

Avation Medical, Inc. v. EMKinetics, Inc.

**IPR No. 2024-01375
U.S. Patent No. 11,224,742**

**IPR No. 2024-01378
U.S. Patent No. 9,002,477**

Petitioner Avation Medical, Inc.'s Demonstratives



Minimal Substantive Challenge to Petitioner's Invalidity Grounds by Patent Owner

- **IPR2024-01378 ('477 Patent)**

- **No dispute** that prior art discloses all limitations of claims 1-10 of the '477 Patent
- **No dispute** that prior art renders claims obvious
- Invalidity Grounds 1-5:
 1. §102: **Svihra** (claim 1)
 2. §103: **Svihra** + Mann / DiLorenzo / Gerber / Bourget (claim 1)
 3. §103: **Svihra** + Mann / DiLorenzo / Gerber / Bourget + POSITA (claims 2-10)
 4. §103: **Amarenco** + Mann / DiLorenzo / Gerber / Bourget (claim 1)
 5. §103: **Amarenco** + Mann / DiLorenzo / Gerber / Bourget + POSITA (claims 2-10)

See IPR2024-01378, Paper 2 at 3-4, Paper 15 at 1.

- **IPR2024-01375 ('742 Patent)**

- **Limited** substantive dispute
- Invalidity Grounds 1-2:
 1. §103: **Svihra** + Mann + Ponsford + POSITA (claims 1-13)
 2. §103: **Amarenco** + Mann + Ponsford + POSITA (claims 1-13)

See IPR2024-01375, Paper 2 at 2-3, Paper 15 at 1.

Limited Issues in Dispute Across IPRs

- IPR2024-01375 ('742 Patent)

- Prior art status of Journal Articles

- **Svihra** is a printed publication

- **Amarenco** is a printed publication

- **Ponsford** is a printed publication

- Prior art discloses “directly” targeting and stimulating PTN branches

- IPR2024-01378 ('477 Patent)

- Prior art status of Journal Articles

- **Svihra** is a printed publication

- **Amarenco** is a printed publication

The Journal Articles Are Prior Art Printed Publications

- It has long been recognized that the touchstone as to whether an asserted reference qualifies as prior art is **public accessibility**. *In re Hall*, 781 F.2d 897, 899 (Fed. Cir. 1986)
 - See IPR2024-01375, Paper 7 at 12; see also IPR2024-01378, Paper 7 at 12.
- Petitioner establishes public accessibility by demonstrating that a reference was “**disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art, exercising reasonable diligence, can locate it.**” *Jazz Pharms., Inc. v. Amneal Pharms., LLC*, 895 F.3d 1347, 1355–56 (Fed. Cir. 2018)
 - See IPR2024-01375, Paper 15 at 3; see also IPR2024-01378, Paper 15 at 4.
- “When there is an **established publisher there is a presumption of public accessibility as of the publication date.**” *Vidstream LLC v. Twitter, Inc.*, 981 F.3d 1060, 1065-66 (Fed. Cir. 2020)
 - See IPR2024-01375, Paper 15 at 3; see also IPR2024-01378, Paper 15 at 4.

Svihra (Ex.1004) Is a Prior Art Printed Publication

- “Hallmarks” of printed publication
- Attorney declaration (Ex.1053)
- Wingeier declaration (Ex.1003)
- Institution Decision
- Corroborating references:
 - Sherif (Ex.1091)
 - Slovak (Ex.1092)
 - Garcia (Ex.1093)

See IPR2024-01375, Paper 2 at 22, Paper 15 at 5-6, 10, 15;
IPR2024-01378, Paper 2 at 15, Paper 15 at 6-7, 10-11, 16-17.



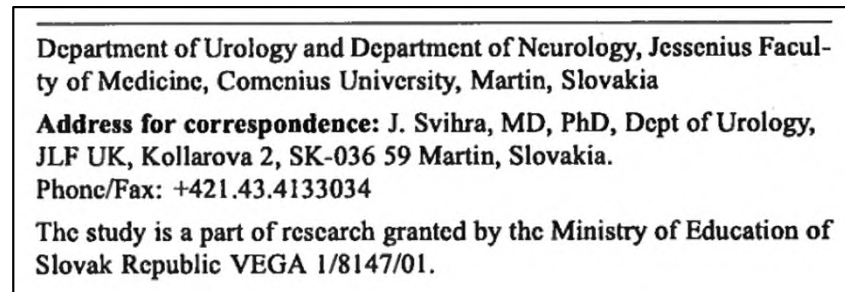
Svihra Includes “Hallmarks” of Publicly Accessible Printed Publication

- Journal name (Bratisl Lek Listy)
 - International medical journal *Bratislava Medical Journal*
 - Published by Faculty of Medicine at Comenius University in Slovakia
- Publication year (2002)
- Volume (103)
- Number/edition (12)
- Page numbers (480-83)
- “Received May 30, 2002”
- “Accepted December 9, 2002”

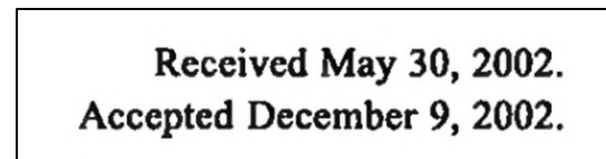
See IPR2024-01375, Paper 15 at 5-6;
IPR2024-01378, Paper 15 at 6-7.



Ex.1004 at 480 (see IPR2024-01375, Paper 15 at 5-6; IPR2024-01378, Paper 15 at 6-7).



Ex.1004 at 480 (see IPR2024-01375, Paper 15 at 5-6; IPR2024-01378, Paper 15 at 6-7).



Ex.1004 at 480 (see IPR2024-01375, Paper 15 at 5-6; IPR2024-01378, Paper 15 at 6-7).

Svihra Was Published and Publicly Accessible

- Svihra (Ex.1004) was properly authenticated

6. A true and correct copy of J. Svihra et al., “Neuromodulative treatment of overactive bladder – noninvasive tibial nerve stimulation,” Bratisl Lek Listy 103(12):480-483 (2002) (“Svihra”) is attached as **Exhibit No. 1004**.

See IPR2024-01375, Paper 15 at 10 (citing Ex.1053 at ¶ 6); IPR2024-01378, Paper 15 at 10 (same).

- No objections to authenticity or hearsay by Patent Owner
- Dr. Wingeier confirmed Svihra was published and accessible

See IPR2024-01375, Paper 21 at 5; IPR2024-01378, Paper 21 at 5.

43. Other research groups published studies that relied on similar noninvasive techniques targeting the posterior tibial nerve in the early 2000’s. For example, Svihra published a study aimed at “us[ing] non-invasive stimulation of the tibial nerve with the intention to achieve desired therapeutic effects without iatrogenic nerve damage using a superficial electrostimulation.” Ex.1004 (Svihra), 480. Svihra’s goal was to develop a modified version of the SANS treatment

See IPR2024-01375, Paper 15 at 10 (citing Ex.1003 at ¶ 43); see also IPR2024-01378, Paper 15 at 10 (citing Ex.1003 at ¶ 44).

Corroborating Evidence is Permissible in Petitioner's Reply

[S]ome limited opportunities exist for the petitioner to present new evidence later, including: (1) in a reply to a patent owner preliminary response; (2) ***in a reply to the patent owner response***; and (3) in a motion to file supplemental information. 37 C.F.R. §§ 42.108(c), 42.23, 42.123. As to the first two opportunities, the evidence must be responsive to the prior briefing. . . .

For example, if the patent owner challenges a reference's status as a printed publication, a petitioner may submit a supporting declaration with its reply to further support its argument that a reference qualifies as a printed publication. See 37 C.F.R. §§ 42.2 (affidavit), 42.23.

Hulu, LLC v. Sound View Innovations, LLC, IPR2018-01039, Paper 29 at 14-15 (PTAB December 20, 2019) (precedential) (emphasis added)

See IPR2024-01375, Paper 21 at 3; IPR2024-01378, Paper 21 at 3.

Non-Contemporaneous Evidence Can Corroborate Public Availability

Although Exhibit 1053, published in 2017, is not contemporaneous evidence of the 2007 publication of McCloskey, it nonetheless is evidence helping to corroborate that McCloskey was, in fact, published in 2007.

More importantly, additional corroborative evidence exists in the record. In particular, another of the three references cited above, i.e., *Ex. 1060, was published relatively shortly after McCloskey, in December 2008, and references McCloskey as being published in the same page range (pages 761–767) of the same volume (45) of the same periodical (Biochemical Genetics) as appears on McCloskey itself.* Compare Ex. 1060, 13 (“Biochem. Genet 2007;45:761–767”), with Ex. 1004, 1 (“Biochem Genet (2007) 45:761–767”). *This evidence is the figurative nail in the coffin for Patent Owner’s argument that McCloskey is not a prior art printed publication.*

Parse Biosciences, Inc. v. 10X Genomics, Inc., IPR2023-00958, Paper 48 at 19-20 (PTAB February 3, 2025) (emphasis added)

See IPR2024-01375, Paper 15 at 16; IPR2024-01378, Paper 15 at 18.

Corroborating Evidence Confirms Svihra Was Published and Publicly Accessible

• Sherif (Ex.1091)

[5] Svihra J, Kurca E, Luptak J, Kliment J. Neuromodulative treatment of overactive bladder – non invasive tibial nerve stimulation. *Bratisl Lek Listy* 2002;103:480–3.

• Slovak (Ex.1092)

[17] Svihra J, Kurca E, Luptak J, Kliment J. Neuromodulative treatment of overactive bladder—noninvasive tibial nerve stimulation. *Bratisl Lek Listy* 2002;103:480–3.

• Garcia (Ex.1093)



25) Svihra J, Kurca E, Luptak J, et al.: Neuromodulative treatment of overactive bladder—noninvasive tibial nerve stimulation. *Bratisl Lek Listy* (Tlacene Vyd), 2002, 103: 480–483 [Bratislava Medical Journal]. [Medline]

See IPR2024-01375, Paper 15 at 15 (citing Ex.1091 at 135 (ref. 5), Ex.1092 at 100 (ref. 17), Ex.1093 at 1340 (ref. 25)); IPR2024-01378, Paper 15 at 16-17 (same).

The Board Found Svihra Is a Publicly Accessible Printed Publication

Patent Owner's arguments at this stage are not persuasive. A simple internet search reveals that "Bratisl Lek Listy," which appears on the header of Svihra, is an abbreviation for Bratislavské lekárske listy—the Bratislava Medical Journal—an international medical journal founded in 1921, published monthly in English, and currently in its 126th volume. See Ex. 3001.¹³ Svihra's header states, in full: "Bratisl Lek Listy 2002; 103 (12): 480-483," which we find skilled artisans would understand to mean that Svihra appeared as an article appearing in volume 103, number 12, of the Bratislava Medical Journal at pages 480–483 and was published in December 2002 (i.e., number 12). See Ex. 1004, 480. Thus, on its face, the reference supports Petitioner's assertion under § 102(b).

Based on the present record, Petitioner has established a reasonable likelihood that Svihra was publicly accessible before the critical date of the '742 patent. Svihra exhibits the necessary hallmarks to support such a finding. Indeed, it exhibits many of the same hallmarks as Amarengo and

Trials@uspto.gov
601-257-7822

Paper 7
Entered: March 18, 2025

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AVATION MEDICAL, INC.,
Petitioner,

v.

EMKINETICS, INC.,
Patent Owner.

IPR2024-01375
Patent 11,224,742 B2

RICA A. FRANKLIN, JOHN G. NEW, and JASON W. MELVIN,
Patent Judges.

