

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Avation Medical, Inc.,
Petitioner

v.

EMKinetics, Inc.,
Patent Owner

Case No. IPR2024-01378
U.S. Patent No. 9,002,477

**PETITION FOR *INTER PARTES* REVIEW
OF U.S. PATENT NO. 9,002,477**

TABLE OF CONTENTS

I.	INTRODUCTION.....	1
II.	COMPLIANCE WITH IPR REQUIREMENTS	2
A.	Certification (§42.204(a))	2
B.	Identification of Challenge (§42.204(b))	2
C.	Fee (§42.15(b)).....	4
D.	Service (§42.205)	4
III.	BACKGROUND TECHNOLOGY	4
A.	OAB and Incontinence	5
B.	Treatment of OAB and UI	5
C.	Electrical Stimulation Feedback and Control	9
IV.	THE ‘477 PATENT	11
A.	Overview	11
B.	Prosecution History	12
C.	Effective Filing Date	13
D.	Person of Ordinary Skill in the Art (“POSA”).....	14
V.	CLAIM CONSTRUCTION	14
VI.	EXPLANATION OF UNPATENTABILITY	14
A.	Ground 1: Svihra (Ex.1004) Anticipates Claim 1.....	14
B.	Ground 2: Svihra (Ex.1004) in View of Mann (Ex.1084), DiLorenzo (Ex.1054), Gerber (Ex.1055), or Bourget (Ex.1056) Renders Obvious Claim 1.....	20
C.	Ground 3: Svihra (Ex.1004) Alone or in Combination with Mann (Ex.1084), DiLorenzo (Ex.1054), Gerber (Ex.1055), or Bourget (Ex.1056), Further in View of the Knowledge of a POSA, Renders Obvious Claims 2-10.....	28
D.	Ground 4: Amarenco (Ex.1005) in View of Mann (Ex.1084), DiLorenzo (Ex.1054), Gerber (Ex.1055), or Bourget (Ex.1056) Renders Obvious Claim 1.....	43
E.	Ground 5: Amarenco (Ex.1005) in Combination with Mann (Ex.1084), DiLorenzo (Ex.1054), Gerber (Ex.1055), or Bourget	

(Ex.1056), Further in View of the Knowledge of a POSA, Renders Obvious Claims 2-10	50
F. Secondary Considerations	62
VII. THE BOARD SHOULD NOT EXERCISE ITS DISCRETION TO DENY INSTITUTION	63
A. §314(a)	63
B. §325(d)	65
VIII. CONCLUSION	68

TABLE OF AUTHORITIES

Cases

<i>Advanced Bionics, LLC v. Med-El Electromedizinische Geräte GmbH,</i> IPR2019-01469, Paper 6 (Feb. 13, 2020) (precedential).....	65
<i>Allied Erecting & Dismantling Co. v. Genesis Attachments, LLC,</i> 825 F.3d 1373 (Fed. Cir. 2016).....	27, 48
<i>Apple Inc. v. Fintiv, Inc.,</i> IPR2020-00019, Paper 11 (PTAB Mar. 20, 2020) (precedential).....	63
<i>Avation Medical, Inc. v. EMKinetics, Inc.,</i> IPR2024-01375 (PTAB)	xii
<i>Avation Medical, Inc. v. EMKinetics, Inc.,</i> No. 4:24-cv-01702 (NDCA)	xii
<i>Avation Medical, Inc. v. EMKinetics, Inc.,</i> PGR2024-00043 (PTAB).....	xii
<i>Becton, Dickinson & Co. v. B. Braun Melsungen AG,</i> IPR2017-01586, Paper 8 (PTAB Dec. 15, 2017)	66
<i>Brunswick Corp. v. Volvo Penta of the Americas, LLC,</i> IPR2020-01512, Paper 15 (PTAB Mar. 11, 2021)	63
<i>New World Medical, Inc. v. Microsurgical Tech., Inc.,</i> IPR2020-01573, Paper 64 (PTAB March 11, 2022)	3
<i>Sand Revolution, II, LLC v. Cont’l Intermodal Grp. Trucking LLC,</i> IPR2019-01393, Paper 24 (PTAB June 16, 2020).....	64

Statutes

35 U.S.C. §102(b)	passim
35 U.S.C. §102(e)	21, 28, 43, 50
35 U.S.C. §112	14
35 U.S.C. §282(b)	14
35 U.S.C. §314(a)	63
35 U.S.C. §325(d)	63, 65, 66

Regulations

37 C.F.R. §42.15(b)	4
37 C.F.R. §42.200(b)	14
37 C.F.R. §42.204(a).....	2
37 C.F.R. §42.204(b)	2
37 C.F.R. §42.205	4
37 C.F.R. §42.8(b)(1).....	xii
37 C.F.R. §42.8(b)(2).....	xii
37 C.F.R. §42.8(b)(3).....	xiii
37 C.F.R. §42.8(b)(4).....	xiii

EXHIBIT LIST

Exhibit No.	Description
1001	U.S. Patent No. 9,002,477 (“’477 patent”)
1002	File History of U.S. Patent No. 9,002,477 (“’477 patent file history”)
1003	Declaration of Dr. Brett Wingeier in Support of Petition for Inter Partes Review of U.S. Patent No. 9,002,477 (“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	[Reserved] ¹
1007	[Reserved]
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”)

¹ Petitioner has reserved certain exhibit numbers in this proceeding in order to, to the extent possible, maintain consistency with the exhibits and exhibit numbering in related proceedings PGR2024-00043 and IPR2024-01375.

Exhibit No.	Description
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”)
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	[Reserved]
1019	[Reserved]
1020	[Reserved]
1021	[Reserved]
1022	[Reserved]
1023	[Reserved]
1024	[Reserved]
1025	[Reserved]

Exhibit No.	Description
1026	[Reserved]
1027	[Reserved]
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	[Reserved]
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	[Reserved]
1032	[Reserved]
1033	[Reserved]
1034	[Reserved]
1035	[Reserved]
1036	[Reserved]
1037	[Reserved]
1038	[Reserved]
1039	[Reserved]
1040	[Reserved]
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”)

Exhibit No.	Description
1044	<i>[Reserved]</i>
1045	<i>[Reserved]</i>
1046	<i>[Reserved]</i>
1047	<i>[Reserved]</i>
1048	U.S. Patent App. No. 11/866,329 to Burnett <i>et al.</i> (“‘329 application”)
1049	<i>[Reserved]</i>
1050	<i>[Reserved]</i>
1051	<i>Avation Medical, Inc. v. EMKinetics, Inc.</i> No. 3:24-cv-01702 (N.D. Cal.) First Amended Complaint, Dkt. No. 5
1052	<i>[Reserved]</i>
1053	Declaration of Todd R. Tucker
1054	U.S. Patent No. 6,366,813 to DiLorenzo filed Jun. 25, 1999 (“DiLorenzo”)
1055	U.S. Patent No. 7,515,965 to Gerber <i>et al.</i> filed Apr. 28, 2005 (“Gerber”)
1056	U.S. Patent No. 7,853,322 to Bourget <i>et al.</i> filed Apr. 28, 2006 (“Bourget”)
1057	<i>[Reserved]</i>
1058	<i>[Reserved]</i>
1059	<i>[Reserved]</i>
1060	<i>[Reserved]</i>
1061	<i>[Reserved]</i>
1062	<i>[Reserved]</i>
1063	<i>[Reserved]</i>
1064	A. Shafik <i>et al.</i> , “Percutaneous Peripheral Neuromodulation in the Treatment of Fecal Incontinence,” <i>European Surgical Research</i> 35(2):103-107 (2003) (“Shafik”)

Exhibit No.	Description
1065	Michael R. van Balken <i>et al.</i> , “Percutaneous Tibial Nerve Stimulation as Neuromodulative Treatment of Chronic Pelvic Pain,” <i>European Urology</i> 43(2):158-163 (2003) (“van Balken 2003”)
1066	U.S. Patent Pub. App. Pub. No. 2005/0143789 to Whitehurst <i>et al.</i> (“Whitehurst”)
1067	U.S. Patent No. 7,610,100 to Jaax <i>et al.</i> filed Dec. 30, 2005 (“Jaax”)
1068	U.S. Patent App. Pub. No. 2005/0021103 to DiLorenzo published January 27, 2005 (“DiLorenzo ‘103”)
1069	U.S. Patent App. Pub. No. 2005/0033372 to Gerber published February 10, 2005 (“Gerber ‘372”)
1070	U.S. Patent App. Pub. No. 2005/0245989 to Davis filed April 28, 2005 (“Davis”)
1071	Jader A. De Lima <i>et al.</i> , “A Low-Cost Neurostimulator with Accurate Pulsed-Current Control,” <i>IEEE Transactions on Biomedical Engineering</i> 49(5):497-500 (2002) (“De Lima”)
1072	<i>[Reserved]</i>
1073	<i>[Reserved]</i>
1074	<i>[Reserved]</i>
1075	<i>[Reserved]</i>
1076	<i>[Reserved]</i>
1077	<i>[Reserved]</i>
1078	<i>[Reserved]</i>
1079	<i>[Reserved]</i>
1080	U.S. Patent Pub. App. Pub. No. 2006/0122660 to Boveja <i>et al.</i> filed Dec. 28, 2005, published Jun. 8, 2006 (“Boveja”)
1081	<i>[Reserved]</i>
1082	<i>[Reserved]</i>

Exhibit No.	Description
1083	<i>[Reserved]</i>
1084	U.S. Patent No. 6,941,171 to Mann et al. filed Aug. 16, 2001 ("Mann")

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 ‘477 patent.

On July 1, 2024, Avation filed a petition for post-grant review (“PGR”) of the ‘943 patent. *See Avation Medical, Inc. v. EMKinetics, Inc.*, PGR2024-00043 (PTAB). On September 3, 2024, Avation filed a petition for IPR regarding the ‘742 patent. *See Avation Medical, Inc. v. EMKinetics, Inc.*, IPR2024-01375 (PTAB).

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

<u>Lead Counsel</u>	<u>Backup Counsel</u>
Todd R. Tucker Reg. No. 40,850 CALFEE, HALTER & GRISWOLD LLP The Calfee Building 1405 East Sixth Street Cleveland, OH 44114 P: 216-622-8231 F: 216-214-0816 ttucker@calfee.com	Kyle T. Deighan Reg. No. 75,525 CALFEE, HALTER & GRISWOLD LLP The Calfee Building 1405 East Sixth Street Cleveland, OH 44114 P: 216-622-8551 F: 216-214-0816 kdeighan@calfee.com Brynna M. W. Wasserman Reg. No. 76,700 CALFEE, HALTER & GRISWOLD LLP The Calfee Building 1405 East Sixth Street Cleveland, OH 44114 P: 216-622-8661 F: 216-214-0816 bwasserman@calfee.com

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 ‘477 patent claims well-known methods of performing electrical stimulation therapy targeting a patient’s posterior tibial nerve (“PTN”) or its branches and using feedback from a sensor to adjust stimulation current. Long before the October 2006 earliest effective filing date of the ‘477 patent, however, the prior art described noninvasive electrical stimulation systems and methods for treating a variety of conditions. To treat patients more effectively and efficiently, many known electrical stimulation systems and methods included components for detecting patient parameters via sensors, such as conventional electromyographic (“EMG”) sensors, and using feedback from the sensors to adjust stimulation parameters, including stimulation current.

