

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Avation Medical, Inc.,
Petitioner

v.

EMKinetics, Inc.,
Patent Owner

Case No. IPR2024-01375
U.S. Patent No. 11,224,742

**PETITION FOR *INTER PARTES* REVIEW
OF U.S. PATENT NO. 11,224,742**

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EXHIBIT LIST

Exhibit No.	Description
1001	U.S. Patent No. 11,224,742 (“’742 patent”)
1002	File History of U.S. Patent No. 11,224,742 (“’742 patent file history”)
1003	Declaration of Dr. Brett Wingeier in Support of Petition for Inter Partes Review of U.S. Patent No. 11,224,742 (“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	<i>[Reserved]</i> ¹
1007	<i>[Reserved]</i>
1008	G. Willy Davila & Minda Neimark, “The Overactive Bladder: Prevalence and Effects on Quality of Life,” <i>Clinical Obstetrics and Gynecology</i> 45(1):173-181 (2002) (“Davila”)
1009	Alan J. Wein & Eric S. Rovner, “Definition and Epidemiology of Overactive Bladder,” <i>Urology</i> 60(Suppl 5A):7-12 (2002) (“Wein”)
1010	Paul Abrams <i>et al.</i> , “Overactive Bladder Significantly Affects Quality of Life,” <i>The American Journal of Managed Care</i> 6(11, Sup.):580-590 (2000) (“Abrams”)
1011	Neeral Kohli & Peter L. Rosenblatt, “Neuromodulation Techniques for the Treatment of the Overactive Bladder,” <i>Clinical Obstetrics and Gynecology</i> 45(1):218-232 (2002) (“Kohli”)
1012	Floor van der Pal <i>et al.</i> , “Current opinion on the working mechanisms of neuromodulation in the treatment of lower urinary

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 IPR2024-01378.

Exhibit No.	Description
	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	L. Zhang & D.P. Rabussay, “Clinical evaluation of safety and human tolerance of electrical sensation induced by electric fields with non-invasive electrodes,” <i>Bioelectrochemistry</i> 56(1-2):233-236 (2002) (“Zhang”)
1025	U.S. Patent No. 6,341,236 to Osorio <i>et al.</i> (“‘236 patent”)
1026	U.S. Patent App. Pub. No. 2007/0021803 to Deem <i>et al.</i> (“US2007/0021803”)
1027	Katherine N. Moore, “Treatment of Urinary Incontinence in Men with Electrical Stimulation: Is Practice Evidence-Based?,” <i>Journal of Wound, Ostomy and Continence Nursing</i> 27(1):20-31 (2000) (“Moore”)
1028	Hermie J. Hermens <i>et al.</i> , “Development of recommendations for SEMG sensors and sensor placement procedures,” <i>Journal of</i>

Exhibit No.	Description
	<i>Electromyography and Kinesiology</i> 10(5):361-374 (2000) (“Hermens”)
1029	U.S. Patent No. 8,206,312 to Farquhar (“’312 patent”)
1030	S. Tahseen Hasan <i>et al.</i> , “Transcutaneous Electrical Nerve Stimulation and Temporary S3 Neuromodulation in Idiopathic Detrusor Instability,” <i>The Journal of Urology</i> 155(6):2005-2011 (1996) (“Hasan”)
1031	U.S. Patent App. Pub. No. 2005/0075670 to Bengtsson (“’670 publication”)
1032	U.S. Patent App. Pub. No. 2007/0276449 to Gunter <i>et al.</i> (“’449 publication”)
1033	U.S. Patent No. 7,801,603 to Westlund <i>et al.</i> (“’603 patent”)
1034	U.S. Patent No. 8,712,546 to Kim <i>et al.</i> (“’546 patent”)
1035	Micael A. Crary <i>et al.</i> , “Biomechanical Correlates of Surface Electromyography Signals Obtained During Swallowing by Healthy Adults,” <i>Journal of Speech, Language, and Hearing Research</i> 49(1):186-193 (2006) (“Crary”)
1036	U.S. Patent No. 7,206,630 to Tarler (“’630 patent”)
1037	Stephen A. Koff & Evan J. Kass, “Abdominal Wall Electromyography: A Noninvasive Technique To Improve Pediatric Urodynamic Accuracy,” <i>The Journal of Urology</i> 127(4):736-739 (1982) (“Koff”)
1038	Michael R. van Balken <i>et al.</i> , “Posterior Tibial Nerve Stimulation as Neuromodulative Treatment of Lower Urinary Tract Dysfunction,” <i>The Journal of Urology</i> 166(3):914-918 (2001) (“van Balken 2001”)
1039	J.L.H. Ruud Bosch, “Electrical neuromodulatory therapy in female voiding dysfunction,” <i>BJU International</i> 98(s1):43-48 (2006) (“Bosch”)
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”)

Exhibit No.	Description
1043	A Martens De Noordhout <i>et al.</i> , “Percutaneous electrical stimulation of lumbosacral roots in man,” <i>Journal of Neurology, Neurosurgery, and Psychiatry</i> 51(2):174-181 (1988) (“Noordhout”)
1044	[Reserved]
1045	[Reserved]
1046	[Reserved]
1047	[Reserved]
1048	U.S. Patent App. No. 11/866,329 to Burnett <i>et al.</i> (“‘329 application”)
1049	[Reserved]
1050	[Reserved]
1051	<i>Avation Medical, Inc. v. EMKinetics, Inc.</i> No. 3:24-cv-01702 (N.D. Cal.) First Amended Complaint, Dkt. No. 5
1052	[Reserved]
1053	Declaration of Todd R. Tucker
1054	[Reserved]
1055	[Reserved]
1056	[Reserved]
1057	[Reserved]
1058	[Reserved]
1059	[Reserved]
1060	[Reserved]
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1074	[Reserved]

Exhibit No.	Description
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	U.S. Patent No. 6,272,383 to Grey <i>et al.</i> (“Grey”)
1082	U.S. Patent No. 5,984,854 to Ishikawa <i>et al.</i> (“Ishikawa”)
1083	U.S. Patent No. 6,735,474 to Loeb <i>et al.</i> (“Loeb”)
1084	U.S. Patent No. 6,941,171 to Mann <i>et al.</i> (“Mann”)
1085	S N Ponsford, “Sensory conduction in medial and lateral plantar nerves,” <i>Journal of Neurology, Neurosurgery, and Psychiatry</i> 51(2):188-191 (1988) (“Ponsford”)
1086	U.S. Patent No. 5,995,873 to Rhodes (“Rhodes”)
1087	U.S. Patent No. 11,844,943 to Rajguru <i>et al.</i> (“‘943 patent”)
1088	<i>Gray’s Anatomy</i> 1123-53 (Peter L. Williams <i>et al.</i> eds., 37th ed. 1989) (“Gray’s”)

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 ‘742 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). Avation is also filing a petition for IPR regarding the ‘477 patent. *See Avation Medical, Inc. v. EMKinetics, Inc.*, IPR2024-1378 (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 Bryнна 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 ‘742 patent claims methods of treating overactive bladder (“OAB”) or incontinence using well-known transdermal electrical stimulation therapy. Well before the October 2006 earliest effective filing date of the ‘742 patent, however, the prior art described treatment of OAB and incontinence using noninvasive electrostimulation techniques. Most notably, Svihra (Ex.1004)—published in 2002 and not considered during the ‘742 patent’s prosecution—describes treating OAB patients using noninvasive electrical stimulation targeting the posterior tibial nerve (“PTN”). The only possible distinction between the sole independent claim of the ‘742 patent and prior art such as Svihra is that the claim requires targeting and delivering stimulation to a **branch** of the PTN. But electrical stimulation of sacral nerves, including the PTN and its branches, was also a well-known and commonly used treatment OAB and incontinence. So too were techniques for directly targeting and delivering electric stimulation directly to the PTN’s branches, including the medial and lateral plantar nerves. These and many other references make clear that the patent claims simply cover what was already well-known in the art, rendering those claims invalid.

Because the evidence demonstrates that claims 1-13 of the ‘742 patent (“Challenged Claims”) are invalid, the Board should institute IPR and find the claims of the ‘742 patent unpatentable.

II. COMPLIANCE WITH IPR REQUIREMENTS

A. Certification (§42.104(a))

Petitioner certifies that the '742 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 '742 patent. This petition is timely filed as Petitioner has not been served with a complaint alleging infringement of the '742 patent as of this petition's filing.

B. Identification of Challenge (§42.104(b))

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

Ground	Claims	Description
1	1-13	Obvious under 35 U.S.C. §103 over Svihra (Ex.1004) in view of Mann (Ex.1084), Ponsford (Ex.1085), and Knowledge of POSA ³

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

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

2	1-13	Obvious 35 U.S.C. §103 over Amarenco (Ex.1005) in view of Mann (Ex.1084), Ponsford (Ex.1085), and Knowledge of POSA
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Petitioner’s challenges are supported by the testimony of Dr. Brett Wingier, an expert in biomedical engineering and stimulation therapy with over 20 years of experience. Ex.1003, ¶¶6-14.

C. Fee (§42.15(b))

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

D. Service (§42.105)

Proof of service is provided below.

III. BACKGROUND TECHNOLOGY

A. Overactive Bladder (“OAB”) and Incontinence

OAB is a condition that encompasses a range of irritative bladder filling and storage symptoms suggestive of lower urinary tract dysfunction. Ex.1008, 173; Ex.1009, 7. In the early 2000s, OAB was defined as “urgency, with or without urge incontinence, usually with frequency and nocturia.” Ex.1009, 7. “Urgency” refers

perspective of an ordinarily skilled artisan and one must consider knowledge generally available to one of ordinary skill in the art.”).

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, ¶¶32-33.

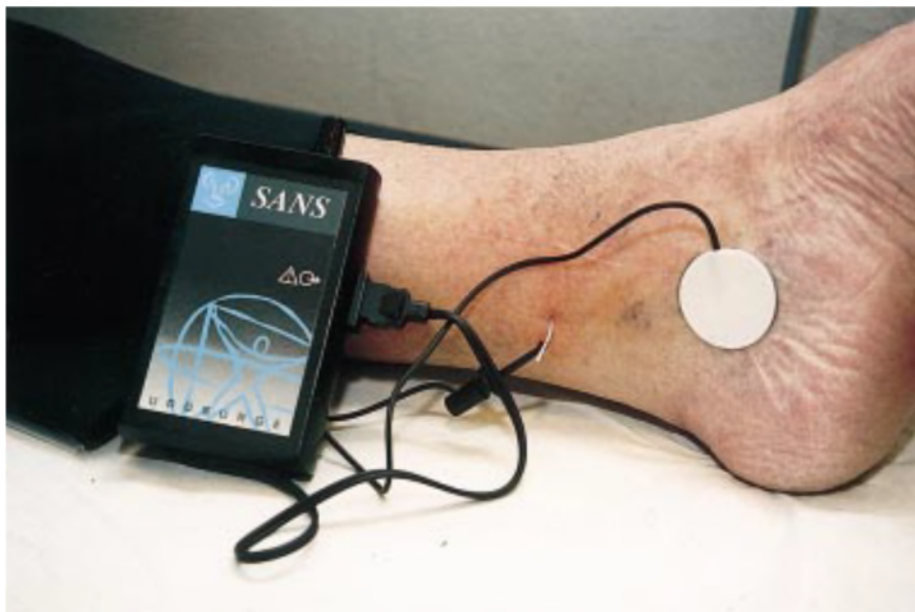
B. Treatment of OAB and UI

Well before 2006, various approaches were used to treat OAB and incontinence, including behavioral modifications, pharmacological therapies, surgery, and neuromodulation. Ex.1011, 219; Ex.1001, 2:35-3:16. Behavioral therapies required adherence to routines, which patients found unattractive. *Id.* Pharmacological interventions often caused unacceptable side effects. *Id.* Surgery was invasive, expensive, and only used when other treatments failed. *Id.* Due to these limitations, neuromodulation techniques were developed to treat OAB and incontinence. Ex.1011, 220; Ex.1003, ¶¶34-35.

Neuromodulation refers to therapeutic techniques involving influencing one neural pathway to modulate activity in another. Ex.1012, 261. By the early 2000’s, neuromodulation was used to treat various conditions. Ex.1013, 232. Electrical stimulation was one common form of neuromodulation used to treat OAB and UI. Ex.1003, ¶¶36-37.

Sacral nerve stimulation (“SNS”) was a well-known technique for treating OAB and incontinence. Ex.1014, 726. SNS involved implanting a pulse generator and electrode to stimulate nerves emanating from the sacral region of the spinal cord, which communicate with muscles controlling urination. *Id.* While effective, the technique was invasive and costly. *Id.*, 727-28; Ex.1001, 2:62-3:4; Ex.1003, ¶38.

