003, ¶209.

15. Claim 36

Amarenco and Johnson would have rendered obvious claim 27. *Supra*, §VI.G.5. Further, Amarenco and the knowledge of a POSA would have rendered this claim obvious for the reasons regarding claim 6. *Supra*, §IV.F.2; Ex.1003, ¶210.

16. Claim 37

Amarenco and Johnson and the knowledge of a POSA would have rendered obvious claim 36. *Supra*, §VI.H.15. Further, Amarenco and the knowledge of a POSA would have rendered this claim obvious for the reasons regarding claim 7. *Supra*, §IV.F.3; Ex.1003, ¶211.

17. Claim 38

Amarenco and Johnson would have rendered obvious claim 27. *Supra*, §VI.G.5. Further, Amarenco and the knowledge of a POSA would have rendered this claim obvious for the reasons regarding claim 6. *Supra*, §IV.F.2; Ex.1003, ¶212.

18. Claim 39

Amarenco and Johnson and the knowledge of a POSA would have rendered obvious claim 38. *Supra*, §VI.H.17. Further, Amarenco and the knowledge of a POSA would have rendered this claim obvious for the reasons regarding claim 7. *Supra*, §IV.F.3; Ex.1003, ¶213.

I. Ground 9: Burnett (Ex.1006) Anticipates Claims 1-3 and 5-13

Burnett published on December 11, 2008. Given that the earliest effective filing date of the ‘943 patent claims is September 20, 2010, Burnett is therefore prior art under AIA 35 U.S.C. §102(a)(1). *Supra*, §IV.B.1. Burnett was cited during prosecution of the ‘943 patent, but was not substantively considered and did not form the basis for any rejections. *Infra*, §VII.B.

1. Claim 1:

a. Element [1.p]

Burnett teaches treating OAB/incontinence using “energy emitting apparatuses and methods.” Ex.1006, [0002], [0089-90]; Ex.1003, ¶215.

b. Element [1.a]

Burnett states “the source of energy for nerve stimulation is electrical energy that is dispensed through . . . a transcutaneous stimulator, such as an electrode 126.” Ex.1006, [0088]. A POSA would understand that transcutaneous stimulation is non-invasive. Ex.1003, ¶216. The energy emitting apparatus disclosed by Burnett is positioned “over ankle 22 . . . to surround a portion of tibial nerve 24.” Ex.1006, [0049]; Ex.1003, ¶216.

c. Element [1.b]

Burnett states “an 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.” Ex.1006, [0088]; Ex.1003, ¶217.

d. Element [1.c]

Burnett’s device “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.” Ex.1006, [0089]; Ex.1003, ¶218.

2. Claim 2

Burnett discloses the limitations of claim 1. *Supra*, §VI.I.1. Further, Burnett states “the source of energy for nerve stimulation is electrical energy that is dispensed through . . . a transcutaneous stimulator, such as an electrode 126.” Ex.1006, [0088]; Ex.1003, ¶219.

3. Claim 3

Burnett discloses the limitations of claim 1. *Supra*, §VI.I.1. Burnett states “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.” Ex.1006, [0058], [0035]; Ex.1003, ¶220.

4. Claim 5

Burnett discloses the limitations of claim 1. *Supra*, §VI.I.1. Further, Burnett’s devices “detect a variety of physiologic changes, including neural impulses, muscular contraction, twitching, etc. that may occur with neural or muscular stimulation.” Ex.1006, [0080]; *see also id.*, [0082] (“[s]ensors 94 may be structured as disposable, single-use, EKG-type patches that are attached to the body outside of cradle 98 along the nerve conduction pathway and are then connected to the logic controller (not shown) before beginning therapy. . . . Once therapy has begun, sensors 94 continue to monitor nerve conduction to ensure that

the correct level of stimulation is being provided.”). A POSA would understand 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.” Ex.1003, ¶221.

5. Claim 6

Burnett discloses the limitations of claim 1. *Supra*, §VI.I.1. Further, Burnett states “the 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.” Ex.1006, [0036]; *see also id.*, [0088]; Ex.1003, ¶222.

6. Claim 7

Burnett discloses the limitations of claim 6. *Supra*, §VI.I.6. Further, Burnett states “sensor 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.” Ex.1003, [0067]; Ex.1003, ¶223.