Most notably, Svihra (Ex.1004)—published in 2002 and not considered during the ‘477 patent’s prosecution—describes treating patients with overactive bladder (“OAB”) using noninvasive electrical stimulation targeting the PTN. Svihra used an EMG device to detect patients’ responses to therapy and adjusted stimulation current based on the feedback. Many other references likewise disclose similar electrostimulation methods and devices that control and adjust stimulation parameters—including stimulation current—based on sensor feedback. These and many other references make clear that the patent simply attempts to cover what was already well-known in the art.

Because the evidence demonstrates that claims 1-10 of the ‘477 patent (“Challenged Claims”) are invalid, the Board should institute IPR and find the claims of the ‘477 patent unpatentable.

II. COMPLIANCE WITH IPR REQUIREMENTS

A. Certification (§42.204(a))

Petitioner certifies that the ‘477 patent is available for IPR. Petitioner is not barred or estopped from requesting IPR 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 ‘477 patent. This petition is timely filed as Petitioner has not been served with a complaint alleging infringement of the ‘477 patent as of this petition’s filing.

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

Petitioner requests cancellation of the Challenged Claims² based on the following Grounds:

² The Challenged Claims are reproduced in the **Claim Appendix** below.

Ground	Claims	Description
1	1	Anticipated under 35 U.S.C. §102 by Svihra (Ex.1004)
2	1	Obvious under 35 U.S.C. §103 over Svihra (Ex.1004) in view of Mann (Ex.1084), DiLorenzo (Ex.1054), Gerber (Ex.1055), or Bourget (Ex.1056)
3	2-10	Obvious under 35 U.S.C. §103 over Svihra (Ex.1004) alone or in combination with Mann (Ex.1084), DiLorenzo (Ex.1054), Gerber (Ex.1055), and Bourget (Ex.1056), in view of Knowledge of POSA ³
4	1	Obvious under 35 U.S.C. §103 over Amarenco (Ex.1005) in view of Mann (Ex.1084), DiLorenzo (Ex.1054), Gerber (Ex.1055), or Bourget (Ex.1056)
5	2-10	Obvious under 35 U.S.C. §103 over Amarenco (Ex.1005) in combination with Mann (Ex.1084),

³ 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.”).

		DiLorenzo (Ex.1054), Gerber (Ex.1055), and Bourget (Ex.1056), in view of Knowledge of POSA0
--	--	---

Petitioner’s challenges are supported by the testimony of Dr. Brett Wingeier, an expert in biomedical engineering and stimulation therapy with over 20 years of experience. Ex.1003, ¶¶6-14.

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

The ‘477 patent generally relates to electrical stimulation therapy. While independent claim 1 is not specific to treating a particular condition, it requires “positioning a first portion of a patient's body relative to an electrical stimulator *such that a posterior tibial nerve or branch thereof* within the first portion of the body is in proximity to the electrical stimulator.” Ex.1001, cl.1 (emphasis added). The patent indicates targeting the PTN is “particularly suited for the treatment of OAB and [urinary incontinence].” Ex.1001, 9:52-54. Moreover, it was well-known that PTN electrostimulation can be used to treat urological conditions such as OAB and incontinence. *Infra*, §III.B. Thus, although claim 1 is not specific to treating

OAB/incontinence and the dependent claims relate to treating a variety of different conditions, the following background focuses on OAB/incontinence.

A. 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, ¶¶33-34.

B. Treatment of OAB and UI

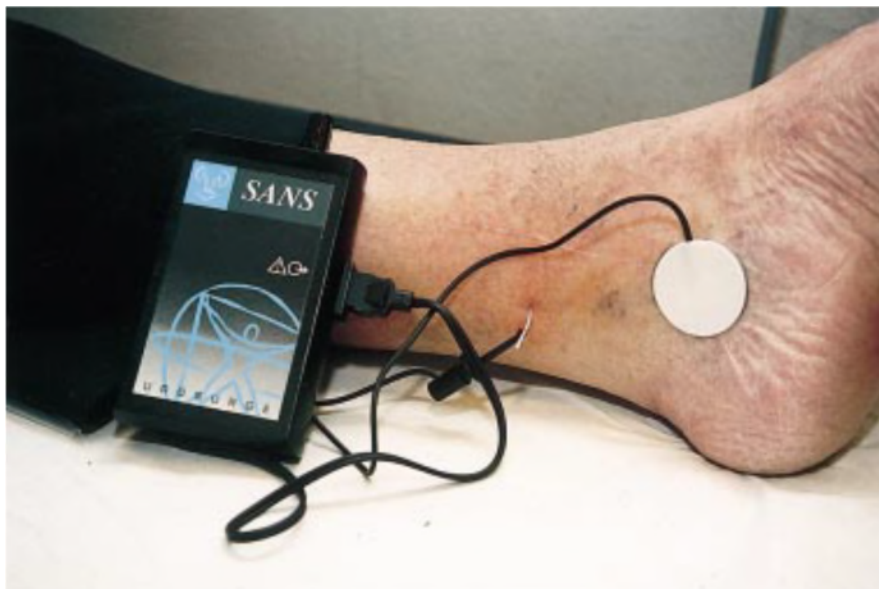
Well before 2006, various approaches were used to treat OAB/incontinence, including behavioral modifications, pharmacological therapies, surgery, and neuromodulation. Ex.1011, 219; Ex.1001, 2:35-3:16. Due to limitations with the other treatments, neuromodulation became a focus for OAB/incontinence treatment. Ex.1011, 220; Ex.1003, ¶¶35-36.

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, a form of neuromodulation, was commonly used to treat OAB/incontinence. Ex.1003, ¶¶37-38.

Sacral nerve stimulation (“SNS”) was well-known for treating OAB/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, ¶39.

Percutaneous PTN stimulation (“PTNS”), or Stoller Afferent Nerve Stimulation (“SANS”), was another known electrostimulation technique. Ex.1014, 727. A needle connected to an electrical stimulator was inserted near the medial malleolus (*i.e.*, ankle) to stimulate the PTN. *Id.*



Ex.1014, 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; Ex.1015, 256 (describing “81% clinical success rate”). PTNS was, however, invasive as it penetrated patients’ skin. Ex.1003, ¶¶40-41.

Noninvasive electrostimulation techniques were also known before 2006. *Id.*, ¶42. Transcutaneous electrical nerve stimulation (“TENS”), commonly used to treat conditions such as pain, was investigated for OAB/incontinence. 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.

McGuire reported on noninvasive PTN electrostimulation in 1983. Ex.1003, ¶43. McGuire’s technique involved applying current via “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 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 electrostimulation to the PTN. *Id.* Svihra used “an electromyographic [EMG] device Nicolet Viking II E” to detect patient response to treatment and found “[i]ntensity of the surface SANS was equal to 70% of intensity, at which the maximal amplitude of response [] registered from the abductor hallucis muscle.” *Id.*, 481. Determination of the maximal amplitude of response would necessarily require adjustment of the current based on EMG sensor feedback. Ex.1003, ¶44.

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, ¶45.

Long before 2006, published reports such as McGuire, Svihra, and Amarenco, among others, demonstrated noninvasively applying PTN electrostimulation was a well-known and effective OAB/incontinence treatment. *See also* Ex.1016, 670; Ex.1017, 243; Ex.1003, ¶46.

C. Electrical Stimulation Feedback and Control

Given the widespread use of electrostimulation therapies, various devices were developed providing ways to monitor patient response to stimulation and adjust stimulation parameters based on feedback. Ex.1003, ¶47. This improved treatment efficacy by ensuring patients received stimulation at optimal parameters and made therapy easier for patients.

Mann, issued September 6, 2005, discloses closed-loop systems for treating incontinence, urgency, frequency, and/or pelvic pain via electrostimulation of nerves including the PTN. Ex.1084, Abstract, 10:65-11:19, 11:43-12:7, 12:42-54, 16:28-41, 25:65-26:9. The system includes a stimulator “controlled via-closed-loop operation” and sensors detecting “[a] need for and/or response to stimulation.” *Id.*, 25:65-26:9. Sensed information is transmitted to the stimulator and “parameters used by the stimulator(s) are automatically adjusted based on the sensed information.” *Id.* Sensors can include EMG sensors for detecting “the muscle activity produced in response to stimulation.” *Id.*, 23:4-15. Adjusted parameters include the amplitude of the electrical current pulse. *Id.*, 15:8-24, 21:48-59. Ex.1003, ¶¶48-49.

DiLorenzo, issued in 2002, discloses electrical stimulation systems that deliver stimulation through electrodes according to treatment parameters derived from sensor feedback. Ex.1054, 3:35-53. The sensor may include EMG

sensors/electrodes, which detect electrical conduction through nerves and/or resulting muscular response. *Id.*, 6:58-67, 9:1-14, 9:34-46, 9:54-65, 23:31-24:23, 29:27-44. Adjusted treatment parameters include pulse amplitude, including voltage or current. *Id.*, 12:18-25, 16:14-26, 19:29-67. Ex.1003, ¶¶50-51.

Bourget, filed April 28, 2006, likewise discloses closed-loop therapy systems that deliver electrostimulation based on sensor feedback. Ex.1056, Abstract, 1:38-41, 2:45-57, 3:52-4:14. The system is “applicable to any type of stimulation therapy,” including treating incontinence, and used with “[a]ny implantable or external medical device.” Ex.1056, 4:23-35, 4:47-60. The sensors measure patient parameters such as EMG signals. *Id.*, 7:32-44. Based on sensor feedback, a stimulation delivery program adjusts stimulation parameters including a “current pulse amplitude.” *Id.*, 4:61-5:1, 8:32-41, 13:19-25. Ex.1003, ¶¶52-53.

Gerber (Ex.1055), filed April 28, 2005, discloses “an implantable neurostimulator and system capable of providing adaptive neurostimulation therapy to alleviate fecal or urinary incontinence.” *Id.*, 2:1-16, 1:16-18. The system includes a neurostimulator, sensors (including for sensing EMG), and a monitor/programmer that automatically adjusts stimulation parameter (including amplitude such as current). *Id.*, 3:35-4:18, 5:19-38, 5:39-6:7, 8:47-67; Ex.1003, ¶¶54-55.

In sum, the prior art demonstrates electrostimulation methods and devices that automatically adjust stimulation current based on sensor feedback that were known long before the '477 patent's earliest priority date.

IV. THE '477 PATENT

A. Overview

The '477 patent relates to stimulation therapy. Ex.1001, Abstract, 5:32-48. The patent indicates various electromagnetic and electric stimulation devices were known and used to treat various conditions. *Id.*, 1:55-5:28. The patent also claims benefit to and incorporates by reference prior applications, including the '329 application, that acknowledge stimulation devices and techniques were known for treating OAB/incontinence, including methods targeting the PTN. Ex.1001, 1:8-51; Ex.1048, [0003]-[0028]; Ex.1003, ¶¶56-58.

The patent discloses apparatuses for providing magnetic or electric stimulation for treating OAB/incontinence. Ex.1001, 8:3-16. While much of the patent relates to electromagnetic and microneedle-based stimulation, the patent discusses electrostimulation "variations" that use an electrical pulse controller 130, electrode 126, and sensor 136. *Id.*, 16:25-46, Fig. 11 (below); Ex.1003, ¶59.