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



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

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

Many studies demonstrated safety and efficacy of SANS. *Id.*, 727-28; Ex.1001,

3:5-16. Stoller, for example, “described an 81% clinical success rate.” Ex.1015, 256. PTNS was, however, invasive given the need to penetrate patients’ skin. Ex.1003, ¶¶39-40.

Noninvasive electrostimulation techniques were also known well before 2006. Ex.1003, ¶41. Transcutaneous electrical nerve stimulation (“TENS”), commonly used to treat various conditions such as pain, was investigated for OAB/incontinence treatment. Ex.1014, 725-26. In TENS, surface electrodes were placed on patients’ skin overlying areas desired for stimulation, including the PTN. *Id.*, 724. Many studies showed positive results in treating OAB/incontinence. *Id.*, 724-25.

For example, McGuire reported on noninvasive PTN electrostimulation in 1983. Ex.1003, ¶42. McGuire’s technique involved applying current via an electrode “applied by a stick-on electrocardiograph-type electrode with a foam backing” to the common peroneal nerve or PTN. Ex.1041, 78-79. McGuire stated “[t]his electrode placement, coupled with a commercially available transcutaneous electrical nerve stimulator used for the control of pain, provides a reasonable method to inhibit detrusor activity.” *Id.*, 79.

In the early 2000’s, studies using similar noninvasive techniques were published. Svihra “tested the effectiveness of modified superficial Stoller’s afferent nerve stimulation (SANS)” in OAB patients. Ex.1004, 480, 481. Svihra attached

electrodes “behind the medial ankle of the left lower extremity” and applied electric stimulation targeting the PTN for 30 minutes/week. *Id.* Svihra concluded the technique “is acceptable and safe conservative treatment in case of [OAB].” *Id.*, 480, 482; Ex.1003, ¶43.

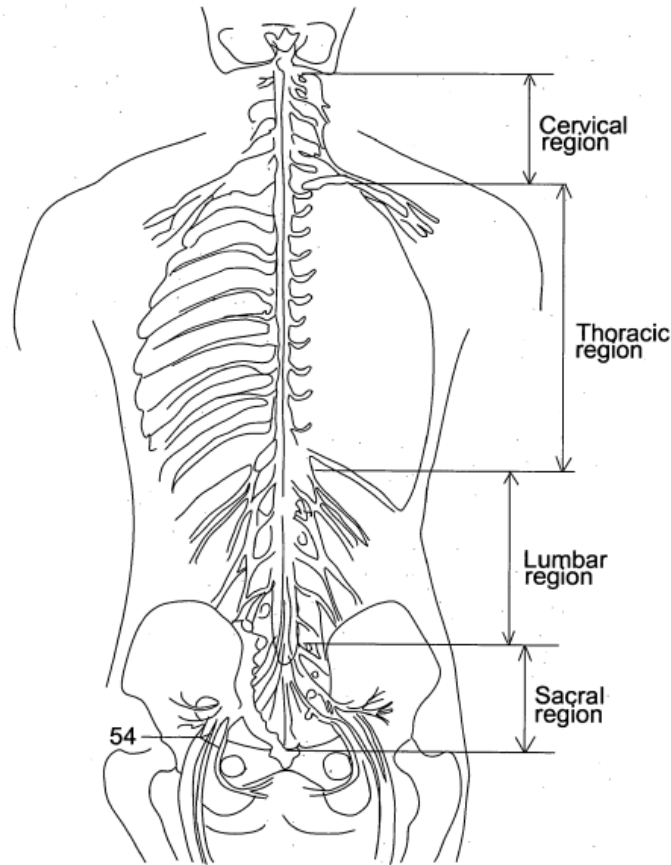
Amarenco published a study on “left [PTN] stimulation using a surface self-adhesive electrode on the ankle skin behind the internal malleolus” in patients “presenting with symptoms (urge incontinence and frequency) secondary to [OAB].” Ex.1005, 2210. Amarenco’s results “suggest an objective acute effect 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, ¶44.

Long before 2006, published reports such as McGuire, Svihra, and Amarenco, among many others, demonstrated that noninvasively applying PTN electrostimulation was a well-known and effective OAB/incontinence treatment. *See also* Ex.1016, 670; Ex.1017, 243; Ex.1003, ¶45.

C. Posterior Tibial Nerve and Branches

The spinal cord is divided into several regions called the cervical, thoracic, lumbar, and sacral regions. Ex.1080, [0028-29], [0085-86], Fig.3A (below), Fig.3B; Ex.1088, 1123. Nerves that emanate from the spinal cord are called spinal nerves, which are named according to the spinal cord level from which they

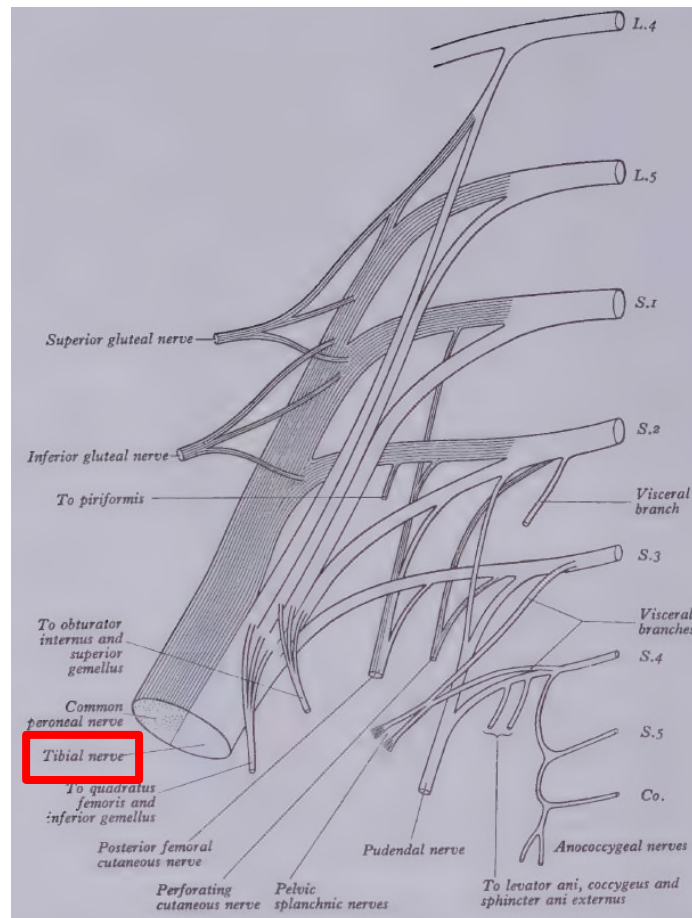
emerge. Ex.1088, 1123. There are, for example, five pairs of lumbar nerves (L1-L5) and five pairs of sacral nerves (S1-S5). *Id.* Nerve fibers from different spinal nerves come together at areas called a nerve plexus. *Id.*, 1143-44; Ex.1003, ¶¶46-47.



Ex.1080, Fig.3A

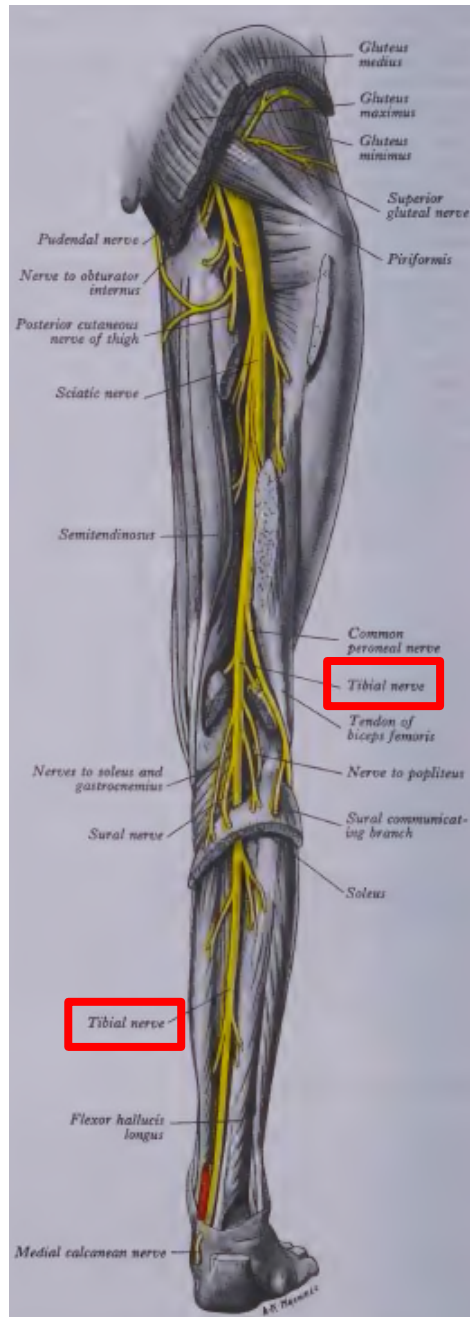
The sacral plexus (shown below) is made up of nerve fibers from lumbar nerves L4-L5 and sacral nerves S1-S4. Ex.1088, 1143-44. Nerves that emanate from the sacral plexus include the superior gluteal nerve, inferior gluteal nerve,

sciatic nerve, posterior femoral cutaneous nerve, and the pudendal nerve. *Id.*, 1144; Ex.1003, ¶¶47-48.



Ex.1088, 1144 (annotated)

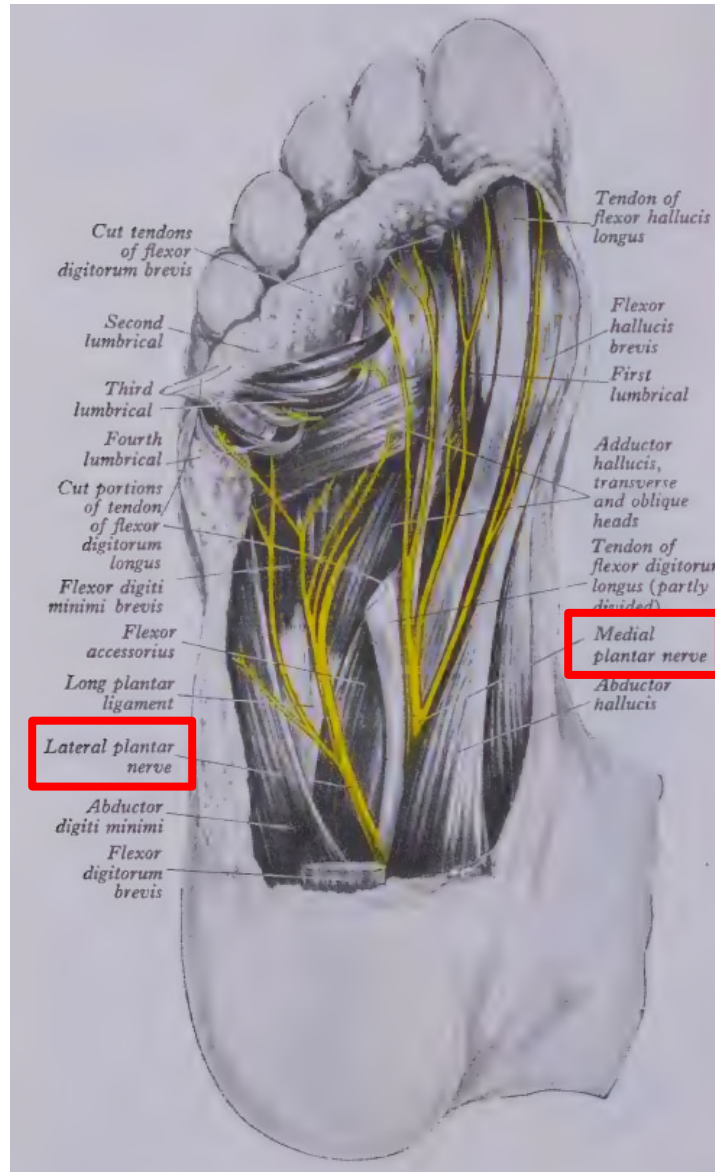
The sciatic nerve branches into the PTN (or tibial nerve) and the fibular nerve (or peroneal nerve). Ex.1088, 1145. The PTN originates from the L4-L5 lumbar nerve roots and the S1-S4 sacral nerve roots. *Id.*, 1145; Ex.1003, ¶¶49-50. As shown below, the PTN runs down the leg and provides motor and sensory innervation to most of the posterior leg and foot. *Id.*



Ex.1088, 1146 (annotated)

The PTN has several branches, including the medial sural cutaneous nerve, medial calcaneal nerve, medial plantar nerve, and lateral plantar nerve. *Id.*, 1145-48;

Ex.1003, ¶50. The medial and lateral plantar nerves, located in the foot, are shown below.



