Avation Medical, Inc. v. EMKinetics, Inc.

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

Petitioner Avation Medical, Inc.'s Demonstratives

AVATION® MEDICAL

Patent Owner Does Not Substantively Challenge Petitioner's Invalidity Grounds

- ***No dispute*** that prior art discloses all limitations of claims 1-39 of the '943 Patent
- ***No dispute*** that prior art renders claims obvious
- Invalidity Grounds 1-10:

1. §102: Svihra (claims 1, 3-5)
2. §103: Svihra / POSITA (claims 2, 6-13)
3. §103: Svihra / Johnson (claims 14, 16-18, 27, 29-31)
4. §103: Svihra / Johnson / POSITA (claims 15, 19-26, 28, 32-39)

→ ***Undisputed by Patent Owner***

5. §102: Amarenco (claims 1-3, 5)
6. §103: Amarenco / POSITA (claims 4, 6-13)
7. §103: Amarenco / Johnson (claims 14-16, 18, 27-29, 31)
8. §103: Amarenco / Johnson / POSITA (claims 17, 19-26, 30, 32-39)

→ ***Undisputed by Patent Owner***

9. §102: Burnett (claims 1-3, 5-13)
10. §103: Burnett / Johnson / POSITA (claims 4, 14-39)

→ ***Undisputed by Patent Owner***

See Paper 12 at 1; Paper 2 at 2-3.

Limited Issues in Dispute

- Prior art status of Journal Articles
  - **Svihra** is a printed publication
  - **Amarenco** is a printed publication
- Prior art status of Burnett
  - **Burnett** is prior art to the claims of the '943 Patent

See Paper 12 at 1, 2-18, 18-22.

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* Paper 8 at 15.
- 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* Paper 12 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* Paper 12 at 4-5.

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.1085)
  - Slovak (Ex.1086)
  - Garcia (Ex.1087)



480 Bratisl Lek Listy 2002; 103 (12): 480–483

TREATMENT

Neuromodulative treatment of overactive bladder – noninvasive tibial nerve stimulation

Svihra J, Kurca E, Luptak J, Kliment J

Department of Urology, Jessenius Faculty of Medicine, Comenius University, Martin, Slovakia **svihru@jfmed.uniba.sk**

Abstract

Background: **Conservative treatment of overactive bladder employes behavioral or invasive neuromodulatory inhibition of miction reflex and administration of anticholinergic drugs.**
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.)***
Key words: overactive bladder, electric nerve stimulation, tibial nerve, anticholinergics.

Symptoms of the lower urinary tract belong to the set of symptoms that greatly affect the patient's quality of life. Overactive bladder (OAB) includes urgency, frequent voiding, nocturia, and urge urinary incontinence (Abrams and Wein, 2000). In most cases, the etiology and exact etiopathogenesis of the disease is unknown. Conservative treatment includes behavioral inhibition of miction reflex and administration of anticholinergic drugs.

In the couple of years, the interest in regulatory mechanisms of lower urinary tract has significantly increased. Invasive treatment by neuromodulation has made new possibilities in regulation of the nerve tracts available, as well as, made the pathophysiology of overactive bladder more clear. The fact, that neuromodulation is one of invasive and financially demanding method, gave rise to the development of minimally invasive peripheral stimulation SANS (Stoller, 1999).

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Phone/Fax: +421.43.4133034

The study is a part of research granted by the Ministry of Education of Slovak Republic VEGA 1/8147/01.

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

Ex.1004 at 480 (*see* Paper 12 at 6-8).

See Paper 1 at 21; Paper 12 at 2, 6-8, 10-11, 16.

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 Paper 12 at 6-7.



480 Bratisl Lek Listy 2002; 103 (12): 480–483

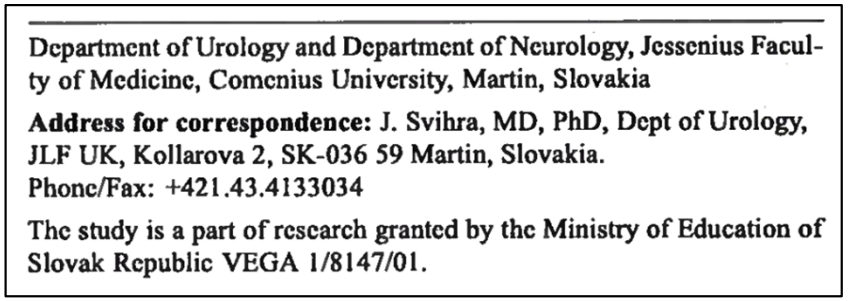
TREATMENT

Neuromodulative treatment of overactive bladder – noninvasive tibial nerve stimulation

Svihra J, Kurca E, Luptak J, Kliment J

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Ex.1004 at 480 (*see* Paper 12 at 6-7).

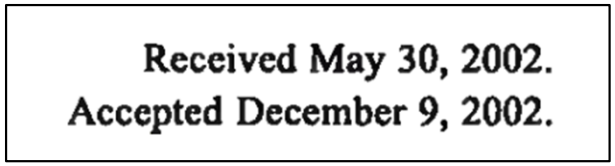


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Phone/Fax: +421.43.4133034

The study is a part of research granted by the Ministry of Education of Slovak Republic VEGA 1/8147/01.

Ex.1004 at 480 (*see* Paper 12 at 6-7).



Received May 30, 2002.
Accepted December 9, 2002.

Ex.1004 at 483 (*see* Paper 12 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 Paper 12 at 10-11 (citing Ex.1053 at ¶ 6).

- No objections to authenticity or hearsay by Patent Owner

See Paper 23 at 5.

- Dr. Wingeier confirmed Svihra was published and accessible

> 46. 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 discussed above—indeed, according to Svihra, "Stoller's stimulation belongs to

See Paper 12 at 10-11 (citing Ex.1003 at ¶ 46).

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 Paper 23 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 Paper 12 at 17-18.

Corroborating Evidence Confirms Svihra Was Published and Publicly Accessible

- **Sherif (Ex.1085)**

[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.1086)**

[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.1087)**



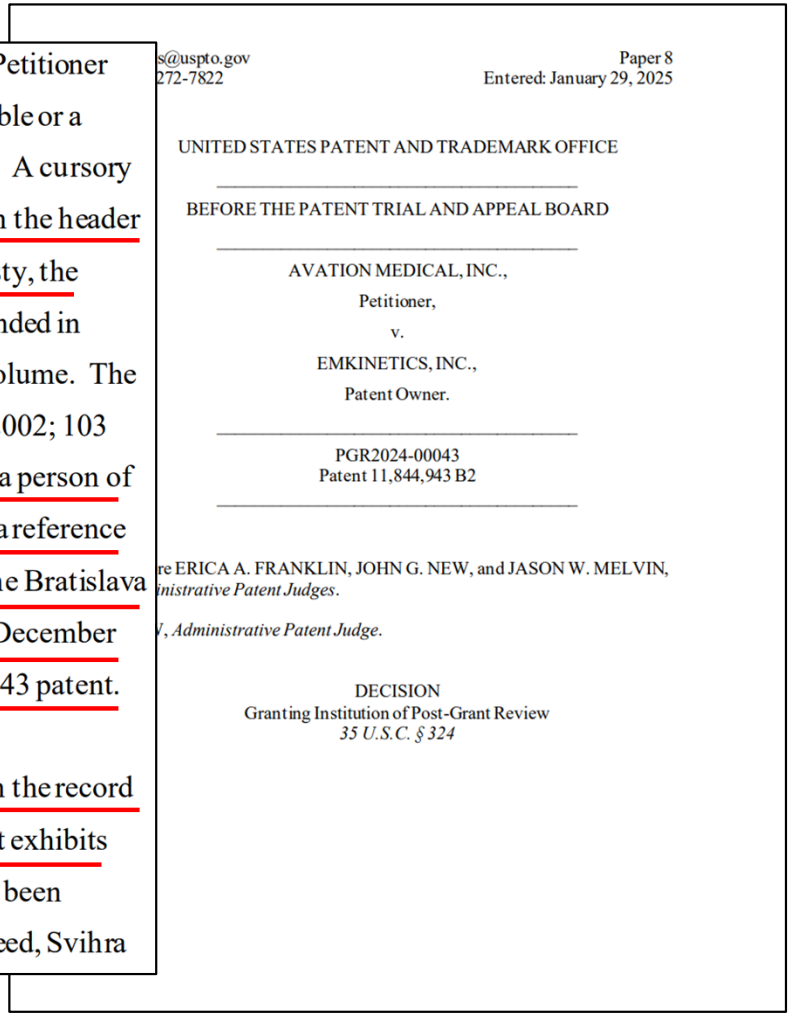
25) Svihra J, Kurca E, Luptak J, et al.: Neuromodulative treatment of overactive bladder—noninvasive tibial nerve stimulation. Bratisl Lek Listy (Tlacene Vyd), 2002, 103: 480–483 [Bratislava Medical Journal]. [Medline]

See Paper 12 at 16 (citing Ex.1085 at 135 (ref. 5), Ex.1086 at 100 (ref. 17), Ex.1087 at 1340 (ref. 25)).