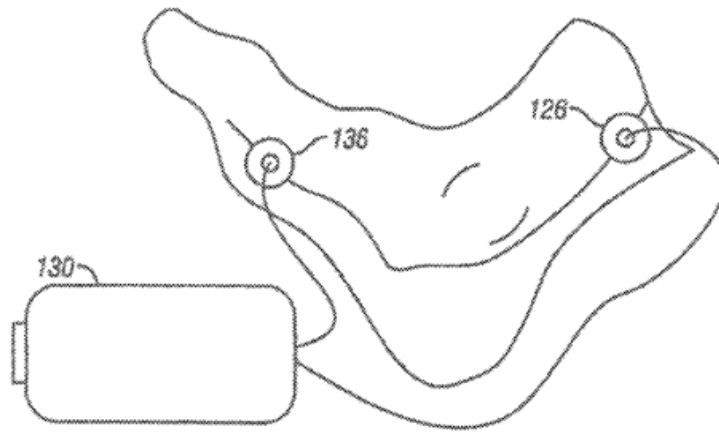


FIG. 11

B. Prosecution History

The '477 patent issued on April 7, 2015 from U.S. 14/085,639 (" '639 application), filed on November 30, 2013. The '639 application was filed with 1 claim directed to electromagnetic therapy. Ex.1002, 258. A preliminary amendment was filed, which cancelled claim 1 and added new claims directed to electrical stimulation therapy. *Id.*, 157-59. On May 28, 2014, the claims were rejected as anticipated and/or obvious. *Id.*, 49-61. As shown in the exemplary claim below, the claims were amended on November 25, 2014 to add various limitations:

2. (Currently Amended): A method of performing electrical stimulation therapy, comprising:

- non-invasively positioning a first portion of a patient's body relative to an electrical stimulator such that a posterior tibial ~~target~~ nerve or branch thereof within the first portion of the body is in proximity to the electrical stimulator;
- passing a current through the electrical stimulator;
- delivering an electrical stimulus from the electrical stimulator to the posterior tibial ~~target~~ nerve or branch thereof;
- detecting electrical conduction through the posterior tibial ~~target~~ nerve or branch thereof or detecting a muscular response caused by an electrical conduction through the posterior tibial ~~target~~ nerve or branch thereof via at least one sensor positioned along a second portion of the body;
- receiving a signal from the at least one sensor indicative of the detected electrical conduction or muscular response thereby providing feedback about the efficacy of the applied electrical stimulation therapy; and
- adjusting the current via a controller in communication with the electrical stimulator based on the feedback.

Id., 30-31. Applicant argued the prior art did not disclose delivering electrical stimulus to the PTN or its branches or noninvasive methods for accessing and treating the PTN. *Id.*, 32-34. A notice of allowance was issued on December 5, 2014. *Id.*, 7-14.

C. Effective Filing Date

The '477 patent claims priority to the '720 provisional filed October 2, 2006. Because the prior art relied upon herein published well before that date, for this Petition alone Avation will assume an October 2, 2006 effective filing date for the '477 patent claims.

D. 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 Claim 1

Svihra (Ex.1004) published in 2002 and is therefore prior art under at least pre-AIA 35 U.S.C. §102(b). Svihra was not cited or considered during prosecution of the ‘477 patent.

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

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 . . . using a superficial electrostimulation” in patients “suffer[ing] from overactive bladder (OAB).” Ex.1004, 480; *see also id.*, 481, 482; Ex.1003, ¶63.

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 goal was to test a modified version of Stoller’s minimally-invasive, percutaneous procedure by using “non-invasive” surface electrodes. *Id.*; Ex.1003, ¶64.

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, ¶65. 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, ¶66. 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 ankle of the left lower extremity” for stimulation of the PTN necessarily means a portion of the patients’ bodies were positioned relative to an electrical stimulator. *Id.*, ¶67.

Svihra indicates electrodes were placed “behind the medial ankle” to stimulate the “tibial nerve.” Ex.1004, 481; *see also id.*, 480 (“non-invasive stimulation of the tibial nerve”). The “tibial nerve” is the PTN. Ex.1003, ¶68. The patent does not explain what “in proximity to” means in this context; rather, the patent merely discloses placing stimulation devices in the vicinity of portions of the body. *Id.*, ¶69. A POSA would understand Svihra positioned electrodes “in proximity to” the patients’ PTN in the same way, by placing “surface electrodes” “behind the medial ankle of the left lower extremity.” Ex.1004, 481; Ex.1003, ¶69.

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” behind the patients’ medial ankle. Ex.1004, 481. For electrostimulation to be applied through “surface electrodes,” the electrodes necessarily would be connected to an electrical stimulator source through which current was passed. Ex.1003, ¶70.

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). Svihra concluded “[n]oninvasive stimulation had improved subjective symptoms related to overactive bladder, had no adverse events, and was well tolerated.” *Id.*, 480. Thus, Svihra delivered electrical stimulus from an electrical stimulator through the electrodes to the PTN. Ex.1003, ¶71.

e. Element [1.d]

A POSA would interpret the “detecting . . .” limitation to encompass detecting using techniques such as EMG based on the claim language and specification. *Id.*, ¶72.

EMG is a measure of muscle response and electrical activity in response to stimulation of muscle by nerves. *Id.*, ¶73; Ex.1042, 120-21; Ex.1043, 174; Ex.1084, 23:8-11. When a nerve activates a muscle, EMG measures the presence (or lack thereof) of electrical conduction of the nerve impulse between the stimulation site and the muscle. *Id.* Detecting electrical conduction through a nerve or detecting muscular response caused by electrical conduction through a nerve, as

recited in the claim, thus refers to detection techniques such as EMG. Ex.1003, ¶73.

The claim also refers to detecting conduction “along a second portion of the body,” which is typical of EMG procedures where electrodes are placed at locations apart from a stimulation site. *Id.*, ¶74; Ex.1028, 367; Ex.1030, 10. Moreover, the claim requires detecting “electrical conduction through” the nerve or “a muscular response caused by electrical conduction through” the nerve, which would be 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, ¶74.

This interpretation is further supported by the specification, which indicates sensors, including EMG sensors and other sensors known in the art, are used to detect electrical conduction and muscular response. *Id.*, ¶75; Ex.1001, 36:32-37 (“[v]arious sensors may be utilized, e.g., a three lead EMG, other EMG electrode, a microneedle electrode, or any sensor for detecting physiologic changes associated with nerve firing and/or muscle contraction”), 25:53-60, 43:5-12. The patent further indicates sensors for detecting electrical conduction such as EMG electrodes were known, and thus this limitation does not cover new or nonobvious features of the alleged invention. Ex.1001, 25:53-60; Ex.1003, ¶75. In any event,

the claim language and specification indicate this limitation includes “detecting” via EMG.

Svihra explicitly states “an electromyographic [EMG] device Nicolet Viking II E” was used to measure “the maximal amplitude of response [] registered from the abductor hallucis muscle” resulting from PTN stimulation. Ex.1004, 481. Using EMG, Svihra measured conduction through the PTN and the response of the abductor hallucis muscle. *Id.*; Ex.1003, ¶76. Svihra does not expressly state EMG sensors/electrodes were used, but a POSA would understand such sensors necessarily must have been used given Svihra’s use of an EMG device and measurement of the “maximal amplitude of response” of the muscle (which is a measure of the electrical signal emanating from the muscle measured via EMG). Ex.1003, ¶¶76, 77.

f. Element [1.e]

Svihra used an EMG device and determined the “[i]ntensity of the surface SANS was equal to 70% of intensity, at which the maximal amplitude of response was registered from the abductor hallucis muscle (stimulation by a constant voltage and regulated intensity of direct current).” Ex.1004, 481. This indicates Svihra necessarily received results from the EMG device because Svihra could not have known the “maximal amplitude” of response, which is a measure of electrical activity, without receiving results of the EMG measurement. Ex.1003, ¶77. Svihra

also clearly used the results to provide feedback about the efficacy of stimulation, as Svihra expressly stated the most effective intensity was 70% based on the muscle response. *Id.*

g. Element [1.f]

Svihra found “[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. “Intensity” in this context refers to the amount of current and/or voltage delivered by the stimulator. Ex.1003, ¶78. Svihra explicitly states the intensity of the current was “regulated,” or adjusted, which was done based on EMG feedback to determine the “maximal” response amplitude. *Id.* Moreover, Svihra determined the “maximal amplitude of response” via EMG, meaning the intensity (*i.e.*, current) of the electrostimulation necessarily was adjusted via a controller to allow Svihra to determine the **maximum** response, as compared to other responses that were not the maximum response. *Id.*

B. Ground 2: Svihra (Ex.1004) in View of Mann (Ex.1084), DiLorenzo (Ex.1054), Gerber (Ex.1055), or Bourget (Ex.1056) Renders Obvious Claim 1

Svihra published in 2002, Mann issued September 6, 2005, and DiLorenzo issued April 2, 2002. All are therefore prior art under at least pre-AIA 35 U.S.C. §102(b). Gerber was filed April 28, 2005 and Bourget was filed April 28, 2006.

Both are therefore prior art under at least pre-AIA 35 U.S.C. §102(e). Other than Mann, none of these references were cited or considered during the ‘477 patent’s prosecution.

1. Claim 1:

a. Element [1.p]

Svihra discloses this limitation. *Supra*, §VI.A.1.a; Ex.1003, ¶80.

b. Element [1.a]

Svihra discloses this limitation. *Supra*, §VI.A.1.b; Ex.1003, ¶¶81-86.

c. Element [1.b]

Svihra discloses this limitation. *Supra*, §VI.A.1.c; Ex.1003, ¶87.

d. Element [1.c]

Svihra discloses this limitation. *Supra*, §VI.A.1.d; Ex.1003, ¶88.

e. Elements [1.d]-[1.f]

As explained, Svihra discloses these limitations. *Supra*, §§VI.A.1.e-VI.A.1.g. If Svihra does not disclose these limitations, it would have been obvious to modify Svihra’s method to perform the “detecting . . . ,” “receiving. . . ,” and “adjusting . . . ” limitations based on Mann, DiLorenzo, Gerber, or Bourget. Ex.1003, ¶89.

Detecting patient responses to electrical stimulation therapy via sensors and adjusting stimulation parameters based on sensor feedback was known long before 2006. *Supra*, §III.C; Ex.1003, ¶90. Mann, DiLorenzo, Gerber, and Bourget

disclose electrostimulation systems and methods that include detecting electrical conduction through nerves and/or resulting muscular response via EMG sensors, receiving the feedback, and automatically adjusting stimulation parameters including current. *Supra*, §III.C; Ex.1003, ¶¶90-94. As explained below, Mann, DiLorenzo, Bourget, and Gerber disclose the “detecting...,” “receiving...,” and “adjusting...” limitations of claim 1. Ex.1003, ¶¶95, 109.

“***detecting*** . . . ” As explained, a POSA would interpret the “detecting . . .” limitation to encompass “detecting...” using EMG based on the claim language and specification. *Supra*, §VI.A.1.e; Ex.1003, ¶96. Each of Mann, DiLorenzo, Bourget, and Gerber disclose the “detecting...” limitation. Ex.1003, ¶96.

Mann’s closed-loop electrostimulation system for targeting nerves including the PTN can include EMG sensors for detecting “the muscle activity produced in response to stimulation.” Ex.1084, 23:4-15, 24:24-28, 25:65-26:20; Ex.1003, ¶97. DiLorenzo’s system likewise includes at least one sensor, including EMG electrodes, “to sense at least one parameter, including but not limited to physiologic values and neural signals, which is indicative of at least one of disease state, magnitude of symptoms, and response to therapy.” Ex.1054, 4:4-18, 6:58-67, 9:1-14, 9:34-46, 9:54-65, 23:31-24:23, 29:27-44; Ex.1003, ¶98. Bourget’s system includes a sensor that senses patient parameters, which can include EMG signals. Ex.1056, 2:45-57, 7:32-44; Ex.1003, ¶99. Gerber’s system includes sensors that

“may provide a variety of information indicative of the level of efficacy achieved by the neurostimulation therapy delivered by neurostimulator,” including EMG. Ex.1055, 3:35-4:18, 5:39-6:7; Ex.1003, ¶100.