Ex.1088, 1148

The '742 patent acknowledges that stimulation methods targeting the sacral nerves and branches for the treatment of OAB/incontinence were well-known by 2006. The patent claims benefit to and incorporates by reference the '329

application, which describes prior known methods for treating OAB/incontinence by stimulating sacral nerves and branches. Ex.1001, 1:8-60; *e.g.*, Ex.1048, [0019] (describing Ishikawa, which discloses treating incontinence using stimulation targeting “branches from 2nd to 4th sacral nerves” including the PTN (see Ex.1082, 3:58-4:23, cl.1)), [0022] (describing Loeb, which discloses electrostimulation of the PTN or “at least one of the somatic nerves that originate from the sacral nerve roots” (see Ex.1083, Abstract, Cl.1, Cl.5)). For example, the ‘329 application cites Mann, which issued September 6, 2005 and discloses an electrostimulation system for treating incontinence, urgency, and frequency by targeting nerves “emanating from the sacral nerve roots,” including “sites along the tibial nerve.” Ex.1048, [0023]; Ex.1084, Abstract, 10:65-11:19, 11:43-12:7, 16:28-41. Mann teaches “[t]he pudendal nerve and its branches are somatic nerves that originate from the sacral nerve roots S2, S3, and S4. These and ***other somatic nerves emanating from the sacral nerve roots are preferably stimulated to treat dysfunctions of perineal structures, such as urinary and/or bowel incontinence, urgency, frequency, and/or pain.***” Ex.1084, 11:50-12:7. “Other somatic nerves emanating from the sacral nerve roots” include the PTN and its branches. Ex.1003, ¶¶55-56.

Many other similar references were also known. Ex.1003, ¶¶51, 54. Boveja (Ex.1080), which was filed December 28, 2005 and published June 8, 2006,

teaches a system for treating urological disorders such as OAB and incontinence. Ex.1080, Abstract, [0002], [0026]. Boveja expressly claims electrically stimulating the PTN and its branches for treating incontinence and other urological disorders—for example, claim 1 recites providing “electrical pulses to sacral nerve(s) and/or its branches or parts thereof in a patient” and the specification defines the term “sacral nerves” as including among others the PTN. *Id.*, Cl.1, [0180]. According to Boveja, the rationale for this treatment is “based on the existence of spinal inhibitory systems that are capable of interrupting a detrusor [] contraction” resulting from electrical stimulation of “***branches and fibers [that] reach the spinal cord via the dorsal roots of the sacral nerves,***” including the PTN and its branches. *Id.*, [0028-29] (emphasis added), [0180], cl.1; Ex.1003, ¶52.

Similarly, Grey discloses noninvasive electrostimulation devices to treat conditions including nausea and upset stomach by stimulating the PTN and branches. Ex.1081, 1:35-53. Grey indicates that stimulating either the PTN or PTN branches, including the medial and lateral plantar nerves, reach the same treatment result. *Id.*, 2:53-60 (“[a]long the back of the calf and ankle, the tibial nerve 10 and its branches (e.g., the medial plantar nerve 11 and lateral plantar nerves 12 under the foot, generally traveling inside the ankle) . . . can be stimulated to cause the same affect [sic] as stimulation of the traditional SP and BL acupuncture points.”). See Ex.1003, ¶53.

Not only was it known that stimulating nerves and branches that emanate from the sacral nerve roots could effectively treat conditions including OAB and incontinence, the prior art also described techniques for directly targeting and delivering electric stimulation directly to branches of the PTN. Ex.1003, ¶¶57-58. For example, Ponsford describes “[a] simple and reliable method of recording medial and lateral plantar nerve sensory action potentials” with “surface electrodes stimulating orthodromically at the sole.” Ex.1085 (Ponsford), 188. Ponsford directly targeted and delivered stimulation to the medial and lateral plantar nerves by placing stimulator electrodes on the sole of the foot lateral to the first metatarsal and between the fourth and fifth metatarsals, respectively. *Id.* By recording sensory action potentials (“SAPs”) (*i.e.*, signals propagated from the stimulation site to the recording site at the ankle), Ponsford confirmed that the medial and lateral plantar nerves were directly targeted and directly received electrical stimulation. *Id.* Ponsford’s study would have indicated to a POSA that stimulation of PTN branches cause signals to travel “upstream” to the PTN and propagate to the roots of the sacral nerves in the same manner as signals induced by stimulating the PTN itself. Ex.1003, ¶57.

Therapeutic methods for directly targeting and delivering stimulation directly to PTN branches were also known. For example, Rhodes describes electrical stimulation methods that create circuits in the body for treating pain.

Ex.1086, Abstract, 3:1-18. The circuits are created by placing a first electrode “adjacent the end or terminus of the right medial plantar nerve” and a second electrode “adjacent the end of terminus of the left sural nerve” and by placing a first electrode “adjacent the terminus of the right sural nerve” and a second electrode “adjacent the terminus of the left medial plantar nerve.” *Id.*, 3:57-4:21. According to Rhodes, stimulation occurs at the location of the first electrode in each circuit—in other words, Rhodes’ method involves electrically stimulating the right medial plantar and sural nerves, both of which are PTN branches. *Id.*, 3:11-18. See Ex.1003, ¶58.

In sum, long before the earliest priority date of the ‘742 patent, the prior art clearly demonstrated that electrostimulation of nerves and branches emanating from the sacral nerve roots, including the PTN and its branches, could treat OAB, incontinence, and other conditions, as well as taught methods for directly targeting and delivering stimulation directly to PTN branches. Ex.1003, ¶59.

IV. THE ‘742 PATENT

A. Overview

The ‘742 patent relates generally to stimulation therapy. Ex.1001, Abstract. The patent indicates that various electromagnetic and electric stimulation devices were known in the prior art and used to treat a variety of conditions. *Id.*, 1:64-5:45. The patent also claims the benefit of and incorporates by reference prior

applications, including the '329 application, that acknowledge many devices and techniques were known for providing electric stimulation to sacral nerves and branches, including the PTN, to treat OAB and incontinence. *Id.*, 1:8-60; Ex.1048, [0003]-[0028]; Ex.1003, ¶¶60-63.

The patent discloses apparatuses and methods for providing magnetic or electrostimulation therapy for treatment of OAB/incontinence. Ex.1001, 8:25-39. While much of the patent relates to electromagnetic therapy and microneedle-based electrostimulation, the patent discusses electrostimulation therapy “variations” that use an electrical pulse controller 130, electrode 126, and sensor 136. *Id.*, 16:61-17:15, Fig. 11 (below); Ex.1003, ¶64.

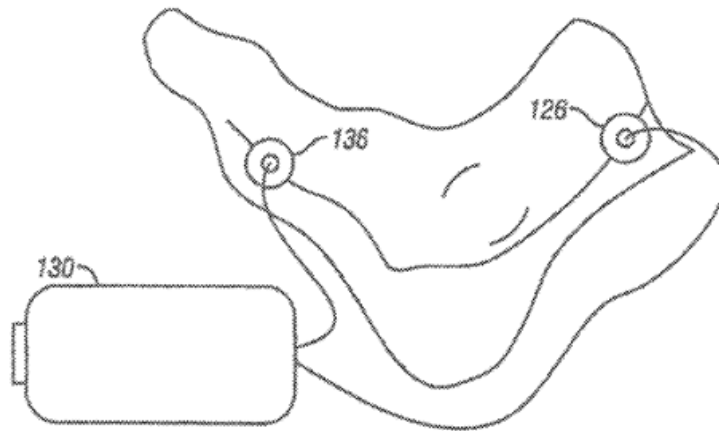


FIG. 11

B. Prosecution History

The '742 patent issued on January 18, 2022 from U.S. App. No. 15/665,152 ("the '152 application), which was filed on July 31, 2017. The original claims of the application were directed to percutaneous electrostimulation. Ex.1002, 363-64. On July 15, 2019, the examiner issued a non-final rejection, which rejected the pending claims as anticipated and obvious. *Id.*, 190-96.

On November 14, 2019, applicant amended the claims including cancelling claims and adding new claims. As shown in exemplary claim 5 below, the amended claims were directed to noninvasive electric stimulation:

5. (Currently Amended): A method of treating overactive bladder or incontinence, comprising:

- non-invasively positioning a transcutaneous electrode on skin first portion of a patient's body relative to an electrical stimulator such that in proximity to a tibial nerve, or a branch of a posterior tibial nerve within the first portion of the body is in proximity to the electrical stimulator thereof;
- inserting an end of a percutaneous needle electrode through the skin in proximity to the tibial nerve, or a branch thereof, the percutaneous needle electrode including a wire disposed opposite the end;
- securing a controller unit to the transcutaneous electrode such that the controller unit is electrically coupled to the transcutaneous electrode, the controller unit including a pulse generator;
- connecting the wire of the percutaneous needle electrode to the controller unit for electrically coupling the percutaneous needle electrode to the controller; and
- activating the pulse generator such that passing a current through the electrical stimulator; and pulses flow along the tibial nerve, or a
- delivering an electrical stimulus from the electrical stimulator to the branch of the posterior tibial nerve thereof, the current pulses configured to treat overactive bladder or incontinence.

Id., 178-80. The examiner issued a final rejection on November 20, 2019. Among other things, the examiner rejected various claims as anticipated by Amarenco (Ex.1005). *Id.*, 164-70.

On March 13, 2020, applicant responded to the rejection. According to applicant, “***Amarenco et al. clearly describes the application of its electrodes behind the ankle for targeting the posterior tibial nerve*** but Amarenco et al. fails to disclose or teach any targeting of any branch of the posterior tibial nerve. Targeting a branch would instead require the repositioning of its electrodes along regions of the foot itself but not the ankle.” *Id.*, 135-36 (emphasis added).

On April 10, 2020, the examiner issued another nonfinal rejection. The examiner did not find applicant’s arguments regarding Amarenco persuasive and further found that combining Amarenco with Mann (U.S. App. Pub. 2002,0055761, which issued as U.S. Pat. 6,941,171 (see Ex.1084)) renders the claims obvious:

Mann, in the same field of endeavor of incontinence control teaches that the tibial nerve is a suitable target for incontinence control through the sacral cord . . . and the branches of nerves projecting from the sacral cord would likewise be suitable locations . . . for stimulation as these also lead to recruitment of the sacral cord and particular branches may offer advantages for the treatment of certain disorders such as avoiding unwanted side effects. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made ***to modify Amarenco by providing stimulation directly and exclusively to a branch of the posterior tibial nerve to provide the predictable results of effectively recruiting***

the sacral cord for incontinence control with particular branches that may offer advantages for the treatment of certain disorders such as avoiding unwanted side effects.

Id., 115-16 (emphasis added).

On August 21, 2020, applicant responded, contending Mann only teaches stimulation of the pudendal nerve and/or its branches via an implantable stimulator. *Id.*, 101-02. Applicant stated that “while Mann et al. may teach the electrical stimulation of the tibial nerve, which is readily accessible near the overlying skin, it does so by the use of an implantable signal generator and electrodes but fails to teach or suggest stimulation to a branch of the posterior tibial nerve anywhere.” *Id.* (emphasis removed).

Another final rejection was issued on October 9, 2020. The examiner was not persuaded by applicant’s arguments, explaining:

Mann recognizes that incontinence control can be effectuated by recruitment of the relevant sacral nerves via the pudendal nerve and/or its branches (mapping to the S2, S3, and S4 nerves) or to the tibial nerve (which maps to the S1, S2, and S3 nerves . . .); and that there is an advantage to stimulating nerve branches to ‘avoid[] recruitment of nerves unrelated to the desired treatment’ The examiner respectfully maintains that ***such disclosures would reasonably lead an artisan of ordinary skill to conclude that stimulation of branches of the tibial nerve would also yield the predictable results of avoiding recruitment of nerves unrelated to the desired treatment.***

Id., 83-84 (emphasis added).

On March 19, 2021, the applicant submitted an amendment and response. The applicant amended exemplary pending claim 5 as follows:

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

Id., 67-69. According to the applicant, Amarenco fails to teach delivering stimulation to a branch of the posterior tibial nerve because Amarenco's electrode is placed behind the internal malleolus, which is proximal to where the posterior tibial nerve branches. *Id.*, 70-72. Applicant further reiterated that Mann fails to teach or suggest stimulation of a branch of the posterior tibial nerve. *Id.*

On August 5, 2021, the application received a notice of allowance, which stated "the closest prior art of record fails to disclose or fairly render unpatentable the combination of elements in claim 5 including ***direct stimulation of a posterior tibial nerve branch*** to treat overactive bladder or incontinence." *Id.*, 46.