The Board Found Svihra Is a Publicly Accessible Printed Publication

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

We conclude that, for the purposes of this Decision and on the record as presently developed, the Svihra reference more likely than not exhibits the necessary hallmarks of a printed publication that would have been publicly accessible as of the critical date of the '943 patent. Indeed, Svihra



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272-7822

Paper 8
Entered: January 29, 2025

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

PGR2024-00043
Patent 11,844,943 B2

re ERICA A. FRANKLIN, JOHN G. NEW, and JASON W. MELVIN,
inistrative Patent Judges.

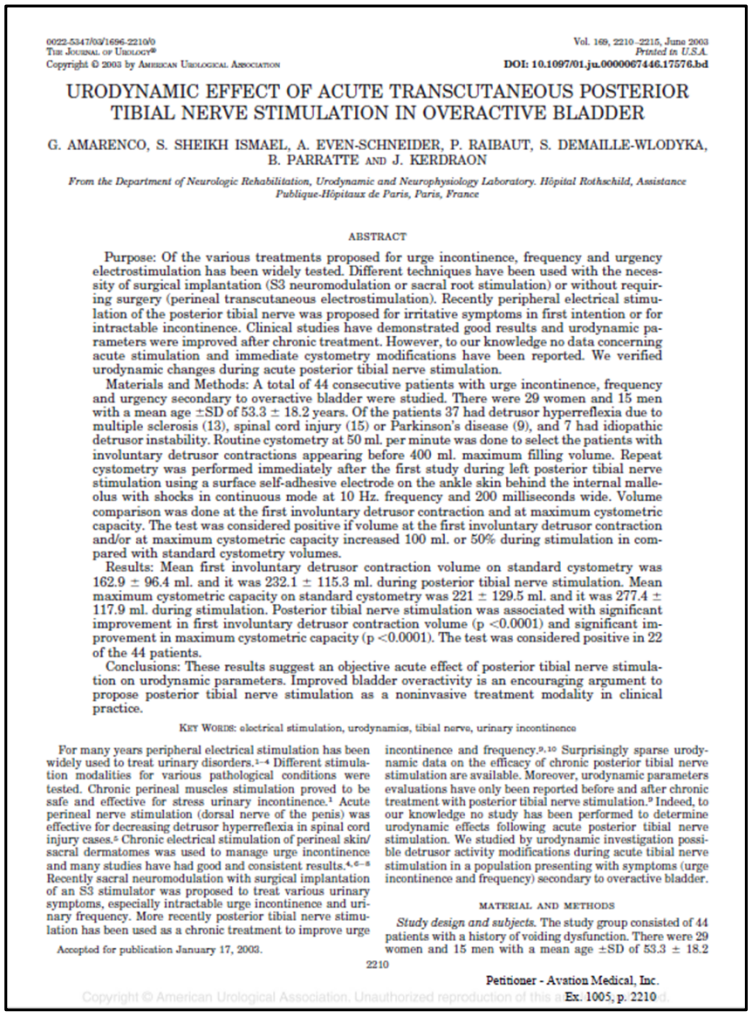
, Administrative Patent Judge.

DECISION
Granting Institution of Post-Grant Review
35 U.S.C. § 324

Paper 8 at 16; *see also* Paper 12 at 7-8.

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

- "Hallmarks" of printed publication
- Attorney declaration (Ex.1053)
- Wingeier declaration (Ex.1003)
- Institution Decision
- '943 Patent "References Cited"
- Amarenco II (Ex.1088)
- Corroborating references:
  - Queralto (Ex.1016)
  - Sherif (Ex.1085)
  - Slovak (Ex.1086)
  - Garcia (Ex.1087)
  - Guo (Ex.1089)



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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 ±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.[5] Chronic electrical stimulation of perineal skin/sacral dermatomes was used to manage urge incontinence and many studies have had good and consistent results.[4,6–8] 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.[9,10] 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.[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.

Accepted for publication January 17, 2003.

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 ±SD of 53.3 ± 18.2

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Ex. 1005, p. 2210
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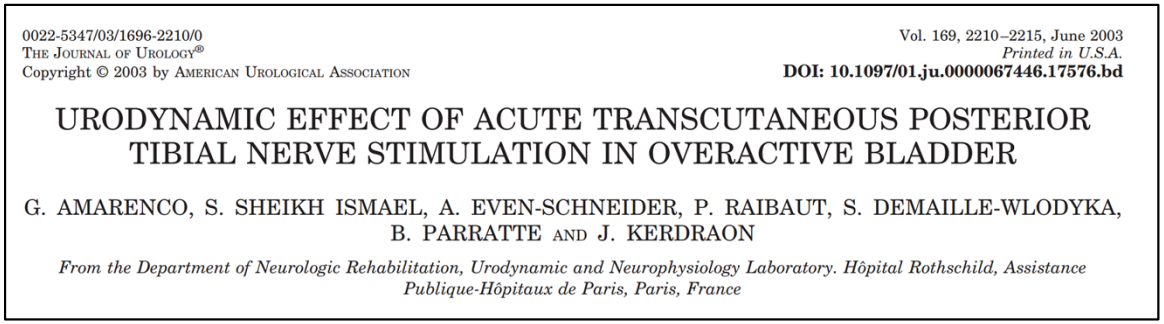
Ex.1005 at 2210 (*see* Paper 12 at 8-9).

See Paper 1 at 44; Paper 12 at 2, 8-9, 10-11, 16-17.

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 Paper 12 at 8-9.



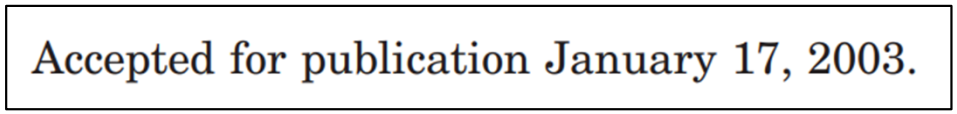
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URODYNAMIC EFFECT OF ACUTE TRANSCUTANEOUS POSTERIOR TIBIAL NERVE STIMULATION IN OVERACTIVE BLADDER

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



Accepted for publication January 17, 2003.

Ex.1005 at 2210 (*see* Paper 12 at 8-9).

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 Paper 12 at 10-11 (citing Ex.1053 at ¶ 7).

- No objections to authenticity or hearsay by Patent Owner

See Paper 23 at 5.