“receiving . . . ” Each of Mann, DiLorenzo, Bourget, and Gerber disclose the “receiving...” limitation. Ex.1003, ¶101.

In Mann’s system, sensed information (*e.g.*, EMG) is transmitted to and received by the stimulator and “parameters used by the stimulator(s) are automatically adjusted based on the sensed information.” Ex.1084, 23:4-34, 25:65-26:20. The sensed information provides feedback about the efficacy of therapy. *E.g., id.*, 23:4-15; Ex.1003, ¶101.

DiLorenzo’s system receives and uses signals from sensors to make real-time adjustments to parameters “to provide optimal control of disease state.” Ex.1054, 8:39-50, 11:8-42, 13:35-53. The system “considers neural response, in the form of the sensory feedback, as an indication of neurological disease state and/or responsiveness to therapy, in the determination of treatment parameters.” *Id.*, 3:49-53. Ex.1003, ¶102. Bourget’s system “detects [a value of the sensed parameter] via the sensor, and automatically controls the medical device to deliver therapy to the patient according to the therapy information associated with the value in response to the detection.” Ex.1056, 2:45-57; *see also id.*, 8:62; Ex.1003, ¶103. An external monitor/programmer in Gerber’s system “may receive

information from neurostimulator 12 and/or sensor 20 by wireless telemetry” and “may record the received information, analyze the information, and adjust stimulation parameters based on the information or some combination thereof.” Ex.1055, 3:50-4:2; *see also id.*, 5:19-21, 5:39-41, 7:19-23; Ex.1003, ¶104.

Given that the sensors in each of these systems can be EMG sensors and that EMG measures electrical conduction through a nerve and/or resulting muscular response, a POSA would appreciate that EMG signals received in these systems are indicative of the electrical conduction and/or resulting muscular response. Ex.1003, ¶104.

“***adjusting . . .***” Each of Mann, DiLorenzo, Bourget, and Gerber disclose the “adjusting...” limitation. *Id.*, ¶105.

Mann’s system transmits sensed information to the stimulator and “parameters used by the stimulator(s) are automatically adjusted based on the sensed information” via a controller. Ex.1084, 25:65-26:9, 22:55-23:34, 15:54-16:2. Parameters adjusted can include the amplitude of the electrical current pulse. *Id.*, 15:8-24, 21:48-59; Ex.1003, ¶105. DiLorenzo uses sensor feedback to determine and adjust stimulation control parameters, including pulse amplitude (pulse voltage or pulse current), which is implemented by a control circuit. Ex.1054, 10:66-11:10, 11:22-12:42, 16:14-26, 19:29-67; Ex.1003, ¶106. In Bourget’s system, sensor feedback is used by a processor to adjust stimulation

parameters by controlling a stimulation pulse generator to deliver stimulation according to a program for delivery. Ex.1056, 8:14-62. The program may define and adjust voltage or current pulse amplitude for stimulation. *Id.*, 4:61-5:1, 8:32-41, 13:19-25; Ex.1003, ¶107. Gerber’s system uses an external monitor/programmer to automatically generate stimulation parameter adjustments, including adjustments to the stimulation amplitude, to be applied by the stimulator with or without further user input. Ex.1055, 2:1-16, 3:66-4:2, 5:19-38, 8:47-67; Ex.1003, ¶108. A POSA would appreciate that the “amplitude” of electrostimulation is the stimulation voltage and/or current. Ex.1003, ¶108. Because adjusting stimulation voltage necessarily adjusts stimulation current and vice-versa, a POSA would understand that references referring to adjusting stimulation amplitude (*e.g.*, Gerber) necessarily disclose adjusting current. *Id.*, ¶108; Ex.1071, 499, Fig.4.

Modifying Svihra’s method to incorporate the systems and techniques of Mann, DiLorenzo, Gerber, or Bourget discussed above for “detecting...,” “receiving...,” and “adjusting...” would have been obvious. As described, each of Svihra, Mann, DiLorenzo, Gerber, and Bourget are directed to similar fields, *i.e.*, electrostimulation systems and methods for treating patients. Ex.1004, 480 (electrostimulation for OAB); Ex.1055, 3:19-49 (electrostimulation for urinary/fecal control disorders); Ex.1054, 3:35-4:3 (electrostimulation for treating

various conditions); Ex.1056, 3:52-4:14, 4:41-51 (electrostimulation for, *e.g.*, incontinence); Ex.1084, 10:65-11:19 (electrostimulation for incontinence). Given this, a POSA would have looked to these references when considering modifications to Svihra’s method. Ex.1003, ¶110.

To the extent EMK argues Svihra would not be considered with these references, that argument is incorrect. *Id.*, ¶111. Regardless of the type of stimulation (*e.g.*, invasive or noninvasive), the nerves targeted for stimulation, or the treated conditions described in the references, a POSA would have considered the systems/techniques of these references discussed above for “detecting...,” “receiving...,” and “adjusting...” to be relevant to Svihra’s method because the features of those systems (*e.g.*, EMG sensors, receiving feedback, adjusting parameters including current, etc.) could be implemented in any type of electrical stimulation system or method. *Id.* Indeed, the references themselves indicate the systems/techniques could be employed in a variety of contexts. *Id.*; *e.g.*, Ex.1054, 6:38-43, 10:24-42, 28:33-56; Ex.1056, 4:23-60; Ex.1055, 3:19-34; Ex.1084, 9:44-10:22. In fact, any argument Svihra would not be considered with references describing other types of electrical stimulation devices/methods is contradicted by Svihra itself—indeed, Svihra explicitly states the invasive SANS procedure motivated the development of Svihra’s noninvasive procedure. Ex.1004, 480-81. Nor can EMK argue that elements of a different type of electrostimulation system

(*e.g.*, implanted sensors) could not be physically incorporated into Svihra's noninvasive technique—what matters is whether “a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention.” *Allied Erecting & Dismantling Co. v. Genesis Attachments, LLC*, 825 F.3d 1373, 1381 (Fed. Cir. 2016) (prior art need not be “physically combinable to render obvious”).

Modifying Svihra's method by implementing the systems/techniques of Mann, DiLorenzo, Gerber, and Bourget discussed above for “detecting...,” “receiving...,” and “adjusting...” was also obvious because it would involve predictable use of prior art elements (*e.g.*, EMG sensors, receiving feedback, adjusting parameters including current, etc.) according to established functions (*e.g.*, sensing EMG signals, transmitting and receiving information, using sensor feedback to adjust parameters including current, etc.) or simple substitution of known elements (*e.g.*, Svihra's EMG device, sensors, current adjustment for the systems/techniques of Mann, DiLorenzo, Gerber, or Bourget discussed above). Ex.1003, ¶¶112-13. A POSA would expect success and the results would be predictable given the widespread, successful use of such systems/techniques in similar electrostimulation devices and methods throughout the art. *Id.*

The prior art itself would also have motivated a POSA to modify Svihra's procedure in this manner. Ex.1003, ¶114. The references describe numerous

benefits of using the systems/techniques discussed above for “detecting...,” “receiving...,” and “adjusting....” *Id.* For example, DiLorenzo indicates the systems/techniques incorporate patient symptomatology and function measures in regulating treatment magnitude, determine the optimum treatment magnitude, expedite satisfactory treatment, reduce physician/patient interactions, and optimize energy efficiency. Ex.1054, 4:38-5:38; *see also* Ex.1056, 2:23-34, 3:5-14, 3:65-4:14, 7:54-65; Ex.1055, 2:14-16; Ex.1084, 10:12-16. A POSA considering modifications to Svihra’s method would be motivated to incorporate the teachings of Mann, DiLorenzo, Bourget, or Gerber described above to achieve the stated benefits, including among others improved feedback, better treatment and side effect regulation, and quicker/more effective treatment. Ex.1003, ¶114.

C. Ground 3: Svihra (Ex.1004) Alone or in Combination with Mann (Ex.1084), DiLorenzo (Ex.1054), Gerber (Ex.1055), or Bourget (Ex.1056), Further in View of the Knowledge of a POSA, Renders Obvious Claims 2-10

As indicated above, Svihra, Mann, and DiLorenzo are prior art under at least pre-AIA 35 U.S.C. §102(b), and Gerber and Bourget are prior art under at least pre-AIA 35 U.S.C. §102(e). Other than Mann, none of these references were cited or considered during the ‘477 patent’s prosecution.

A POSA would have considered these references with additional prior art evidencing the knowledge of a POSA (such as the references discussed below) as all are directed to similar fields, *i.e.*, electrostimulation systems and methods for

treating various conditions of patients. That some references describing treatment of a given condition via PTN electrostimulation use different types of electrostimulation procedures (*e.g.*, invasive or noninvasive) is irrelevant to whether a POSA would have tried or been motivated to try using Svihra's method (as modified by Mann, DiLorenzo, Gerber, or Bourget) to treat a given condition. Ex.1003, ¶¶119, 124, 129, 134, 139, 144, 150, 156, 161. The successful use of electrical stimulation to treat a given condition, whether invasive or noninvasive, would suggest other types of electrical stimulation could also be successful and motivate a POSA to try, including using noninvasive electrostimulation. *Id.* In fact, any argument Svihra would not be considered with references describing other types of electrical stimulation devices/methods is contradicted by Svihra itself—indeed, Svihra explicitly states the invasive SANS procedure motivated the development of Svihra's noninvasive procedure. Ex.1004, 480-81.

1. Claim 2

Svihra alone or in combination with Mann, DiLorenzo, Bourget, or Gerber discloses the limitations of claim 1. *Supra*, §§VI.A.1, VI.B.1. Further, Svihra's method involved delivering electrical stimulation to the PTN. Ex.1004, 480 (“non-invasive stimulation of the tibial nerve”), 481 (“therapeutic stimulation of the tibial nerve”); Ex.1003, ¶¶116. Although Svihra treated OAB patients, it would have

been obvious to use Svihra's method to treat other conditions, such as fecal incontinence. Ex.1003, ¶116.

A POSA would have known well before 2006 that many conditions, including fecal incontinence, could be treated by electrically stimulating the PTN. *Id.*, ¶117. A study by Queralto "assess[ed] the efficiency of posterior tibial nerve (PTN) transcutaneous electrical nerve stimulation (TENS) in the treatment of anal idiopathic incontinence," *i.e.* fecal incontinence. Ex.1016, 670. Queralto stimulated the PTN using a self-adhesive surface stimulation electrode. *Id.* Queralto's results indicated that noninvasive PTN stimulation for treating fecal incontinence was effective. *Id.*, 672. Similarly, Shafik applied PTN stimulation to treat fecal incontinence and achieved improvement in 78% of patients. Ex.1064, Abstract.

Using Svihra's technique to treat fecal incontinence would have been obvious. First, treating fecal incontinence using Svihra's method would have involved applying known techniques (*e.g.*, Queralto's and Shafik's PTN electrostimulation to treat fecal incontinence) to improve a known process (Svihra's PTN electrostimulation method). Ex.1003, ¶118. Second, it would have been obvious to try using Svihra's method to treat fecal incontinence given the finite number of known solutions for treating the condition. *Id.*, ¶119. Third, design incentives and market forces would prompt variations to Svihra's method given known work in the field by, *e.g.*, Queralto and Shafik, including the need to

identify treatments for conditions such as fecal incontinence. *Id.*, ¶120. A POSA would have expected success modifying Svihra's procedure in this manner and the results would have been predictable given the known and successful use of PTN electrostimulation to treat fecal incontinence throughout the art in similar procedures. *Id.*, ¶¶118-20.