Thus, the ***sole reason*** the claims were allowed over Amarenco and Mann was the addition of the "directly targeted" and "directly receives" claim limitations. The examiner apparently believed that although it would have been obvious to modify Amarenco to provide stimulation to a PTN branch and a POSA

would have been motivated to do so based on Mann, the claims were allowable because the prior art of record did not show directly stimulating a PTN branch. As explained below, however, the prior art (*e.g.*, Ponsford (Ex.1085) and Rhodes (Ex.1086)) teaches precisely how to provide stimulation to branches of the PTN, and a POSA could have easily applied these techniques in Amarenco's method to directly target and deliver stimulation to the PTN's branches for the reasons acknowledged by the examiner in Mann and many other reasons, rendering the claims of the '742 patent obvious.

C. Effective Filing Date

The '742 patent claims priority to the '720 provisional filed October 2, 2006. Because the prior art relied upon in this Petition published well before that date, for this Petition alone Avation will assume an October 2, 2006 effective filing date for the '742 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, ¶¶20-21.

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) in View of Mann (Ex.1084), Ponsford (Ex.1085), and the Knowledge of a POSA Renders Obvious Claims 1-13**

Svihra (Ex.1004) published in 2002, Mann (Ex.1084) issued September 6, 2005, and Ponsford (Ex.1085) published in 1988, and are therefore prior art under pre-AIA 35 U.S.C. §102(b). Svihra and Ponsford were not cited or considered during prosecution of the ‘742 patent. Although Mann was cited, the Board should not exercise discretion to deny institution under §325(d). *Infra*, §VII.B.

1. **Claim 1:**

a. Element [1.p]

Svihra discloses “us[ing] non-invasive stimulation of the tibial nerve with the intention to achieve desired therapeutic effects” in patients “suffer[ing] from overactive bladder (OAB).” Ex.1004, 480. Svihra states “[n]oninvasive stimulation

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

had improved subjective symptom related to overactive bladder, had no adverse events and was well tolerated.” *Id.*; Ex.1003, ¶71.⁵

b. Element [1.a]

Svihra performed “non-invasive stimulation of the tibial nerve” via “electrode[s] attached behind the medial ankle of the left lower extremity.” Ex.1004, 480; *see also id.*, 481. Svihra’s stated goal was to test a modified version of Stoller’s minimally-invasive, percutaneous procedure by instead using “non-invasive” surface electrodes. *Id.*; Ex.1003, ¶72.

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, ¶73. 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 would necessarily require electrodes connected to an electrical stimulator source. Ex.1003, ¶74. Thus, the “surface electrodes” and/or the electrical stimulator source are an “electrical stimulator,” as claimed. *Id.* Additionally, a POSA would understand electrodes “placed behind the medial

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

ankle of the left lower extremity” for PTN stimulation necessarily indicates a portion of the patients’ bodies were positioned relative to an electrical stimulator, as claimed. *Id.*, ¶75.

Svihra indicates electrodes were placed “behind the medial ankle” to stimulate the “tibial nerve.” Ex.1004, 481; *see also id.*, 480 (“[t]he aim of this study was to use non-invasive stimulation of the tibial nerve”). The “tibial nerve” is the PTN. Ex.1003, ¶76. Although Svihra directly targeted the PTN, it would have been obvious to modify Svihra’s method to directly target and deliver stimulation to a branch of the PTN.

Treating conditions such as OAB and incontinence by electrically stimulating nerves emanating from the sacral nerve roots, including the PTN and PTN branches, was well-known by 2006. *Supra*, §III.C; Ex.1003, ¶¶77-83. Mann discloses electrostimulation systems for treating incontinence, urgency, and frequency by targeting nerves “emanating from the sacral nerve roots,” including “sites along the tibial nerve.” Ex.1084, Abstract, 10:65-11:19, 11:43-12:7, 16:28-41. Mann teaches “[t]he pudendal nerve and its branches are somatic nerves that originate from the sacral nerve roots S2, S3, and S4. These and *other somatic nerves emanating from the sacral nerve roots are preferably stimulated to treat dysfunctions of perineal structures, such as urinary and/or bowel incontinence, urgency, frequency, and/or pain.*” Ex.1084, 11:50-12:7. A POSA would

understand that the PTN and its branches are “[o]ther somatic nerves emanating from the sacral nerve roots.” Ex.1003, ¶77.

Similarly, Boveja discloses electrically stimulating “sacral nerves and/or its branches,” including the PTN and branches, to treat urological disorders including OAB and incontinence. Ex.1080, Abstract, [0002], [0026], [0180], cl.1; Ex.1003, ¶78. Boveja indicates the rationale for this treatment is “based on the existence of spinal inhibitory systems that are capable of interrupting a detrusor [] contraction” caused by electrostimulation of “***branches and fibers [that] reach the spinal cord via the dorsal roots of the sacral nerves.***” Ex.1080, [0028-29] (emphasis added). Likewise, Grey discloses noninvasive electrical stimulation to treat conditions including nausea and upset stomach by stimulating the PTN and branches, including the medial and lateral plantar nerves. Ex.1081, 1:35-53, 2:53-60. Importantly, Grey indicates that targeting the PTN ***or*** PTN branches would cause the same therapeutic effect. *Id.*; Ex.1003, ¶79.

Methods and techniques for ***how*** to directly target and deliver stimulation directly to PTN branches were also well known. *Supra*, §III.C. For example, Ponsford discloses recording SAPs by noninvasively electrically stimulating the medial and lateral plantar nerves. Ex.1085, 188; Ex.1003, ¶80. Ponsford directly targeted and delivered stimulation to the medial and lateral plantar nerves by placing stimulator electrodes on the sole of the patients’ foot lateral to the first

metatarsal and between the fourth and fifth metatarsals, respectively. Ex.1085, 188. By recording SAPs (*i.e.*, signals propagated from the stimulation site to the recording site at the ankle), Ponsford confirmed the medial and lateral plantar nerves were directly targeted and directly received electrostimulation. Ex.1003, ¶80. Ponsford's study would have indicated to a POSA that stimulation of PTN branches cause signals to travel "upstream" to the PTN and propagate to the sacral nerve roots in the same manner as signals induced by stimulating the PTN itself. *Id.*, ¶¶80-81. A POSA would appreciate that Ponsford's electrode placement and stimulation method could be applied to therapeutic methods in addition to recording SAPs. *Id.*

Therapeutic methods targeting branches of the PTN were also known. Ex.1003, ¶82. Rhodes discloses delivering electrical stimulation via circuits created using noninvasive self-adherent electrodes for treating pain. Ex.1086, Abstract, 3:1-18, 3:57-4:21. Rhodes creates one circuit by placing a first electrode "adjacent the end or terminus of the right medial plantar nerve" and a second electrode "adjacent the end of terminus of the left sural serve," and a second circuit by placing a first electrode "adjacent the terminus of the right sural serve" and a second electrode "adjacent the terminus of the left medial plantar nerve." *Id.*, 3:57-4:21. Rhodes indicates the circuits stimulate the nerves at the first electrodes' location, *i.e.*, the right medial plantar and sural nerves. *Id.*, 3:11-18. In other words,

Rhodes' treatment involves electrically stimulating the right medial plantar and sural nerves, both of which are PTN branches. *Supra*, §III.C; Ex.1003, ¶82.

Accordingly, based on the prior art, a POSA would have appreciated the following:

- (1) OAB/incontinence can be treated by electrically stimulating nerves and branches that reach the spinal cord via the sacral nerve roots, including the PTN and its branches. *E.g.*, Ex.1084 (Mann), 11:50-12:7; Ex.1080 (Boveja), [0028-29], [0180], cl.1; Ex.1003, ¶83.
- (2) Conditions treatable via electrostimulation of the PTN can also be treated by stimulating the medial and lateral plantar nerves, *i.e.*, PTN branches, with similar efficacy. *E.g.*, Ex.1081 (Grey), 1:35-53, 2:53-60; Ex.1003, ¶83.
- (3) Directly targeting and stimulating PTN branches causes signals to travel to the PTN and upstream to the spinal cord via the sacral nerve roots. *E.g.*, Ex.1085 (Ponsford), 188-89; Ex.1003, ¶83.
- (4) Precisely **how** to directly target and deliver stimulation directly to PTN branches. *E.g.*, Ex.1085 (Ponsford), 188-89; Ex.1086 (Rhodes), 3:11-18, 3:57-4:21; Ex.1003, ¶83.

Based on these disclosures and a POSA's knowledge, modifying Svihra's procedure to directly target and deliver stimulation directly to a branch of the PTN

would have been obvious. Ex.1003, ¶¶84-91. Directly targeting and delivering stimulation to a branch of the PTN such as the medial or lateral plantar nerve, rather than the PTN, would have involved simple substitution of known elements (*i.e.*, substituting a PTN branch for the PTN in Svihra’s method) or applying known techniques to improve a known process (*i.e.*, directly targeting a PTN branch rather than the PTN). Ex.1003, ¶84. A POSA would expect success and the results would be predictable given the widespread, successful use of electrical stimulation directly targeting sacral nerves—including the PTN and branches—throughout the art in similar procedures (*e.g.*, Boveja, Mann), the explicit teachings that conditions treatable by electrically stimulating the PTN can also be treated by stimulating the medial and lateral plantar nerves (*e.g.*, Grey), and the widespread, successful use of techniques for directly targeting and stimulating PTN branches (*e.g.*, Ponsford and Rhodes). *Id.*

Additionally, it would have been obvious to try directly targeting and delivering electrostimulation to PTN branches in Svihra’s method. *Id.*, ¶85. There are a finite number of nerves that reach the spinal cord via the sacral nerve roots and a finite number of locations along such nerves, including branches. *Id.* Based on Svihra and similar references that teach stimulating the PTN for OAB/incontinence treatment (*supra*, §§III.B-III.C), a POSA would have been motivated to try directly targeting other locations along the PTN such as branches. Ex.1003, ¶85. A POSA

would expect success for the same reasons discussed above. *See id.* That some of the prior art known to a POSA may relate to invasive electrostimulation would not have dissuaded a POSA from trying to directly target and stimulate PTN branches. *Id.*, ¶86. Many references teach noninvasive methods of targeting and stimulating nerves and branches, including to treat OAB/incontinence (*e.g.*, Grey, Ponsford, Rhodes). Moreover, the knowledge of any electrostimulation techniques, invasive or noninvasive, to treat OAB/incontinence by targeting nerves and branches would have suggested to and motivated a POSA to try noninvasive techniques that are more convenient and less painful. *Id.*

Electrically stimulating PTN branches, rather than the PTN itself, is also nothing more than an obvious design choice. *Id.*, ¶87. The '742 patent specification does not ascribe any significance or criticality to targeting a PTN branch, such as improved treatments or unexpected results. A POSA seeking to improve Svihra's method could simply move Svihra's surface electrodes from one location to another and based on knowledge of the art, would have expected similar results. *Id.* For example, a POSA would have understood that patient convenience could be improved by moving the electrodes to the underside of the patient's foot to directly target PTN branches, so the electrodes are less visible and more discrete. *Id.*

Finally, the prior art itself would have motivated a POSA to modify Svihra's technique to directly target and deliver stimulation to PTN branches. *Id.*, ¶88.

Boveja indicates that electrically stimulating nerves that reach the spinal cord via the sacral nerve roots, in particular the S3 root, are “capable of interrupting a detrusor [] contraction” to treat OAB/incontinence. Ex.1080, [0028-29]. Given that the PTN and its branches reach the spinal cord via the S3 root, a POSA would be motivated to directly target those nerves to treat OAB/incontinence. Ex.1003, ¶88. Moreover, Mann indicates “selective stimulation of a given branch(es) may offer advantages for the treatment of certain disorders,” including “avoid[ing] recruitment of nerves unrelated to the desired treatment.” Ex.1084, 12:26-41. Thus, a POSA would be motivated to try modifying Svihra by targeting PTN branches to avoid recruiting other nerves near Svihra’s original stimulation site. Ex.1003, ¶88. Notably, during prosecution, the examiner likewise found a POSA would have been motivated to combine Amarenco with Mann for similar reasons. *Supra*, §IV.B.