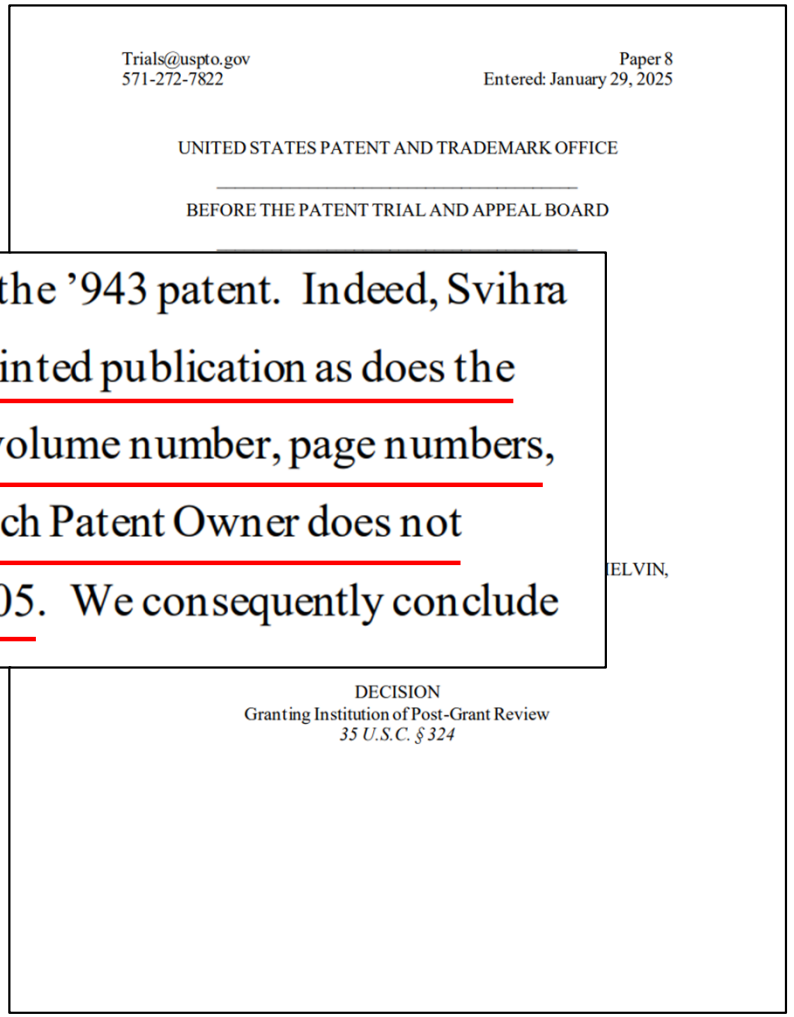
- Dr. Wingeier confirmed Amarenco was published and accessible

> 47. 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 Paper 12 at 10-11 (citing Ex.1003 at ¶ 47).

Petitioner Avation Medical, Inc., PGR2024-00043
DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

The Board Found Amarenco Includes Hallmarks of a Printed Publication



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571-272-7822

Paper 8
Entered: January 29, 2025

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

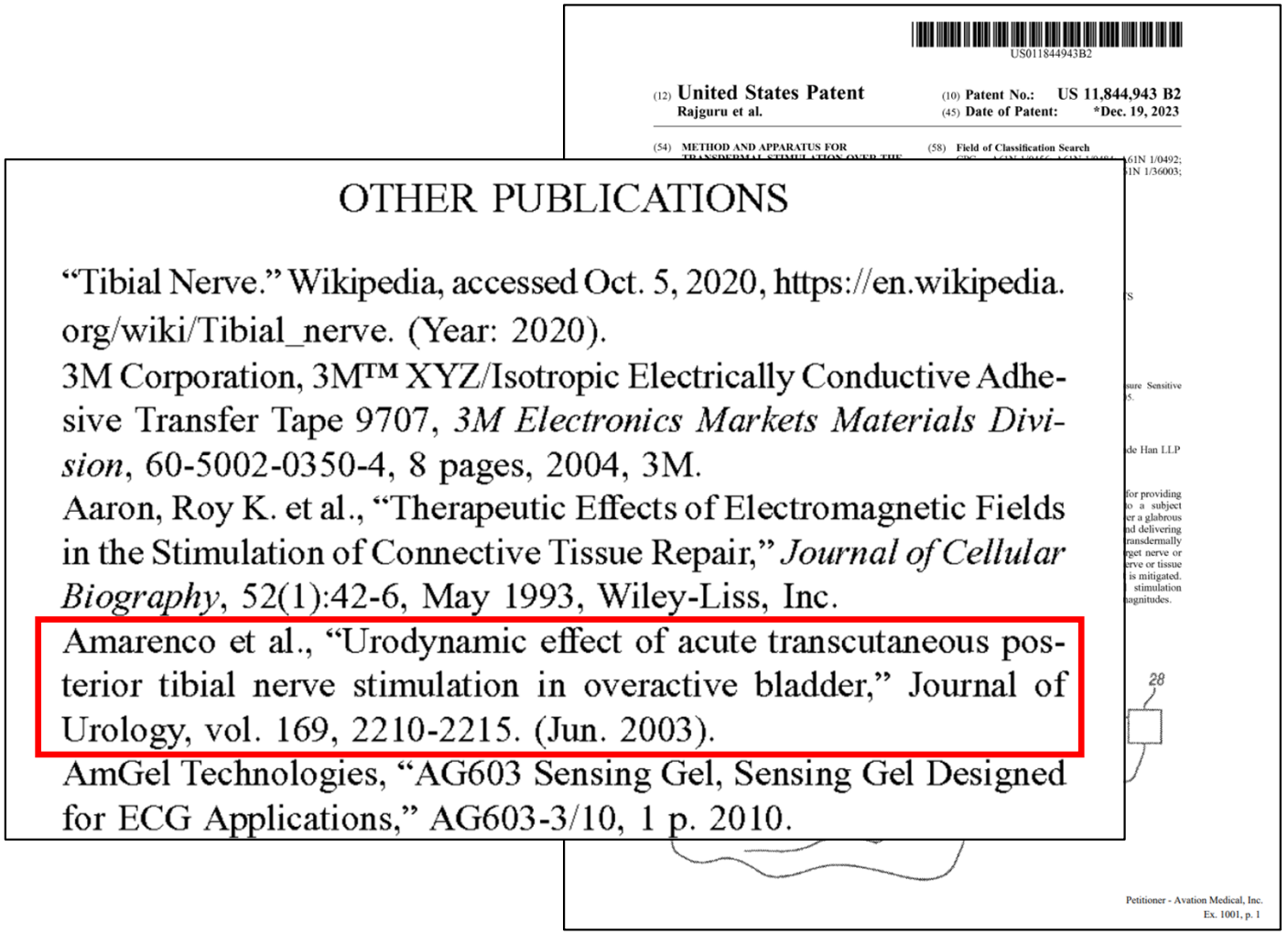
publicly accessible as of the critical date of the '943 patent. Indeed, Svihra exhibits many of the same hallmarks of a printed publication as does the Amarenco reference, e.g., journal title and volume number, page numbers, date of acceptance for publication, etc., which Patent Owner does not dispute is a printed publication. *See* Ex. 1005. We consequently conclude

IELVIN,

DECISION
Granting Institution of Post-Grant Review
35 U.S.C. § 324

Paper 8 at 16; *see also* Paper 12 at 9.

The ‘943 Patent Confirms Amarenco Was Published and Publicly Accessible



US011844943B2

(12) **United States Patent**
Rajguru et al.

(10) **Patent No.: US 11,844,943 B2**
(45) **Date of Patent: *Dec. 19, 2023**

(54) METHOD AND APPARATUS FOR

(58) **Field of Classification Search**

OTHER PUBLICATIONS

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Aaron, Roy K. et al., “Therapeutic Effects of Electromagnetic Fields in the Stimulation of Connective Tissue Repair,” *Journal of Cellular Biography*, 52(1):42-6, May 1993, Wiley-Liss, Inc.

Amarenco et al., “Urodynamic effect of acute transcutaneous posterior tibial nerve stimulation in overactive bladder,” Journal of Urology, vol. 169, 2210-2215. (Jun. 2003).

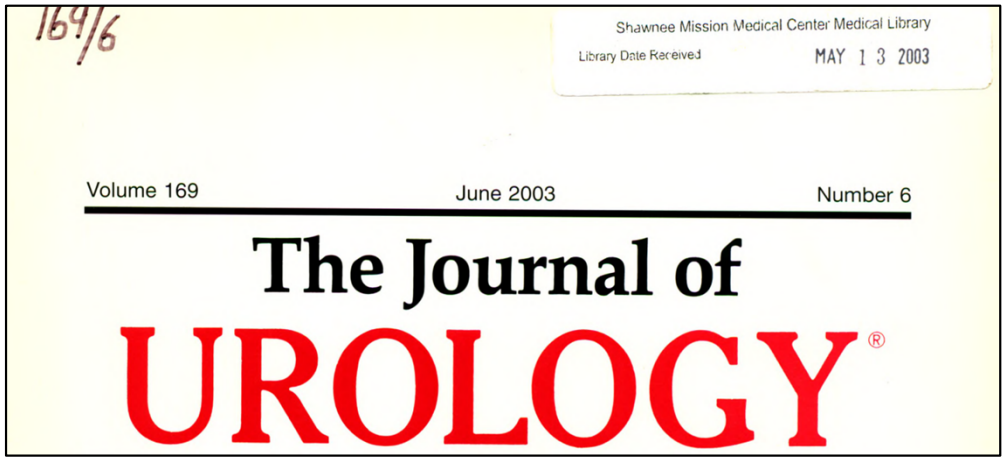
AmGel Technologies, “AG603 Sensing Gel, Sensing Gel Designed for ECG Applications,” AG603-3/10, 1 p. 2010.