, *Administrative Patent Judge.*

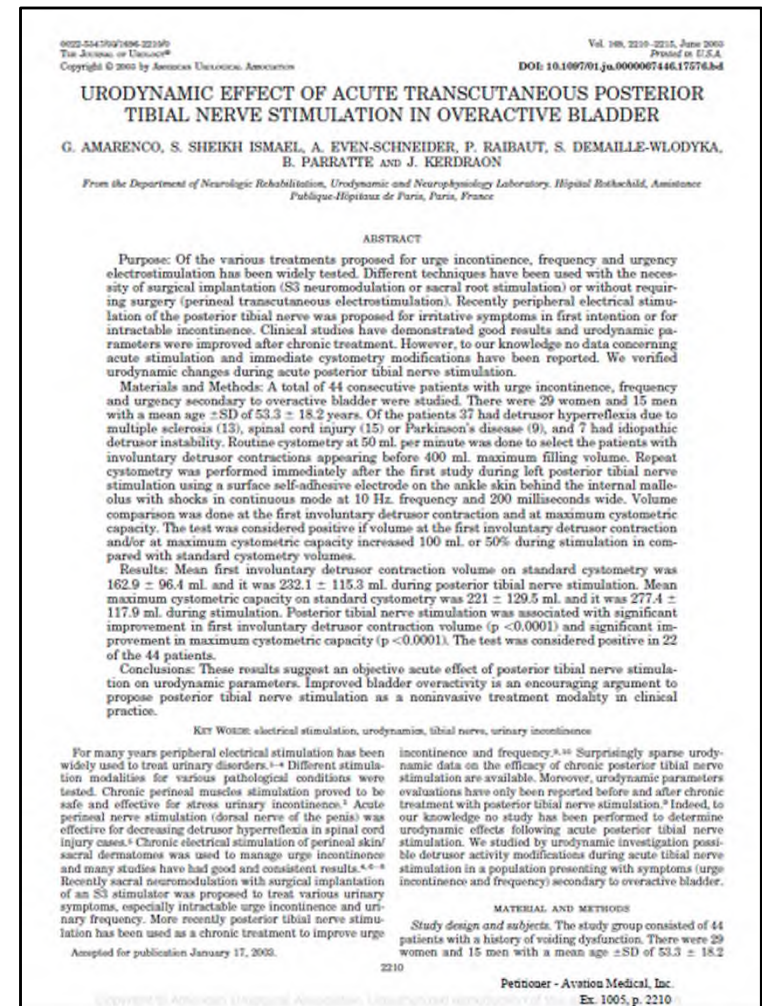
DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314

Paper IPR2024-01375, Paper 7 at 13; see
also IPR2024-01378, Paper 7 at 13.

Amarenco (Ex.1005) Is a Prior Art Printed Publication

- “Hallmarks” of printed publication
- Attorney declaration (Ex.1053)
- Wingeier declaration (Ex.1003)
- Institution Decision
- ‘742 Patent “References Cited”
- Related ‘943 Patent “References Cited”
- Amarenco II (Ex.1094)
- Corroborating references:
 - Queralto (Ex.1016)
 - Sherif (Ex.1091)
 - Slovak (Ex.1092)
 - Garcia (Ex.1093)
 - Guo (Ex.1095)

See IPR2024-01375, Paper 2 at 44, Paper 15 at 6-7, 10, 15-16;
IPR2024-01378, Paper 2 at 43, Paper 15 at 7-8, 10-11, 17-18.

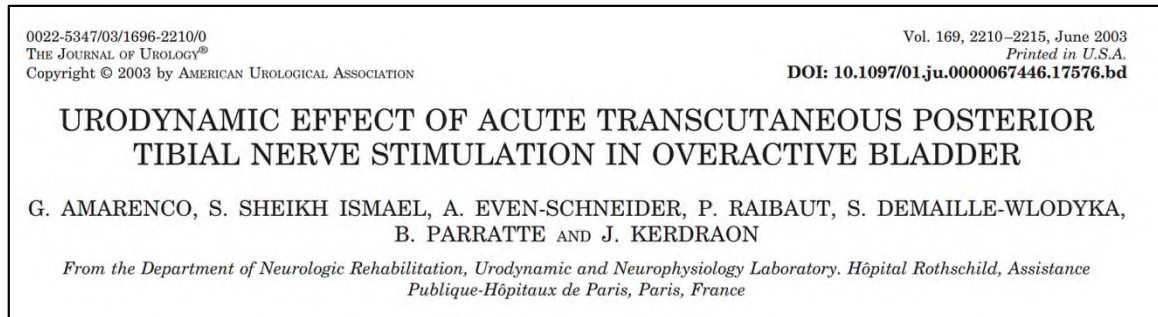


Ex.1005 at 2210 (see IPR2024-01375, Paper 15 at 6-7; IPR2024-01378, Paper 15 at 7-8).

Amarenco Includes “Hallmarks” of Publicly Accessible Printed Publication

- Journal name (The Journal of Urology)
- Publication date (June 2003)
- Volume (169)
- Page numbers (2210-15)
- Copyright information (“Copyright © 2003 by American Urological Association”)
- Digital Object Identifier (“DOI”)
- “Accepted for publication January 17, 2003”

See IPR2024-01375, Paper 15 at 6-7;
IPR2024-01378, Paper 15 at 7-8.



Accepted for publication January 17, 2003.

Ex.1005 at 2210 (see IPR2024-01375, Paper 15
at 6-7; IPR2024-01378, Paper 15 at 7-8).

Amarenco Was Published and Publicly Accessible

- Amarenco (Ex.1005) was properly authenticated

7. A true and correct copy of G. Amarenco et al., “Urodynamic Effect of Acute Transcutaneous Posterior Tibial Nerve Stimulation in Overactive Bladder,” J. Urology 169: 2210-2215 (2003) (“Amarenco”) is attached as **Exhibit No. 1005**.

See IPR2024-01375, Paper 15 at 10 (citing Ex.1053 at ¶ 7); IPR2024-01378, Paper 15 at 10 (same).

- No objections to authenticity or hearsay by Patent Owner
- Dr. Wingeier confirmed Amarenco was published and accessible

See IPR2024-01375, Paper 21 at 5; IPR2024-01378, Paper 21 at 5.

44. In 2003, Amarenco published a similar study that tested noninvasive electrical stimulation targeting patients’ posterior tibial nerve. According to Amarenco, “[o]f the various treatments proposed for urge incontinence, frequency and urgency electrostimulation has been widely tested. Different techniques have been used with the necessity of surgical implantation (S3 neuromodulation or sacral root stimulation) or without requiring surgery (perineal transcutaneous electrostimulation). Recently peripheral electrical stimulation of the posterior tibial nerve was proposed for irritative symptoms in first intention or for intractable incontinence. Clinical studies have demonstrated good results and urodynamic parameters were improved after chronic treatment.” Ex.1005 (Amarenco), 2210.

See IPR2024-01375, Paper 15 at 10 (citing Ex.1003 at ¶ 44); see also IPR2024-01378, Paper 15 at 10 (citing Ex.1003 at ¶ 45).

The Board Found Amarengo Includes Hallmarks of a Printed Publication

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571-272-7822

Paper 7
Entered: March 18, 2025

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AVATION MEDICAL, INC.,
Petitioner

finding. Indeed, it exhibits many of the same hallmarks as Amarengo and Ponsford—e.g., journal title and volume number, page numbers, date of acceptance for publication—and Patent Owner does not dispute those references are applicable prior art. See Ex. 1005; Ex. 1085. We conclude that

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314

Paper IPR2024-01375, Paper 7 at 13; see
also IPR2024-01378, Paper 7 at 13.

The '742 Patent and Related '943 Patent Confirm Amarenco Was Published and Publicly Accessible


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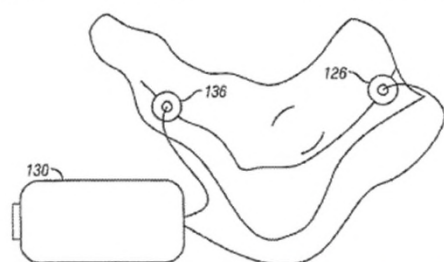
(12) United States Patent Burnett (54) METHODS AND DEVICES FOR PERFORMING ELECTRICAL STIMULATION TO TREAT VARIOUS CONDITIONS (71) Applicant: EMKinetics, Inc., San Francisco, CA (US) (72) Inventor: Daniel R. Burnett, San Francisco, CA (US) (73) Assignee: EMKinetics, Inc., San Francisco, CA (US) (*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35	(10) Patent No.: US 11,224,742 B2 (45) Date of Patent: Jan. 18, 2022 (56) References Cited U.S. PATENT DOCUMENTS <table border="0" style="width: 100%;"> <tr> <td style="width: 50%;">2,003,392 A 2,893,392 A</td> <td style="width: 50%;">6,1935 Rucker 7,1959 Wagner et al. (Continued)</td> </tr> </table> FOREIGN PATENT DOCUMENTS <table border="0" style="width: 100%;"> <tr> <td style="width: 50%;">EP 2493551 GB 2298370</td> <td style="width: 50%;">9,2012 9,1996 (Continued)</td> </tr> </table> OTHER PUBLICATIONS acute transcutaneous pos- terior bladder," Jun. 2003, (Year: 2003).* Helin Hagade Han LLP methods for electro- stimulation. One or more stimulators may be included. conductive coils consti- tute or magnetic field or other body tissues one or more sensors may be provided to provide feedback magnetic induction able to vary a current field focused upon the tissues based on the of a patient. In certain fields may be inter- muscle or tissue without	2,003,392 A 2,893,392 A	6,1935 Rucker 7,1959 Wagner et al. (Continued)	EP 2493551 GB 2298370	9,2012 9,1996 (Continued)
2,003,392 A 2,893,392 A	6,1935 Rucker 7,1959 Wagner et al. (Continued)				
EP 2493551 GB 2298370	9,2012 9,1996 (Continued)				

OTHER PUBLICATIONS

**Amarenco et al., "Urodynamic effect of acute transcutaneous pos-
terior tibial nerve stimulation in overactive bladder," Jun. 2003,
Journal of Urology, vol. 169, 2210-2215. (Year: 2003).***

CPC: A61N 1/36007; A61N 1/36031; A61N 1/0456
See application file for complete search history.

13 Claims, 37 Drawing Sheets

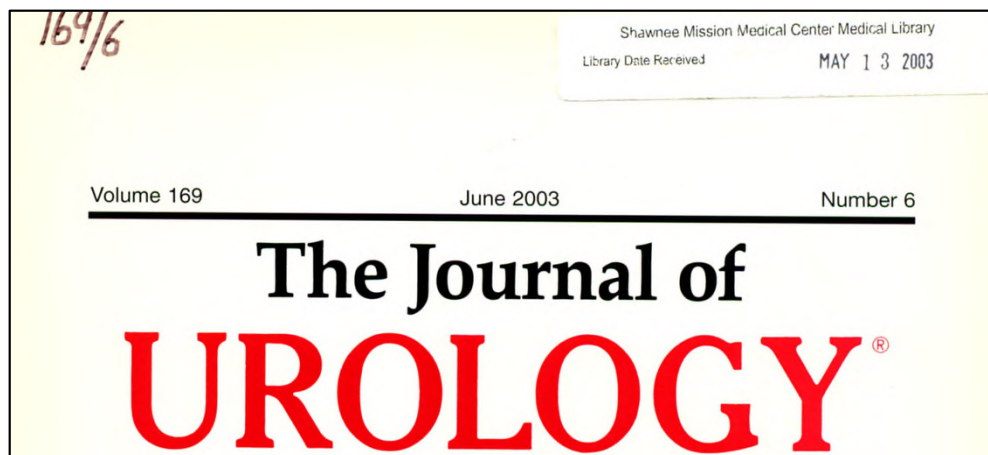


Petitioner - Avation Medical, Inc.
Ex. 1001, p. 1

See IPR2024-01375, Paper 15 at 15-16 (citing Ex.1001 at [56]; Ex.1087 at [56]);
IPR2024-01378, Paper 15 at 17-18 (citing Ex.1087 at [56]; Ex.1098 at [56]).

Amarenco II Confirms Amarenco Was Published and Publicly Accessible

- Cover and copyright pages of Amarenco II confirm journal, volume/edition, and publication in June 2003



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See IPR2024-01375, Paper 15 at 15 (citing Ex.1094 at 1-4); IPR2024-01378, Paper 15 at 17 (same).

- Table of contents of Amarenco II confirms Amarenco appeared in vol. 169, no. 6 of the *Journal of Urology* beginning on page 2210

Urodynamic Effect of Acute Transcutaneous Posterior Tibial Nerve Stimulation in Overactive Bladder. G. Amarenco, S. S. Ismael, A. Even-Schneider, P. Raibaut, S. Demaille-Wlodyka, B. Parratte and J. Kerdraon	2210
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See IPR2024-01375, Paper 15 at 15 (citing Ex.1094 at 4-6); IPR2024-01378, Paper 15 at 17 (same).

Amarenco Is Identical to Amarenco II

• Amarenco (Ex.1005)

• Amarenco II (Ex.1094)

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URODYNAMIC EFFECT OF ACUTE TRANSCUTANEOUS POSTERIOR TIBIAL NERVE STIMULATION IN OVERACTIVE BLADDER

G. AMARENCO, S. SHEIKH ISMAEL, A. EVEN-SCHNEIDER, P. RAIBAUT, S. DEMAILLE-WLODYKA, B. PARRATTE AND J. KERDRAON

From the Department of Neurologic Rehabilitation, Urodynamic and Neurophysiology Laboratory, Hôpital Rothschild, Assistance Publique-Hôpitaux de Paris, Paris, France

ABSTRACT

Purpose: Of the various treatments proposed for urge incontinence, frequency and urgency electrostimulation has been widely tested. Different techniques have been used with the necessity of surgical implantation (S3 neuromodulation or sacral root stimulation) or without requiring surgery (perineal transcutaneous electrostimulation). Recently peripheral electrical stimulation of the posterior tibial nerve was proposed for irritative symptoms in first intention or for intractable incontinence. Clinical studies have demonstrated good results and urodynamic parameters were improved after chronic treatment. However, to our knowledge no data concerning acute stimulation and immediate cystometry modifications have been reported. We verified urodynamic changes during acute posterior tibial nerve stimulation.