7. Claim 8

Burnett discloses the limitations of claim 1. *Supra*, §VI.I.1. Burnett also discloses the limitations of this claim. *Supra*, §VI.I.5; Ex.1003, ¶224.

8. Claim 9

Burnett discloses the limitations of claim 8. *Supra*, §VI.I.8. Further, Burnett discloses the limitations of this claim. *Supra*, §VI.I.6; Ex.1003, ¶225.

9. Claim 10

Burnett discloses the limitations of claim 1. *Supra*, §VI.I.1. Burnett also discloses the limitations of this claim. *Supra*, §VI.I.5; Ex.1003, ¶226.

10. Claim 11

Burnett discloses the limitations of claim 10. *Supra*, §VI.I.9. Further, Burnett discloses the limitations of this claim. *Supra*, §VI.I.6; Ex.1003, ¶227.

11. Claim 12

Burnett discloses the limitations of claim 1. *Supra*, §VI.I.1. Burnett also discloses the limitations of this claim. *Supra*, §VI.I.5; Ex.1003, ¶228.

12. Claim 13

Burnett discloses the limitations of claim 12. *Supra*, §VI.I.11. Further, Burnett discloses the limitations of this claim. *Supra*, §VI.I.6; Ex.1003, ¶229.

J. Ground 10: Burnett (Ex.1006) in View of Johnson (Ex.1007) and the Knowledge of a POSA Renders Obvious Claims 4 and 14-39

1. Claim 4

Burnett discloses the limitations of claim 1. *Supra*, §VI.I.1. Further, Burnett states “[t]he inductive magnetic pulses continue for an appropriate duration of use, for example, for 15-30 minutes.” Ex.1006, [0102]. Further, application of electrostimulation for 30 minutes per week for the treatment of OAB/incontinence was known in the art. Ex.1004, 481; Ex.1038, 915; Ex.1039, 44; Ex.1003, ¶¶231-32. To the extent Burnett does not disclose electrostimulation for weekly 30-minute treatments, it would have been obvious to modify Burnett’s teachings to apply electrical stimulation in 30-minute, weekly treatment sessions. Ex.1003, ¶233. Modifying Burnett in this manner would have involved applying known techniques to improve known processes and/or combining prior art elements to known methods—namely, applying known, successful weekly 30-minute treatment sessions to Burnett’s method. *Id.* A POSA would have found results to be predictable based on the knowledge of the art, in which this precise treatment duration and frequency was known and used successfully to treat OAB/incontinence. *Id.*

2. Claim 14:

a. Element [14.p]

Burnett discloses this limitation. *Supra*, §VI.I.1.a; Ex.1003, ¶234.

b. Element [14.a]

Burnett discloses nearly all elements of this limitation. *Supra*, §VI.I.1.b. Burnett uses an electrode placed on the user's skin. Ex.1006, [0088]. Other types of electrodes and electrode placements were also well known before 2006. Ex.1003, ¶¶235-36. Johnson, for example, discloses electric stimulators and garment systems. Ex.1007, 1:11-15. Johnson sought to improve on prior electric stimulators, which were large, inconvenient, and uncomfortable. *Id.*, 2:9-20. Johnson thus discloses electric stimulators "for direct attachment onto a garment electrode," including socks, stockings, sleeves, wraps, gloves, or other types of garments, *id.*, 3:2-15, 3:26-28, cl.4, as well as attachment via a "connector strap." *Id.*, 6:18-20. *See also* Ex.1022, 4:25-51 (disclosing socks that "position electrically conductive patches correctly relative to the nerves to which electrical connection is made"); Ex.1003, ¶236.

A POSA would have found it obvious to modify Burnett's teachings to position the electrical stimulator within a sock. Ex.1003, ¶237. Positioning Burnett's electrodes within a sock would have involved nothing more than simple substitution of known elements (substituting Burnett's electrodes for Johnson's sock/garment electrodes) or combining prior art elements according to known methods (combining Burnett's electrodes with Johnson's sock/garment electrodes). *Id.* Additionally, it would have been obvious to try use of Johnson's sock/garment

electrodes given the finite number of types of stimulator electrodes that could be used in stimulation procedures and the finite number of ways to position electrodes on a user's body. *Id.* A POSA would have expected success modifying Burnett's procedure in this manner and the results would have been predictable given the use such electrodes in the prior art such as in Johnson. *Id.* Moreover, a POSA would have also been motivated to modify Burnett in this manner based on the teachings of the art itself, including to improve user comfort and convenience, as disclosed by Johnson. Ex.1007, 2:9-20; Ex.1003, ¶237.

c. Element [14.b]

Burnett discloses this limitation. *Supra*, §VI.I.1.c; Ex.1003, ¶238.

d. Element [14.c]

Burnett discloses this limitation. *Supra*, §VI.I.1.d; Ex.1003, ¶239.