To the extent EMK contends Avation’s argument should be rejected because the Amarenco/Mann combination was overcome during prosecution, EMK is mistaken. As explained, to overcome an obviousness rejection over Amarenco and Mann, applicant amended the claims to further require “directly target[ing]” a branch of the PTN and that the branch “directly receives the electrical stimulation.” *Id.* The claims were allowed because, according to the examiner’s reasons for allowance, the prior art of record did not disclose “direct stimulation of a posterior

tibial nerve branch to treat overactive bladder or incontinence.” *Id.* Regardless of whether the prior art explicitly shows an embodiment or example where a PTN branch was stimulated, however, a POSA could have directly targeted and delivered stimulation to a PTN branch by simply moving the electrodes from a location overlaying the PTN to a location overlaying a PTN branch. Ex.1003, ¶89. Given that the examiner acknowledged a POSA would have been motivated to do so with predictable results based on Mann’s teachings, combining Amarenco or Svihra with Mann alone would have rendered the claims obvious. *Id.*

Nonetheless, the prior art cited in this petition (*e.g.*, Ponsford and Rhodes) ***does disclose*** directly targeting and delivering electrical stimulation directly to branches of the PTN. Ex.1003, ¶90. Ponsford, for example, confirmed that the medial and lateral plantar nerves were directly targeted and directly received stimulation by measuring SAPs. *Id.*; Ex.1085, 189. A POSA would be motivated to apply the techniques described in Ponsford (and/or Rhodes) to directly target and deliver stimulation directly to PTN branches for the reasons discussed above. Ex.1003, ¶¶84-91. Thus, any assertion Avation’s argument is the same/similar to the argument overcome during prosecution is incorrect.

c. Element [1.b]

Svihra’s “therapeutic stimulation of tibial nerve” involved “stimulation by a constant voltage and regulated intensity of direct current” via “surface electrodes”

placed behind the patients' medial ankle. Ex.1004, 481. To apply electrical stimulation through "surface electrodes," the electrodes necessarily would be connected to an electrical stimulator source through which current was passed. Ex.1003, ¶92.

d. Element [1.c]

Svihra states "[a]fter a control stimulation accompanied by optimization of the electrode position and set intensity of stimulation ***we had proceeded on with a therapeutic stimulation of tibial nerve,***" which involved "stimulation by a constant voltage and regulated intensity of direct current." Ex.1004, 481 (emphasis added). Thus, Svihra delivered electrical stimulus from an electrical stimulator through the electrodes to the PTN. Ex.1003, ¶93. Moreover, Svihra's study included "patients with overactive bladder (OAB)." Ex.1004, 481. Svihra states "[n]oninvasive stimulation had improved subjective symptom related to [OAB], had no adverse events and was well tolerated." *Id.*, 480, 481-82; Ex.1003, ¶94.

It would have been obvious to modify Svihra's technique such that a branch of the PTN "directly receives" electrical stimulation. Ex.1003, ¶95. For the reasons discussed above, modifying Svihra to directly target a PTN branch would have been obvious. *Supra*, §VI.A.1.b; Ex.1003, ¶¶84-91. As explained, the prior art teaches applying electrostimulation to the PTN and branches treats OAB/incontinence ***and*** discloses how to directly target and deliver stimulation

directly to branches of the PTN. *Supra*, §VI.A.1.b; Ex.1003, ¶¶77-83, 96.

Modifying Svihra's technique in this manner would necessarily cause electrical stimulus to be delivered to and directly received by the PTN branch. Ex.1003, ¶¶95-96. Ponsford, for example, confirmed that the medial and lateral plantar nerves were directly targeted and directly received stimulation by measuring SAPs, showing that signals received by the PTN branches site traveled to the PTN. Ex.1085, 189; Ex.1003, ¶80.

2. Claim 2

Svihra in view of Mann, Ponsford, and the knowledge of a POSA render obvious claim 1. *Supra*, §VI.A.1. Further, claim 2 does not cover a novel or nonobvious features of the alleged invention. The patent does not indicate that the electrode used in the method is novel in any way. Moreover, other applications and patents in the same family as the '742 patent indicate that any type of electrode, including known, prior art TENS patches, can be used in the stimulation methods disclosed and claimed. *E.g.*, Ex.1087, 46:28-39; Ex.1003, ¶97.

Setting that aside, Svihra used "surface electrodes," which a POSA would interpret as likely referring to an "electrode patch." Ex.1004, 481; Ex.1003, ¶98. Moreover, "electrode patches" for electrostimulation were known in the art. *E.g.*, Ex.1024, 234 ("electrode patches"); Ex.1025 ("electrode patch" for electrostimulation of vagus nerve); Ex.1026 ("dermal patch" for nerve

stimulation); Ex.1027, 24 (“self-adhesive patch electrodes” for TENS treatment of incontinence); Ex.1003, ¶99.

Even if Svihra’s surface electrodes are not an “electrode patch,” modifying Svihra to “position[] an electrode patch in communication with the electrical stimulator” would have been obvious. Using an “electrode patch” in place of Svihra’s “surface electrodes” would have involved nothing more than simple substitution of known elements (substituting “surface electrodes” for known “electrode patches”) or predictable use of prior art elements according to established functions (using known “electrode patches” to provide electrostimulation). Ex.1003, ¶100. Additionally, it would have been obvious to try use of known “electrode patches” given the finite number of types of electrodes that could be used for electrostimulation. *Id.* A POSA would expect success modifying Svihra’s procedure and the results would be predictable given the widespread, successful use of “electrode patches” throughout the art in similar procedures. *Id.*

Modifying Svihra’s procedure to directly target and deliver stimulation to a branch of the PTN (*supra*, §VI.A.1) and further to use an “electrode patch” as discussed above would necessarily result in placement of the patch “upon a foot” of the patient. *Id.*, ¶101. A POSA would have been aware of the location of PTN branches. *Supra*, §III.C. Moreover, a POSA would appreciate the stimulating

electrode (or “electrode patch”) would need to be positioned “upon a foot” overlaying the branch, would have been aware of techniques known in the art for doing so, and would have done so to ensure the branch directly receives stimulation from the electrode (or “electrode patch”). *E.g.*, Ex.1085, 188; Ex.1086, 3:11-18, 3:57-4:21; Ex.1003, ¶¶101-02.

3. Claim 3

Svihra in view of Mann, Ponsford, and the knowledge of a POSA render obvious claim 1. *Supra*, §VI.A.1. Further, Svihra used an electromyographic (“EMG”) device, which measures electrical activity and muscle response resulting from stimulation of muscle by nerves. Ex.1004, 481; Ex.1003, ¶103. Svihra states “[i]ntensity of the surface SANS was equal to 70% of intensity, ***at which the maximal amplitude of response was registered from the abductor hallucis muscle*** (stimulation by a constant voltage and regulated intensity of direct current).” Ex.1004, 481 (emphasis added). In other words, Svihra measured the electrical signal emanating from the muscle as a result of electrical stimulation, which is “detecting a muscular response.” Ex.1003, ¶104.

4. Claim 4

Svihra in view of Mann, Ponsford, and the knowledge of a POSA render obvious claim 1. *Supra*, §VI.A.1. Further, Svihra explicitly states stimulation was applied once per week for 30 minutes. Ex.1004, 481 (“[s]urface stimulation of 30

minutes duration was repeated once a week for a period of 5 weeks.”); Ex.1003, ¶105.

5. Claim 5

Svihra in view of Mann, Ponsford, and the knowledge of a POSA render obvious claim 1. *Supra*, §VI.A.1. Further, Svihra used an EMG device, which measures electrical activity and muscle response resulting from stimulation of muscle by nerves. Ex.1004, 481 (“electromyographic device Nicolet Viking II E”); Ex.1003, ¶106. Svihra states “the maximal amplitude of response was registered from the abductor hallucis muscle,” Ex.1004, 481, which refers to the maximum electrical signal from the patients’ muscle as a result of stimulation therapy. Ex.1003, ¶107. Measurement of electrical signals from patients are “physiological parameter[s] detected from the patient.” *Id.* A POSA would understand that because Svihra determined the “maximal amplitude of response” the results were necessarily displayed to Svihra, because otherwise Svihra could not have known the maximum electrical signal response, *i.e.*, “maximal amplitude.” *Id.*

6. Claim 6

Svihra in view of Mann, Ponsford, and the knowledge of a POSA render obvious claim 1. *Supra*, §VI.A.1. Further, a POSA would interpret claim 6 to encompass detecting for the presence or lack of presence of electrical conduction

using techniques such as EMG based on the claim language and specification.

Ex.1003, ¶108.

EMG is a measure of muscle response and electrical activity in response to stimulation of muscle by a nerve. *Id.*, ¶109; Ex.1042, 120-21; Ex.1043, 174; Ex.1084, 23:8-11. When a nerve activates a muscle, EMG measures the presence or lack of presence of electrical conduction of the nerve impulse between the stimulation site and the muscle. Ex.1003, ¶109. Detecting for the presence or lack of presence of electrical conduction, as recited in claim 6, thus refers to detection techniques such as EMG. *Id.*

The claim also refers to detecting lack of conduction “at a second portion of the patient’s body distant from the first portion,” which is typical of EMG procedures in which EMG electrodes are commonly placed at locations distant from a stimulation site. *Id.*, ¶110; Ex.1028, 367; Ex.1030, 10. Moreover, the claim requires detecting “for a lack of **presence** of electrical conduction.” EMG measurements indicate there is/is not electrical conduction in the muscle. Ex.1003, ¶110. This in turn necessarily indicates the **presence** (or lack of presence) of electrical conduction in the nerve stimulating that muscle. *Id.* This interpretation is further supported by the specification, which indicates sensors are used to detect the presence or lack of presence of electrical conduction at a second portion of a patient’s body as an indicator of electrode migration, malfunction, or placement.

Id., ¶112; Ex.1001, 5:54-59, 16:61:17:15, 37:46-51; *see also id.*, 11:8-18, 15:49-53, 24:56-64, 26:45-51, 44:27-40. The patent further indicates sensors for detecting electrical conduction, such as EMG electrodes, were known, and thus claim 6 does not cover any new or nonobvious features of the alleged invention. Ex.1001, 11:8-18, 15:49-53, 24:56-64, 26:45-51, 37:46-51, 44:27-40; Ex.1003, ¶113. In any event, the claim language and specification indicate claim 6 encompasses detection techniques such as EMG. Ex.1003, ¶113.

Well before 2006, EMG was a conventional technique for detecting the presence or lack of presence of electrical conduction at a second portion of a patient's body and was commonly used during electrostimulation procedures. *Id.*, ¶115; Ex.1042, 119; Ex.1028, 361; Ex.1029, 1:45-63; Ex.1084, 23:8-11. EMG electrodes were typically placed at a second portion of a patient's body away from the stimulation site, Ex.1030, 10; Ex.1028, 367; Ex.1003, ¶115, and a variety of types of EMG electrodes including surface electrodes that measure electrical activity through skin tissue were used. Ex.1003, ¶115; Ex.1030, 3, 10; Ex.1028, 362. It was also known well before 2006 that electrodes could be improperly positioned, migrate, and/or malfunction during electric stimulation procedures. Ex.1003, ¶116; Ex.1087, 3:2-4 (background); Ex.1031, [0024]; Ex.1032, [0005]; Ex.1033, 1:41-48; Ex.1084, 18:1-17, 18:30-33. EMG was thus used to detect improper electrode placement, migration, and malfunction. Ex.1003, ¶117;

Ex.1030, 7 (EMG “confirmed satisfactory positioning of the electrode” during electrostimulation for treatment of OAB), 10 (EMG used to “confirm [electrodes] continued optimum position”); Ex.1034, 12:28-45 (EMG used to confirm electrode placement); Ex.1084, 18:1-34 (EMG responses during test stimulation used to **“confirm proper lead and/or catheter location, to confirm response,** and/or to determine preliminary stimulator settings” and after electrode placement to **“confirm the lead/catheter has not shifted out of position.”**) (emphasis added), 18:50-54, 18:60-64, 19:43-50, 20:15-22.

Given the teachings in the prior art to use EMG for these purposes and the conventional use of EMG, a POSA would have found it obvious to use EMG to detect improper electrode placement, migration, and/or malfunction. Ex.1003, ¶118. Indeed, it was well known that EMG measures electrical conduction (or lack of conduction) in muscle stimulated by a nerve and of a nerve impulse between a stimulation site and muscle. *Id.*; Ex.1042, 120-21; Ex.1084, 23:8-11. A POSA would thus recognize that a lack of EMG signal from a muscle corresponding to a nerve that was electrically stimulated necessarily means there is an issue with the patients’ nerve or an issue with the stimulator electrode, such as improper placement, migration, or malfunction. Ex.1003, ¶118.