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

See Paper 12 at 17 (citing Ex.1001 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 Paper 12 at 16-17 (citing Ex.1088 at 1-4).

- 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

See Paper 12 at 16-17 (citing Ex.1088 at 4-6).

Amarenco Is Identical to Amarenco II

- **Amarenco (Ex.1005)**



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Vol. 169, 2210–2215, June 2003
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DOI: 10.1097/01.ju.0000067446.17576.bd

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 ±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.[5] Chronic electrical stimulation of perineal skin/sacral dermatomes was used to manage urge incontinence and many studies have had good and consistent results.[4,6–8] 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.[9,10] 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.[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.

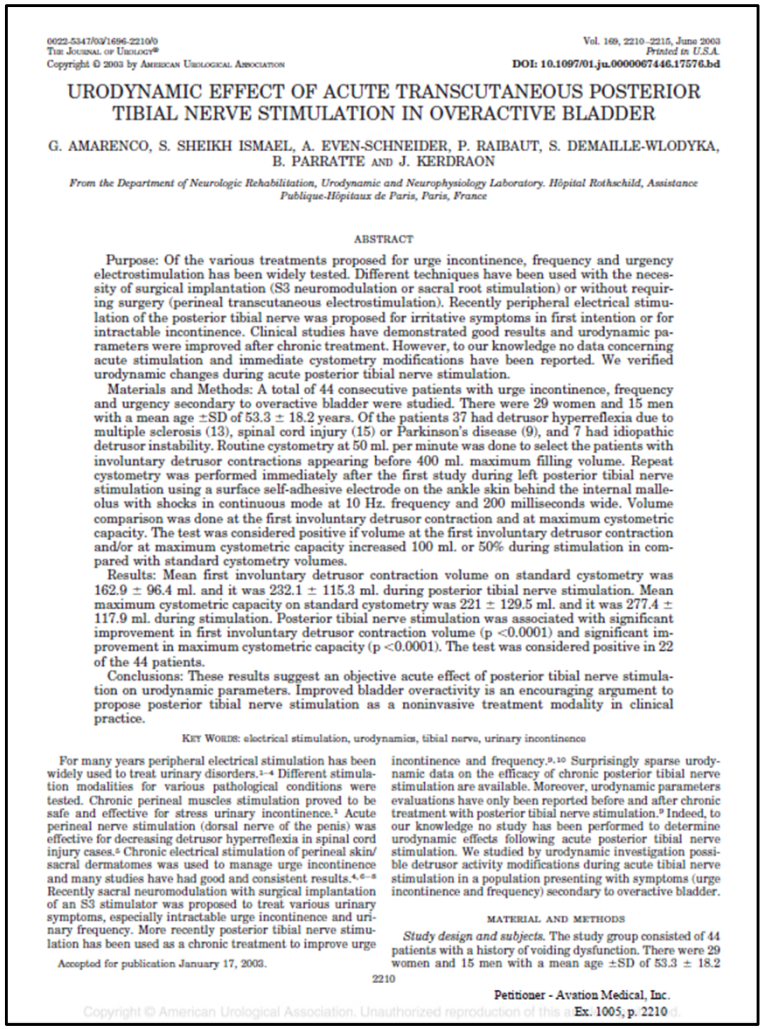
Accepted for publication January 17, 2003.

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 ±SD of 53.3 ± 18.2

Petitioner - Avation Medical, Inc.
Ex. 1088, p. 9
Avation Medical, Inc. v. EMKinetics, Inc., PGR2024-00043

- **Amarenco II (Ex.1088)**



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2210

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

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See Paper 12 at 17 (citing Ex.1088 at 9-14, Ex.1005 at 2210-15).

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.1085)**

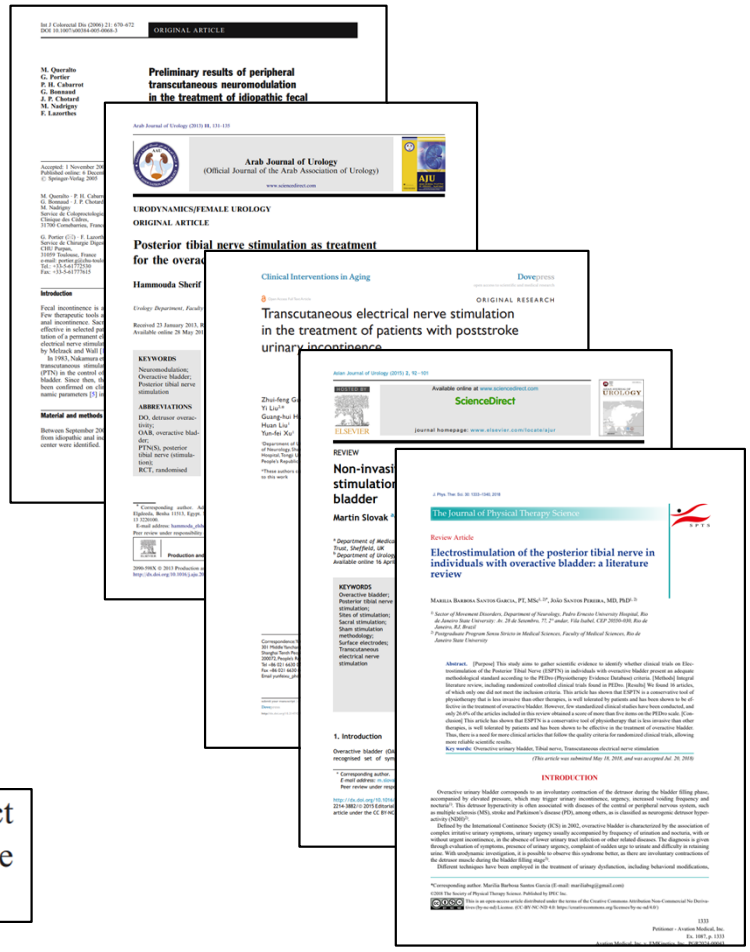
> [29] Amarenco G, Ismael SS, Even-Schneider A, Raibaut P, Demaille-Wlodyka S, Parratte B, et al. Urodynamic effect of acute transcutaneous posterior tibial nerve stimulation in overactive bladder. *J Urol* 2003;**169**:2210–5.

- **Slovak (Ex.1086)**

> [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.1089)**

> 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.1087)**

> 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 Paper 12 at 17 (citing Ex.1016 at 672 (ref. 5), Ex. 1085 at 135 (ref. 29), Ex.1086 at 100 (ref. 37), Ex.1087 at 1340 (ref. 5), Ex. 1089 at 856 (ref. 11)).

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 Paper 12 at 9 (citing Ex.1028 at 361), 10 (citing Ex.1053 at ¶ 30); Paper 23 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.1086) at 100 (reference 12)
    - Guo (Ex.1089) at 856 (reference 24)

See Paper 12 at 10 (citing Ex.1030 at 1), 10 (citing Ex.1053 at ¶ 32), 17 (citing Ex.1086 at 100 (ref. 12), Ex.1089 at 856 (ref. 24)); Paper 23 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 Paper 12 at 9-10 (citing Ex.1042 at 119), 10 (citing Ex.1053 at ¶44); Paper 23 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 Paper 12 at 10 (citing Ex.1043 at 174), 10 (citing Ex.1053 at ¶45); Paper 23 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	✓