3. Claim 15

Burnett and Johnson and the knowledge of a POSA renders obvious claim 14. *Supra*, §VI.J.2. Further, Burnett discloses the additional limitations of this claim. *Supra*, §VI.I.2; Ex.1003, ¶240.

4. Claim 16

Burnett and Johnson and the knowledge of a POSA renders obvious claim 14. *Supra*, §VI.J.2. Further, Burnett discloses the additional limitations of this claim. *Supra*, §VI.I.3; Ex.1003, ¶241.

5. Claim 17

Burnett and Johnson and the knowledge of a POSA renders obvious claim 14. *Supra*, §VI.J.2. Further, Burnett and the knowledge of a POSA would have rendered this claim obvious for the reasons regarding claim 4. *Supra*, §IV.J.1; Ex.1003, ¶242.

6. Claim 18

Burnett and Johnson and the knowledge of a POSA renders obvious claim 14. *Supra*, §VI.J.2. Further, Burnett discloses the additional limitations of this claim. *Supra*, §VI.I.4; Ex.1003, ¶243.

7. Claim 19

Burnett and Johnson and the knowledge of a POSA renders obvious claim 14. *Supra*, §VI.J.2. Further, Burnett discloses the additional limitations of this claim. *Supra*, §VI.I.5; Ex.1003, ¶244.

8. Claim 20

Burnett and Johnson and the knowledge of a POSA renders obvious claim 19. *Supra*, §VI.J.7. Further, Burnett discloses the additional limitations of this claim. *Supra*, §VI.I.6; Ex.1003, ¶245.

9. Claim 21

Burnett and Johnson and the knowledge of a POSA renders obvious claim 14. *Supra*, §VI.J.2. Further, Burnett discloses the additional limitations of this claim. *Supra*, §VI.I.7; Ex.1003, ¶246.

10. Claim 22

Burnett and Johnson and the knowledge of a POSA renders obvious claim 21. *Supra*, §VI.J.9. Further, Burnett discloses the additional limitations of this claim. *Supra*, §VI.I.8; Ex.1003, ¶247.

11. Claim 23

Burnett and Johnson and the knowledge of a POSA renders obvious claim 14. *Supra*, §VI.J.2. Further, Burnett discloses the additional limitations of this claim. *Supra*, §VI.I.9; Ex.1003, ¶248.

12. Claim 24

Burnett and Johnson and the knowledge of a POSA renders obvious claim 23. *Supra*, §VI.J.11. Further, Burnett discloses the additional limitations of this claim. *Supra*, §VI.I.10; Ex.1003, ¶249.

13. Claim 25

Burnett and Johnson and the knowledge of a POSA renders obvious claim 14. *Supra*, §VI.J.2. Further, Burnett discloses the additional limitations of this claim. *Supra*, §VI.I.11; Ex.1003, ¶250.

14. Claim 26

Burnett and Johnson and the knowledge of a POSA renders obvious claim 25. *Supra*, §VI.J.13. Further, Burnett discloses the additional limitations of this claim. *Supra*, §VI.I.12; Ex.1003, ¶251.

15. Claim 27:

a. Element [27.p]

Burnett discloses this limitation. *Supra*, §VI.I.1.a; Ex.1003, ¶252.

b. Element [27.a]

Burnett discloses nearly all elements of this limitation. *Supra*, §VI.I.1.b.

Burnett uses an electrode placed on the user's skin. Ex.1006, [0088]. Other types of electrodes and electrode placements were also well known before 2006.

Ex.1003, ¶¶253-54. Johnson, for example, discloses electric stimulators and garment systems. Ex.1007, 1:11-15. Johnson sought to improve on prior electric stimulators, which were large, inconvenient, and uncomfortable. *Id.*, 2:9-20.

Johnson thus discloses electric stimulators “for direct attachment onto a garment electrode,” including socks, stockings, sleeves, wraps, gloves, or other types of garments, *id.*, 3:2-15, 3:26-28, cl.4, as well as attachment via a “connector strap.”