Materials and Methods: A total of 44 consecutive patients with urge incontinence, frequency and urgency secondary to overactive bladder were studied. There were 29 women and 15 men with a mean age $\pm$ SD of 53.3 ± 18.2 years. Of the patients 37 had detrusor hyperreflexia due to multiple sclerosis (13), spinal cord injury (15) or Parkinson's disease (9), and 7 had idiopathic detrusor instability. Routine cystometry at 50 ml. per minute was done to select the patients with involuntary detrusor contractions appearing before 400 ml. maximum filling volume. Repeat cystometry was performed immediately after the first study during left posterior tibial nerve stimulation using a surface self-adhesive electrode on the ankle skin behind the internal malleolus with shocks in continuous mode at 10 Hz. frequency and 200 milliseconds wide. Volume comparison was done at the first involuntary detrusor contraction and at maximum cystometric capacity. The test was considered positive if volume at the first involuntary detrusor contraction and/or at maximum cystometric capacity increased 100 ml. or 50% during stimulation in compared with standard cystometry volumes.

Results: Mean first involuntary detrusor contraction volume on standard cystometry was 162.9 ± 96.4 ml. and it was 232.1 ± 115.3 ml. during posterior tibial nerve stimulation. Mean maximum cystometric capacity on standard cystometry was 221 ± 129.5 ml. and it was 277.4 ± 117.9 ml. during stimulation. Posterior tibial nerve stimulation was associated with significant improvement in first involuntary detrusor contraction volume ($p < 0.0001$) and significant improvement in maximum cystometric capacity ($p < 0.0001$). The test was considered positive in 22 of the 44 patients.

Conclusions: These results suggest an objective acute effect of posterior tibial nerve stimulation on urodynamic parameters. Improved bladder overactivity is an encouraging argument to propose posterior tibial nerve stimulation as a noninvasive treatment modality in clinical practice.

KEY WORDS: electrical stimulation, urodynamics, tibial nerve, urinary incontinence

For many years peripheral electrical stimulation has been widely used to treat urinary disorders.¹⁻⁴ Different stimulation modalities for various pathological conditions were tested. Chronic perineal muscles stimulation proved to be safe and effective for stress urinary incontinence.¹ Acute perineal nerve stimulation (dorsal nerve of the penis) was effective for decreasing detrusor hyperreflexia in spinal cord injury cases.² Chronic electrical stimulation of perineal skin/sacral dermatomes was used to manage urge incontinence and many studies have had good and consistent results.⁴⁻⁶ Recently sacral neuromodulation with surgical implantation of an S3 stimulator was proposed to treat various urinary symptoms, especially intractable urge incontinence and urinary frequency. More recently posterior tibial nerve stimulation has been used as a chronic treatment to improve urge incontinence and frequency.^{7,8} Surprisingly sparse urodynamic data on the efficacy of chronic posterior tibial nerve stimulation are available. Moreover, urodynamic parameters evaluations have only been reported before and after chronic treatment with posterior tibial nerve stimulation.⁹ Indeed, to our knowledge no study has been performed to determine urodynamic effects following acute posterior tibial nerve stimulation. We studied by urodynamic investigation possible detrusor activity modifications during acute tibial nerve stimulation in a population presenting with symptoms (urge incontinence and frequency) secondary to overactive bladder.

MATERIAL AND METHODS

Study design and subjects. The study group consisted of 44 patients with a history of voiding dysfunction. There were 29 women and 15 men with a mean age $\pm$ SD of 53.3 ± 18.2

Pentecor - Avation Medical, Inc.
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Ex. 1005, p. 2210.

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URODYNAMIC EFFECT OF ACUTE TRANSCUTANEOUS POSTERIOR TIBIAL NERVE STIMULATION IN OVERACTIVE BLADDER

G. AMARENCO, S. SHEIKH ISMAEL, A. EVEN-SCHNEIDER, P. RAIBAUT, S. DEMAILLE-WLODYKA, B. PARRATTE AND J. KERDRAON

From the Department of Neurologic Rehabilitation, Urodynamic and Neurophysiology Laboratory, Hôpital Rothschild, Assistance Publique-Hôpitaux de Paris, Paris, France

ABSTRACT

Purpose: Of the various treatments proposed for urge incontinence, frequency and urgency electrostimulation has been widely tested. Different techniques have been used with the necessity of surgical implantation (S3 neuromodulation or sacral root stimulation) or without requiring surgery (perineal transcutaneous electrostimulation). Recently peripheral electrical stimulation of the posterior tibial nerve was proposed for irritative symptoms in first intention or for intractable incontinence. Clinical studies have demonstrated good results and urodynamic parameters were improved after chronic treatment. However, to our knowledge no data concerning acute stimulation and immediate cystometry modifications have been reported. We verified urodynamic changes during acute posterior tibial nerve stimulation.

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Results: Mean first involuntary detrusor contraction volume on standard cystometry was 162.9 ± 96.4 ml. and it was 232.1 ± 115.3 ml. during posterior tibial nerve stimulation. Mean maximum cystometric capacity on standard cystometry was 221 ± 129.5 ml. and it was 277.4 ± 117.9 ml. during stimulation. Posterior tibial nerve stimulation was associated with significant improvement in first involuntary detrusor contraction volume ($p < 0.0001$) and significant improvement in maximum cystometric capacity ($p < 0.0001$). The test was considered positive in 22 of the 44 patients.

Conclusions: These results suggest an objective acute effect of posterior tibial nerve stimulation on urodynamic parameters. Improved bladder overactivity is an encouraging argument to propose posterior tibial nerve stimulation as a noninvasive treatment modality in clinical practice.

Key Words: electrical stimulation, urodynamics, tibial nerve, urinary incontinence

For many years peripheral electrical stimulation has been widely used to treat urinary disorders.¹⁻⁴ Different stimulation modalities for various pathological conditions were tested. Chronic perineal muscles stimulation proved to be safe and effective for stress urinary incontinence.¹ Acute perineal nerve stimulation (dorsal nerve of the penis) was effective for decreasing detrusor hyperreflexia in spinal cord injury cases.² Chronic electrical stimulation of perineal skin/sacral dermatomes was used to manage urge incontinence and many studies have had good and consistent results.⁴⁻⁶ Recently sacral neuromodulation with surgical implantation of an S3 stimulator was proposed to treat various urinary symptoms, especially intractable urge incontinence and urinary frequency. More recently posterior tibial nerve stimulation has been used as a chronic treatment to improve urge incontinence and frequency.^{7,8} Surprisingly sparse urodynamic data on the efficacy of chronic posterior tibial nerve stimulation are available. Moreover, urodynamic parameters evaluations have only been reported before and after chronic treatment with posterior tibial nerve stimulation.⁹ Indeed, to our knowledge no study has been performed to determine urodynamic effects following acute posterior tibial nerve stimulation. We studied by urodynamic investigation possible detrusor activity modifications during acute tibial nerve stimulation in a population presenting with symptoms (urge incontinence and frequency) secondary to overactive bladder.

MATERIAL AND METHODS

Study design and subjects. The study group consisted of 44 patients with a history of voiding dysfunction. There were 29 women and 15 men with a mean age $\pm$ SD of 53.3 ± 18.2

Pentecor - Avation Medical, Inc.
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Ex. 1094, p. 9

See IPR2024-01375, Paper 15 at 15 (citing Ex.1094 at 9-14, Ex.1005 at 2210-15); IPR2024-01378, Paper 15 at 17 (same).

Petitioner Avation Medical, Inc., IPR Nos. 2024-01375, 2024-01378

Corroborating Evidence Confirms Amarenco Was Published and Publicly Accessible

- Queralto (Ex.1016)

5. Amarenco G, Ismael SS, Even-Schneider A et al (2003) Urodynamic effect of acute transcutaneous posterior tibial nerve stimulation in overactive bladder. *J Urol* 169:2210–2215

- Sherif (Ex. 1091)

[29] Amarenco G, Ismael SS, Even-Schneider A, Raibaut P, Demaille-Wlodyka S, Parratte B, et al. Urodynamic effect of acute transcutaneous posterior tibial nerve stimulation in overactive bladder. *J Urol* 2003;169:2210–5.

- Slovak (Ex.1092)

[37] Amarenco G, Ismael SS, Even-Schneider A, Raibaut P, Demaille-Wlodyka S, Parratte B, et al. Urodynamic effect of acute transcutaneous posterior tibial nerve stimulation in overactive bladder. *J Urol* 2003;169:2210–5.

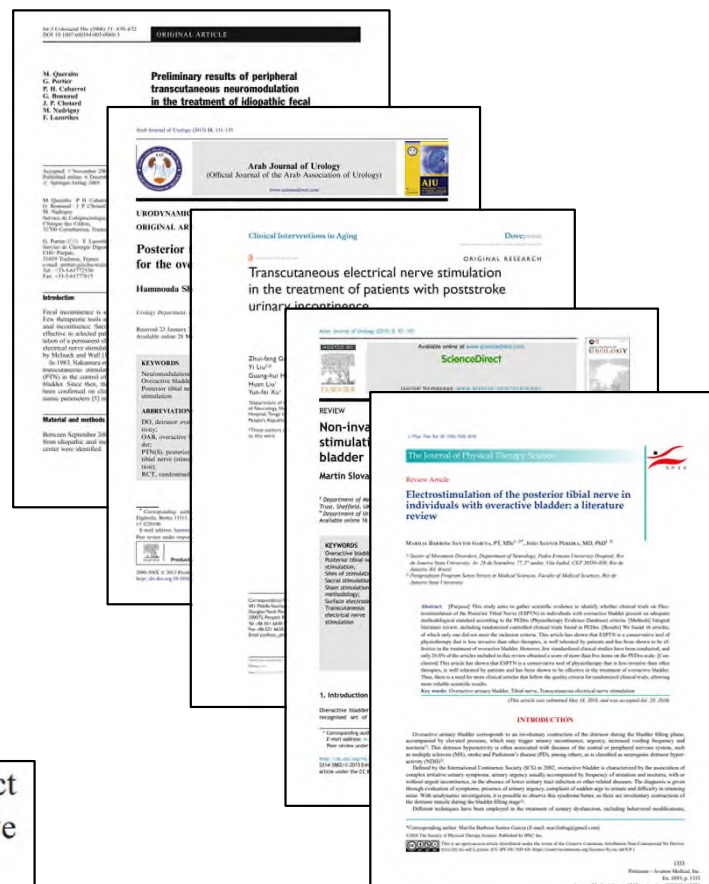
- Guo (Ex.1095)

11. Amarenco G, Ismael SS, Even-Schneider A, et al. Urodynamic effect of acute transcutaneous posterior tibial nerve stimulation in overactive bladder. *J Urol*. 2003;169(6):2210–2215.