As discussed above, Svihra used an EMG device to measure the amplitude of response from the muscle. Ex.1004, 481. Even if Svihra did not explicitly state

the EMG results were used to detect for the presence or lack of presence of electrical conduction, a POSA would have found it obvious based on the above-described knowledge in the art to modify Svihra's procedure to detect for the presence or lack of presence of electrical conduction at a second portion of a patient's body as an indicator of electrode migration, electrode malfunction, and proper electrode placement. Ex.1003, ¶¶114, 119. Modifying Svihra's procedure (which already involves measuring EMG, Ex.1004, 481) in this way would have involved simply using prior art elements according to known functions (*i.e.*, using Svihra's EMG to determine electrode parameters, including improper electrode placement, migration, and/or malfunction, and therapeutic efficacy) and/or applying known techniques to improve a known process (*i.e.*, using Svihra's EMG signals in known ways, including indicating proper placement, migration, or malfunction of electrodes). Ex.1003, ¶119. A POSA would understand the results would be predictable, given the conventional nature of EMG and the use of EMG for similar reasons in the art. *Id.*; Ex.1030, 7, 10; Ex.1034, 12:28-45; Ex.1084, 18:1-34. Moreover, a POSA would have also been motivated to modify Svihra in this manner based on the teachings of the art itself, including to "confirm satisfactory positioning of the electrode" (proper electrode placement) or confirm the electrode's "continued optimum position" (electrode migration). Ex.1030, 7, 10; *see also* Ex.1084, 18:1-17, 18:30-34; Ex.1003, ¶119.

7. Claim 7

Svihra in view of Mann, Ponsford, and the knowledge of a POSA render obvious claim 6. *Supra*, §VI.A.6. Further, claim 7 does not cover a novel or nonobvious features of the alleged invention. The patent explicitly states that sensors are used to detect the presence or lack of presence of electrical conduction and that any known sensor can be used. Ex.1001, 24:56-64, 37:46-51; Ex.1003, ¶120.

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

Moreover, various sensors/electrodes, including “electrode patches,” were known and could be used for EMG. Ex. 1003, ¶122; Ex.1035, 188 (electrode “patch” for surface EMG); Ex.1036, 5:33-50 (“electrode patch” for detecting physiological signal such as EMG); Ex.1037, 736 (“sticky surface patch electrodes” for EMG).

Even if Svihra does not explicitly disclose the specific type of EMG sensor/electrode used in the EMG measurements conducted in his procedure, a POSA would have found it obvious to modify Svihra’s procedure to use an “electrode patch” for detecting the presence of electrical conduction. Ex.1003, ¶¶121, 123. Using an “electrode patch” in place of Svihra’s EMG sensor/electrode would have involved simple substitution of known elements (substituting EMG sensors/electrodes for known “electrode patches”) or predictable use of prior art

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

8. Claim 8

Svihra in view of Mann, Ponsford, and the knowledge of a POSA render obvious claim 1. *Supra*, §VI.A.1. Claim 8 is nearly identical to claim 6 except stating “an indicator of electrode malfunction.” As discussed, modifying Svihra to detect lack of presence of electrical conduction at a second portion of a patient’s body as an indicator of electrode migration, electrode malfunction, and proper electrode placement would have been obvious. *Supra*, §VI.A.6. Thus, claim 8 is obvious for the same reasons regarding claim 6. *Id.*; Ex.1003, ¶124.

9. Claim 9

Svihra in view of Mann, Ponsford, and the knowledge of a POSA render obvious claim 8. *Supra*, §VI.A.8. Claim 9 is nearly identical to claim 7. As discussed, modifying Svihra to use “electrode patch[es]” for detecting electrical

conduction would have been obvious. *Supra*, §VI.A.7. Thus, claim 9 is obvious for the same reasons regarding claim 7. *Id.*; Ex.1003, ¶125.

10. Claim 10

Svihra in view of Mann, Ponsford, and the knowledge of a POSA render obvious claim 1. *Supra*, §VI.A.1. Claim 10 is nearly identical to claim 6 except stating “an indicator of proper electrode placement.” As discussed, modifying Svihra to detect lack of presence of electrical conduction at a second portion of a patient’s body as an indicator of electrode migration, electrode malfunction, and proper electrode placement would have been obvious. *Supra*, §VI.A.6. Thus, claim 10 is obvious for the same reasons regarding claim 6. *Id.*; Ex.1003, ¶126.

11. Claim 11

Svihra in view of Mann, Ponsford, and the knowledge of a POSA render obvious claim 10. *Supra*, §VI.A.10. Claim 11 is nearly identical to claim 7. As discussed, modifying Svihra to use an “electrode patch” for detecting electrical conduction would have been obvious. *Supra*, §VI.A.7. Thus, claim 11 is obvious for the same reasons regarding claim 7. *Id.*; Ex.1003, ¶127.

12. Claim 12

Svihra in view of Mann, Ponsford, and the knowledge of a POSA render obvious claim 1. *Supra*, §VI.A.1. Claim 12 is nearly identical to claim 6 except stating detecting for conduction “through tissue” and “as an indicator of electrode

placement.” As discussed, modifying Svihra to detect lack of presence of electrical conduction (including using surface EMG electrodes that detect through skin tissue) at a second portion of a patient’s body as an indicator of electrode migration, electrode malfunction, and proper electrode placement would have been obvious. *Supra*, §VI.A.6. Thus, claim 12 is obvious for the same reasons regarding claim 6. *Id.*; Ex.1003, ¶128.

13. Claim 13

Svihra in view of Mann, Ponsford, and the knowledge of a POSA render obvious claim 1. *Supra*, §VI.A.12. Claim 13 is nearly identical to claim 7. As discussed, modifying Svihra to use an “electrode patch” for detecting the presence of electrical conduction would have been obvious. *Supra*, §VI.A.7. Thus, claim 13 is obvious for the same reasons regarding claim 7. *Id.*; Ex.1003, ¶129.

B. Ground 2: Amarenco (Ex.1005) in View of Mann (Ex.1084), Ponsford (Ex.1085), and the Knowledge of a POSA Renders Obvious Claims 1-13

Amarenco (Ex.1005) published in 2003, Mann (Ex.1084) issued September 6, 2005, and Ponsford (Ex.1085) published in 1988, and are therefore prior art under pre-AIA 35 U.S.C. §102(b). Ponsford was not cited or considered during prosecution of the ‘742 patent. Although Amarenco and Mann were considered, the Board should not exercise discretion to deny institution under §325(d). *Infra*, §VII.B.

1. Claim 1:

a. Element [1.p]

Amarenco studied “acute tibial nerve stimulation in a population presenting with symptoms (urge incontinence and frequency) secondary to [OAB].” Ex.1005, 2210; Ex.1003, ¶131.

b. Element [1.a]

Amarenco’s procedure involved “left [PTN] stimulation using a surface self-adhesive electrode on the ankle skin behind the internal malleolus with shocks in continuous mode at 10Hz. frequency and 200 milliseconds wide.” Ex.1005, 2210. Amarenco states “[s]timulation was done using a ***self-adhesive surface stimulation electrode without an implanted needle electrode. Contact electrodes were placed with electrode gel on the ankle skin with the negative electrode behind the internal malleolus and the positive electrode 10 cm. above the negative electrode.***” *Id.*, 2211 (emphasis added).

Amarenco explicitly states the procedure was “non-invasive.” Ex.1005, 2214. A POSA would also understand “self-adhesive surface stimulation electrode[s]” do not break the skin and thus the procedure was non-invasive. Ex.1003, ¶¶132-33. 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, ¶134.

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, ¶133.

Amarenco indicates “surface self-adhesive electrodes on the ankle skin behind the internal malleolus” were used to stimulate the “left [PTN].” Ex.1005, 2210. Although Amarenco targeted the PTN, it would have been obvious to modify Amarenco’s method to target a branch of the PTN with the electrical stimulator. Ex.1003, ¶135.

As explained above, treating conditions such as OAB/incontinence by electrically stimulating nerves emanating from the sacral nerve roots, including the PTN and PTN branches, was well-known by 2006. *Supra*, §§III.C, VI.A.1.b; Ex.1003, ¶¶136-38. Mann discloses treating incontinence, urgency, and frequency via electrostimulation targeting nerves “emanating from the sacral nerve roots,” including “sites along the tibial nerve.” Ex.1084, Abstract, 10:65-11:19, 11:43-12:7, 16:28-41. Mann teaches “[t]he pudendal nerve and its branches are somatic nerves that originate from the sacral nerve roots S2, S3, and S4. These and **other**

somatic nerves emanating from the sacral nerve roots are preferably stimulated to treat dysfunctions of perineal structures, such as urinary and/or bowel incontinence, urgency, frequency, and/or pain.” Ex.1084, 11:50-12:7. The PTN and its branches are “[o]ther somatic nerves emanating from the sacral nerve roots.” Ex.1003, ¶136.

Methods and techniques for **how** to directly target and deliver stimulation directly to PTN branches were also well known. *Supra*, §§III.C, VI.A.1.b; Ex.1003, ¶¶139-42. Ponsford discloses a method of recording SAPs by noninvasively electrically stimulating the medial and lateral plantar nerves. Ex.1085, 188; Ex.1003, ¶139. Ponsford directly targeted and delivered stimulation to the medial and lateral plantar nerves by placing stimulator electrodes on the sole of the patients’ foot lateral to the first metatarsal and between the fourth and fifth metatarsals, respectively. *Id.* By recording SAPs (*i.e.*, signals propagated from the stimulation site to the recording site at the ankle), Ponsford confirmed that the medial and lateral plantar nerves were directly targeted and directly received electrical stimulation. Ex.1003, ¶139. Ponsford’s study would indicate to a POSA that stimulation of PTN branches cause signals to travel “upstream” to the PTN and propagate to the sacral nerve roots in the same manner as signals induced by stimulating the PTN itself. Ex.1003, ¶140. A POSA would appreciate that Ponsford’s electrode placement and stimulation method could be applied to

electrical stimulation therapies in addition to recording sensory actions potentials. *Id.*, ¶139.

Based on these disclosures and the knowledge of a POSA, modifying Amarenco's procedure to directly target and deliver stimulation to a branch of the PTN would have been obvious. *Id.*, ¶143. Directly targeting and delivering stimulation to a branch of the PTN, rather than the PTN, would have involved simple substitution of known elements (*i.e.*, substituting a PTN branch for the PTN in Amarenco's method) or applying known techniques to improve a known process (*i.e.*, directly targeting a PTN branch rather than the PTN). *Id.* A POSA would have expected success modifying Amarenco's procedure in this manner and the results would have been predictable given the widespread, successful use of electrical stimulation directly targeting sacral nerves—including the PTN and branches—throughout the art in similar procedures (*e.g.*, Boveja, Mann), the explicit teachings in the art that conditions known to be treatable by electrically stimulating the PTN can also be treated by stimulating the medial and lateral plantar nerves (*e.g.*, Grey), and the widespread, successful use of techniques for directly targeting PTN branches (*e.g.*, Ponsford and Rhodes). *Id.*

Additionally, it would have been obvious to try directly targeting and delivering electrostimulation to PTN branches in Amarenco's method. *Id.*, ¶144. Given the finite number of nerves reaching the spinal cord via sacral nerve roots

and the finite number of locations along such nerves (including branches), as well as the teachings of Amarenco and similar references that stimulating the PTN treats OAB/incontinence, a POSA would have been motivated to try directly targeting other locations along the PTN such as branches. *Supra*, §§III.B, III.C; Ex.1003, ¶144. A POSA would have expected success for the same reasons discussed above. *Id.*, ¶144. The fact that some references may relate to invasive electrostimulation would not have dissuaded a POSA from trying to directly target and deliver stimulation to PTN branches. *Id.*, ¶145. Many references known to a POSA teach noninvasive methods of targeting and stimulating nerves and branches, including to treat OAB/incontinence (*e.g.*, Grey, Ponsford, Rhodes). *Id.* Moreover, the knowledge of any electrostimulation techniques, invasive or noninvasive, to treat OAB/incontinence by targeting nerves and branches would have suggested to and motivated a POSA to try noninvasive techniques that could make the treatment more convenient and less painful. *Id.*

Electrically stimulating a branch of the PTN, rather than the PTN itself, is also nothing more than an obvious design choice. *Id.*, ¶146. The '742 patent specification does not ascribe any significance or criticality to targeting a branch of the PTN, such as improved treatment or unexpected results. A POSA seeking to improve Amarenco's method could simply move Amarenco's surface electrodes from one location to another and based on knowledge of the art, would have

expected similar results. *Id.* For example, a POSA would have understood that patient convenience could be improved by moving the electrodes to the underside of the patient's foot to directly target PTN branches, so that the electrodes are less visible and more discrete. *Id.*

Finally, the prior art itself would have motivated a POSA to modify Amarenco's technique to directly target and deliver stimulation to a branch of the PTN. *Id.*, ¶147. For example, Boveja indicates that electrically stimulating nerves that reach the spinal cord via the sacral nerve roots, in particular the S3 root, are "capable of interrupting a detrusor [] contraction" to treat OAB/incontinence. Ex.1080, [0028-29]. Given that PTN branches reach the spinal cord via the S3 root, a POSA would have been motivated to directly target those nerves to treat OAB/incontinence. Ex.1003, ¶147. Likewise, according to Mann, "selective stimulation of a given branch(es) may offer advantages for the treatment of certain disorders," including "avoid[ing] recruitment of nerves unrelated to the desired treatment." Ex.1084, 12:26-41. Thus, a POSA would have been motivated to try modifying Amarenco by targeting PTN branches to avoid recruiting other nerves near Amarenco's original stimulation site. Ex.1003, ¶147. Notably, during prosecution, the examiner likewise found a POSA would have been motivated to combine Amarenco with Mann for similar reasons. *Supra*, §IV.B.