2. Claim 3

Svihra alone or in combination with Mann, DiLorenzo, Bourget, or Gerber discloses the limitations of claim 1. *Supra*, §§VI.A.1, VI.B.1. Further, Svihra's method involved delivering electrical stimulation to the PTN. Ex.1004, 480, 481; Ex.1003, ¶121. Although Svihra treated OAB patients, it would have been obvious to use Svihra's method to treat other conditions, such as restless leg syndrome. Ex.1003, ¶121.

A POSA would have known well before 2006 that many conditions, including restless leg syndrome, could be treated by electrically stimulating the PTN. *Id.*, ¶122. DiLorenzo '103 discloses electrical stimulation systems with stimulating electrodes that can be "adjacent to" (*i.e.*, noninvasive) stimulation sites including "a peripheral nerve" in the "lower extremities," including the PTN. Ex.1068, Abstract, [0019], [0072], [0093], [0175], [0348]. Restless leg syndrome is a disease state that can be treated using DiLorenzo '103's system. *Id.*, cls.128-31.

Using Svihra's technique to treat restless leg syndrome would have been obvious. First, treating restless leg syndrome using Svihra's method would have involved applying known techniques (*e.g.*, DiLorenzo 103's PTN electrostimulation to treat restless leg syndrome) to improve a known process (Svihra's PTN electrostimulation method). Ex.1003, ¶123. Second, it would have been obvious to try using Svihra's method to treat restless leg syndrome given the finite number of known solutions for treating the condition. *Id.*, ¶124. Third, design incentives and market forces would prompt variations to Svihra's method given known work in the field by, *e.g.*, DiLorenzo '103, including the need to identify treatments for conditions such as restless leg syndrome. *Id.*, ¶125. A POSA would have expected success modifying Svihra's procedure in this manner and the results would have been predictable given the known and successful use of PTN electrostimulation to treat restless leg syndrome throughout the art in similar procedures. *Id.*, ¶¶123-25.

3. Claim 4

Svihra alone or in combination with Mann, DiLorenzo, Bourget, or Gerber discloses the limitations of claim 1. *Supra*, §§VI.A.1, VI.B.1. Further, Svihra's method involved delivering electrical stimulation to the PTN. Ex.1004, 480, 481; Ex.1003, ¶126. Although Svihra treated OAB patients, it would have been obvious

to use Svihra's method to treat other conditions, such as premature ejaculation. Ex.1003, ¶126.

A POSA would have known well before 2006 that many conditions, including premature ejaculation, could be treated by electrically stimulating the PTN. *Id.*, ¶127. Gerber '372 describes electrical stimulation therapies by delivering electrical stimuli to the sacral nerves, which is defined as "any one of the sacral nerves, portions of the sacral nerve(s), nerves neurologically connected to any one of the sacral nerves and in relatively close physical proximity thereto, and extensions or branches of any one of the sacral nerves." Ex.1069, Abstract, [0002], [0064]. The PTN emanates from and is a branch of sacral nerves S1-S4. Ex.1003, ¶127. Gerber '372's therapy can be used to treat sexual dysfunctions including premature ejaculation. Ex.1069, [0004], [0021], [0047-49], cl.1.

Using Svihra's technique to treat premature ejaculation would have been obvious. First, treating premature ejaculation using Svihra's method would have involved applying known techniques (*e.g.*, Gerber's PTN electrostimulation to treat premature ejaculation) to improve a known process (Svihra's PTN electrostimulation method). Ex.1003, ¶128. Second, it would have been obvious to try using Svihra's method to treat premature ejaculation given the finite number of known solutions for treating the condition. *Id.*, ¶129. Third, design incentives and market forces would prompt variations to Svihra's method given known work in

the field by, *e.g.*, Gerber ‘372, including the need to identify treatments for conditions such as premature ejaculation. *Id.*, ¶130. A POSA would have expected success modifying Svihra’s procedure in this manner and the results would have been predictable given the known and successful use of PTN electrostimulation to treat premature ejaculation throughout the art in similar procedures. *Id.*, ¶128-30.

4. Claim 5

Svihra alone or in combination with Mann, DiLorenzo, Bourget, or Gerber discloses the limitations of claim 1. *Supra*, §§VI.A.1, VI.B.1. Further, Svihra’s method involved delivering electrical stimulation to the PTN. Ex.1004, 480, 481; Ex.1003, ¶131. Although Svihra treated OAB patients, it would have been obvious to use Svihra’s method to treat other conditions, such as chronic pain. Ex.1003, ¶131.

A POSA would have known well before 2006 that many conditions, including chronic pain, could be treated by electrically stimulating the PTN. *Id.*, ¶132. van Balken 2003 describes using percutaneous PTN stimulation for patients with chronic pain and concluded PTN stimulation “may have a place in the treatment of patients with chronic pain.” Ex.1065, 158. Whitehurst likewise treated chronic pain by providing electrostimulation to peripheral nerves including the PTN. Ex.1066, [0005], [0015], [0055].

Using Svihra's technique to treat chronic pain would have been obvious. First, treating chronic pain using Svihra's method would have involved applying known techniques (*e.g.*, van Balken 2003's and Whitehurst's PTN electrostimulation to treat chronic pain) to improve a known process (Svihra's PTN electrostimulation method). Ex.1003, ¶133. Second, it would have been obvious to try using Svihra's method to treat chronic pain given the finite number of known solutions for treating the condition. *Id.*, ¶134. Third, design incentives and market forces would prompt variations to Svihra's method given known work in the field by, *e.g.*, van Balken 2003 and Whitehurst, including the need to identify treatments for conditions such as chronic pain. *Id.*, ¶135. A POSA would have expected success modifying Svihra's procedure in this manner and the results would have been predictable given the known and successful use of PTN electrostimulation to treat chronic pain throughout the art in similar procedures. *Id.*, ¶¶133-35.

5. Claim 6

Svihra alone or in combination with Mann, DiLorenzo, Bourget, or Gerber discloses the limitations of claim 1. *Supra*, §§VI.A.1, VI.B.1. Further, Svihra's method involved delivering electrical stimulation to the PTN. Ex.1004, 480, 481; Ex.1003, ¶136. Although Svihra treated OAB patients, it would have been obvious to use Svihra's method to treat other conditions, such as osteoarthritis or arthritis. Ex.1003, ¶136.

A POSA would have known well before 2006 that many conditions, including osteoarthritis or arthritis, could be treated by electrically stimulating the PTN. *Id.*, ¶137. Jaax describes providing electrostimulation to a stimulation site such as the PTN for treating osteoarthritis. Ex.1067, 3:13-21, 5:40-49, 5:50-6:11. Whitehurst likewise treated chronic pain associated with conditions including rheumatoid arthritis by providing electrostimulation to peripheral nerves including the PTN. Ex.1066, [0005], [0015], [0017], [0055].

Using Svihra's technique to treat osteoarthritis or arthritis would have been obvious. First, treating osteoarthritis or arthritis using Svihra's method would have involved applying known techniques (*e.g.*, Jaax's and Whitehurst's PTN electrostimulation to treat osteoarthritis or arthritis) to improve a known process (Svihra's PTN electrostimulation method). Ex.1003, ¶138. Second, it would have been obvious to try using Svihra's method to treat osteoarthritis or arthritis given the finite number of known solutions for treating the condition. *Id.*, ¶139. Third, design incentives and market forces would prompt variations to Svihra's method given known work in the field by, *e.g.*, Jaax and Whitehurst, including the need to identify treatments for conditions such as osteoarthritis or arthritis. *Id.*, ¶140. A POSA would have expected success modifying Svihra's procedure in this manner and the results would have been predictable given the known and successful use of

PTN electrostimulation to treat osteoarthritis or arthritis throughout the art in similar procedures. *Id.*, ¶¶138-40.

6. Claim 7

Svihra alone or in combination with Mann, DiLorenzo, Bourget, or Gerber discloses the limitations of claim 1. *Supra*, §§VI.A.1, VI.B.1. Further, Svihra's method involved delivering electrical stimulation to the PTN. Ex.1004, 480, 481; Ex.1003, ¶141. Although Svihra treated OAB patients, it would have been obvious to use Svihra's method to treat other conditions, such as neuropathic pain. Ex.1003, ¶¶141.

A POSA would have known well before 2006 that many conditions, including neuropathic pain, could be treated by electrically stimulating the PTN. *Id.*, ¶142. Whitehurst treated neuropathic pain by providing electrostimulation to peripheral nerves including the PTN. Ex.1066, [0005], [0015], [0017-18], [0028-29], [0055]. Whitehurst explicitly indicates electrical stimulation should be applied to the PTN responsible for the neuropathic pain. *Id.*

Using Svihra's technique to treat neuropathic pain would have been obvious. First, treating neuropathic pain using Svihra's method would have involved applying known techniques (*e.g.*, Whitehurst's PTN electrostimulation to treat neuropathic pain) to improve a known process (Svihra's PTN electrostimulation method). Ex.1003, ¶143. Second, it would have been obvious to try using Svihra's

method to treat neuropathic pain given the finite number of known solutions for treating the condition. *Id.*, ¶144. Third, design incentives and market forces would prompt variations to Svihra's method given known work in the field by, *e.g.*, Whitehurst, including the need to identify treatments for conditions such as neuropathic pain. *Id.*, ¶145. A POSA would have expected success modifying Svihra's procedure in this manner and the results would have been predictable given the known and successful use of PTN electrostimulation to treat neuropathic pain throughout the art in similar procedures. *Id.*, ¶¶143-46.

7. Claim 8

Svihra alone or in combination with Mann, DiLorenzo, Bourget, or Gerber discloses the limitations of claim 1. *Supra*, §§VI.A.1, VI.B.1. Further, Svihra's method involved delivering electrical stimulation to the PTN. Ex Ex.1004, 480, 481; Ex.1003, ¶147. Although Svihra treated OAB patients, it would have been obvious to use Svihra's method to treat other conditions, such as neuralgia. Ex.1003, ¶147.

A POSA would have known well before 2006 that many conditions, including neuralgia, could be treated by electrically stimulating the PTN. *Id.*, ¶148. For example, Whitehurst treated chronic pain including neuralgia by providing electrostimulation to peripheral nerves including the PTN. Ex.1066, [0005], [0015], [0019-20], [0055].

Using Svihra's technique to treat neuralgia would have been obvious. First, treating neuralgia using Svihra's method would have involved applying known techniques (*e.g.*, Whitehurst's PTN electrostimulation to treat neuralgia) to improve a known process (Svihra's PTN electrostimulation method). Ex.1003, ¶149. Second, it would have been obvious to try using Svihra's method to treat neuralgia given the finite number of known solutions for treating the condition. *Id.*, ¶150. Third, design incentives and market forces would prompt variations to Svihra's method given known work in the field by, *e.g.*, Whitehurst, including the need to identify treatments for conditions such as neuralgia. *Id.*, ¶151. A POSA would have expected success modifying Svihra's procedure in this manner and the results would have been predictable given the known and successful use of PTN electrostimulation to treat neuralgia throughout the art in similar procedures. *Id.*, ¶¶149-51.

8. Claim 9

Svihra alone or in combination with Mann, DiLorenzo, Bourget, or Gerber discloses the limitations of claim 1. *Supra*, §§VI.A.1, VI.B.1. Further, Svihra's method involved delivering electrical stimulation to the PTN. Ex.1004, 480, 481; Ex.1003, ¶152. Although Svihra treated OAB patients, it would have been obvious to use Svihra's method to treat other conditions, such as atrophy. Ex.1003, ¶152.