- Garcia (Ex.1093)

5) Amarenco G, Ismael SS, Even-Schneider A, et al.: Urodynamic effect of acute transcutaneous posterior tibial nerve stimulation in overactive bladder. *J Urol*, 2003, 169: 2210–2215. [Medline] [CrossRef]

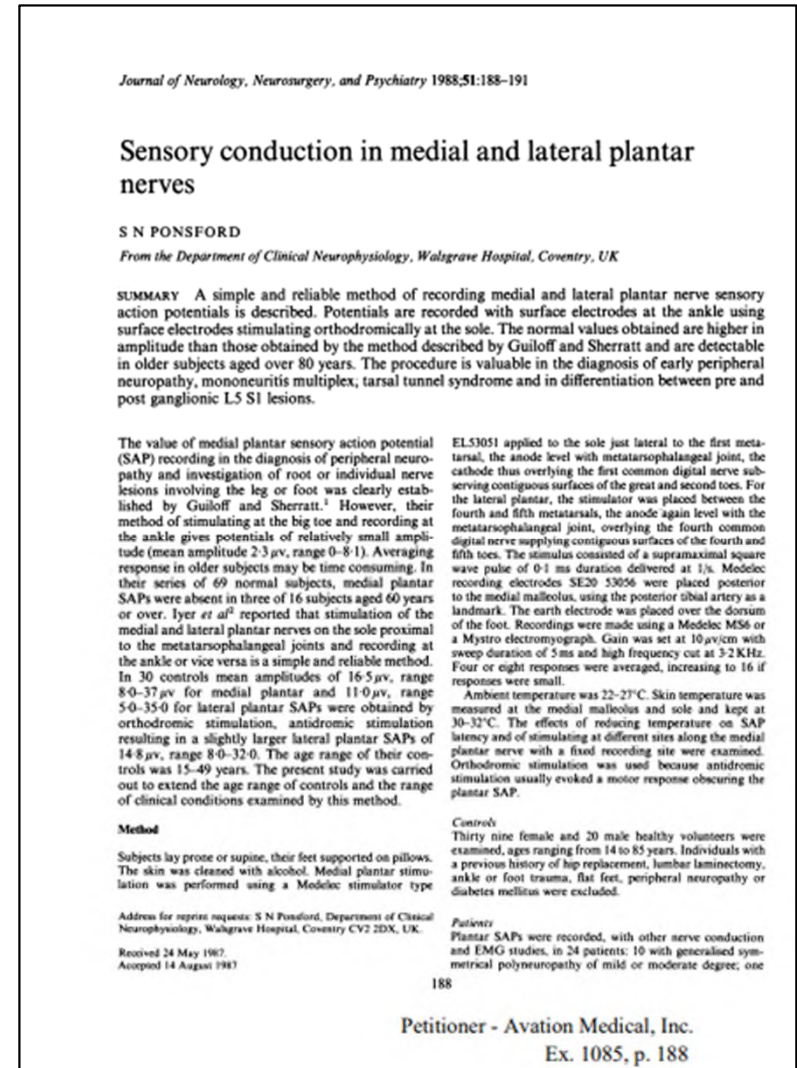
See IPR2024-01375, Paper 15 at 15 (citing Ex.1016 at 672 (ref. 5), Ex. 1091 at 135 (ref. 29), Ex.1092 at 100 (ref. 37), Ex.1093 at 1340 (ref. 5), Ex. 1095 at 856 (ref. 11)); IPR2024-01378, Paper 15 at 17 (same).



Ponsford (Ex.1085) Is a Prior Art Printed Publication

- “Hallmarks” of printed publication
- Attorney declaration (Ex.1053)
- Institution Decision
- Corroborating references:
 - Krämer (Ex.1099)
 - Galloway (Ex.1100)

See IPR2024-01375, Paper 2 at 22;
Paper 15 at 7-8, 10, 16.



Ex.1085 at 188 (see IPR2024-01375,
Paper 15 at 7-8).

Ponsford Includes “Hallmarks” of Publicly Accessible Printed Publication

- Journal name
(*Journal of Neurology*)
- Publication year
(1988)
- Volume (51)
- Page numbers (188-91)
- “Received 24 May 1987”
- “Accepted 14 August 1987”

See IPR2024-01375, Paper 15 at 7-8.

Journal of Neurology, Neurosurgery, and Psychiatry 1988;51:188-191

Sensory conduction in medial and lateral plantar nerves

S N PONSFORD

From the Department of Clinical Neurophysiology, Walsgrave Hospital, Coventry, UK

Ex.1085 at 188 (see IPR2024-01375, Paper 15 at 7-8).

**Received 24 May 1987.
Accepted 14 August 1987**

Ex.1085 at 188 (see IPR2024-01375, Paper 15 at 7-8).

Ponsford Was Published and Publicly Accessible

- Ponsford (Ex.1085) was properly authenticated

44. A true and correct copy of S N Ponsford, “Sensory conduction in medial and lateral plantar nerves,” *Journal of Neurology, Neurosurgery, and Psychiatry* 51(2):188-191 (1988) (“Ponsford”) is attached as **Exhibit No. 1085**.

See IPR2024-01375, Paper 15 at 10 (citing Ex.1053 at ¶ 44).

- No objections to authenticity or hearsay by Patent Owner

See IPR2024-01375, Paper 21 at 5.

The Board Found Ponsford Includes Hallmarks of a Printed Publication

Trials@uspto.gov 571-272-7822 Paper 7 Entered: March 18, 2025 UNITED STATES PATENT AND TRADEMARK OFFICE _____ BEFORE THE PATENT TRIAL AND APPEAL BOARD _____ AVATION MEDICAL, INC., Petitioner	finding. Indeed, it exhibits <u>many of the same hallmarks as Amarengo and Ponsford—e.g., journal title and volume number, page numbers, date of acceptance for publication—and Patent Owner does not dispute those references are applicable prior art. See Ex. 1005; Ex. 1085. We conclude that</u>
DECISION Granting Institution of <i>Inter Partes</i> Review 35 U.S.C. § 314	

Paper IPR2024-01375, Paper 7 at 13.

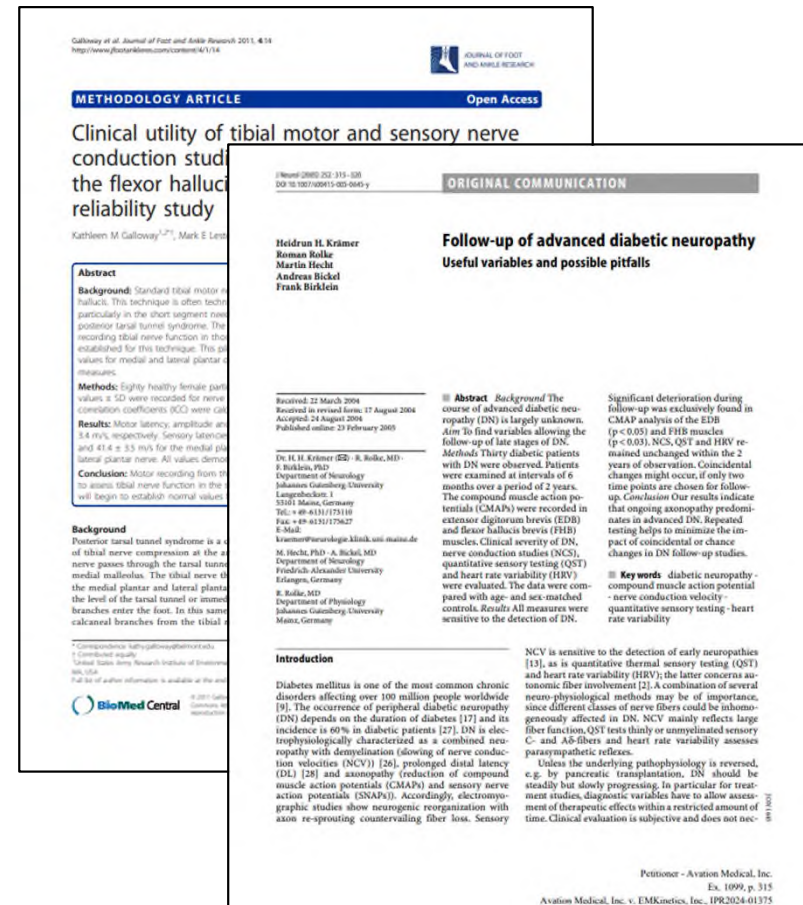
Corroborating Evidence Confirms Ponsford Was Published and Publicly Accessible

- Krämer (Ex.1099)

23. Ponsford SN (1988) Sensory conduction in medial and lateral plantar nerves. *J Neurol Neurosurg Psychiatry* 51:188-191

- Galloway (Ex.1100)

33. Ponsford SN: Sensory conduction in medial and lateral plantar nerves. *J Neurol Neurosurg Psychiatry* 1988, 51:188-91.



See IPR2024-01375, Paper 15 at 16 (citing Ex. 1099 at 320 (ref.23), Ex. 1100 at 9 (ref. 33).

Exemplary Evidence Demonstrating Other “Journal Articles” Are Prior Art Printed Publications

- **Hermens (Ex.1028)**

- Hallmarks of printed publication - published in volume 10 of the *Journal of Electromyography and Kinesiology* on pages 361-74 in 2000
- Copyright information “© Elsevier Science Ltd.”
- Properly authenticated; no objections to authenticity or hearsay by Patent Owner

See IPR2024-01375, Paper 15 at 8-10 (citing Ex.1028 at 361), 10 (citing Ex.1053 at ¶ 22), Paper 21 at 5; IPR2024-01378, Paper 15 at 8-10, Paper 21 at 5.

- **Hasan (Ex.1030)**

- Hallmarks of printed publication - published in volume 155(6) of *The Journal of Urology* on pages 2005-11 in June 1996
- “ISSN: 0022-5347” and “Accession: 00076734-199606000-00055”
- Properly authenticated; no objections to authenticity or hearsay by Patent Owner
- Corroborating evidence
 - Slovak (Ex.1092) at 100 (reference 12)
 - Guo (Ex.1095) at 856 (reference 24)

See IPR2024-01375, Paper 15 at 8-10 (citing Ex.1030 at 1), 10 (citing Ex.1053 at ¶ 24), 16 (citing Ex.1092 at 100 (ref. 12), Ex.1095 at 856 (ref. 24)), Paper 21 at 5; IPR2024-01378, Paper 15 at 8-10, Paper 21 at 5.

- **Hof (Ex.1042)**

- Hallmarks of printed publication - published in volume 3 of *Human Movement Science* on pages 119-153 in 1984
- Copyright information “© 1984, Elsevier Science Publishers B.V.”
- Properly authenticated; no objections to authenticity or hearsay by Patent Owner

See IPR2024-01375, Paper 15 at 8-10 (citing Ex.1042 at 119), 10 (citing Ex.1053 at ¶ 35), Paper 21 at 5; IPR2024-01378, Paper 15 at 8-10, Paper 21 at 5.

- **Noordhout (Ex.1043)**

- Hallmarks of printed publication - published in volume 51 of *Journal of Neurology, Neurosurgery, and Psychiatry* on pages 174-81 in 1988
- “Received 1 May 1987 and in revised form 20 July 1987” and “Accepted 27 July 1987”
- Properly authenticated; no objections to authenticity or hearsay by Patent Owner

See IPR2024-01375, Paper 15 at 8-10 (citing Ex.1043 at 174), 10 (citing Ex.1053 at ¶ 36); Paper 21 at 5; IPR2024-01378, Paper 15 at 8-10, Paper 21 at 5.

All “Journal Articles” Are Prior Art Printed Publications

Exhibit	Use	Printed Publication Hallmarks?
Ex.1008	Background, state of the art	✓
Ex.1009	Background, state of the art	✓
Ex.1010	Background, state of the art	✓
Ex.1011	Background, state of the art	✓
Ex.1012	Background, state of the art	✓
Ex.1013	Background, state of the art	✓
Ex.1014	Background, state of the art	✓
Ex.1015	Background, state of the art	✓
Ex.1016	Background, state of the art	✓
Ex.1017	Background, state of the art	✓
Ex.1024	State of the art, knowledge of POSA	✓
Ex.1027	State of the art, knowledge of POSA	✓
Ex.1035	State of the art, knowledge of POSA	✓
Ex.1037	State of the art, knowledge of POSA	✓
Ex.1038	State of the art, knowledge of POSA	✓
Ex.1039	State of the art, knowledge of POSA	✓
Ex.1041	Background, state of the art, knowledge of POSA	✓
Ex.1064	State of the art, knowledge of POSA	✓
Ex.1065	State of the art, knowledge of POSA	✓
Ex. 1088	Background, state of the art	✓

See IPR2024-01375, Paper 15 at 2, 8-10; IPR2024-01378, Paper 15 at 2, 8-10, 16n.3.