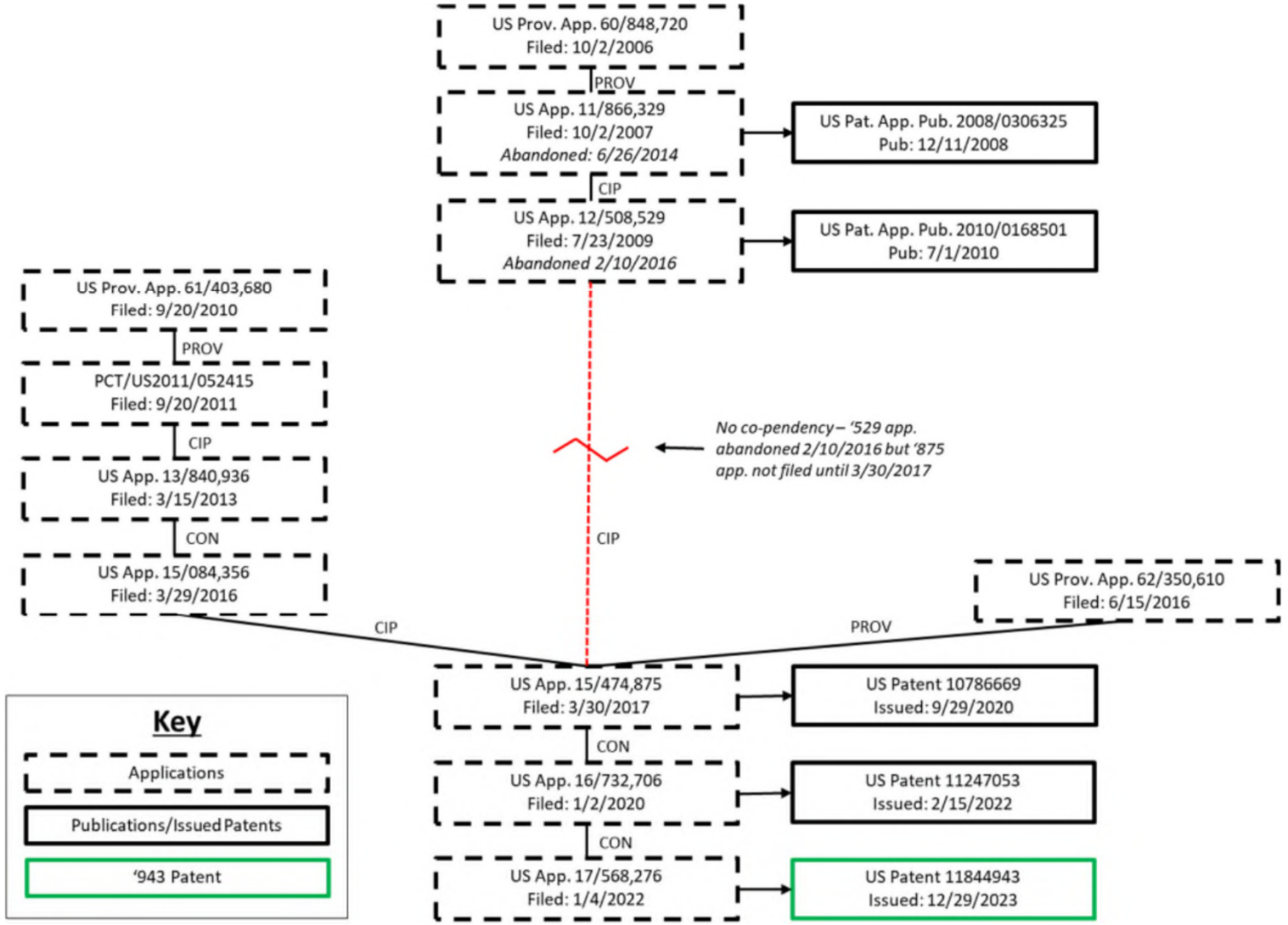
See Paper 12 at 2, 9-11, 16 n.1.

Limited Issues in Dispute

- Prior art status of Journal Articles
  - **Svihra** is a printed publication ✓
  - **Amarenco** is a printed publication ✓
- Prior art status of Burnett
  - **Burnett** is prior art to the claims of the '943 Patent

See Paper 12 at 1, 2-18, 18-22.

Burnett (Ex.1006) Is Prior Art to the '943 Patent



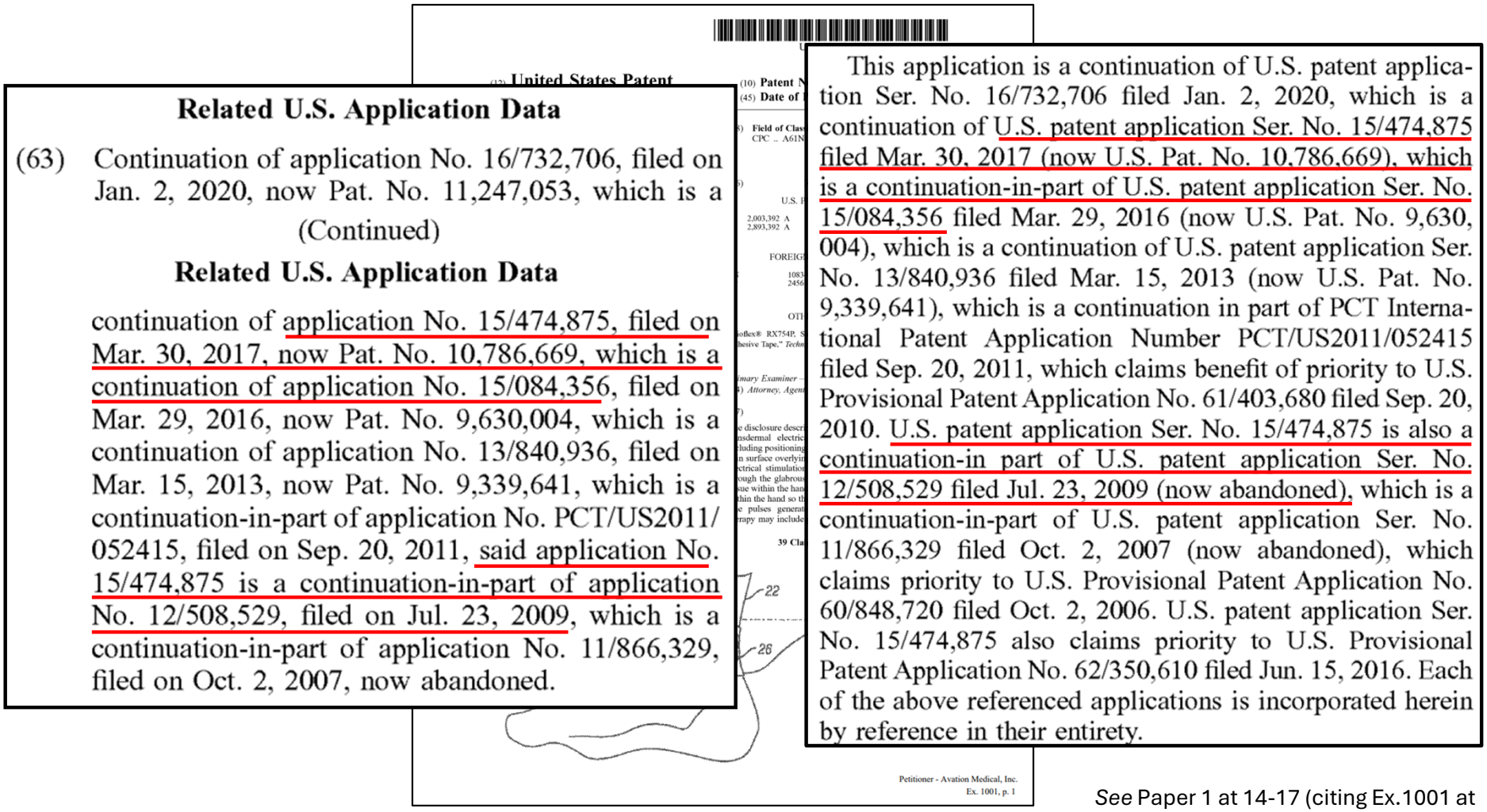
See Paper 1 at 14-17, 65; Paper 8 at 54-57.

The ‘943 Patent’s Broken Priority Chain

- **35 U.S.C. § 120:**
  - An application for patent for an invention disclosed in the manner provided by section 112(a) (other than the requirement to disclose the best mode) in an application previously filed in the United States, or as provided by section 363 or 385, which names an inventor or joint inventor in the previously filed application shall have the same effect, as to such invention, as though filed on the date of the prior application, ***if filed before the patenting or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the filing date of the first application*** and if it contains or is amended to contain a specific reference to the earlier filed application.

See Paper 1 at 16; Paper 8 at 56.