Id., 6:18-20. *See also* Ex.1022, 4:25-51 (disclosing socks that “position electrically conductive patches correctly relative to the nerves to which electrical connection is made”); Ex.1003, ¶254.

Even if Burnett does not disclose positioning an electrical stimulator upon a strap secured over a foot of the patient, a POSA would have found it obvious to modify Burnett's teachings to position the electrical stimulator upon a strap. *Id.*, ¶255. Positioning Burnett's electrodes upon a strap would have involved nothing more than simple substitution of known elements (substituting Burnett's electrodes

for Johnson's electrical stimulator/strap) or combining prior art elements according to known methods (combining Burnett's electrodes with Johnson's stimulator/strap). *Id.* Additionally, it would have been obvious to try use of Johnson's stimulator/strap given the finite number of types of stimulator electrodes that could be used in stimulation procedures and the finite number of ways to position electrodes on a user's body. *Id.* A POSA would have expected success modifying Burnett's procedure in this manner and the results would have been predictable given the use such electrodes in the prior art such as in Johnson. *Id.* Moreover, a POSA would have also been motivated to modify Burnett in this manner based on the teachings of the art itself, including to improve user comfort and convenience, as disclosed by Johnson. Ex.1007, 2:9-20; Ex.1003, ¶255.

c. Element [27.b]

Burnett discloses this limitation. *Supra*, §VI.I.1.c; Ex.1003, ¶256.

d. Element [27.c]

Burnett discloses this limitation. *Supra*, §VI.I.1.d; Ex.1003, ¶257.

16. Claim 28

Burnett and Johnson and the knowledge of a POSA renders obvious claim 27. *Supra*, §VI.J.15. Further, Burnett discloses the additional limitations of this claim. *Supra*, §VI.I.2; Ex.1003, ¶258.

17. Claim 29

Burnett and Johnson and the knowledge of a POSA renders obvious claim 27. *Supra*, §VI.J.15. Further, Burnett discloses the additional limitations of this claim. *Supra*, §VI.I.3; Ex.1003, ¶259.

18. Claim 30

Burnett and Johnson and the knowledge of a POSA renders obvious claim 14. *Supra*, §VI.I.15. Further, Burnett and the knowledge of a POSA discloses the additional limitations of this claim. *Supra*, §VI.J.1; Ex.1003, ¶260.

19. Claim 31

Burnett and Johnson and the knowledge of a POSA renders obvious claim 27. *Supra*, §VI.J.15. Further, Burnett discloses the additional limitations of this claim. *Supra*, §VI.I.4; Ex.1003, ¶261.

20. Claim 32

Burnett and Johnson and the knowledge of a POSA renders obvious claim 27. *Supra*, §VI.J.15. Further, Burnett discloses the additional limitations of this claim. *Supra*, §VI.I.5; Ex.1003, ¶262.

21. Claim 33

Burnett and Johnson and the knowledge of a POSA renders obvious claim 32. *Supra*, §VI.J.20. Further, Burnett discloses the additional limitations of this claim. *Supra*, §VI.I.6; Ex.1003, ¶263.

22. Claim 34

Burnett and Johnson and the knowledge of a POSA renders obvious claim 27. *Supra*, §VI.J.15. Further, Burnett discloses the additional limitations of this claim. *Supra*, §VI.I.7; Ex.1003, ¶264.

23. Claim 35

Burnett and Johnson and the knowledge of a POSA renders obvious claim 34. *Supra*, §VI.J.22. Further, Burnett discloses the additional limitations of this claim. *Supra*, §VI.I.8; Ex.1003, ¶265.

24. Claim 36

Burnett and Johnson and the knowledge of a POSA renders obvious claim 27. *Supra*, §VI.J.15. Further, Burnett discloses the additional limitations of this claim. *Supra*, §VI.I.9; Ex.1003, ¶266.

25. Claim 37

Burnett and Johnson and the knowledge of a POSA renders obvious claim 36. *Supra*, §VI.J.24. Further, Burnett discloses the additional limitations of this claim. *Supra*, §VI.I.10; Ex.1003, ¶267.

26. Claim 38

Burnett and Johnson and the knowledge of a POSA renders obvious claim 27. *Supra*, §VI.J.15. Further, Burnett discloses the additional limitations of this claim. *Supra*, §VI.I.11; Ex.1003, ¶268.