Petitioner Avation Medical, Inc., IPR Nos. 2024-01375, 2024-01378

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Limited Issues in Dispute Across IPRs

- IPR2024-01375 ('742 Patent)

- Prior art status of Journal Articles

- **Svihra** is a printed publication



- **Amarenco** is a printed publication



- **Ponsford** is a printed publication



- Prior art discloses “directly” targeting and stimulating PTN branches

- IPR2024-01378 ('477 Patent)

- Prior art status of Journal Articles

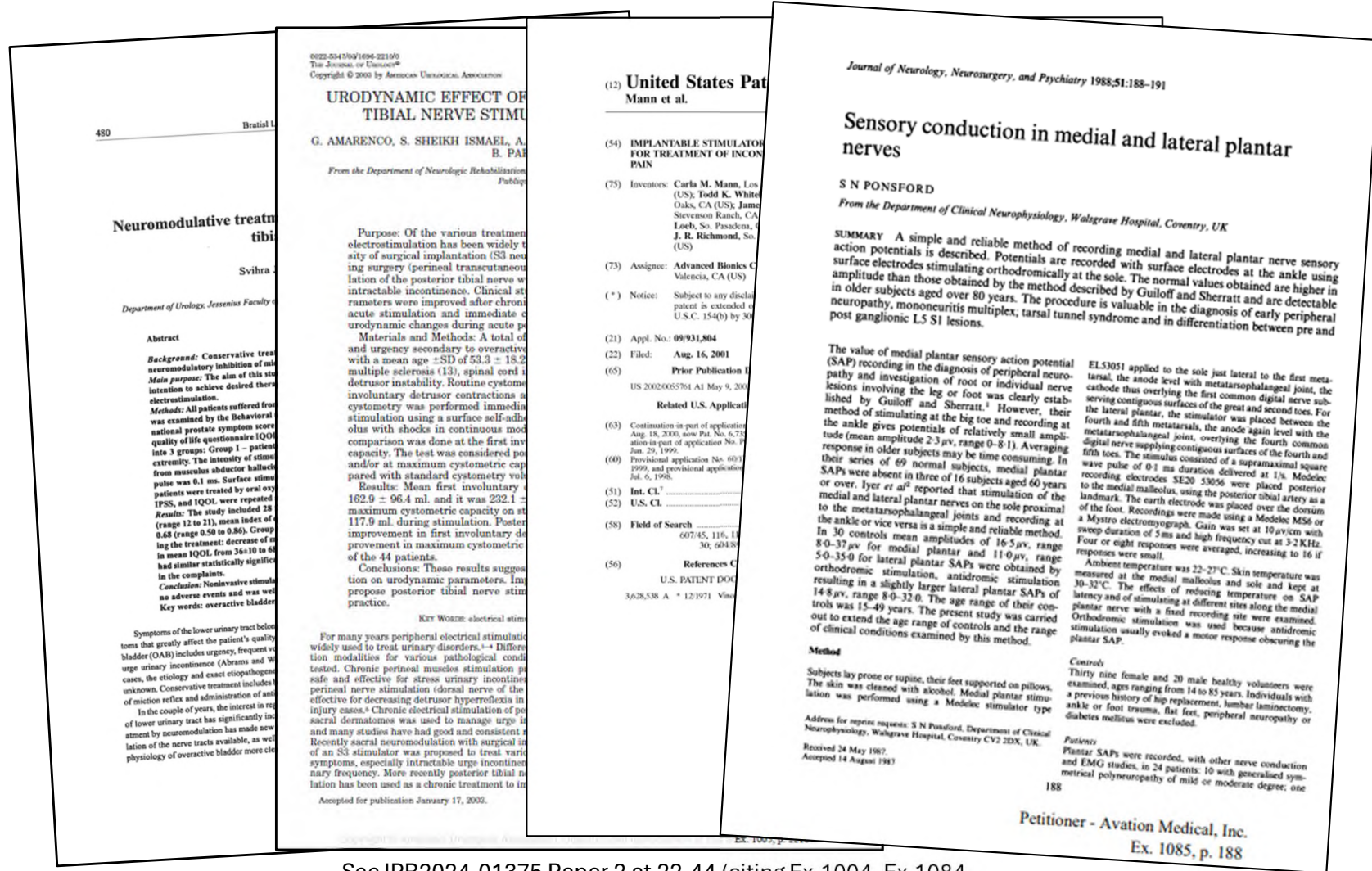
- **Svihra** is a printed publication



- **Amarenco** is a printed publication



Claims 1-13 of the '742 Patent Are Unpatentable



See IPR2024-01375 Paper 2 at 22-44 (citing Ex.1004, Ex.1084, Ex.1085), 44-63 (citing Ex.1005, Ex.1084, Ex.1085).

Petitioner Avation Medical, Inc., IPR Nos. 2024-01375, 2024-01378

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Invalidity Grounds (IPR2024-01375)

1. §103: **Svihra** + Mann + Ponsford
+ POSITA (claims 1-13)

2. §103: **Amarenco** + Mann +
Ponsford + POSITA (claims 1-13)

See IPR2024-01375, Paper 2 at 2-3.

No Dispute that Svihra Discloses Essentially All Elements

Main purpose: The aim of this study was to use non-invasive stimulation of the tibial nerve with the intention to achieve desired therapeutic effects without iatrogenic nerve damage using a superficial electrostimulation.

Methods: All patients suffered from overactive bladder (OAB) without bladder outlet obstruction. OAB was examined by the Behavioral urge score BUS (0.0 – the best and 1.0 – the worst score), the International prostate symptom score IPSS (0 – the best and 35 – the worst score) and the Incontinence quality of life questionnaire IQOL (0.0 – the worst and 1.0 – the best index). The patients were divided into 3 groups: Group I – patients with electrode attached behind the medial ankle of the left lower extremity. The intensity of stimulation corresponded to 70 % of the maximum amplitude of response from musculus abductor hallucis. Frequency of stimulation was 1 Hz and duration of the square impulse was 0.1 ms. Surface stimulation lasted 30 minutes and was repeated once a week. Group II – patients were treated by oral oxybutynin 5 mg t.i.d. Group III – patients without treatment. The BUS, IPSS, and IQOL were repeated after the treatment.

Results: The study included 28 females of average age 54 year (range 45 to 63). Mean IPSS was 17 (range 12 to 21), mean index of quality of life IQOL was 30 (range 12 to 78) and mean BUS score was 0.68 (range 0.50 to 0.86). Group I with stimulation did achieve statistically significant changes following the treatment: decrease of mean IPSS from 17 ± 3 points to 6 ± 4 points after the treatment, increase in mean IQOL from 36 ± 10 to 68 ± 20 and decrease of mean BUS from 0.65 ± 0.12 to 0.43 ± 0.16 . Group II had similar statistically significant differences after the treatment of OAB. Group III noted no changes in the complaints.

Conclusion: Noninvasive stimulation had improved subjective symptom related to overactive bladder, had no adverse events and was well tolerated. (Fig. 1, Tab. 1, Ref. 18.)

(12): 480–483

T
active bladder – noninvasive
stimulation

ek J, Kliment J

University, Martin, Slovakia svihra@jfmf.uniba.sk

bladder employs behavioral or invasive
stimulation of anticholinergic drugs.
stimulation of the tibial nerve with the
iatrogenic nerve damage using a superficial

(B) without bladder outlet obstruction. OAB
the best and 1.0 – the worst score), the Inter-
35 – the worst score) and the Incontinence
– the best index). The patients were divided
behind the medial ankle of the left lower
% of the maximum amplitude of response
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Group III noted no changes in the complaints.

symptom related to overactive bladder, had
Ref. 18.)
tibial nerve, anticholinergics.

stimulation is one of invasive and financially demanding meth-
ods. The rise to the development of minimally invasive periph-
eral nerve stimulation (Stoller, 1999).

Department of Urology and Department of Neurology, Jessenius Facul-
ty of Medicine, Comenius University, Martin, Slovakia
For correspondence: J. Svihra, MD, PhD, Dept of Urology,
K. Kollarova 2, SK-036 59 Martin, Slovakia.
Fax: +421 43 4133034
This study is a part of research granted by the Ministry of Education of
the Slovak Republic VEGA 1/0147/01.

Petitioner - Avation Medical, Inc.
Ex. 1004, p. 480

See IPR2024-01375, Paper 2 at 22-32 (citing
Ex.1004 at 480).

No Dispute that Amarengo Discloses Essentially All Elements

Purpose: Of the various treatments proposed for urge incontinence, frequency and urgency electrostimulation has been widely tested. Different techniques have been used with the necessity of surgical implantation (S3 neuromodulation or sacral root stimulation) or without requiring surgery (perineal transcutaneous electrostimulation). Recently peripheral electrical stimulation of the posterior tibial nerve was proposed for irritative symptoms in first intention or for intractable incontinence. Clinical studies have demonstrated good results and urodynamic parameters were improved after chronic treatment. However, to our knowledge no data concerning acute stimulation and immediate cystometry modifications have been reported. We verified urodynamic changes during acute posterior tibial nerve stimulation.

Materials and Methods: A total of 44 consecutive patients with urge incontinence, frequency and urgency secondary to overactive bladder were studied. There were 29 women and 15 men with a mean age $\pm$ SD of 53.3 ± 18.2 years. Of the patients 37 had detrusor hyperreflexia due to multiple sclerosis (13), spinal cord injury (15) or Parkinson's disease (9), and 7 had idiopathic detrusor instability. Routine cystometry at 50 ml. per minute was done to select the patients with involuntary detrusor contractions appearing before 400 ml. maximum filling volume. Repeat cystometry was performed immediately after the first study during left posterior tibial nerve stimulation using a surface self-adhesive electrode on the ankle skin behind the internal malleolus with shocks in continuous mode at 10 Hz. frequency and 200 milliseconds wide. Volume comparison was done at the first involuntary detrusor contraction and at maximum cystometric capacity. The test was considered positive if volume at the first involuntary detrusor contraction and/or at maximum cystometric capacity increased 100 ml. or 50% during stimulation in compared with standard cystometry volumes.

Results: Mean first involuntary detrusor contraction volume on standard cystometry was 162.9 ± 96.4 ml. and it was 232.1 ± 115.3 ml. during posterior tibial nerve stimulation. Mean maximum cystometric capacity on standard cystometry was 221 ± 129.5 ml. and it was 277.4 ± 117.9 ml. during stimulation. Posterior tibial nerve stimulation was associated with significant improvement in first involuntary detrusor contraction volume ($p < 0.0001$) and significant improvement in maximum cystometric capacity ($p < 0.0001$). The test was considered positive in 22 of the 44 patients.

Conclusions: These results suggest an objective acute effect of posterior tibial nerve stimulation on urodynamic parameters. Improved bladder overactivity is an encouraging argument to propose posterior tibial nerve stimulation as a noninvasive treatment modality in clinical practice.

Vol. 109, 2210-2215, June 2000
Printed in U.S.A.
DOI: 10.1097/01.ju.00000607446.17076.b4

ACUTE TRANSCUTANEOUS POSTERIOR TIBIAL NERVE STIMULATION IN OVERACTIVE BLADDER

EVEN-SCHNEIDER, P. RAIBAUT, S. DEMAÏLLE-WŁODYKA, J. KRATTE AND J. KERDRAON

Urodynamic and Neurophysiology Laboratory, Hôpital Bataillon, Assistance Publique-Hôpitaux de Paris, Paris, France

ABSTRACT

ts proposed for urge incontinence, frequency and urgency electrostimulation has been widely tested. Different techniques have been used with the necessity of surgical implantation (S3 neuromodulation or sacral root stimulation) or without requiring surgery (perineal transcutaneous electrostimulation). Recently peripheral electrical stimulation of the posterior tibial nerve was proposed for irritative symptoms in first intention or for intractable incontinence. Clinical studies have demonstrated good results and urodynamic parameters were improved after chronic treatment. However, to our knowledge no data concerning acute stimulation and immediate cystometry modifications have been reported. We verified urodynamic changes during acute posterior tibial nerve stimulation.

Materials and Methods: A total of 44 consecutive patients with urge incontinence, frequency and urgency secondary to overactive bladder were studied. There were 29 women and 15 men with a mean age $\pm$ SD of 53.3 ± 18.2 years. Of the patients 37 had detrusor hyperreflexia due to multiple sclerosis (13), spinal cord injury (15) or Parkinson's disease (9), and 7 had idiopathic detrusor instability. Routine cystometry at 50 ml. per minute was done to select the patients with involuntary detrusor contractions appearing before 400 ml. maximum filling volume. Repeat cystometry was performed immediately after the first study during left posterior tibial nerve stimulation using a surface self-adhesive electrode on the ankle skin behind the internal malleolus with shocks in continuous mode at 10 Hz. frequency and 200 milliseconds wide. Volume comparison was done at the first involuntary detrusor contraction and at maximum cystometric capacity. The test was considered positive if volume at the first involuntary detrusor contraction and/or at maximum cystometric capacity increased 100 ml. or 50% during stimulation in compared with standard cystometry volumes.

Results: Mean first involuntary detrusor contraction volume on standard cystometry was 162.9 ± 96.4 ml. and it was 232.1 ± 115.3 ml. during posterior tibial nerve stimulation. Mean maximum cystometric capacity on standard cystometry was 221 ± 129.5 ml. and it was 277.4 ± 117.9 ml. during stimulation. Posterior tibial nerve stimulation was associated with significant improvement in first involuntary detrusor contraction volume ($p < 0.0001$) and significant improvement in maximum cystometric capacity ($p < 0.0001$). The test was considered positive in 22 of the 44 patients.

Conclusions: These results suggest an objective acute effect of posterior tibial nerve stimulation on urodynamic parameters. Improved bladder overactivity is an encouraging argument to propose posterior tibial nerve stimulation as a noninvasive treatment modality in clinical practice.

stimulation, urodynamic, tibial nerve, urinary incontinence

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MATERIAL AND METHODS

Study design and subjects. The study group consisted of 44 patients with a history of voiding dysfunction. There were 29 women and 15 men with a mean age $\pm$ SD of 53.3 ± 18.2

2210

Petitotier - Avatronics Medical, Inc.
Ex. 1005, p. 2210

See IPR2024-01375, Paper 2 at 44-52 (citing Ex.1005 at 2210).