A POSA would have known well before 2006 that many conditions, including atrophy, could be treated by electrically stimulating the PTN. *Id.*, ¶¶153-54. For example, it was known in the art that atrophy can occur as a result of paralysis or osteoarthritis. Ex.1070, [0003] (atrophy secondary to limb paralysis in stroke patients); Ex.1067, 1:26-34 (rest due to osteoarthritis may result in muscle atrophy); Ex.1003, ¶153. A POSA would recognize that techniques for treating paralysis or osteoarthritis would also treat complications caused by paralysis or osteoarthritis, such as atrophy. Ex.1003, ¶153. Whitehurst discloses treating paralysis by providing electrostimulation to peripheral nerves including the PTN. Ex.1066, [0005], [0015], [0020], [0055]. DiLorenzo ‘103 discloses a system for “electrical stimulation of peripheral nerves, such as stimulation of the tibial or peroneal nerves for use in eliciting the flexion withdrawal reflex to facilitate gait restoration in paraplegics.” Ex.1068, Abstract, [0019], [0072], [0348]. A paraplegic is a person with paralysis; therefore, electrostimulation of the PTN can be used to treat paralysis. Ex.1003, ¶154. Jaax describes providing electrostimulation to a stimulation site such as the PTN for treating osteoarthritis. Ex.1067, 3:13-21, 5:40-49, 5:50-6:11.

Using Svihra’s technique to treat atrophy would have been obvious. First, treating atrophy using Svihra’s method would have involved applying known techniques (*e.g.*, Whitehurst’s, DiLorenzo ‘103’s, and Jaax’s PTN

electrostimulation to treat paralysis or osteoarthritis, which were known to cause atrophy) to improve a known process (Svihra's PTN electrostimulation method). Ex.1003, ¶155. Second, it would have been obvious to try using Svihra's method to treat atrophy given the finite number of known solutions for treating the condition. *Id.*, ¶156. Third, design incentives and market forces would prompt variations to Svihra's method given known work in the field by, *e.g.*, Whitehurst, DiLorenzo '103, Jaax, including the need to identify treatments for conditions that cause atrophy. *Id.*, ¶157. A POSA would have expected success modifying Svihra's procedure in this manner and the results would have been predictable given the known and successful use of PTN electrostimulation to treat conditions that can cause atrophy, including paralysis or osteoarthritis, throughout the art in similar procedures. *Id.*, ¶¶155-57.

9. Claim 10

Svihra alone or in combination with Mann, DiLorenzo, Bourget, or Gerber discloses the limitations of claim 1. *Supra*, §§VI.A.1, VI.B.1. Further, Svihra's method involved delivering electrical stimulation to the PTN. Ex.1004, 480, 481; Ex.1003, ¶158. Although Svihra treated OAB patients, it would have been obvious to use Svihra's method to treat other conditions, such as paralysis. Ex.1003, ¶158.

A POSA would have known well before 2006 that many conditions, including paralysis, could be treated by electrically stimulating the PTN. *Id.*, ¶159.

For example, Whitehurst treated chronic pain causing paralysis by providing electrostimulation to peripheral nerves including the PTN. Ex.1066, [0005], [0015], [0020], [0055]. DiLorenzo ‘103 discloses a system for “electrical stimulation of peripheral nerves, such as stimulation of the tibial or peroneal nerves for use in eliciting the flexion withdrawal reflex to facilitate gait restoration in paraplegics.” Ex.1068, Abstract, [0019], [0072], [0348]. A paraplegic is a person with paralysis; therefore, electrostimulation of the PTN can be used to treat paralysis. Ex.1003, ¶159.

Using Svihra’s technique to treat paralysis would have been obvious. First, treating paralysis using Svihra’s method would have involved applying known techniques (*e.g.*, Whitehurst’s and DiLorenzo ‘103’s PTN electrostimulation to treat paralysis) to improve a known process (Svihra’s PTN electrostimulation method). Ex.1003, ¶160. Second, it would have been obvious to try using Svihra’s method to treat paralysis given the finite number of known solutions for treating the condition. *Id.*, ¶161. Third, design incentives and market forces would prompt variations to Svihra’s method given known work in the field by, *e.g.*, Whitehurst and DiLorenzo ‘103, including the need to identify treatments for conditions such as paralysis. *Id.*, ¶162. A POSA would have expected success modifying Svihra’s procedure in this manner and the results would have been predictable given the

known and successful use of PTN electrostimulation to treat paralysis throughout the art in similar procedures. *Id.*, ¶160-62.

D. Ground 4: Amarenco (Ex.1005) in View of Mann (Ex.1084), DiLorenzo (Ex.1054), Gerber (Ex.1055), or Bourget (Ex.1056) Renders Obvious Claim 1

Amarenco (Ex.1005) published in 2003, Mann (Ex.1084) issued September 6, 2005, and DiLorenzo (Ex.1054) issued April 2, 2002, and all are therefore prior art under at least pre-AIA 35 U.S.C. §102(b). Gerber (Ex.1055) was filed on April 28, 2005 and Bourget (Ex.1056) was filed April 28, 2006, and both are therefore prior art under at least pre-AIA 35 U.S.C. §102(e). Other than Mann, the other references were not cited or considered during prosecution of the ‘477 patent.

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. The 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.” *Id.*; Ex.1003, ¶164.

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); Ex.1003, ¶165.

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, ¶166. 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, ¶166. 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 was positioned relative to an electrical stimulator, as claimed. Ex.1005, 2211; Ex.1003, ¶166.

Amarenco indicates “surface self-adhesive electrodes on the ankle skin behind the internal malleolus” were used to stimulate the “left [PTN].” Ex.1005, 2210. A POSA would understand Amarenco’s electrodes were “in proximity to” the patients’ PTN because the electrodes were placed “on the ankle skin behind the internal malleolus” and provided electrical stimulation to the patients’ PTN. Ex.1003, ¶167.

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, ¶168.

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, ¶169. 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, ¶169.

e. Element [1.d]-[1.f]

Amarenco provides EMG results, indicating the researchers measured EMG signals via EMG sensors/electrodes. Ex.1005, 2212, Figs.3-4; Ex.1003, ¶170. If it is determined Amarenco does not disclose the “detecting . . .,” “receiving. . .,” and “adjusting . . .” limitations, it would have been obvious to modify Amarenco’s method to perform these steps based on Mann, DiLorenzo, Gerber, or Bourget. Ex.1003, ¶170.

As discussed, detecting patient responses to electrostimulation via sensors and adjusting stimulation parameters based on sensor feedback was known long before 2006. *Supra*, §III.C; Ex.1003, ¶171. Mann, DiLorenzo, Gerber, and Bourget disclose electrostimulation systems and methods that include detecting electrical conduction through nerves and/or resulting muscular response via EMG sensors, receiving the feedback, and automatically adjusting stimulation parameters including current. *Supra*, §III.C; Ex.1003, ¶¶171-75. Thus, as explained, Mann, DiLorenzo, Bourget, and Gerber disclose the “detecting,” “receiving,” and “adjusting” limitations of claim 1. Ex.1003, ¶176.

“*detecting* . . .” A POSA would have interpreted the “detecting . . .” limitation to encompass “detecting...” using EMG based on the claim language

and specification. *Supra*, §VI.A.1.e; Ex.1003, ¶177. As explained above, each of Mann, DiLorenzo, Bourget, and Gerber disclose the “detecting” limitation. *Supra*, §VI.B.1.e.; Ex.1003, ¶¶178-81.

“**receiving . . .**” As explained above, each of Mann, DiLorenzo, Bourget, and Gerber disclose the “receiving...” limitation. *Supra*, §VI.B.1.e.; Ex.1003, ¶¶182-85.

“**adjusting . . .**” As explained above, each of Mann, DiLorenzo, Bourget, and Gerber disclose the “adjusting...” limitation. *Supra*, §VI.B.1.e.; Ex.1003, ¶¶186-89.

Modifying Amarenco’s method to incorporate the systems/techniques of Mann, DiLorenzo, Gerber, or Bourget discussed above for “detecting...,” “receiving...,” and “adjusting...” would have been obvious. As described, each of Amarenco, Mann, DiLorenzo, Gerber, and Bourget are directed to similar fields, *i.e.*, electrostimulation systems and methods for treating patients. Ex.1005, 2210 (electrostimulation for OAB); Ex.1055, 3:19-49 (electrostimulation for urinary/fecal control disorders); Ex.1054, 3:35-4:3 (electrostimulation for treating various conditions); Ex.1056, 3:52-4:14, 4:41-51 (electrostimulation for, *e.g.*, incontinence); Ex.1084, 10:65-11:19 (electrostimulation for incontinence). Given this, a POSA would have looked to these references when considering modifications to Amarenco’s method. Ex.1003, ¶190.

To the extent EMK argues Amarengo would not be considered with these references, that argument is incorrect. *Id.*, ¶191. Regardless of the type of stimulation (*e.g.*, invasive or noninvasive), the nerves targeted for stimulation, or the treated conditions described, a POSA would have considered the systems/techniques of these references discussed above for “detecting...,” “receiving...,” and “adjusting...” to be relevant to Amarengo’s method because the features of those systems (*e.g.*, EMG sensors, receiving feedback, adjusting parameters including current, etc.) could be implemented in any type of electrostimulation system or method. *Id.* Indeed, the references themselves indicate the systems/techniques could be employed in a variety of contexts. *E.g.*, Ex.1054, 6:38-43, 10:24-42, 28:33-56; Ex.1056, 4:23-60; Ex.1055, 3:19-34; Ex.1084, 9:44-10:22. This argument is also contradicted by prior art such as Svihra, which explicitly states the invasive SANS procedure motivated the development of Svihra’s noninvasive procedure. Ex.1004, 480-81. Nor can EMK argue that elements of a different type of electrostimulation system (*e.g.*, implanted sensors) could not be physically incorporated into Amarengo’s noninvasive technique—what matters is whether “‘a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention.’” *Allied Erecting & Dismantling Co. v. Genesis Attachments, LLC*, 825 F.3d 1373, 1381 (Fed. Cir. 2016) (prior art need not be “physically combinable to render obvious”).

Modifying Amarenco's method by implementing the systems/techniques of Mann, DiLorenzo, Gerber, and Bourget discussed above for "detecting...", "receiving...", and "adjusting..." was also obvious because it would involve predictable use of prior art elements (*e.g.*, EMG sensors, receiving feedback, adjusting parameters including current, etc.) according to established functions (*e.g.*, sensing EMG signals, transmitting and receiving information, using sensor feedback to adjust parameters including current, etc.) or simple substitution of known elements (*e.g.*, Amarenco's EMG device for the systems/techniques of Mann, DiLorenzo, Gerber, or Bourget discussed above). Ex.1003, ¶¶192-93. A POSA would expect success and the results would be predictable given the widespread, successful use of such systems/techniques in similar electrostimulation devices and methods throughout the art. *Id.*

The prior art itself would also have motivated a POSA to modify Amarenco's procedure in this manner. *Id.*, ¶194. The references describe numerous benefits of the systems/techniques discussed above for "detecting...", "receiving...", and "adjusting..." *Id.* For example, DiLorenzo indicates the systems/techniques incorporate patient symptomatology and function measures in regulating treatment magnitude, determine the optimum treatment magnitude, expedite satisfactory treatment, reduce physician/patient interactions, and optimize energy efficiency. Ex.1054, 4:38-5:38; *see also* Ex.1056, 2:23-34, 3:5-14, 3:65-

4:14, 7:54-65; Ex.1055, 2:14-16; Ex.1084, 10:12-16. A POSA considering modifications to Amarenco's method would be motivated to incorporate the teachings of Mann, DiLorenzo, Bourget, or Gerber described above to achieve the stated benefits, including among others improved feedback, better treatment and side effect regulation, and quicker/more effective treatment. Ex.1003, ¶194.