27. Claim 39

Burnett and Johnson and the knowledge of a POSA renders obvious claim 38. *Supra*, §VI.J.26. Further, Burnett discloses the additional limitations of this claim. *Supra*, §VI.I.2; Ex.1003, ¶269.

K. Secondary Considerations

The Examiner did not rely on secondary considerations when allowing the claims. Therefore, Petitioner need not address any purported secondary considerations. The Board should institute trial to address any new evidence PO might offer. *E.g., Brunswick Corp. v. Volvo Penta of the Americas, LLC*, IPR2020-01512, Paper 15 at 47 (PTAB Mar. 11, 2021). Regardless, Petitioner is unaware of any secondary considerations evidence, and any such evidence PO may provide cannot outweigh the strong *prima facie* case of obviousness. Petitioner reserves the right to respond to secondary considerations evidence raised by PO in due course.

L. Ground 11: Claims 1-39 Lack Enablement

Claims 1-39 of the '943 patent are unpatentable under 35 U.S.C. §112 because the specification does not enable the claimed subject matter. "Enablement requires that the specification teach those in the art to make and use the invention without 'undue experimentation.'" *In re Vaeck*, 947 F.2d 488, 495 (Fed. Cir. 1991). "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). According to the

Federal Circuit, “where the specification teaches against a purported aspect of an invention, such a teaching ‘is itself evidence that at least a significant amount of experimentation would have been necessary to practice the claimed invention.’”

Liebel-Flarsheim Co. v. Medrad, Inc., 481 F.3d 1371, 1379 (Fed. Cir. 2007)

(quoting *AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1244 (Fed. Cir. 2003)).

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. While the patent indicates that electrical stimulation can be safely applied across a “glabrous surface” (such as the palm of the hand or bottom of the foot, see Ex.1003, ¶271), the patent clearly indicates that applying electrical stimulation to a “non-glabrous surface” (such as the “medial malleolus” or inner ankle, *id.*) is painful, impractical, and not feasible:

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, 50:35-51:3 (emphasis added).

The patent's explicit statements that electric stimulation should **not** be applied at non-glabrous surfaces such as a patient's ankle teaches against the claimed invention. Ex.1003, ¶¶272-73. Indeed, independent claims 1, 14, and 27, and all claims dependent therefrom, require "non-invasively positioning a first portion of a patient's body *near an ankle* relative to an electrical stimulator."

Ex.1001, cls. 1, 14, 27 (emphasis added). But the statements in the 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. *See AK Steel*, 344 F.3d at 1244 ("the specification warns that silicon content above 0.5% in the aluminum coating causes coating problems. Such a statement discourages experimentation with coatings having more than 0.5% silicon, undue or otherwise."). Accordingly, because a significant, undue amount of experimentation would have been required to practice the claimed invention, the claims of the '943 patent are invalid for lack of enablement. Ex.1003, ¶¶272-73.

VII. THE BOARD SHOULD NOT EXERCISE ITS DISCRETION TO DENY INSTITUTION

The Board should decline to exercise its discretion to not institute trial under §324(a) or §325(d), as none of the factors support doing so here.

A. §324(a)

The parties are involved in the NDCA litigation in the United States District Court for the Northern District of California, but that litigation is at an early stage and the *Fintiv* factors identified favor institution. *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 at 5-6 (PTAB Mar. 20, 2020) (precedential) (“Fintiv”).

Factor 1 (Possibility of Stay). While Petitioner intends to seek a stay of the NDCA litigation following the filing of petitions for PGR/IPR of the ‘943, ‘477, and ‘742 patents, the NDCA litigation is not currently stayed. This factor is thus neutral.

Factor 2 (Trial Date). The court has not yet issued a scheduling order in the NDCA litigation and no trial date has been set. Trial is thus unlikely to occur before November 2025, the anticipated date of a final written decision in this proceeding. The facts relevant to Factor 2 strongly favor institution.

Factor 3 (Investment in Parallel Proceeding). To date, the parties have invested little in the NDCA litigation. The initial case management conference is scheduled for July 2, 2024, EMK has yet to make an appearance in the case and

has not yet answered the complaint, no case schedule has been entered, and discovery has yet to begin. The facts relevant to Factor 3 strongly favor institution.