The '742 Patent Does Not Specifically Define “Directly” Targeting / Stimulating a Nerve

Based on my review of the '742 patent, the patent does not describe what “directly target[ing]” a nerve means in the context of noninvasive electrical stimulation, nor explain the difference between “targeting” a nerve versus “directly targeting” a nerve. Rather, the patent simply discloses providing stimulation by placing a variety of noninvasive devices over areas of the body that are intended to be stimulated. For example, Figure 11 of the '742 patent is the only embodiment shown in the patent that arguably shows noninvasive electrical stimulation of the posterior tibial nerve. Ex.1001 ('742 patent), Fig.11. Simply placing Svihra's surface electrodes over a branch of the posterior tibial nerve for the reasons discussed above would “directly target” the branch in the same way. Given that, as discussed above, the “surface electrodes” and/or the electrical stimulator source are an “electrical stimulator,” in my opinion a branch of the posterior tibial nerve within the first portion of the patients' bodies would be directly targeted by the electrical stimulator, as claimed.

Ex.1003 at ¶ 89 (see IPR2024-01375, Paper 2 at 30-31); see also Ex.1003 at ¶ 148 (see IPR2024-01375, Paper 2 at 51).

Dr. Brett Wingeier, PhD

U.S. Patent No. 11,224,742

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AVATION MEDICAL, INC.,
Petitioner

v.

EMKINETICS, INC.,
Patent Owner

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

EX. 1003 - DECLARATION OF DR. BRETT WINGEIER

Petitioner - Avation Medical, Inc.
Ex. 1003, p. 1

The Prior Art Discloses Treating OAB/Incontinence by Stimulating the PTN and Branches

 US006941171B2	
(12) United States Patent Mann et al.	(10) Patent No.: US 6,941,171 B2 (45) Date of Patent: Sep. 6, 2005

The 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. For instance,

(22) Filed: Aug. 16, 2001 (65) Prior Publication Data US 2002/0065761 A1 May 9, 2002	(74) Attorney, Agent, or Firm—Laura Hlubay Bishop, Bryant R. Gold (57) ABSTRACT A method and system for treatment of incontinence.
--	---

Another preferred stimulation location for purposes of the present invention is the tibial nerve. The tibial nerve is relatively easily accessible (i.e., relatively near the overlying skin with no muscle between the nerve and the skin) at two sites in the leg: at the level of the ankle, immediately posterior to the medial malleolus and posterior tibial artery and vein; and at the level of the knee, in the popliteal fossa (i.e., the back of the knee), immediately lateral to the popliteal artery and vein. Other sites along the tibial nerve, although not as easily accessible, are acceptable stimulation sites. Unilateral or bilateral stimulation is possible. For

 Petitioner - Avation Medical, Inc. Ex. 1084, p. 1

 US 2006/0122660 A1	
(19) United States (12) Patent Application Publication Boveja et al.	(10) Pub. No.: US 2006/0122660 A1 (43) Pub. Date: Jun. 8, 2006
(54) METHOD AND SYSTEM FOR MODULATING SACRAL NERVES AND/OR ITS BRANCHES IN A PATIENT TO PROVIDE THERAPY FOR UROLOGICAL DISORDERS AND/OR FECAL INCONTINENCE, USING RECTANGULAR AND/OR COMPLEX ELECTRICAL PULSES	Publication Classification (51) Int. Cl. A61N 1/08 (2006.01) (52) U.S. Cl. 607/40 (76) Inventors: Birinder R. Boveja, Milwaukee, WI US: Anand Wadhwa, Milwaukee (57) ABSTRACT

[0029] The rationale of this treatment modality is based on the existence of spinal inhibitory systems that are capable of interrupting a detrusor 392 contraction. Inhibition can be achieved by electrical stimulation of afferent anorectal branches of the pelvic nerve, afferent sensory fibers in the pudendal nerve and muscle afferents from the limbs. Most of these branches and fibers reach the spinal cord via the dorsal roots of the sacral nerves 54. Of the sacral nerve roots the S₃ root is the most practical for use in chronic pulsed electrical stimulation, although S₄ and S₂ along with S₃ may be stimulated.

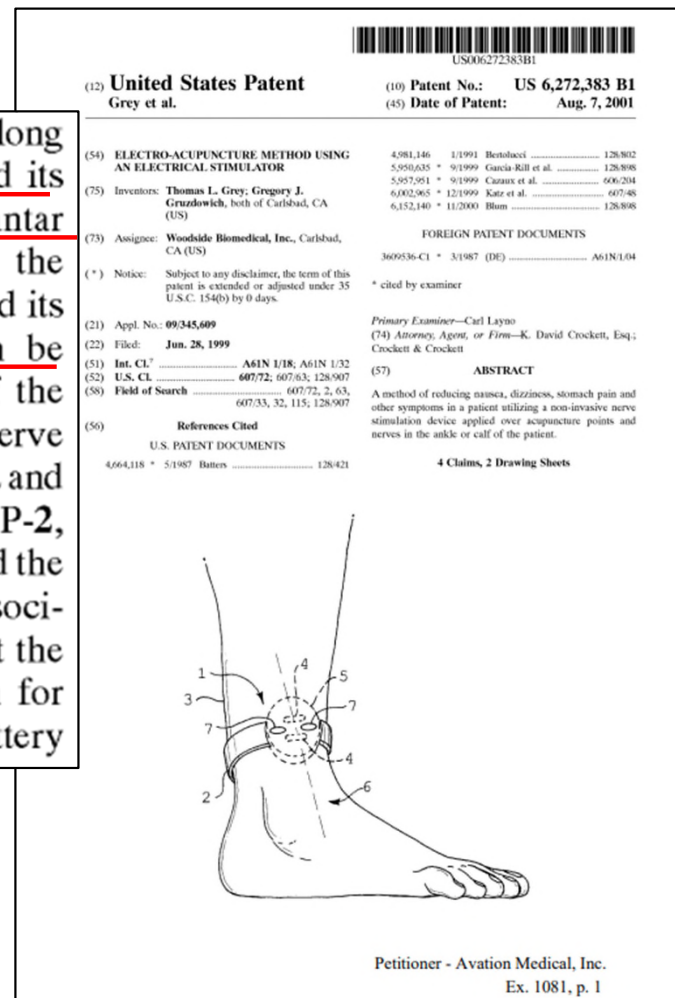

Petitioner - Avation Medical, Inc. Ex. 1080, p. 1

IPR2024-01375, Paper 2 at 24-25 (citing Ex.1084 at 11:50-12:7; Ex.1080 at [0029]), Paper 15 at 20-21.

The Prior Art Teaches that Conditions Treatable Via Electrostimulation of the PTN Can Also Be Treated by Stimulating PTN Branches

and can be stimulated to provide therapeutic relief. Along 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) and elements of the musculo-cutaneous nerve and its branches (generally traveling outside the ankle) can be stimulated to cause the same affect as stimulation of the traditional SP and BL acupuncture points. The tibial nerve and its branches run along the path established by the BL and SP acupuncture points. This indicates that, for the SP-2, SP-3 and SP-4 (Spleen Channel) acupuncture points, and the BL-55, BL-59, and BL-60 acupuncture points, their associated nerve structures can be stimulated by electrodes at the back of the ankle, since this is a convenient location for placement of a bracelet or wristwatch-like, wearable battery

IPR2024-01375, Paper 2 at 25 (citing Ex.1081 at 2:53-60), Paper 15 at 19-20.



The Prior Art Teaches that Directly Targeting / Stimulating PTN Branches Causes Signals to Travel Upstream to the Spinal Cord

80. Additionally, it was also well known by 2006 *how* to directly target branches of the posterior tibial nerve with electric stimulation, and that stimulation of branches of the posterior tibial nerve would induce signals in the tibial nerve itself that would necessarily propagate to the sacral plexus and related structures in the same manner as signals induced by stimulation of the tibial nerve itself. For example, Ponsford teaches “[a] simple and reliable method of recording medial and lateral plantar nerve sensory action potentials” in which “[p]otentials are recorded with surface electrodes at the ankle using surface electrodes stimulating orthodromically at the sole.” Ex.1085 (Ponsford), 188. According to Ponsford:

IPR2024-01375, Paper 2 at 25 (citing Ex.1003 at ¶ 80).

Declaration of Dr. Brett Wingeier, PhD

U.S. Patent No. 11,224,742

INTELLLECTUAL PROPERTY AND TRADEMARK OFFICE

INTELLLECTUAL PROPERTY TRIAL AND APPEAL BOARD

AVATION MEDICAL, INC.,
Petitioner

v.

BIOMECHANICAL KINETICS, INC.,
Patent Owner

PATENT NO. 11,224,742
No. IPR2024-01375

DECLARATION OF DR. BRETT WINGEIER

Petitioner - Avation Medical, Inc.
Ex. 1003, p. 1

The Prior Art Teaches How to Directly Target / Stimulate PTN Branches

SUMMARY A simple and reliable method of recording medial and lateral plantar nerve sensory action potentials is described. Potentials are recorded with surface electrodes at the ankle using surface electrodes stimulating orthodromically at the sole. The normal values obtained are higher in amplitude than those obtained by the method described by Guiloff and Sherratt and are detectable in older subjects aged over 80 years. The procedure is valuable in the diagnosis of early peripheral neuropathy, mononeuritis multiplex; tarsal tunnel syndrome and in differentiation between pre and post ganglionic L5 S1 lesions.

Neurosurgery, and Psychiatry 1988;51:188-191

duction in medial and lateral plantar

Clinical Neurophysiology, Walsgrave Hospital, Coventry, UK

Method

Subjects lay prone or supine, their feet supported on pillows. The skin was cleaned with alcohol. Medial plantar stimulation was performed using a Medelec stimulator type EL53051 applied to the sole just lateral to the first metatarsal, the anode level with metatarsophalangeal joint, the cathode thus overlying the first common digital nerve subserving contiguous surfaces of the great and second toes. For the lateral plantar, the stimulator was placed between the fourth and fifth metatarsals, the anode again level with the metatarsophalangeal joint, overlying the fourth common digital nerve supplying contiguous surfaces of the fourth and fifth toes. The stimulus consisted of a supramaximal square wave pulse of 0.1 ms duration delivered at 1/s. Medelec recording electrodes SE20 53056 were placed posterior to the medial malleolus, using the posterior tibial artery as a landmark. The earth electrode was placed over the dorsum of the foot. Recordings were made using a Medelec MS6 or a Mystro electromyograph. Gain was set at 10 $\mu\text{V}/\text{cm}$ with sweep duration of 5 ms and high frequency cut at 3.2 KHz. Four or eight responses were averaged, increasing to 16 if responses were small.

and reliable method of recording medial and lateral plantar nerve sensory action potentials is described. Potentials are recorded with surface electrodes at the ankle using surface electrodes stimulating orthodromically at the sole. The normal values obtained are higher in amplitude than those obtained by the method described by Guiloff and Sherratt and are detectable in older subjects aged over 80 years. The procedure is valuable in the diagnosis of early peripheral neuropathy, mononeuritis multiplex, tarsal tunnel syndrome and in differentiation between pre and post ganglionic L5 S1 lesions.

The value of medial plantar sensory action potential (SAP) recording in the diagnosis of peripheral neuropathy and investigation of root or individual nerve lesions involving the leg or foot was clearly established by Guiloff and Sherratt.¹ However, their method of stimulating at the big toe and recording at the ankle gives potentials of relatively small amplitude (mean amplitude 2.3 μV , range 0-8.1). Averaging response in older subjects may be time consuming. In their series of 69 normal subjects, medial plantar SAPs were absent in three of 16 subjects aged 60 years or over. Iyer *et al*² reported that stimulation of the medial and lateral plantar nerves on the sole proximal to the metatarsophalangeal joints and recording at the ankle or vice versa is a simple and reliable method. In 30 controls mean amplitudes of 16.5 μV , range 8.0-37 μV for medial plantar and 11.0 μV , range 5.0-35.0 for lateral plantar SAPs were obtained by orthodromic stimulation, antidromic stimulation resulting in a slightly larger lateral plantar SAPs of 14.8 μV , range 8.0-32.0. The age range of their controls was 15-49 years. The present study was carried out to extend the age range of controls and the range of clinical conditions examined by this method.

EL53051 applied to the sole just lateral to the first metatarsal, the anode level with metatarsophalangeal joint, the cathode thus overlying the first common digital nerve subserving contiguous surfaces of the great and second toes. For the lateral plantar, the stimulator was placed between the fourth and fifth metatarsals, the anode again level with the metatarsophalangeal joint, overlying the fourth common digital nerve supplying contiguous surfaces of the fourth and fifth toes. The stimulus consisted of a supramaximal square wave pulse of 0.1 ms duration delivered at 1/s. Medelec recording electrodes SE20 53056 were placed posterior to the medial malleolus, using the posterior tibial artery as a landmark. The earth electrode was placed over the dorsum of the foot. Recordings were made using a Medelec MS6 or a Mystro electromyograph. Gain was set at 10 $\mu\text{V}/\text{cm}$ with sweep duration of 5 ms and high frequency cut at 3.2 KHz. Four or eight responses were averaged, increasing to 16 if responses were small.