E. Ground 5: Amarenco (Ex.1005) in Combination with Mann (Ex.1084), DiLorenzo (Ex.1054), Gerber (Ex.1055), or Bourget (Ex.1056), Further in View of the Knowledge of a POSA, Renders Obvious Claims 2-10

As indicated above, Amarenco, Mann, and DiLorenzo are prior art under at least pre-AIA 35 U.S.C. §102(b), and Gerber and Bourget are prior art under at least pre-AIA 35 U.S.C. §102(e). Other than Mann, none of these references were cited or considered during the '477 patent's prosecution.

A POSA would have considered these references with additional prior art evidencing the knowledge of a POSA (such as the references discussed below) as all are directed to similar fields, *i.e.*, electrostimulation systems and methods for treating various conditions of patients. That some references describing treatment of a given condition via PTN electrostimulation use different types of electrostimulation procedures (*e.g.*, invasive or noninvasive) is irrelevant to whether a POSA would have tried or been motivated to try using Amarenco's method (as modified by Mann, DiLorenzo, Gerber, or Bourget) to treat a given condition. Ex.1003, ¶¶199, 204, 209, 214, 219, 224, 230, 236, 241. The successful

use of electrical stimulation to treat a given condition, whether invasive or noninvasive, would suggest other types of electrical stimulation could also be successful and motivate a POSA to try, including using noninvasive electrostimulation. *Id.* This is further supported by other prior art known to a POSA such as Svihra, which explicitly states the invasive SANS procedure motivated the development of Svihra's noninvasive procedure. Ex.1004, 480-81.

1. Claim 2

Amarenco in combination with Mann, DiLorenzo, Bourget, or Gerber discloses the limitations of claim 1. *Supra*, §§VI.D.1. Further, Amarenco's method involved delivering electrical stimulation to the PTN. Ex.1005, 2210 ("left posterior tibial nerve stimulation"); Ex.1003, ¶196. Although Amarenco treated OAB patients, it would have been obvious to use Amarenco's method to treat other conditions, such as fecal incontinence. Ex.1003, ¶196.

A POSA would have known well before 2006 that many conditions, including fecal incontinence, could be treated by electrically stimulating the PTN. *Id.*, ¶197; *supra*, §VI.C.1 (discussing Queralto and Shafik); Ex.1016, 670, 672; Ex.1064, Abstract.

Using Amarenco's technique to treat fecal incontinence would have been obvious. First, treating fecal incontinence using Amarenco's method would have involved applying known techniques (*e.g.*, Queralto's and Shafik's PTN

electrostimulation to treat fecal incontinence) to improve a known process (Amarenco's PTN electrostimulation method). Ex.1003, ¶198. Second, it would have been obvious to try using Amarenco's method to treat fecal incontinence given the finite number of known solutions for treating the condition. *Id.*, ¶199. Third, design incentives and market forces would prompt variations to Amarenco's method given known work in the field by, *e.g.*, Queralto and Shafik, including the need to identify treatments for conditions such as fecal incontinence. *Id.*, ¶200. A POSA would have expected success modifying Amarenco's procedure in this manner and the results would have been predictable given the known and successful use of PTN electrostimulation to treat fecal incontinence throughout the art in similar procedures. *Id.*, ¶¶198-200.

2. Claim 3

Amarenco in combination with Mann, DiLorenzo, Bourget, or Gerber discloses the limitations of claim 1. *Supra*, §§VI.D.1. Further, Amarenco's method involved delivering electrical stimulation to the PTN. Ex.1005, 2210; Ex.1003, ¶201. Although Amarenco treated OAB patients, it would have been obvious to use Amarenco's method to treat other conditions, such as restless leg syndrome. Ex.1003, ¶201.

A POSA would have known well before 2006 that many conditions, including restless leg syndrome, could be treated by electrically stimulating the

PTN. *Id.*, ¶202; *supra*, §VI.C.2 (discussing DiLorenzo ‘103); Ex.1068, Abstract, [0019], [0072], [0093], [0175], [0348], cls.128-31.

Using Amarenco’s technique to treat restless leg syndrome would have been obvious. First, treating restless leg syndrome using Amarenco’s method would have involved applying known techniques (*e.g.*, DiLorenzo ‘103’s PTN electrostimulation to treat restless leg syndrome as taught by, *e.g.*, DiLorenzo ‘103) to improve a known process (Amarenco’s PTN electrostimulation method). Ex.1003, ¶203. Second, it would have been obvious to try using Amarenco’s method to treat restless leg syndrome given the finite number of known solutions for treating the condition. *Id.*, ¶204. Third, design incentives and market forces would prompt variations to Amarenco’s method given known work in the field by, *e.g.*, DiLorenzo ‘103, including the need to identify treatments for conditions such as restless leg syndrome. *Id.*, ¶205. A POSA would have expected success modifying Amarenco’s procedure in this manner and the results would have been predictable given the known and successful use of PTN electrostimulation to treat restless leg syndrome throughout the art in similar procedures. *Id.*, ¶¶203-05.

3. Claim 4

Amarenco in combination with Mann, DiLorenzo, Bourget, or Gerber discloses the limitations of claim 1. *Supra*, §§VI.D.1. Further, Amarenco’s method involved delivering electrical stimulation to the PTN. Ex.1005, 2210; Ex.1003,

¶206. Although Amarenco treated OAB patients, it would have been obvious to use Amarenco's method to treat other conditions, such as premature ejaculation. Ex.1003, ¶206.

A POSA would have known well before 2006 that many conditions, including premature ejaculation, could be treated by electrically stimulating the PTN. *Id.*, ¶207; *supra*, §VI.C.3 (discussing Gerber '372); Ex.1069, Abstract, [0002], [0064], [0004], [0021], [0047-49], cl.1.

Using Amarenco's technique to treat premature ejaculation would have been obvious. First, treating premature ejaculation using Amarenco's method would have involved applying known techniques (*e.g.*, Gerber '372's PTN electrostimulation to treat premature ejaculation) to improve a known process (Amarenco's PTN electrostimulation method). Ex.1003, ¶208. Second, it would have been obvious to try using Amarenco's method to treat premature ejaculation given the finite number of known solutions for treating the condition. *Id.*, ¶209. Third, design incentives and market forces would prompt variations to Amarenco's method given known work in the field by, *e.g.*, Gerber '372, including the need to identify treatments for conditions such as premature ejaculation. *Id.*, ¶210. A POSA would have expected success modifying Amarenco's procedure in this manner and the results would have been predictable given the known and

successful use of PTN electrostimulation to treat premature ejaculation throughout the art in similar procedures. *Id.*, ¶¶208-10.

4. Claim 5

Amarenco in combination with Mann, DiLorenzo, Bourget, or Gerber discloses the limitations of claim 1. *Supra*, §§VI.D.1. Further, Amarenco's method involved delivering electrical stimulation to the PTN. Ex.1005, 2210; Ex.1003, ¶211. Although Amarenco treated OAB patients, it would have been obvious to use Amarenco's method to treat other conditions, such as chronic pain. Ex.1003, ¶211.

A POSA would have known well before 2006 that many conditions, including chronic pain, could be treated by electrically stimulating the PTN. *Id.*, ¶212; *supra*, §VI.C.4 (discussing van Balken 2003 and Whitehurst); Ex.1065, 158; Ex.1066, [0005], [0015], [0055].

Using Amarenco's technique to treat chronic pain would have been obvious. First, treating chronic pain using Amarenco's method would have involved applying known techniques (*e.g.*, van Balken 2003's and Whitehurst's PTN electrostimulation to treat chronic pain) to improve a known process (Amarenco's PTN electrostimulation method). Ex.1003, ¶213. Second, it would have been obvious to try using Amarenco's method to treat chronic pain given the finite number of known solutions for treating the condition. *Id.*, ¶214. Third, design

incentives and market forces would prompt variations to Amarenco's method given known work in the field by, *e.g.*, van Balken 2003 and Whitehurst, including the need to identify treatments for conditions such as chronic pain. *Id.*, ¶215. A POSA would have expected success modifying Amarenco's procedure in this manner and the results would have been predictable given the known and successful use of PTN electrostimulation to treat chronic pain throughout the art in similar procedures. *Id.*, ¶¶213-15.

5. Claim 6

Amarenco in combination with Mann, DiLorenzo, Bourget, or Gerber discloses the limitations of claim 1. *Supra*, §§VI.D.1. Further, Amarenco's method involved delivering electrical stimulation to the PTN. Ex.1005, 2210; Ex.1003, ¶216. Although Amarenco treated OAB patients, it would have been obvious to use Amarenco's method to treat other conditions, such as osteoarthritis or arthritis. Ex.1003, ¶216.

A POSA would have known well before 2006 that many conditions, including osteoarthritis or arthritis, could be treated by electrically stimulating the PTN. *Id.*, ¶217; *supra*, §VI.C.5 (discussing Jaax and Whitehurst); Ex.1067, 3:13-21, 5:40-49, 5:50-6:11; Ex.1066, [0005], [0015], [0017], [0055].

Using Amarenco's technique to treat osteoarthritis or arthritis would have been obvious. First, treating osteoarthritis or arthritis using Amarenco's method

would have involved applying known techniques (*e.g.*, Jaax's and Whitehurst's PTN electrostimulation to treat osteoarthritis or arthritis) to improve a known process (Amarenco's PTN electrostimulation method). Ex.1003, ¶218. Second, it would have been obvious to try using Amarenco's method to treat osteoarthritis or arthritis given the finite number of known solutions for treating the condition. *Id.*, ¶219. Third, design incentives and market forces would prompt variations to Amarenco's method given known work in the field by, *e.g.*, Jaax and Whitehurst, including the need to identify treatments for conditions such as osteoarthritis or arthritis. *Id.*, ¶220. A POSA would have expected success modifying Amarenco's procedure in this manner and the results would have been predictable given the known and successful use of PTN electrostimulation to treat osteoarthritis or arthritis throughout the art in similar procedures. *Id.*, ¶¶218-20.

6. Claim 7

Amarenco in combination with Mann, DiLorenzo, Bourget, or Gerber discloses the limitations of claim 1. *Supra*, §§VI.D.1. Further, Amarenco's method involved delivering electrical stimulation to the PTN. Ex.1005, 2210; Ex.1003, ¶221. Although Amarenco treated OAB patients, it would have been obvious to use Amarenco's method to treat other conditions, such as neuropathic pain. Ex.1003, ¶221.

A POSA would have known well before 2006 that many conditions, including neuropathic pain, could be treated by electrically stimulating the PTN. *Id.*, ¶222; *supra*, §VI.C.6 (discussing Whitehurst); Ex.1066, [0005], [0015], [0017-18], [0028-29], [0055].

Using Amarenco's technique to treat neuropathic pain would have been obvious. First, treating neuropathic pain using Amarenco's method would have involved applying known techniques (*e.g.*, Whitehurst's PTN electrostimulation to treat neuropathic pain) to improve a known process (Amarenco's PTN electrostimulation method). Ex.1003, ¶223. Second, it would have been obvious to try using Amarenco's method to treat neuropathic pain given the finite number of known solutions for treating the condition. *Id.*, ¶224. Third, design incentives and market forces would prompt variations to Amarenco's method given known work in the field by, *e.g.*, Whitehurst, including the need to identify treatments for conditions such as neuropathic pain. *Id.*, ¶225. A POSA would have expected success modifying Amarenco's procedure in this manner and the results would have been predictable given the known and successful use of PTN electrostimulation to treat neuropathic pain throughout the art in similar procedures. *Id.*, ¶¶223-26.