Factor 4 (Overlapping Issues). Petitioner’s complaint in the NDCA litigation asserts noninfringement, *not invalidity*, of the ‘943, ‘477, and ‘742 patents. There are thus currently few issues that are likely to overlap between the NDCA litigation and this proceeding. Should invalidity be raised in the NDCA litigation, Petitioner hereby stipulates that if trial is instituted in this proceeding it will not assert in the NDCA litigation that any challenged claim of the ‘943 patent is invalid on the same grounds raised during this proceeding.

Factors 5 (Overlapping Parties). The fact that a Petitioner is involved in a related district court proceeding does not favor the Board exercising its discretion under §324(a)—as the Board has found previously, “it is far from an unusual circumstance that a petitioner” is also a district court defendant. *Sand Revolution, II, LLC v. Cont’l Intermodal Grp. Trucking LLC*, IPR2019-01393, Paper 24 at 12-13 (PTAB June 16, 2020). The Board routinely finds that other factors outweigh Factor 5, and that is the case here.

Factor 6 (Petition Strength/Other Considerations). The proposed grounds in this Petition strongly favor institution. As explained above, the ‘943 patent claims are invalid for a variety of reasons and based on various prior art references as well as lack of enablement. Further, as explained below, the Examiner erred in

concluding the claimed methods were patentable advances—the methods are taught or suggested by the prior art. Therefore, Factor 6 strongly favors institution.

The balance of considerations under the *Fintiv* factors strongly favors institution of trial.

B. §325(d)

The Board should respectfully not exercise its discretion to deny institution under §325(d). In determining whether to exercise discretion to institute, the Board considers the following:

1. whether the same or substantially the same art previously was presented to the Office or whether the same or substantially the same arguments previously were presented to the Office; and
2. if either condition of first part of the framework is satisfied, whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of challenged claims.

Advanced Bionics, LLC v. Med-El Electromedizinische Geräte GMBH, IPR2019-01469, Paper 6 at 10 (Feb. 13, 2020) (precedential). The Board also considers various non-exclusive factors as part of the two-part framework as set forth in *Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 at 17-18 (PTAB Dec. 15, 2017) (precedential as to § III.C.5, first para.).

The art and arguments presented in this petition are not the same or substantially the same as those presented to the Office during prosecution.

Moreover, the Examiner plainly erred in a manner material to the patentability of the Challenged Claims of the '943 patent. Therefore, discretionary denial under §325(d) is not warranted here.

1. The Art and Arguments Presented Are Not the Same or Substantially the Same as Those Previously Presented to the Office.

The art and arguments presented in this petition are *not* the same or substantially the same as those previously presented to the Office. As an initial matter, *over 450 references* were cited during prosecution of the '943 patent. See Ex.1001, [56]. Even if some of the art relied upon by Petitioner overlaps with references cited during prosecution, PO cannot be allowed to dump hundreds of references on the Office during prosecution and then avoid PGR by claiming the art was previously cited to the Office. In any event, many of Petitioner's prior art grounds rely on references and/or arguments that were not before the Office during prosecution of the '943 patent. For example, Svihra and various secondary references used in Petitioner's obviousness grounds were not cited during prosecution. Moreover, while Amarenco and Burnett were before the Office during prosecution, these references were not considered in combination with many of the secondary references relied on in this Petition. Thus, none of Petitioner's Svihra-based grounds (Grounds 1-4) and several of the other prior-art based grounds present art and/or arguments that were not previously before the Office.

Although Amarenco (Ex.1005) was cited in a third-party submission and Burnett (Ex.1006) was cited in an IDS, it is clear that neither reference nor the arguments presented were properly considered. The Board routinely declines exercising discretion under §325(d) when a relied-upon reference “was neither applied against the claims nor discussed by the Examiner.” *See, e.g., Digital Check Corp. d/b/a ST Imaging v. E-Imagedata Corp.*, IPR2017-00178, Paper 6 at 12-13 (PTAB Apr. 25, 2017); *Fox Factory, Inc. v. SRAM, LLC*, IPR2016-01876, Paper 8 at 7-9 (PTAB Apr. 3, 2017); *Zip-Top LLC v. Stasher, Inc.*, IPR2018-01216, Paper 14 at 35-36 (PTAB Jan. 17, 2019). Here, the Examiner did not substantively discuss the references, did not rely on the references as the basis for any rejections, and in fact did not make a single anticipation or obviousness rejection during prosecution at all. The record shows the Examiner did not properly evaluate the prior art and did not appreciate the prior arts’ relevance to the claims.