Method

Subjects lay prone or supine, their feet supported on pillows. The skin was cleaned with alcohol. Medial plantar stimulation was performed using a Medelec stimulator type

Controls

Thirty nine female and 20 male healthy volunteers were examined, ages ranging from 14 to 85 years. Individuals with a previous history of hip replacement, lumbar laminectomy, ankle or foot trauma, flat feet, peripheral neuropathy or diabetes mellitus were excluded.

Address for reprint requests: S N Pandorf, Department of Clinical Neurophysiology, Walsgrave Hospital, Coventry CV2 2DX, UK.

Received 24 May 1987
Accepted 14 August 1987

Patients

Plantar SAPs were recorded, with other nerve conduction and EMG studies, in 24 patients: 10 with generalised symmetrical polyneuropathy of mild or moderate degree, one

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Petitioner - Avation Medical, Inc.
Ex. 1085, p. 188

IPR2024-01375, Paper 2 at 25 (citing Ex.1085 at 188).

Dr. Wingeier Confirms Obviousness of Directly Targeting / Stimulating PTN Branches

Declaration of Dr. Brett Wingeier, PhD

U.S. Patent No. 11,224,742

84. Based on these disclosures in the prior art, in my opinion it would have been obvious to modify Svihra's procedure to directly target and deliver stimulation to a branch of the posterior tibial nerve with electric stimulation. First,

IPR2024-01375, Paper 2 at 27-28 (citing Ex.1003 at ¶ 84).

AVATION MEDICAL, INC.,
Petitioner

v.

EMKINETICS, INC.,

143. Based on these disclosures in the prior art, in my opinion, it would have been obvious to modify Amarenco's procedure to directly target and deliver stimulation to a branch of the posterior tibial nerve with electric stimulation. First,

IPR2024-01375, Paper 2 at 48 (citing Ex.1003 at ¶ 143).

Petitioner - Avation Medical, Inc.
Ex. 1003, p. 1

Limited Issues in Dispute Across IPRs

- IPR2024-01375 ('742 Patent)

- Prior art status of Journal Articles

- **Svihra** is a printed publication 

- **Amarenco** is a printed publication 

- **Ponsford** is a printed publication 

- Prior art discloses “directly” targeting and stimulating PTN branches 

- IPR2024-01378 ('477 Patent)

- Prior art status of Journal Articles

- **Svihra** is a printed publication 

- **Amarenco** is a printed publication 

Claims 1-10 of the '477 Patent Are Unpatentable



See IPR2024-01378, Paper 2 at 14-43 (citing Ex.1004), 43-62 (citing Ex.1005).

Petitioner Avation Medical, Inc., IPR Nos. 2024-01375, 2024-01378
DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Invalidity Grounds (IPR2024-01378)

1. §102: **Svihra** (claim 1)
 2. §103: **Svihra** + Mann / DiLorenzo / Gerber / Bourget (claim 1)
 3. §103: **Svihra** + Mann / DiLorenzo / Gerber / Bourget + POSITA (claims 2-10)
4. §103: **Amarenco** + Mann / DiLorenzo / Gerber / Bourget (claim 1)
 5. §103: **Amarenco** + Mann / DiLorenzo / Gerber / Bourget + POSITA (claims 2-10)

See IPR2024-01378, Paper 2 at 3-4.

Grounds 1-3: Svihra (Ex.1004) Invalidates the Challenged Claims



Ex.1004 at 480; see IPR2024-01378, Paper 2 at 14-43.

Petitioner Avation Medical, Inc., IPR Nos. 2024-01375, 2024-01378
DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Svihra Discloses All Elements

Main purpose: The aim of this study was to use non-invasive stimulation of the tibial nerve with the intention to achieve desired therapeutic effects without iatrogenic nerve damage using a superficial electrostimulation.

Methods: All patients suffered from overactive bladder (OAB) without bladder outlet obstruction. OAB was examined by the Behavioral urge score BUS (0.0 – the best and 1.0 – the worst score), the International prostate symptom score IPSS (0 – the best and 35 – the worst score) and the Incontinence quality of life questionnaire IQOL (0.0 – the worst and 1.0 – the best index). The patients were divided into 3 groups: Group I – patients with electrode attached behind the medial ankle of the left lower extremity. The intensity of stimulation corresponded to 70 % of the maximum amplitude of response from musculus abductor hallucis. Frequency of stimulation was 1 Hz and duration of the square impulse was 0.1 ms. Surface stimulation lasted 30 minutes and was repeated once a week. Group II – patients were treated by oral oxybutynin 5 mg t.i.d. Group III – patients without treatment. The BUS, IPSS, and IQOL were repeated after the treatment.

Results: The study included 28 females of average age 54 year (range 45 to 63). Mean IPSS was 17 (range 12 to 21), mean index of quality of life IQOL was 30 (range 12 to 78) and mean BUS score was 0.68 (range 0.50 to 0.86). Group I with stimulation did achieve statistically significant changes following the treatment: decrease of mean IPSS from 17 ± 3 points to 6 ± 4 points after the treatment, increase in mean IQOL from 36 ± 10 to 68 ± 20 and decrease of mean BUS from 0.65 ± 0.12 to 0.43 ± 0.16 . Group II had similar statistically significant differences after the treatment of OAB. Group III noted no changes in the complaints.

Conclusion: Noninvasive stimulation had improved subjective symptom related to overactive bladder, had no adverse events and was well tolerated. (Fig. 1, Tab. 1, Ref. 18.)

(12): 480–483

T
active bladder – noninvasive
stimulation

ek J, Kliment J

University, Martin, Slovakia svihra@jfmf.uniba.sk

bladder employs behavioral or invasive
stimulation of anticholinergic drugs.
stimulation of the tibial nerve with the
iatrogenic nerve damage using a superficial

(B) without bladder outlet obstruction. OAB
the best and 1.0 – the worst score), the Inter-
35 – the worst score) and the Incontinence
– the best index). The patients were divided
behind the medial ankle of the left lower
% of the maximum amplitude of response
on was 1 Hz and duration of the square im-
pulse was repeated once a week. Group II –
III – patients without treatment. The BUS,

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symptom related to overactive bladder, had
Ref. 18.)
tibial nerve, anticholinergics.

stimulation is one of invasive and financially demanding meth-
ods. The aim of this study was to use non-invasive stimulation of the tibial nerve with the
intention to achieve desired therapeutic effects without iatrogenic nerve damage using a superficial
electrostimulation SANS (Stoller, 1999).

Department of Urology and Department of Neurology, Jessenius Faculty
of Medicine, Comenius University, Martin, Slovakia
For correspondence: J. Svihra, MD, PhD, Dept of Urology,
K. Kollarova 2, SK-036 59 Martin, Slovakia.
Fax: +421 43 4133034
This study is a part of research granted by the Ministry of Education of
the Slovak Republic VEGA 1/0147/01.

Petitioner - Avation Medical, Inc.
Ex. 1004, p. 480

See IPR2024-01378, Paper 2 at 14-43 (citing Ex.1004 at 480).

Dr. Wingeier Confirms Svihra Discloses All Elements

Declaration of Dr. Brett Wingeier, PhD

U.S. Patent No. 9,002,477

- Claim 1 is anticipated under 35 U.S.C. § 102 by Svihra (Ex.1004);
- Claim 1 is rendered obvious under 35 U.S.C. § 103 by Svihra (Ex.1004) in combination with Mann (Ex.1084), DiLorenzo (Ex.1054), Gerber (Ex.1055), or Bourget (Ex.1056);
- Claims 2-10 are rendered obvious under 35 U.S.C. § 103 by Svihra (Ex.1004) alone or in combination with Mann (Ex.1084), DiLorenzo (Ex.1054), Gerber (Ex.1055), or Bourget (Ex.1056), further in view of the knowledge of a POSA;

U.S. PATENT AND TRADEMARK OFFICE

BOARD OF APPEALS AND APPEAL BOARD

Aviation Medical, Inc.,
Petitioner

Aviation Medical, Inc.,
Attorney

U.S. Patent No. 9,002,477
24-01378

DR. BRETT WINGEIER

Petitioner - Aviation Medical, Inc.
Ex. 1003, p. 1

See IPR2024-01378, Ex.1003 at ¶ 243.

Petitioner's Svihra Grounds 1-3 and Board's Findings on Institution Are Undisputed by Patent Owner

Trials@uspto.gov
571-272-7822

Paper 7
Entered: March 18, 2025

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

We conclude that Petitioner has identified sufficient reason that skilled artisans would have modified Svihra's approach to incorporate the systems and techniques of Mann, DiLorenzo, Gerber, and Bourget, and that the asserted combination renders obvious claim 1's limitations. Accordingly, this ground supports institution.

VIN,

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314

See IPR2024-01378, Paper 7 at 31.

Grounds 4-5: Amarengo (Ex.1005) Invalidates the Challenged Claims



Ex.1005 at 2210; see IPR2024-01378, Paper 2 at 43-62.

Amarengo Discloses All Elements

Purpose: Of the various treatments proposed for urge incontinence, frequency and urgency electrostimulation has been widely tested. Different techniques have been used with the necessity of surgical implantation (S3 neuromodulation or sacral root stimulation) or without requiring surgery (perineal transcutaneous electrostimulation). Recently peripheral electrical stimulation of the posterior tibial nerve was proposed for irritative symptoms in first intention or for intractable incontinence. Clinical studies have demonstrated good results and urodynamic parameters were improved after chronic treatment. However, to our knowledge no data concerning acute stimulation and immediate cystometry modifications have been reported. We verified urodynamic changes during acute posterior tibial nerve stimulation.

Materials and Methods: A total of 44 consecutive patients with urge incontinence, frequency and urgency secondary to overactive bladder were studied. There were 29 women and 15 men with a mean age $\pm$ SD of 53.3 ± 18.2 years. Of the patients 37 had detrusor hyperreflexia due to multiple sclerosis (13), spinal cord injury (15) or Parkinson's disease (9), and 7 had idiopathic detrusor instability. Routine cystometry at 50 ml. per minute was done to select the patients with involuntary detrusor contractions appearing before 400 ml. maximum filling volume. Repeat cystometry was performed immediately after the first study during left posterior tibial nerve stimulation using a surface self-adhesive electrode on the ankle skin behind the internal malleolus with shocks in continuous mode at 10 Hz. frequency and 200 milliseconds wide. Volume comparison was done at the first involuntary detrusor contraction and at maximum cystometric capacity. The test was considered positive if volume at the first involuntary detrusor contraction and/or at maximum cystometric capacity increased 100 ml. or 50% during stimulation in compared with standard cystometry volumes.

Results: Mean first involuntary detrusor contraction volume on standard cystometry was 162.9 ± 96.4 ml. and it was 232.1 ± 115.3 ml. during posterior tibial nerve stimulation. Mean maximum cystometric capacity on standard cystometry was 221 ± 129.5 ml. and it was 277.4 ± 117.9 ml. during stimulation. Posterior tibial nerve stimulation was associated with significant improvement in first involuntary detrusor contraction volume ($p < 0.0001$) and significant improvement in maximum cystometric capacity ($p < 0.0001$). The test was considered positive in 22 of the 44 patients.

Conclusions: These results suggest an objective acute effect of posterior tibial nerve stimulation on urodynamic parameters. Improved bladder overactivity is an encouraging argument to propose posterior tibial nerve stimulation as a noninvasive treatment modality in clinical practice.

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ACUTE TRANSCUTANEOUS POSTERIOR TIBIAL NERVE STIMULATION IN OVERACTIVE BLADDER

EVEN-SCHNEIDER, P. RAIBAUT, S. DEMAÏLLE-WŁODYKA, J. GRATTE AND J. KERDRAON

Urodynamic and Neurophysiology Laboratory, Hôpital Bataillon, Assistance Publique-Hôpitaux de Paris, Paris, France

ABSTRACT

Its proposed for urge incontinence, frequency and urgency electrostimulation. Different techniques have been used with the necessity of surgical implantation (S3 neuromodulation or sacral root stimulation) or without requiring surgery (perineal transcutaneous electrostimulation). Recently peripheral electrical stimulation of the posterior tibial nerve was proposed for irritative symptoms in first intention or for intractable incontinence. Clinical studies have demonstrated good results and urodynamic parameters were improved after chronic treatment. However, to our knowledge no data concerning acute stimulation and immediate cystometry modifications have been reported. We verified urodynamic changes during acute posterior tibial nerve stimulation.