To the extent EMK contends Avation's argument should be rejected because the Amarenco/Mann combination was overcome during prosecution, EMK is mistaken. As explained, to overcome an obviousness rejection based on Amarenco and Mann, applicant amended the claims to further require "directly target[ing]" a branch of the PTN and that the branch "directly receives the electrical stimulation." *Supra*, §IV.B. The claims were allowed because, according to the examiner's reasons for allowance, the prior art of record did not disclose "direct stimulation of a posterior tibial nerve branch to treat overactive bladder or incontinence." *Id.* Regardless of whether the prior art explicitly shows an embodiment or example where a PTN branch was stimulated, however, a POSA could have directly targeted and delivered stimulation to a branch of the PTN by simply moving the electrodes from a location overlaying the PTN to a location overlaying a PTN branch. Ex.1003, ¶148. Given that the examiner acknowledged a POSA would be motivated to do so with predictable results based on Mann, combining Amarenco with Mann alone would have rendered the claims obvious. *Id.*

Nonetheless, the prior art cited in this petition (*e.g.*, Ponsford (Ex.1085) and Rhodes (Ex.1086)) **does disclose** directly targeting and delivering electrical stimulation directly to branches of the PTN. Ex.1003, ¶149. Ponsford, for example, confirmed that the medial and lateral plantar nerves were directly targeted and directly received stimulation by measuring SAPs. *Id.*; Ex.1085, 189. A POSA

would have been motivated to apply the techniques described in Ponsford (and/or Rhodes) demonstrating how to directly target and deliver stimulation to PTN branches for the reasons discussed above. Ex.1003, ¶149. Thus, any assertion Avation’s argument is the same/similar to the argument overcome during prosecution is incorrect.

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, ¶151.

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, ¶152. 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, ¶153.

It would have been obvious to modify Amarenco's technique such that a branch of the PTN, rather than the PTN, "directly receives" the electrical stimulation. For the reasons discussed above, modifying Amarenco to directly target a branch of the PTN would have been obvious. *Supra*, §VI.B.1.b; Ex.1003, ¶154. The prior art teaches applying electrostimulation to the PTN and branches treats OAB/incontinence **and** discloses how to directly target and deliver stimulation directly to PTN branches. *Supra*, §VI.B.1.b; Ex.1003, ¶154. Modifying Amarenco in this manner would necessarily cause electrical stimulus from Amarenco's electrical stimulator to be delivered to and directly received by the branch of the PTN. Ex.1003, ¶¶154-55. Ponsford, for example, confirmed that the medial and lateral plantar nerves were directly targeted and directly received stimulation by measuring SAPs, showing that signals received at the stimulation site traveled to the PTN. *Id.*; Ex.1085, 189.

2. Claim 2

Amarenco in view of Mann, Ponsford, and the knowledge of a POSA render obvious claim 1. *Supra*, §VI.B.1. Further, claim 2 does not cover a novel or nonobvious features of the alleged invention. *Supra*, §VI.A.1. Setting that aside, Amarenco used a "self-adhesive surface stimulation electrode" that was placed "on

the ankle skin with the negative electrode behind the internal malleolus and the positive electrode 10 cm. above the negative electrode.” Ex.1005, 2211. A “self-adhesive surface stimulation electrode” is an “electrode patch.” Ex.1003, ¶156.

Modifying Amarenco’s procedure to directly target and deliver stimulation to a branch of the PTN (*supra*, §VI.B.1) would necessarily result in placement of the electrode patch “upon a foot” of the patient. A POSA would have been aware of the location of PTN branches. *Supra*, §III.C. Moreover, a POSA would appreciate the stimulating electrode (or “electrode patch”) would need to be positioned “upon a foot” overlaying the branch, would have been aware of techniques known in the art for doing so, and would have done so to ensure the branch directly receives the stimulation from the electrode patch. *E.g.*, Ex.1085, 188; Ex.1086, 3:11-18, 3:57-4:21; Ex.1003, ¶¶157-58.

3. Claim 3

Amarenco in view of Mann, Ponsford, and the knowledge of a POSA render obvious claim 1. *Supra*, §VI.B.1. Further, Amarenco states “[t]he correct position of the negative electrode was determined by visualization of rhythmic flexion of the toes secondary to plantar muscle contraction during stimulation delivered at 1 hz.” Ex.1005, 2211. “Flexion of the toes” and “muscle contractions” are muscular responses caused by Amarenco’s stimulation of the PTN. Ex.1003, ¶159.

4. Claim 4

Amarenco in view of Mann, Ponsford, and the knowledge of a POSA render obvious claim 1. *Supra*, §VI.B.1. Further, application of electrostimulation for 30 minutes per week for the treatment of OAB/incontinence was known. Ex.1004, 481; Ex.1038, 915; Ex.1039, 44; Ex.1003, ¶161. While Amarenco did not disclose multiple 30-minute treatment sessions, it would have been obvious to modify Amarenco to apply electrostimulation in 30-minute, weekly treatment sessions. Ex.1003, ¶162. Modifying Amarenco in this manner would have involved applying known techniques to improve known processes and/or combining prior art elements to known methods—namely, using Amarenco’s method in known, successful weekly 30-minute treatment sessions. *Id.* A POSA would have found results to be predictable based on the knowledge of the art, given that this precise treatment duration and frequency was known and used successfully to treat OAB/incontinence. *Id.*

5. Claim 5

Amarenco in view of Mann, Ponsford, and the knowledge of a POSA render obvious claim 1. *Supra*, §VI.B.1. Further, Amarenco performed cystometry before and after PTN stimulation “with computerized analysis of results.” Ex.1005, 2211. As shown in Figs.3-4, Amarenco also performed EMG, which measures electrical

activity and response to muscle stimulation by a nerve. *Id.*, Figs.3-4 (below);

Ex.1003, ¶163.

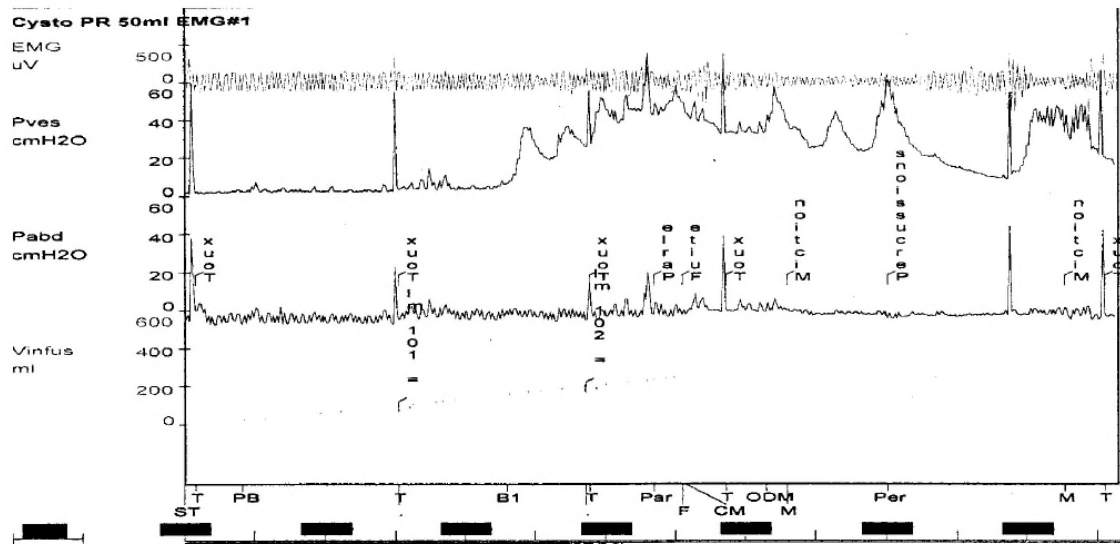


FIG. 3. Standard cystometry in 42-year-old patient with multiple sclerosis presenting with urge incontinence, frequency and urgency shows overactive bladder with noninhibited detrusor contraction.

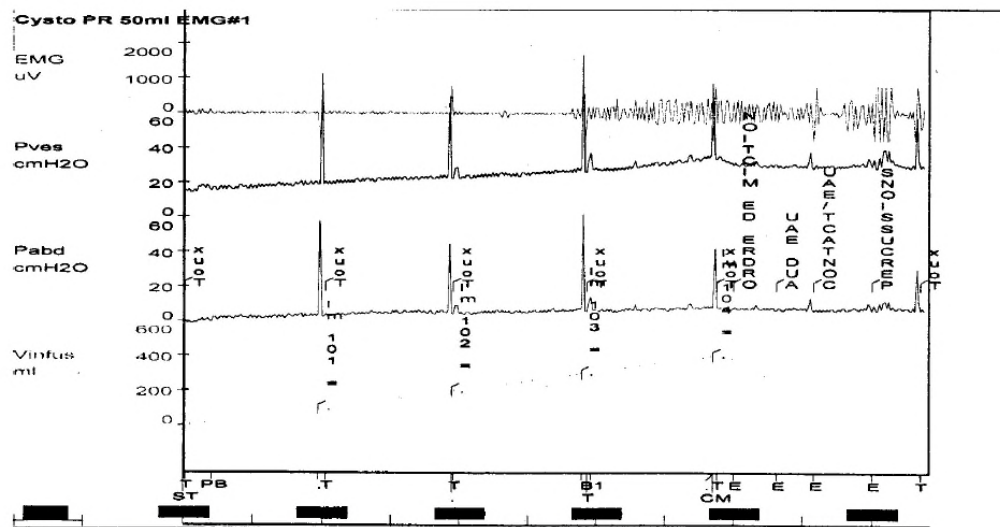


FIG. 4. Cystometry following surface stimulation with 10 Hz. of posterior tibial nerve at ankle demonstrates improvement in urodynamic parameters with suppression of involuntary detrusor contractions.

Cystometry and EMG are “physiological parameters” detected from Amarenco’s patients and displayed, as shown in the figures. Ex.1003, ¶163.

6. Claim 6

Amarenco in view of Mann, Ponsford, and the knowledge of a POSA render obvious claim 1. *Supra*, §VI.B.1. Further, as discussed above, a POSA would have interpreted claim 6 to encompass detecting for the presence or lack of presence of electrical conduction using techniques such as EMG based on the claim language and specification. *Supra*, §VI.A.6; Ex.1003, ¶¶164-69.

Further, as discussed above, EMG was a conventional technique for detecting the presence or lack of presence of electrical conduction at a second portion of a patient's body and was commonly used during electrical stimulation procedures. Ex.1003, ¶171; Ex.1042, 119; Ex.1084, 23:8-11; Ex.1028, 361; Ex.1029, 1:45-63. EMG electrodes were typically placed at a second portion of a patient's body away from the stimulation site, Ex.1003, ¶171; Ex.1030, 10; Ex.1028, 367, and a variety of types of EMG electrodes including surface electrodes that measure electrical activity through skin tissue were used. Ex.1003, ¶171; Ex.1030, 3, 10; Ex.1028, 362. It was also known well before 2006 that electrodes could be improperly positioned, migrate, and/or malfunction during electric stimulation procedures. Ex.1003, ¶172; Ex.1087, 3:2-4 (background); Ex.1031, [0024]; Ex.1032, [0005]; Ex.1033, 1:41-48; Ex.1084, 18:1-17, 18:30-33. EMG was thus used to detect improper electrode placement, migration, and malfunction. Ex.1003, ¶173; Ex.1030, 7 (EMG "confirmed satisfactory positioning

of the electrode” during electrostimulation for treatment of OAB), 10 (EMG used to “confirm [electrodes] continued optimum position”); Ex.1034, 12:28-45 (EMG used to confirm electrode placement); Ex.1084, 18:1-34 (EMG responses during test stimulation used to “**confirm proper lead and/or catheter location**, to **confirm response**, and/or to determine preliminary stimulator settings” and after electrode placement to “**confirm the lead/catheter has not shifted out of position.**”) (emphasis added), 18:50-54, 18:60-64, 19:43-50, 20:15-22.