2. The Examiner Materially Erred in Allowing the Challenged Claims.

Even if the Board determines the same or substantially the same art or arguments relied upon in this Petition were previously considered, the Examiner materially erred in allowing the Challenged Claims. Indeed, as shown above, the Challenged Claims are invalid over the prior art, including Amarenco and Burnett. Moreover, the Examiner clearly overlooked these references, as the Examiner not only failed to reject the claims over these references, but failed to issue any

anticipation/obviousness rejections at all. The Examiner further erred by relying on the October 2, 2006 filing date of the '720 provisional as the priority date of the claims of the '943 patent, which led the Examiner to overlook Burnett as prior art.

The Examiner's material errors are further demonstrated by the rejection of nearly identical claims over Amarenco in a related application and PO's statements regarding the reference. During prosecution of the '742 patent,⁶ the pending claims were directed to treating OAB/UI. Ex.1050, 178. Pending claim 5 is exemplary:

A method of treating overactive bladder or incontinence comprising:

non-invasively positioning a first portion of a patient's body relative to an electrical stimulator such that ***a branch of a posterior tibial nerve*** within the first portion of the body is in proximity to the electrical stimulator;

passing a current through the electrical stimulator; and

delivering an electrical stimulus from the electrical stimulator to the branch of the posterior tibial nerve to treat overactive bladder or incontinence.

⁶ The '742 patent, like the '943 patent, claims benefit to the '529 application through a series of continuations/CIPs. Ex.1050, 289.

Id. The Examiner (notably, a different Examiner than the Examiner of the ‘943 patent) rejected the claims, including pending claim 5, as anticipated by Amarenco. *Id.*, 167.

In response, PO argued that Amarenco “fails to disclose ‘positioning a first portion of a patient’s body relative to an electrical stimulator such that **a branch of a posterior nerve . . . is in proximity to the electrical stimulator.**” *Id.*, 135 (emphasis in original). As PO stated: “**Amarenco et al. clearly describes the application of its electrodes behind the ankle for targeting the posterior tibial nerve** but Amarenco et al. fails to disclose or teach any targeting of any branch of the posterior tibial nerve.” *Id.*, 136 (emphasis added). Thus, not only did PO admit Amarenco discloses noninvasively applying electrodes near an ankle to target the PTN, the fact PO’s sole argument to distinguish Amarenco was the reference does not target a **branch** of the PTN clearly shows the relevance of Amarenco to the ‘943 patent’s claims. Setting PO’s admissions aside, the fact Amarenco was applied to nearly identical claims during prosecution of a related application demonstrates that the Examiner of the ‘943 patent materially erred by not even substantively considering Amarenco and allowing the Challenged Claims to issue.

3. The Petition Presents Additional Evidence and Arguments.

Although Amarenco and Burnett were cited during prosecution, many of Petitioner’s other references—including Svihra—were not. Thus, the Petition

presents art and arguments that were not previously before the Office. Likewise, other arguments in the Petition, including lack of enablement, were not previously before the Office and strongly favor institution. Moreover, the Petition also cites the expert testimony of Dr. Brett Wingeier (Ex.1003), which provides a POSA's understanding of the state of the art, prior art, claims, and invalidity, thus warranting reconsideration of the art and arguments. Because the same or similar prior art/arguments were not previously before the Office and the Examiner erred in allowing the Challenged Claims of the '943 patent, the Board should decline exercising discretion under §325(d) and institute PGR.

VIII. CONCLUSION

For the foregoing reasons, PGR of claims 1-39 of the '943 patent is respectfully requested.

Dated: July 1, 2024

Respectfully submitted,

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Claim Appendix

Claim 1:

[1.p] A method of treating overactive bladder or incontinence, comprising:

[1.a] 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;

[1.b] passing a current through the electrical stimulator; and

[1.c] 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.

Claim 2:

The method of claim 1 wherein non-invasively positioning comprises positioning an electrode patch in communication with the electrical stimulator near an ankle of the patient.

Claim 3:

The method of claim 1 further comprising detecting a muscular response caused by an electrical conduction or stimulation of the posterior tibial nerve.

Claim 4:

The method of claim 1 wherein delivering the electrical stimulus comprises activating the electrical stimulator for a duration of about 30 minutes per week to treat the patient.

Claim 5:

The method of claim 1 further comprising displaying physiological parameters detected from the patient.

Claim 6:

The method of claim 1 further comprising 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.