Materials and Methods: A total of 44 consecutive patients with urge incontinence, frequency and urgency secondary to overactive bladder were studied. There were 29 women and 15 men with a mean age $\pm$ SD of 53.3 ± 18.2 years. Of the patients 37 had detrusor hyperreflexia due to multiple sclerosis (13), spinal cord injury (15) or Parkinson's disease (9), and 7 had idiopathic detrusor instability. Routine cystometry at 50 ml. per minute was done to select the patients with involuntary detrusor contractions appearing before 400 ml. maximum filling volume. Repeat cystometry was performed immediately after the first study during left posterior tibial nerve stimulation using a surface self-adhesive electrode on the ankle skin behind the internal malleolus with shocks in continuous mode at 10 Hz. frequency and 200 milliseconds wide. Volume comparison was done at the first involuntary detrusor contraction and at maximum cystometric capacity. The test was considered positive if volume at the first involuntary detrusor contraction and/or at maximum cystometric capacity increased 100 ml. or 50% during stimulation in compared with standard cystometry volumes.

Results: Mean first involuntary detrusor contraction volume on standard cystometry was 162.9 ± 96.4 ml. and it was 232.1 ± 115.3 ml. during posterior tibial nerve stimulation. Mean maximum cystometric capacity on standard cystometry was 221 ± 129.5 ml. and it was 277.4 ± 117.9 ml. during stimulation. Posterior tibial nerve stimulation was associated with significant improvement in first involuntary detrusor contraction volume ($p < 0.0001$) and significant improvement in maximum cystometric capacity ($p < 0.0001$). The test was considered positive in 22 of the 44 patients.

Conclusions: These results suggest an objective acute effect of posterior tibial nerve stimulation on urodynamic parameters. Improved bladder overactivity is an encouraging argument to propose posterior tibial nerve stimulation as a noninvasive treatment modality in clinical practice.

Key words: urge incontinence, frequency, urgency, electrostimulation, tibial nerve, urinary incontinence

Urinary incontinence and frequency.¹⁻¹⁰ Surprisingly sparse urodynamic data on the efficacy of chronic posterior tibial nerve stimulation are available. Moreover, urodynamic parameters evaluations have only been reported before and after chronic treatment with posterior tibial nerve stimulation.¹¹ Indeed, to our knowledge no study has been performed to determine urodynamic effects following acute posterior tibial nerve stimulation. We studied by urodynamic investigation possible detrusor activity modifications during acute tibial nerve stimulation in a population presenting with symptoms (urge incontinence and frequency) secondary to overactive bladder.

MATERIAL AND METHODS

Study design and subjects. The study group consisted of 44 patients with a history of voiding dysfunction. There were 29 women and 15 men with a mean age $\pm$ SD of 53.3 ± 18.2

2210

Petitotier - Avatronic Medical, Inc.
Ex. 1005, p. 2210

See IPR2024-01378, Paper 2 at 43-62 (citing Ex.1005 at 2210).

Dr. Wingeier Confirms Amarenco Discloses All Elements

Declaration of Dr. Brett Wingeier, PhD

U.S. Patent No. 9,002,477

- Claim 1 is rendered obvious under 35 U.S.C. § 103 by Amarenco (Ex.1005) in combination with Mann (Ex.1084), DiLorenzo (Ex.1054), Gerber (Ex.1055), or Bourget (Ex.1056);

OFFICE

BOARD

AVATION MEDICAL, INC.,
Petitioner

- Claims 2-10 are rendered obvious under 35 U.S.C. § 103 by Amarenco (Ex.1005) in combination with Mann (Ex.1084), DiLorenzo (Ex.1054), Gerber (Ex.1055), or Bourget (Ex.1056), further in view of the knowledge of a POSA.

WINGEIER

Petitioner - Avation Medical, Inc.
Ex. 1003, p. 1

See IPR2024-01378, Ex.1003 at ¶ 243.

Petitioner's Amarengo Grounds 4-5 and Board's Findings on Institution Are Undisputed by Patent Owner

Trials@uspto.gov
571-272-7822

Paper 7
Entered: March 18, 2025

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Other than as discussed above, Patent Owner does not contest Petitioner's showing regarding obviousness of claim 1 over Amarengo in combination with Mann, DiLorenzo, Bourget, or Gerber. We have reviewed Petitioner's contentions, including the uncontested aspects, and conclude that Petitioner has adequately supported institution. *See Pet. 43–50.*

Granting Institution of *Inter Partes* Review
35 U.S.C. § 314

See IPR2024-01378, Paper 7 at 35.

Claims 1-13 of the '742 Patent and Claims 1-10 of the '477 Patent Are Unpatentable

- Svihra is a prior art printed publication
- Amarenco is a prior art printed publication
- Ponsford is a prior art printed publication
- The prior art discloses “directly” targeting and stimulating PTN branches
- ***The Board should find Petitioner has proven, by a preponderance of the evidence, that claims 1-13 of the '742 Patent and claims 1-10 of the '477 Patent are unpatentable***

Back-Up Slides

Patent Owner's Motions to Exclude

Rebuttal Evidence on Reply Is Permissible

- **37 C.F.R. § 42.23(b):**
 - “**A reply may only respond to arguments raised in the corresponding** opposition, patent owner preliminary response, **patent owner response**, or decision on institution. **A sur-reply** may only respond to arguments raised in the corresponding reply and **may not be accompanied by new evidence** other than deposition transcripts of the cross-examination of any reply witness.” See 37 C.F.R. § 42.23(b).

See IPR2024-01375, Paper 21 at 2; IPR2024-01378, Paper 21 at 2.

- **Consolidated Trial Practice Guide (Nov. 2019) at 73:**
 - “A party also **may submit rebuttal evidence in support of its reply.**”

See IPR2024-01375, Paper 21 at 2; IPR2024-01378, Paper 21 at 2.

- **Hulu, LLC v. Sound View Innovations, LLC, IPR2018-01039, Paper 29 at 14-15 (PTAB December 20, 2019) (precedential):**
 - “**[S]ome limited opportunities exist for the petitioner to present new evidence later, including:** (1) in a reply to a patent owner preliminary response; (2) **in a reply to the patent owner response**; and (3) in a motion to file supplemental information. 37 C.F.R. §§ 42.108(c), 42.23, 42.123. As to the first two opportunities, the evidence must be responsive to the prior briefing. . . .

For example, if the patent owner challenges a reference’s status as a printed publication, a petitioner may submit a supporting declaration with its reply to further support its argument that a reference qualifies as a printed publication. See 37 C.F.R. §§ 42.2 (affidavit), 42.23.”

See IPR2024-01375, Paper 21 at 3; IPR2024-01378, Paper 21 at 3.

Petitioner's Reply Evidence Properly Responded to Patent Owner Response

Paper 12

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AVATION MEDICAL, INC.,
Petitioner,
v.
EMKINETICS, INC.,
Patent Owner.

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

PATENT OWNER'S RESPONSE

1. **Grounds 1 & 2.** Petitioner has failed to carry its burden of proving that the non-patent references (Exs. 1004-05, 1008-17, 1024, 1027-28, 1030, 1035, 1037-39, 1041-43, 1085, 1088) cited in the Petition were publicly accessible before any alleged critical date and has failed to carry its attendant burden of proving that these references qualify as prior art. These references include the primary references on which both grounds in the Petition (Grounds 1 and 2) are based (Svihra, Ex. 1004; Amarenco, Ex. 1005), as well as many other references on

See IPR2024-01375, Paper 12 at 1.

Paper 12

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AVATION MEDICAL, INC.,
Petitioner,
v.
EMKINETICS, INC.,
Patent Owner.

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

PATENT OWNER'S RESPONSE

Petitioner has failed to carry its burden of proving that the non-patent references (Exs. 1004-05, 1008-17, 1028, 1030, 1041-43, 1064-65) cited in the Petition were publicly accessible before any alleged critical date and has failed to carry its attendant burden of proving that these references qualify as prior art. These references include the primary references on which all grounds in the Petition (Grounds 1-5) are based (Svihra, Ex. 1004; Amarenco, Ex. 1005), as well as many other references on which these grounds are based (Exs. 1008-17, 1028, 1030, 1041-43, 1064-65). Whether Petitioner has carried its burden of proving the

See IPR2024-01378, Paper 12 at 1.

Reply Evidence Is Not Supplemental Information

- **37 C.F.R. § 42.123:**

- Relates to filing of “supplemental information,” not reply evidence

See IPR2024-01375, Paper 21 at 5-6; IPR2024-01378, Paper 21 at 5-6.

- ***Hulu, LLC v. Sound View Innovations, LLC*, IPR2018-01039, Paper 66 (PTAB October 5, 2021):**

- Rejected patent owner’s contentions that because petitioner did not submit supplemental information, public accessibility evidence submitted with petitioner’s reply was untimely. *Id.* at 24-26.
- Board found new evidence of public accessibility of reference submitted with petitioner’s reply constituted proper rebuttal evidence and was permissible under PTAB rules. *Id.* at 26, 32-33.

See IPR2024-01375, Paper 21 at 4, 6-7; IPR2024-01378, Paper 21 at 4, 6-7.

Patent Owner Concedes Petitioner's Reply Evidence Was Proper

move to exclude such evidence, as Patent Owner seeks here. *Id.* While Patent Owner does not specifically contend that Petitioner raised an entirely “new issue” in Reply, the CTPG notes that “[e]xamples of indications that a new issue has been

See IPR2024-01375, Paper 22 at 3; see *also* IPR2024-01378, Paper 22 at 3.

But what happened here is that Petitioner tried to submit evidence in Reply (Paper 15) that it should have included with its case-in-chief, *i.e.*, the Petition

See IPR2024-01375, Paper 22 at 3; see *also* IPR2024-01378, Paper 22 at 3.

As discussed above, Patent Owner does *not* contend that Petitioner's Reply (Paper 15) exceeded the scope of a proper reply within the meaning of 37 C.F.R. § 42.23(b). Thus, the instruction in the CTPG, cited by Petitioner (Paper 21 (citing

See IPR2024-01375, Paper 22 at 4-5; see *also* IPR2024-01378, Paper 22 at 4.

Paper No. 22

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AVATION MEDICAL, INC.,

Petitioner,

v.

EMKINETICS, INC.,

Patent Owner

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

PATENT OWNER'S REPLY TO PETITIONER'S OPPOSITION TO
MOTION TO EXCLUDE EVIDENCE

‘742 Patent Claims 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.

‘477 Patent Claims Appendix

- **Claim 1:**
 - [1.p] A method of performing electrical stimulation therapy, comprising:
 - [1.a] non-invasively positioning a first portion of a patient's body relative to an electrical stimulator such that a posterior tibial nerve or branch thereof within the first portion of the body is in proximity to the electrical stimulator;
 - [1.b] passing a current through the electrical stimulator;
 - [1.c] delivering an electrical stimulus from the electrical stimulator to the posterior tibial nerve or branch thereof;
 - [1.d] detecting electrical conduction through the posterior tibial nerve or branch thereof or detecting a muscular response caused by an electrical conduction through the posterior tibial nerve or branch thereof via at least one sensor positioned along a second portion of the body;
 - [1.e] receiving a signal from the at least one sensor indicative of the detected electrical conduction or muscular response thereby providing feedback about the efficacy of the applied electrical stimulation therapy; and
 - [1.f] adjusting the current via a controller in communication with the electrical stimulator based on the feedback.
- **Claim 2:** The method of claim 1, wherein the electrical stimulus is delivered to the posterior tibial nerve or branch thereof to treat fecal incontinence.
- **Claim 3:** The method of claim 1, wherein the electrical stimulus is delivered to the posterior tibial nerve or branch thereof to treat restless leg syndrome.
- **Claim 4:** The method of claim 1, wherein the electrical stimulus is delivered to the posterior tibial nerve or branch thereof to treat premature ejaculation.
- **Claim 5:** The method of claim 1, wherein the electrical stimulus is delivered to the posterior tibial nerve or branch thereof to treat chronic pain.
- **Claim 6:** The method of claim 1, wherein the electrical stimulus is delivered to the posterior tibial nerve or branch thereof to treat osteoarthritis or arthritis.
- **Claim 7:** The method of claim 1, wherein the electrical stimulus is delivered to the posterior tibial nerve or branch thereof responsible for neuropathic pain to treat neuropathic pain.
- **Claim 8:** The method of claim 1, wherein the electrical stimulus is delivered to the posterior tibial nerve or branch thereof to treat neuralgia.
- **Claim 9:** The method of claim 1, wherein the electrical stimulus is delivered to the posterior tibial nerve or branch thereof to treat atrophy.
- **Claim 10:** The method of claim 1, wherein the electrical stimulus is delivered to the posterior tibial nerve or branch thereof to treat paralysis.