The ‘943 Patent Distinguishes Family Branches and Does Not Identify Familial Relationships Across Branches



Related U.S. Application Data

(63) Continuation of application No. 16/732,706, filed on Jan. 2, 2020, now Pat. No. 11,247,053, which is a

(Continued)

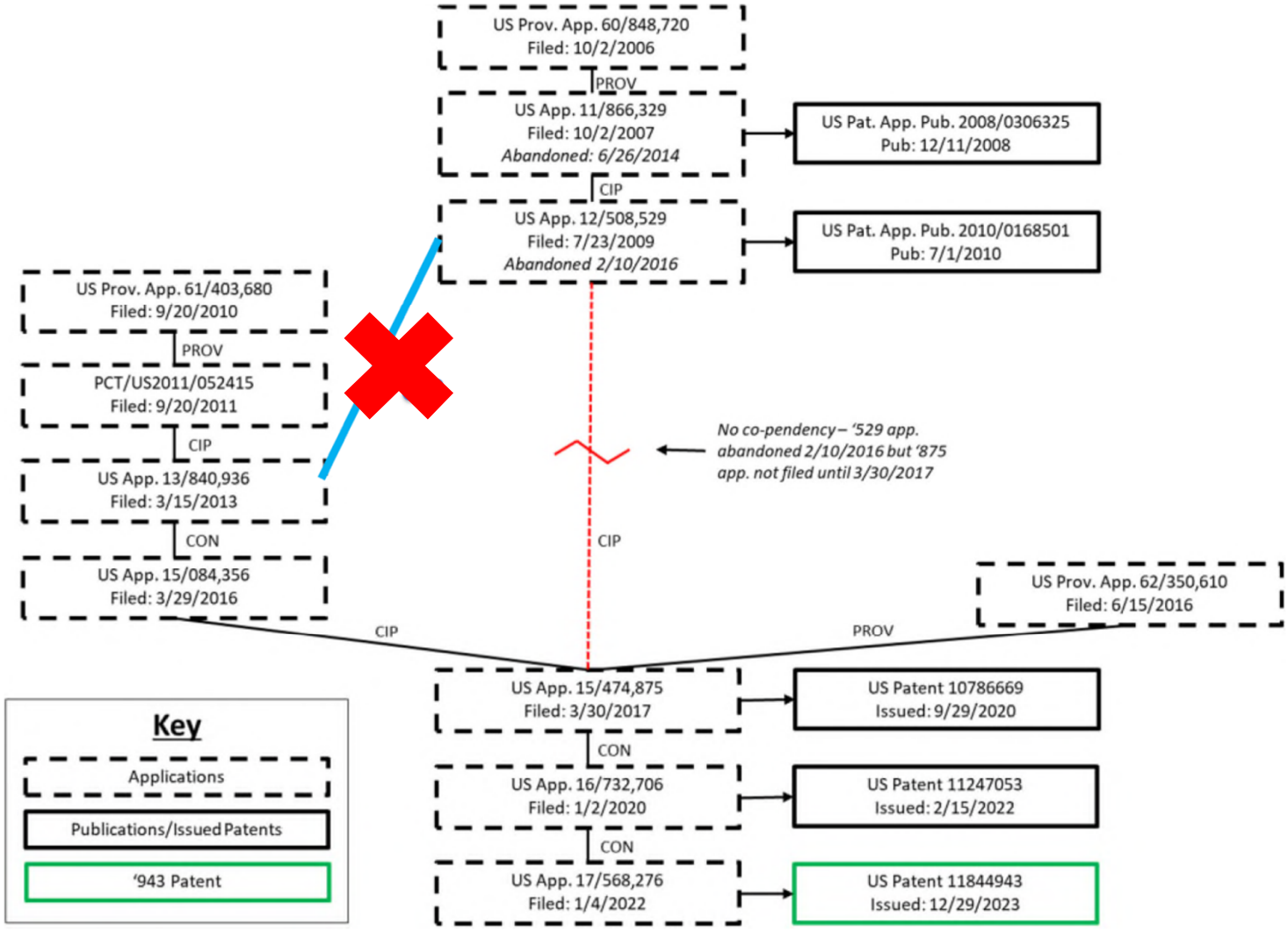
Related U.S. Application Data

continuation of application No. 15/474,875, filed on Mar. 30, 2017, now Pat. No. 10,786,669, which is a continuation of application No. 15/084,356, filed on Mar. 29, 2016, now Pat. No. 9,630,004, which is a continuation of application No. 13/840,936, filed on Mar. 15, 2013, now Pat. No. 9,339,641, which is a continuation-in-part of application No. PCT/US2011/052415, filed on Sep. 20, 2011, said application No. 15/474,875 is a continuation-in-part of application No. 12/508,529, filed on Jul. 23, 2009, which is a continuation-in-part of application No. 11/866,329, filed on Oct. 2, 2007, now abandoned.

This application is a continuation of U.S. patent application Ser. No. 16/732,706 filed Jan. 2, 2020, which is a continuation of U.S. patent application Ser. No. 15/474,875 filed Mar. 30, 2017 (now U.S. Pat. No. 10,786,669), which is a continuation-in-part of U.S. patent application Ser. No. 15/084,356 filed Mar. 29, 2016 (now U.S. Pat. No. 9,630,004), which is a continuation of U.S. patent application Ser. No. 13/840,936 filed Mar. 15, 2013 (now U.S. Pat. No. 9,339,641), which is a continuation in part of PCT International Patent Application Number PCT/US2011/052415 filed Sep. 20, 2011, which claims benefit of priority to U.S. Provisional Patent Application No. 61/403,680 filed Sep. 20, 2010. U.S. patent application Ser. No. 15/474,875 is also a continuation-in part of U.S. patent application Ser. No. 12/508,529 filed Jul. 23, 2009 (now abandoned), which is a continuation-in-part of U.S. patent application Ser. No. 11/866,329 filed Oct. 2, 2007 (now abandoned), which claims priority to U.S. Provisional Patent Application No. 60/848,720 filed Oct. 2, 2006. U.S. patent application Ser. No. 15/474,875 also claims priority to U.S. Provisional Patent Application No. 62/350,610 filed Jun. 15, 2016. Each of the above referenced applications is incorporated herein by reference in their entirety.

See Paper 1 at 14-17 (citing Ex.1001 at [63], 1:8-30); Paper 8 at 55-56 (citing Ex.1001 at [63]); Paper 12 at 18-22.

Patent Owner Cannot Rewrite the Record



See Paper 11 at 14.

Patent Owner Concedes '943 Patent's Priority Chain Is Broken

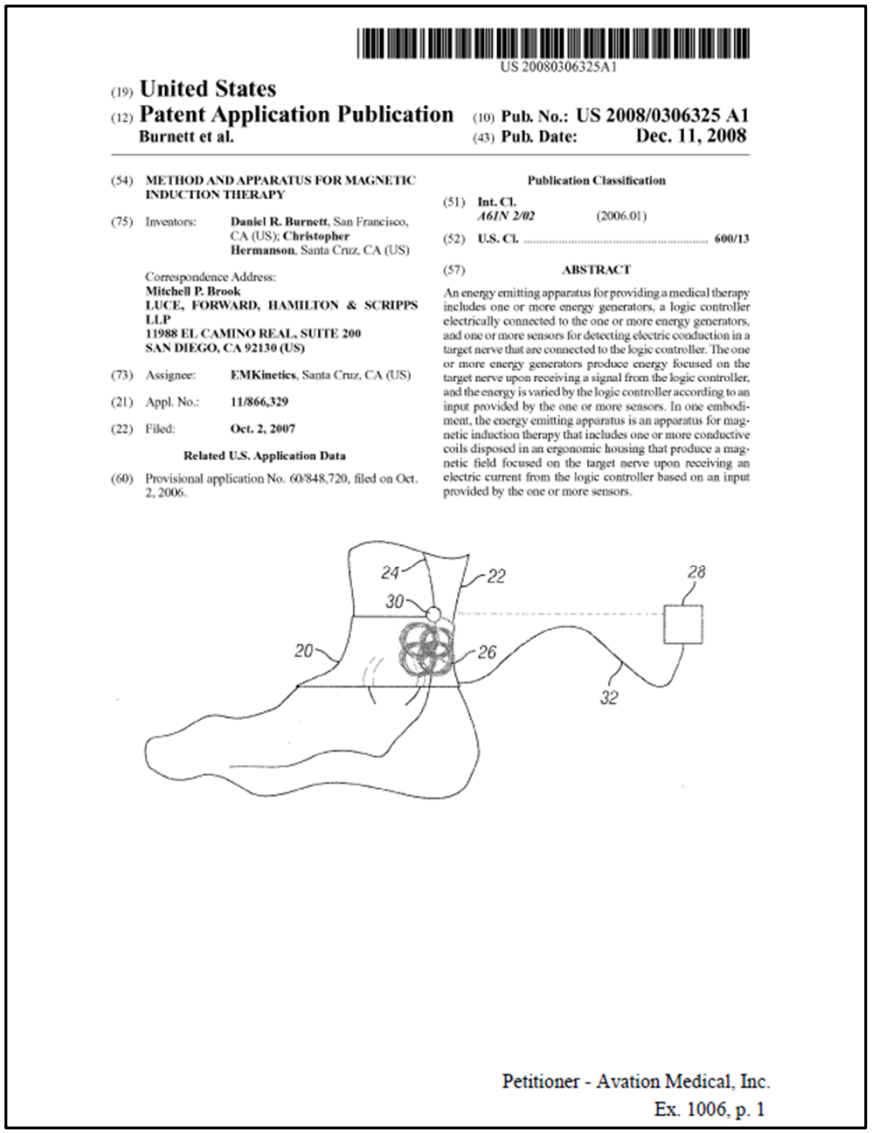
- Patent Owner *admits t*he '943 Patent is "***missing [] a statement that U.S. Application No. 13/840,936 was also a continuation-in-part of 12/508,529***." *See* Paper 11 at 13 (emphasis added).
- *Droplets, Inc. v. E*TRADE Bank*, 887 F.3d 1309 (Fed. Cir. 2018):
  - 35 U.S.C. § 120 "requires that ***the patent application 'contain a specific reference to the earlier filed application'*** to which it purports to claim priority." *Id*. at 1315.
  - "[T]he application claiming the benefit of one or more prior-filed copending nonprovisional applications must include 'a reference to each such prior-filed application, identifying it by application number (consisting of the series code and serial number)' and ***indicating 'the relationship of the applications (i.e., whether the later-filed application is a continuation, divisional, or continuation-in-part of the prior-filed nonprovisional application or international application)***'" *Id*. (citing 37 C.F.R. § 1.78(d)(3)) (emphasis added).
  - *See* Paper 12 at 20-21.