7. Claim 8

Amarenco in combination with Mann, DiLorenzo, Bourget, or Gerber discloses the limitations of claim 1. *Supra*, §§VI.D.1. Further, Amarenco's method involved delivering electrical stimulation to the PTN. Ex.1005, 2210; Ex.1003, ¶227. Although Amarenco treated OAB patients, it would have been obvious to use Amarenco's method to treat other conditions, such as neuralgia. Ex.1003, ¶227.

A POSA would have known well before 2006 that many conditions, including neuralgia, could be treated by electrically stimulating the PTN. *Id.*, ¶228. *See supra*, §VI.C.7 (discussing Whitehurst); Ex.1069, [0005], [0015], [0019-20], [0055].

Using Amarenco's technique to treat neuralgia would have been obvious. First, treating neuralgia using Amarenco's method would have involved applying known techniques (*e.g.*, Whitehurst's PTN electrostimulation to treat neuralgia) to improve a known process (Amarenco's PTN electrostimulation method). Ex.1003, ¶229. Second, it would have been obvious to try using Amarenco's method to treat neuralgia given the finite number of known solutions for treating the condition. *Id.*, ¶230. Third, design incentives and market forces would prompt variations to Amarenco's method given known work in the field by, *e.g.*, Whitehurst, including the need to identify treatments for conditions such as neuralgia. *Id.*, ¶231. A POSA

would have expected success modifying Amarenco's procedure in this manner and the results would have been predictable given the known and successful use of PTN electrostimulation to treat neuralgia throughout the art in similar procedures. *Id.*, ¶¶229-31.

8. Claim 9

Amarenco alone or in combination with Mann, DiLorenzo, Bourget, or Gerber discloses the limitations of claim 1. *Supra*, §§VI.A.1, VI.B.1. Further, Amarenco's method involved delivering electrical stimulation to the PTN. Ex.1004, 480, 481; Ex.1003, ¶232. Although Amarenco treated OAB patients, it would have been obvious to use Amarenco's method to treat other conditions, such as atrophy. Ex.1003, ¶232.

A POSA would have known well before 2006 that many conditions, including atrophy and conditions causing atrophy such as paralysis or osteoarthritis, could be treated by electrically stimulating the PTN. *Id.*, ¶¶233-34; *supra*, §VI.C.8 (discussing Whitehurst, DiLorenzo '103, and Jaax); Ex.1070, [0003]; Ex.1067, 1:26-34, 13-21, 5:40-49, 5:50-6:11; Ex.1066, [0005], [0015], [0020], [0055]; Ex.1068, Abstract, [0019], [0072], [0348].

Using Amarenco's technique to treat atrophy would have been obvious. First, treating atrophy using Amarenco's method would have involved applying known techniques (*e.g.*, Whitehurst's, DiLorenzo '103's, and Jaax's PTN

electrostimulation to treat paralysis or osteoarthritis, which were known to cause atrophy) to improve a known process (Amarenco's PTN electrostimulation method). Ex.1003, ¶235. Second, it would have been obvious to try using Amarenco's method to treat atrophy given the finite number of known solutions for treating the condition. *Id.*, ¶236. Third, design incentives and market forces would prompt variations to Amarenco's method given known work in the field by, *e.g.*, Whitehurst, DiLorenzo '103, Jaax, including the need to identify treatments for conditions that cause atrophy. *Id.*, ¶237. A POSA would have expected success modifying Amarenco's procedure in this manner and the results would have been predictable given the known and successful use of PTN electrostimulation to treat conditions that can cause atrophy, including paralysis or osteoarthritis, throughout the art in similar procedures. *Id.*, ¶¶235-37.

9. Claim 10

Amarenco in combination with Mann, DiLorenzo, Bourget, or Gerber discloses the limitations of claim 1. *Supra*, §§VI.D.1. Further, Amarenco's method involved delivering electrical stimulation to the PTN. Ex.1005, 2210; Ex.1003, ¶238. Although Amarenco treated OAB patients, it would have been obvious to use Amarenco's method to treat other conditions, such as paralysis. Ex.1003, ¶238.

A POSA would have known well before 2006 that many conditions, including paralysis, could be treated by electrically stimulating the PTN. *Id.*, ¶239;

supra, §VI.C.9 (discussing Whitehurst and DiLorenzo ‘103); Ex.1066, [0005], [0015], [0020], [0055]; Ex.1068, Abstract, [0019], [0072], [0348].

Using Amarenco’s technique to treat paralysis would have been obvious. First, treating paralysis using Amarenco’s method would have involved applying known techniques (*e.g.*, Whitehurst’s and DiLorenzo ‘103’s PTN electrostimulation to treat paralysis) to improve a known process (Amarenco’s PTN electrostimulation method). Ex.1003, ¶240. Second, it would have been obvious to try using Amarenco’s method to treat paralysis given the finite number of known solutions for treating the condition. *Id.*, ¶241. Third, design incentives and market forces would prompt variations to Amarenco’s method given known work in the field by, *e.g.*, Whitehurst and DiLorenzo ‘103, including the need to identify treatments for conditions such as paralysis. *Id.*, ¶242. A POSA would have expected success modifying Amarenco’s procedure in this manner and the results would have been predictable given the known and successful use of PTN electrostimulation to treat paralysis throughout the art in similar procedures. *Id.*, ¶¶240-42.

F. 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.

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

The Board should decline to exercise its discretion to not institute trial under §314(a) or §325(d), as none of the factors support doing so here.

A. §314(a)

The parties are involved in litigation in the U.S. District Court for the Northern District of California, but that litigation is at an early stage and the *Fintiv* factors 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, ‘742, and ‘477 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 March 2026, 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 October 1, 2024, 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 ‘477 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 §314(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 ‘477 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 ‘477 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, ***approximately 330 references*** were cited during prosecution of the ‘477 patent. *See* Ex.1001, [56]. Even if some of the art relied upon by Petitioner overlaps with references submitted in IDS’s during prosecution, PO cannot be allowed to dump hundreds of references on the Office during prosecution and then avoid IPR by claiming the art was previously cited to the Office. In any event, Petitioner’s invalidity grounds rely primarily on references and/or arguments that were not before the Office during prosecution of the ‘477 patent. None of Svihra, Amarenco, DiLorenzo, Gerber, or Bourget were cited or considered during

prosecution. The Office has therefore not considered any of Petitioner's grounds or unpatentability arguments.

Thus, this petition presents art and arguments that were not previously before the Office, strongly favoring institution.

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.

The claims of the '477 patent should not have been allowed. In the reasons for allowance, the examiner stated "[t]he subject matter for the independent claims could not be found or was not suggested in the prior art." Ex.1002, 12. The art cited in this petition—much of which was not cited or considered by the examiner—demonstrates that the examiner's belief that the art did not disclose the subject matter of the claims was incorrect. Not only does the prior art teach noninvasive electrostimulation of the PTN to treat OAB/incontinence, it also teaches a variety of electrostimulation systems that include sensors for detecting conduction or muscular response and controllers for adjusting the stimulation current based on sensor feedback. *Supra*, §§III.B-C, VI.A-E. Given the examiner's

stated reasons for allowance, the examiner's failure to appreciate these teachings in the art constitutes clear material error in allowing the claims to issue.

3. The Petition Presents Additional Evidence and Arguments.

Although several secondary references relied on herein were cited during prosecution, many of Petitioner's other key references—including Svihra, Amarenco, DiLorenzo, Bourget, and Gerber—were not. Thus, the petition presents art and arguments that were not previously before the Office. 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 '477 patent, the Board should decline exercising discretion under §325(d) and institute IPR.

VIII. CONCLUSION

For the foregoing reasons, IPR of claims 1-10 of the '477 patent is respectfully requested.

Dated: September 5, 2024

Respectfully submitted,

/s/ Todd R. Tucker

Todd R. Tucker (Reg. No. 40,850)

ttucker@calfee.com

Kyle Deighan (Reg. No. 75,525)

kdeighan@calfee.com

CALFEE, HALTER & GRISWOLD LLP

The Calfee Building

1405 East Sixth Street

Cleveland, Ohio 44114

P: 216-622-8200

F: 216-241-0816

Attorneys for Petitioner

Claim Appendix

Claim 1:

[1.p] A method of performing electrical stimulation therapy, comprising:

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

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

[1.c] delivering an electrical stimulus from the electrical stimulator to the posterior tibial nerve or branch thereof;

[1.d] detecting electrical conduction through the posterior tibial nerve or branch thereof or detecting a muscular response caused by an electrical conduction through the posterior tibial nerve or branch thereof via at least one sensor positioned along a second portion of the body;

[1.e] receiving a signal from the at least one sensor indicative of the detected electrical conduction or muscular response thereby providing feedback about the efficacy of the applied electrical stimulation therapy; and

[1.f] adjusting the current via a controller in communication with the electrical stimulator based on the feedback.

Claim 2:

The method of claim 1, wherein the electrical stimulus is delivered to the posterior tibial nerve or branch thereof to treat fecal incontinence.

Claim 3:

The method of claim 1, wherein the electrical stimulus is delivered to the posterior tibial nerve or branch thereof to treat restless leg syndrome.

Claim 4:

The method of claim 1, wherein the electrical stimulus is delivered to the posterior tibial nerve or branch thereof to treat premature ejaculation.

Claim 5:

The method of claim 1, wherein the electrical stimulus is delivered to the posterior tibial nerve or branch thereof to treat chronic pain.

Claim 6:

The method of claim 1, wherein the electrical stimulus is delivered to the posterior tibial nerve or branch thereof to treat osteoarthritis or arthritis.

Claim 7:

The method of claim 1, wherein the electrical stimulus is delivered to the posterior tibial nerve or branch thereof responsible for neuropathic pain to treat neuropathic pain.

Claim 8:

The method of claim 1, wherein the electrical stimulus is delivered to the posterior tibial nerve or branch thereof to treat neuralgia.

Claim 9:

The method of claim 1, wherein the electrical stimulus is delivered to the posterior tibial nerve or branch thereof to treat atrophy.

Claim 10:

The method of claim 1, wherein the electrical stimulus is delivered to the posterior tibial nerve or branch thereof to treat paralysis.

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 13,086 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: September 5, 2024

/s/ Todd R. Tucker

Todd R. Tucker (Reg. No. 40,850)

ttucker@calfee.com

Kyle Deighan (Reg. No. 75,525)

kdeighan@calfee.com

CALFEE, HALTER & GRISWOLD LLP

The Calfee Building

1405 East Sixth Street

Cleveland, Ohio 44114

P: 216-622-8200

F: 216-241-0816

Attorneys for Petitioner

CERTIFICATE OF SERVICE

The undersigned certifies that the foregoing **PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 9,002,477 and ACCOMPANYING EXHIBITS** were served as of the below date on the following individuals in accordance with 37 C.F.R. §42.105(a):

Gerasimow Law
Attn: David A. Gerasimow
211 W. Wacker Drive, Ste. 1717
Chicago, IL 60606

Levine Bagade Han LLP
Attn: Sanjay Bagade, Johny Han, David Levine, Laura Gallagher, Grant
McAdams, Daniel Xu, Lucas Paez, and Seth Littleford
2400 Geng Road, Suite 120
Palo Alto, CA 94303

Dated: September 5, 2024

/s/ Todd R. Tucker

Todd R. Tucker

Attorney for Petitioner