Given the teachings in the prior art to use EMG for these purposes and the conventional use of EMG overall, a POSA would have found it obvious to use EMG to detect improper electrode placement, migration, and/or malfunction. Ex.1003, ¶174. Indeed, it was well known that EMG measures electrical conduction (or lack of conduction) in muscle stimulated by a nerve and of a nerve impulse between a stimulation site and muscle. *Id.*; Ex.1042, 120-21; Ex.1084, 23:8-11. A POSA would thus recognize that a lack of EMG signal from a muscle corresponding to a nerve that was electrically stimulated necessarily means there is an issue with the patients’ nerve or an issue with the stimulator electrode, such as improper placement, migration, or malfunction. Ex.1003, ¶174.

As discussed above, Amarenco used EMG to measure the electrical activity and muscle response from patients. Ex.1005, Figs.3-4; Ex.1003, ¶170. Even if Amarenco did not explicitly state the EMG results were used to detect for the

presence or lack of presence of electrical conduction, a POSA would have found it obvious based on the above-described knowledge in the art to modify Amarenco's procedure to detect for the presence or lack of presence of electrical conduction at a second portion of a patient's body as an indicator of electrode migration, electrode malfunction, and proper electrode placement. Ex.1003, ¶¶170, 175. Modifying Amarenco's procedure (which already involved measuring EMG, Ex.1005, Figs.3-4) in this way would have involved simply using prior art elements according to their known functions (*i.e.*, using Amarenco's EMG to determine electrode parameters, including improper electrode placement, migration, and/or malfunction, and therapeutic efficacy) and/or applying known techniques to improve a known process (*i.e.*, improving Amarenco's procedure by using EMG signals in known ways, including indicating proper electrode placement, electrode migration, or electrode malfunction). Ex.1003, ¶175. A POSA would understand the results would be predictable, given the conventional nature of EMG and the use of EMG for similar reasons in the art. *Id.*; Ex.1030, 7, 10; Ex.1034, 12:28-45; Ex.1084, 18:1-34. Moreover, a POSA would have also been motivated to modify Amarenco in this manner based on the teachings of the art itself, including to "confirm satisfactory positioning of the electrode" (proper electrode placement) or confirm the electrode's "continued optimum position"

(electrode migration). Ex.1030, 7, 10; *see also* Ex.1084, 18:1-17, 18:30-34; Ex.1003, ¶175.

7. Claim 7

Amarenco in view of Mann, Ponsford, and the knowledge of a POSA render obvious claim 6. *Supra*, §VI.B.6. Further, claim 7 does not cover a novel or nonobvious features of the alleged invention. The patent explicitly states that sensors are used to detect electrical conduction and that any known sensor can be used in the method. Ex.1001, 24:56-64, 37:46-51; Ex.1003, ¶176.

Setting that aside, Amarenco performed EMG measurements. Ex.1005, Figs.3-4; Ex.1003, ¶177. Moreover, various sensors/electrodes, including “electrode patches,” could be used for EMG. Ex. 1003, ¶178; Ex.1035, 188 (electrode “patch” for surface EMG); Ex.1036, 5:33-50 (“electrode patch” for detecting physiological signal such as EMG); Ex.1037, 736 (“sticky surface patch electrodes” for EMG).

Even if Amarenco does not explicitly disclose the specific type of EMG sensor/electrode used in the procedure, a POSA would have found it obvious to modify Amarenco’s procedure to use an “electrode patch” for detecting the presence of electrical conduction. Ex.1003, ¶179. Using an “electrode patch” in place of Amarenco’s EMG sensor/electrode would have involved simple substitution of known elements (substituting EMG electrodes for known “electrode

patches”) or predictable use of prior art elements according to established functions (using known “electrode patches” for EMG). *Id.* Additionally, it would have been obvious to try using “electrode patches” for EMG given the finite number of types of sensors/electrodes used in EMG procedures. *Id.* A POSA would have expected success modifying Amarenco’s procedure and the results would have been predictable given the widespread, successful use of EMG “electrode patches” throughout the art in similar procedures. *Id.*

8. Claim 8

Amarenco in view of Mann, Ponsford, and the knowledge of a POSA render obvious claim 1. *Supra*, §VI.B.1. Claim 8 is nearly identical to claim 6 except stating “an indicator of electrode malfunction.” As discussed, modifying Amarenco to detect lack of presence of electrical conduction at a second portion of a patient’s body as an indicator of electrode migration, electrode malfunction, and proper electrode placement would have been obvious. *Supra*, §VI.B.6. Thus, claim 8 is obvious for the same reasons regarding claim 6. *Id.*; Ex.1003, ¶180.

9. Claim 9

Amarenco in view of Mann, Ponsford, and the knowledge of a POSA render obvious claim 8. *Supra*, §VI.B.8. Claim 9 is nearly identical to claim 7. As discussed, modifying Amarenco to use an “electrode patch” for detecting the

presence of electrical conduction would have been obvious. *Supra*, §VI.B.7. Thus, claim 9 is obvious for the same reasons regarding claim 7. *Id.*; Ex.1003, ¶181.

10. Claim 10

Amarenco in view of Mann, Ponsford, and the knowledge of a POSA render obvious claim 1. *Supra*, §VI.B.1. Claim 10 is nearly identical to claim 6 except stating “an indicator of proper electrode placement.” As discussed, modifying Amarenco to detect lack of presence of electrical conduction at a second portion of a patient’s body as an indicator of electrode migration, electrode malfunction, and proper electrode placement would have been obvious. *Supra*, §VI.B.6. Thus, claim 10 is obvious for the same reasons regarding claim 6. *Id.*; Ex.1003, ¶182.

11. Claim 11

Amarenco in view of Mann, Ponsford, and the knowledge of a POSA render obvious claim 10. *Supra*, §VI.B.10. Claim 11 is nearly identical to claim 7. As discussed, modifying Amarenco to use an “electrode patch” for detecting the presence of electrical conduction would have been obvious. *Supra*, §VI.B.7. Thus, claim 11 is obvious for the same reasons regarding claim 7. *Id.*; Ex.1003, ¶183.

12. Claim 12

Amarenco in view of Mann, Ponsford, and the knowledge of a POSA render obvious claim 1. *Supra*, §VI.B.1. Claim 12 is nearly identical to claim 6 except stating conduction is “through tissue” and is “an indicator of electrode placement.”

As discussed, modifying Amarenco to detect lack of presence of electrical conduction (including using surface EMG electrodes that detect through skin tissue) at a second portion of a patient's body as an indicator of electrode migration, electrode malfunction, and proper electrode placement would have been obvious. *Supra*, §VI.B.6. Thus, claim 12 is obvious for the same reasons regarding claim 6. *Id.*; Ex.1003, ¶184.

13. Claim 13

Amarenco in view of Mann, Ponsford, and the knowledge of a POSA render obvious claim 12. *Supra*, §VI.B.12. Claim 13 is nearly identical to claim 7. As discussed, modifying Amarenco to use an “electrode patch” for detecting the presence of electrical conduction would have been obvious. *Supra*, §VI.B.7. Thus, claim 13 is obvious for the same reasons regarding claim 7. *Id.*; Ex.1003, ¶185.

C. 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 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, ‘477, and ‘742 patents, the NDCA litigation is not currently stayed. This factor is thus neutral.

Factor 2 (Trial Date). The court has not yet issued a scheduling order in the NDCA litigation and no trial date has been set. Trial is thus unlikely to occur before 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 ‘742 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 ‘742 patent claims are invalid for a variety of reasons and based on various prior art references. 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 during prosecution. Moreover, the

examiner plainly erred in a manner material to the patentability of the Challenged Claims. 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 400 references*** were cited during prosecution of the ‘742 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 on references and/or arguments that were not before the Office during prosecution of the ‘742 patent. For example, Svihra (used in Petitioner’s Ground 1) and Ponsford (used in both Petitioner’s Grounds 1 and 2) were not cited or considered during prosecution. The Office has therefore not considered either of Petitioner’s invalidity grounds forming the basis of this petition, which by itself is, respectfully, sufficient to deny exercising discretion under §325(d) and instituting this IPR.

Moreover, while Amarenco and Mann were before the Office during prosecution, they were not considered in combination with the prior art cited in this

petition. More specifically, Amarenco and Mann were not considered in combination with Ponsford or any of the other secondary references cited herein that demonstrate the knowledge of a POSA, which show: (1) conditions known to be treatable by electrically stimulating the PTN can also be treated by stimulating the medial and lateral plantar nerves, *i.e.*, PTN branches, with similar efficacy; (2) OAB and incontinence can be treated by electrically stimulating nerves and branches that reach the spinal cord via the sacral nerve roots, including the PTN and its branches; and (3) techniques (including descriptions of the exact locations to place electrodes) for directly targeting PTN branches such that the branch of the PTN directly receives the stimulation. *See supra*, §§VI.A.1.b, VI.A.1.d, VI.B.1.b, VI.B.1.d.

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

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. As shown above, the Challenged Claims are invalid over the prior art.

The claims of the '742 patent should not have been allowed over the examiner's Amarenco and Mann obviousness combination. As explained, during

prosecution the examiner issued several rejections over Amarenco in combination with Mann. *Supra*, §IV.B. Applicant only overcame the examiner’s rejections by amending the claims to require “a branch of a posterior tibial nerve within the first portion of the body is directly targeted by the electrical stimulator” and delivering stimulus “such that the branch directly receives the electrical stimulation.” *Id.* The claims were allowed because, according to the examiner, the prior art of record did not disclose “direct stimulation of a posterior tibial nerve branch to treat overactive bladder or incontinence.” *Id.* Evidently, the examiner believed that although Amarenco discloses electrically stimulating the PTN to treat OAB and Mann discloses motivation for a POSA to target branches of nerves including the PTN, the claims were allowable because neither reference actually shows an embodiment or example where a PTN branch was directly stimulated. As an initial matter, this logic is faulty because it is well within the skill of a POSA to modify Amarenco to directly stimulate a branch of the PTN by simply moving Amarenco’s surface electrodes to a location overlaying a PTN branch. *Supra*, §§VI.B.1.b, VI.B.1.d. Moreover, the art cited in this petition in combination with Amarenco demonstrates that the examiner’s belief the prior art does not disclose direct stimulation of a branch of the PTN is simply not the case. Not only does the prior art teach nerves and branches that reach the spinal cord through the sacral nerve roots—including the PTN and its branches—can be electrically stimulated to

treat OAB/incontinence, the examiner failed to recognize that the prior art also teaches specific techniques for directly targeting and delivering electrical stimulation to PTN branches including the medial and lateral plantar nerves and the sural nerve. *Supra*, §§VI.A.1.b, VI.A.1.d, VI.B.1.b, VI.B.1.d. 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 Amarenco and Mann were cited during prosecution, many of Petitioner's other references—including Svihra and Ponsford—were not. Moreover, Petitioner's obviousness combinations based on Svihra and Amarenco were also not considered during prosecution. 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 '742 patent to issue, the Board should decline exercising discretion under §325(d) and institute IPR.

VIII. CONCLUSION

For the foregoing reasons, IPR of claims 1-13 of the '742 patent is respectfully requested.

Dated: September 3, 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 treating overactive bladder or incontinence, comprising:

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

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

[1.c] delivering an electrical stimulus from the electrical stimulator to the branch of the posterior tibial nerve such that the branch directly receives the electrical stimulation to treat overactive bladder or incontinence.

Claim 2:

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

Claim 3:

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

Claim 4:

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

Claim 5:

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

Claim 6:

The method of claim 1 further comprising detecting for a lack of presence of electrical conduction at a second portion of the patient's body distant from the first portion as an indicator of electrode migration from the first portion.

Claim 7:

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

Claim 8:

The method of claim 1 further comprising detecting for a lack of presence of electrical conduction at a second portion of the patient's body distant from the first portion as an indicator of electrode malfunction from the first portion.

Claim 9:

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

Claim 10:

The method of claim 1 further comprising detecting for a lack of presence of electrical conduction at a second portion of the patient's body distant from the first portion as an indicator of proper electrode placement upon the first portion.

Claim 11:

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

Claim 12:

The method of claim 1 further comprising detecting for a lack of presence of electrical conduction through tissue at a second portion of the patient's body distant from the first portion as an indicator of electrode placement upon the first portion.

Claim 13:

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

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 13,743 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 3, 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. 11,224,742 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, Johnney 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 3, 2024

/s/ Todd R. Tucker

Todd R. Tucker

Attorney for Petitioner