The Board Rejected Patent Owner's Priority Date Argument at Institution

- "***[S]imply to claim the priority benefit of an earlier application is not necessarily to receive it***. *See In re NTP, Inc.*, 654 F.3d 1268, 1276 (Fed. Cir. 2011) (holding that 'a patent's claims are not entitled to an earlier priority date merely because the patentee claims priority....Rather, for a patent's claims to be entitled to an earlier priority date, the patentee must demonstrate that the claims meet the requirements of 35 U.S.C. § 120.')."
  - *See* Paper 8 at 55.
- "Based on the current record, we are persuaded that ***the abandonment of the '529 application prior to filing of the continuation-in-part '875 application broke the priority chain leading to the '720 provisional application***, and the '943 patent cannot, therefore, claim the priority benefit of the '720 provisional application's October 2, 2006 filing date. Consequently, ***the earliest date of which the '943 patent could possibly claim the priority benefit is that of U.S. Patent Provisional Application Ser. No. 61/403,680...which has a filing date of September 20, 2010***."
  - *See* Paper 8 at 56-57.
- "***Burnett (i.e., the '329 application) was filed on October 2, 2007 and thus antedates the '680 provisional application***. Consequently, Patent Owner's argument fails based on the current record, and ***Burnett is prior art to the '943 patent.***"
  - *See* Paper 8 at 57.

Burnett (Ex.1006) Is Prior Art

- '943 Patent priority benefit claims:
  - Branch 1 – earliest priority date of September 20, 2010 (filing date of U.S. Prov. App. 61/403,680)
  - Branch 2 – '529 application abandoned prior to filing of the continuation-in-part '875 application
- Earliest effective filing date of the '943 Patent is September 20, 2010
- Burnett (Ex.1006) filed October 2, 2007 and published December 11, 2008
- ***Burnett (Ex.1006) is therefore prior art to the claims of the '943 Patent***



US 20080306325A1

(19) **United States**

(12) **Patent Application Publication**
Burnett et al.

(10) **Pub. No.: US 2008/0306325 A1**
(43) **Pub. Date: Dec. 11, 2008**

(54) **METHOD AND APPARATUS FOR MAGNETIC INDUCTION THERAPY**

(75) Inventors: **Daniel R. Burnett**, San Francisco, CA (US); **Christopher Hermanson**, Santa Cruz, CA (US)

Correspondence Address:
Mitchell P. Brook
LUCE, FORWARD, HAMILTON & SCRIPPS LLP
11988 EL CAMINO REAL, SUITE 200
SAN DIEGO, CA 92130 (US)

(73) Assignee: **EMKinetics**, Santa Cruz, CA (US)

(21) Appl. No.: **11/866,329**

(22) Filed: **Oct. 2, 2007**

Related U.S. Application Data

(60) Provisional application No. 60/848,720, filed on Oct. 2, 2006.

Publication Classification

(51) **Int. Cl.**
A61N 2/02 (2006.01)

(52) **U.S. Cl.** **600/13**

(57) **ABSTRACT**

An energy emitting apparatus for providing a medical therapy includes one or more energy generators, a logic controller electrically connected to the one or more energy generators, and one or more sensors for detecting electric conduction in a target nerve that are connected to the logic controller. The one or more energy generators produce energy focused on the target nerve upon receiving a signal from the logic controller, and the energy is varied by the logic controller according to an input provided by the one or more sensors. In one embodiment, the energy emitting apparatus is an apparatus for magnetic induction therapy that includes one or more conductive coils disposed in an ergonomic housing that produce a magnetic field focused on the target nerve upon receiving an electric current from the logic controller based on an input provided by the one or more sensors.

Petitioner - Avation Medical, Inc.
Ex. 1006, p. 1

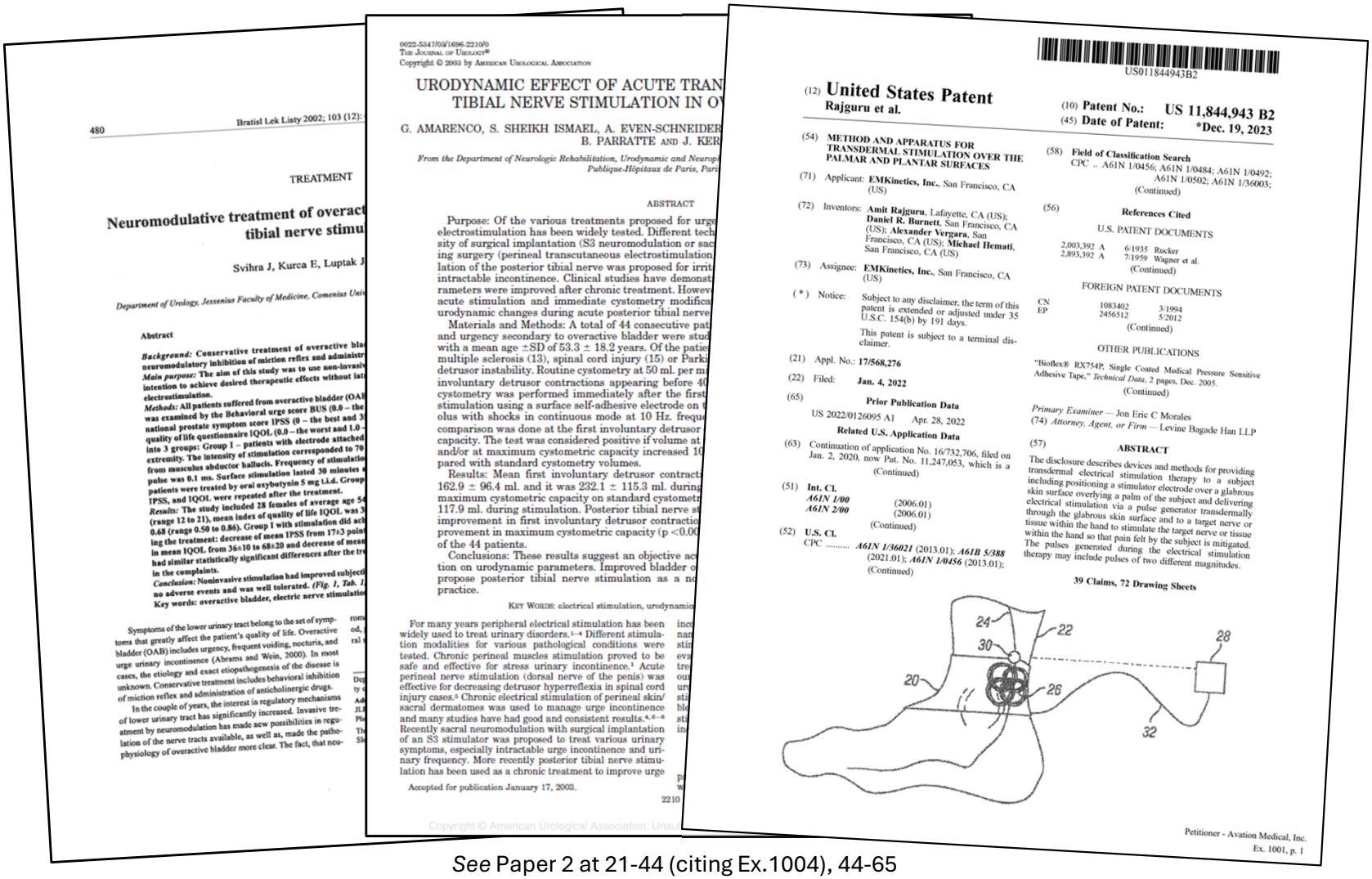
See Paper 1 at 14-17; Paper 12 at 18-22.