Claim 7:

The method of claim 6 wherein detecting for the presence of electrical conduction comprises detecting via an electrode patch positioned upon the second portion.

Claim 8:

The method of claim 1 further comprising 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.

Claim 9:

The method of claim 8 wherein detecting for the presence of electrical conduction comprises detecting via an electrode patch positioned upon the second portion.

Claim 10:

The method of claim 1 further comprising 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.

Claim 11:

The method of claim 10 wherein detecting for the presence of electrical conduction comprises detecting via an electrode patch positioned upon the second portion.

Claim 12:

The method of claim 1 further comprising 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.

Claim 13:

The method of claim 12 wherein detecting for the presence of electrical conduction through tissue comprises detecting via an electrode patch positioned upon the second portion.

Claim 14:

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

[14.a] 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;

[14.b] passing a current through the electrical stimulator; and

[14.c] 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.

Claim 15:

The method of claim 14 wherein non-invasively positioning comprises positioning an electrode patch in communication with the electrical stimulator near an ankle of the patient.

Claim 16:

The method of claim 14 further comprising detecting a muscular response caused by an electrical conduction or stimulation of the posterior tibial nerve.

Claim 17:

The method of claim 14 wherein delivering the electrical stimulus comprises activating the electrical stimulator for a duration of about 30 minutes per week to treat the patient.

Claim 18:

The method of claim 14 further comprising displaying physiological parameters detected from the patient.

Claim 19:

The method of claim 14 further comprising 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.

Claim 20:

The method of claim 19 wherein detecting for the presence of electrical conduction comprises detecting via an electrode patch positioned upon the second portion.

Claim 21:

The method of claim 14 further comprising 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.

Claim 22:

The method of claim 21 wherein detecting for the presence of electrical conduction comprises detecting via an electrode patch positioned upon the second portion.

Claim 23:

The method of claim 14 further comprising 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.

Claim 24:

The method of claim 23 wherein detecting for the presence of electrical conduction comprises detecting via an electrode patch positioned upon the second portion.

Claim 25:

The method of claim 14 further comprising 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.

Claim 26:

The method of claim 25 wherein detecting for the presence of electrical conduction through tissue comprises detecting via an electrode patch positioned upon the second portion.

Claim 27:

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

[27.a] 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;

[27.b] passing a current through the electrical stimulator; and

[27.c] 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.

Claim 28:

The method of claim 27 wherein non-invasively positioning comprises positioning an electrode patch in communication with the electrical stimulator near an ankle of the patient.

Claim 29:

The method of claim 27 further comprising detecting a muscular response caused by an electrical conduction or stimulation of the posterior tibial nerve.

Claim 30:

The method of claim 27 wherein delivering the electrical stimulus comprises activating the electrical stimulator for a duration of about 30 minutes per week to treat the patient.

Claim 31:

The method of claim 27 further comprising displaying physiological parameters detected from the patient.

Claim 32:

The method of claim 27 further comprising 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.

Claim 33:

The method of claim 32 wherein detecting for the presence of electrical conduction comprises detecting via an electrode patch positioned upon the second portion.

Claim 34:

The method of claim 27 further comprising 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.

Claim 35:

The method of claim 34 wherein detecting for the presence of electrical conduction comprises detecting via an electrode patch positioned upon the second portion.

Claim 36:

The method of claim 27 further comprising 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.

Claim 37:

The method of claim 36 wherein detecting for the presence of electrical conduction comprises detecting via an electrode patch positioned upon the second portion.

Claim 38:

The method of claim 27 further comprising 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.

Claim 39:

The method of claim 38 wherein detecting for the presence of electrical conduction through tissue comprises detecting via an electrode patch positioned upon the second portion.

CERTIFICATE OF COMPLIANCE

The undersigned certifies that this Petition complies with the type-volume limitations of 37 C.F.R. §42.24 because it contains 17,040 words (as determined by the Microsoft Word word-processing system used to prepare the Petition), excluding the parts of the Petition exempted by 37 C.F.R. §42.24.

Dated: July 1, 2024

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CERTIFICATE OF SERVICE

The undersigned certifies that the foregoing **PETITION FOR POST GRANT REVIEW OF U.S. PATENT NO. 11,844,943 and ACCOMPANYING EXHIBITS (Ex.1001-1053)** were served as of the below date on the following individuals in accordance with 37 C.F.R. §42.105(a):

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