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See Paper 12 at 1, 2-18, 18-22.

Claims 1-39 of the ‘943 Patent Are Unpatentable



Bratisl Lek Listy 2002; 103 (12):

TREATMENT

Neuromodulative treatment of overact
tibial nerve stimu

Svihra J, Kurca E, Luptak J

Department of Urology, Jessenius Faculty of Medicine, Comenius Uni

Abstract

0022-5347/03/1696-2210/0
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URODYNAMIC EFFECT OF ACUTE TRAN
TIBIAL NERVE STIMULATION IN O

G. AMARENCO, S. SHEIKH ISMAEL, A. EVEN-SCHNEIDER
B. PARRATTE AND J. KER

From the Department of Neurologic Rehabilitation, Urodynamic and Neurop
Publique-Hôpitaux de Paris, Pari

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KEY WORDS: electrical stimulation, urodynamic

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.[5] Chronic electrical stimulation of perineal skin/sacral dermatomes was used to manage urge incontinence and many studies have had good and consistent results.[4,6–8] 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

Accepted for publication January 17, 2003.

2210

US011844943B2

(12) United States Patent
Rajguru et al.

(10) Patent No.: US 11,844,943 B2
(45) Date of Patent: *Dec. 19, 2023

(54) METHOD AND APPARATUS FOR TRANSDERMAL STIMULATION OVER THE PALMAR AND PLANTAR SURFACES

(71) Applicant: EMKinetics, Inc., San Francisco, CA (US)

(72) Inventors: Amit Rajguru, Lafayette, CA (US); Daniel R. Burnett, San Francisco, CA (US); Alexander Vergara, San Francisco, CA (US); Michael Hemati, 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 U.S.C. 154(b) by 191 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: 17/568,276

(22) Filed: Jan. 4, 2022

(65) Prior Publication Data

US 2022/0126095 A1 Apr. 28, 2022

Related U.S. Application Data

(63) Continuation of application No. 16/732,706, filed on Jan. 2, 2020, now Pat. No. 11,247,053, which is a (Continued)

(51) Int. Cl.
A61N 1/00 (2006.01)
A61N 2/00 (2006.01)
(Continued)

(52) U.S. Cl.
CPC A61N 1/36021 (2013.01); A61B 5/388 (2021.01); A61N 1/0456 (2013.01);
(Continued)

(58) Field of Classification Search
CPC .. A61N 1/0456; A61N 1/0484; A61N 1/0492; A61N 1/0502; A61N 1/36003;
(Continued)

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Primary Examiner — Jon Eric C Morales
(74) *Attorney, Agent, or Firm* — Levine Bagade Han LLP

(57) ABSTRACT

The disclosure describes devices and methods for providing transdermal electrical stimulation therapy to a subject including positioning a stimulator electrode over a glabrous skin surface overlying a palm of the subject and delivering electrical stimulation via a pulse generator transdermally through the glabrous skin surface and to a target nerve or tissue within the hand to stimulate the target nerve or tissue within the hand so that pain felt by the subject is mitigated. The pulses generated during the electrical stimulation therapy may include pulses of two different magnitudes.

39 Claims, 72 Drawing Sheets

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

See Paper 2 at 21-44 (citing Ex.1004), 44-65 (citing Ex.1005), 65-79 (citing Ex.1006).

Invalidity Grounds

1. §102: Svihra (claims 1, 3-5)
2. §103: Svihra / POSITA (claims 2, 6-13)
3. §103: Svihra / Johnson (claims 14, 16-18, 27, 29-31)
4. §103: Svihra / Johnson / POSITA (claims 15, 19-26, 28, 32-39)
5. §102: Amarenco (claims 1-3, 5)
6. §103: Amarenco / POSITA (claims 4, 6-13)
7. §103: Amarenco / Johnson (claims 14-16, 18, 27-29, 31)
8. §103: Amarenco / Johnson / POSITA (claims 17, 19-26, 30, 32-39)
9. §102: Burnett (claims 1-3, 5-13)
10. §103: Burnett / Johnson / POSITA (claims 4, 14-39)
11. §112: Enablement (claims 1-39)

See Paper 2 at 2-3.

Petitioner Avation Medical, Inc., PGR2024-00043
DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Petitioner's Evidence v. Patent Owner's Evidence

Petitioner's Evidence	Patent Owner's Evidence
• Svihra (Ex.1004) • Amarenco (Ex.1005) • Burnett (Ex.1006) • Dr. Wingeier (Ex.1003)	• None

Petitioner's Evidence v. Patent Owner's Evidence

Petitioner's Evidence	Patent Owner's Evidence
• Svihra (Ex.1004) ✓ • Amarenco (Ex.1005) ✓ • Burnett (Ex.1006) ✓ • Dr. Wingeier (Ex.1003) ✓	• None

Petitioner's Evidence v. Patent Owner's Evidence

Petitioner's Evidence	Patent Owner's Evidence

• Svihra (Ex.1004) ✓
• Amarenco (Ex.1005) ✓
• Burnett (Ex.1006) ✓
• Dr. Wingeier (Ex.1003) ✓
	• None
	  • No expert declaration
	  • Deposition of Avation's expert?
	  • Other evidence?

Petitioner's Evidence v. Patent Owner's Evidence

Petitioner's Evidence	Patent Owner's Evidence
• Svihra (Ex.1004) ✓	• None
• Amarenco (Ex.1005) ✓	✗ • ~~Expert declaration?~~
• Burnett (Ex.1006) ✓	✗ • ~~Deposition of Avation's expert?~~
• Dr. Wingeier (Ex.1003) ✓	✗ • ~~Other evidence?~~

Grounds 1-4: Svihra (Ex.1004) Invalidates the Challenged Claims



480 Bratisl Lek Listy 2002; 103 (12): 480–483

TREATMENT

Neuromodulative treatment of overactive bladder – noninvasive tibial nerve stimulation

Svihra J, Kurca E, Luptak J, Kliment J

Department of Urology, Jessenius Faculty of Medicine, Comenius University, Martin, Slovakia. **svihra@jfmed.uniba.sk**

Abstract

Background: **Conservative treatment of overactive bladder employes behavioral or invasive neuromodulatory inhibition of miction reflex and administration of anticholinergic drugs.**
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.)***
Key words: overactive bladder, electric nerve stimulation, tibial nerve, anticholinergics.

Symptoms of the lower urinary tract belong to the set of symptoms that greatly affect the patient's quality of life. Overactive bladder (OAB) includes urgency, frequent voiding, nocturia, and urge urinary incontinence (Abrams and Wein, 2000). In most cases, the etiology and exact etiopathogenesis of the disease is unknown. Conservative treatment includes behavioral inhibition of miction reflex and administration of anticholinergic drugs.

In the couple of years, the interest in regulatory mechanisms of lower urinary tract has significantly increased. Invasive treatment by neuromodulation has made new possibilities in regulation of the nerve tracts available, as well as, made the pathophysiology of overactive bladder more clear. The fact, that neuromodulation is one of invasive and financially demanding method, gave rise to the development of minimally invasive peripheral stimulation SANS (Stoller, 1999).

Department of Urology and Department of Neurology, Jessenius Faculty of Medicine, Comenius University, Martin, Slovakia

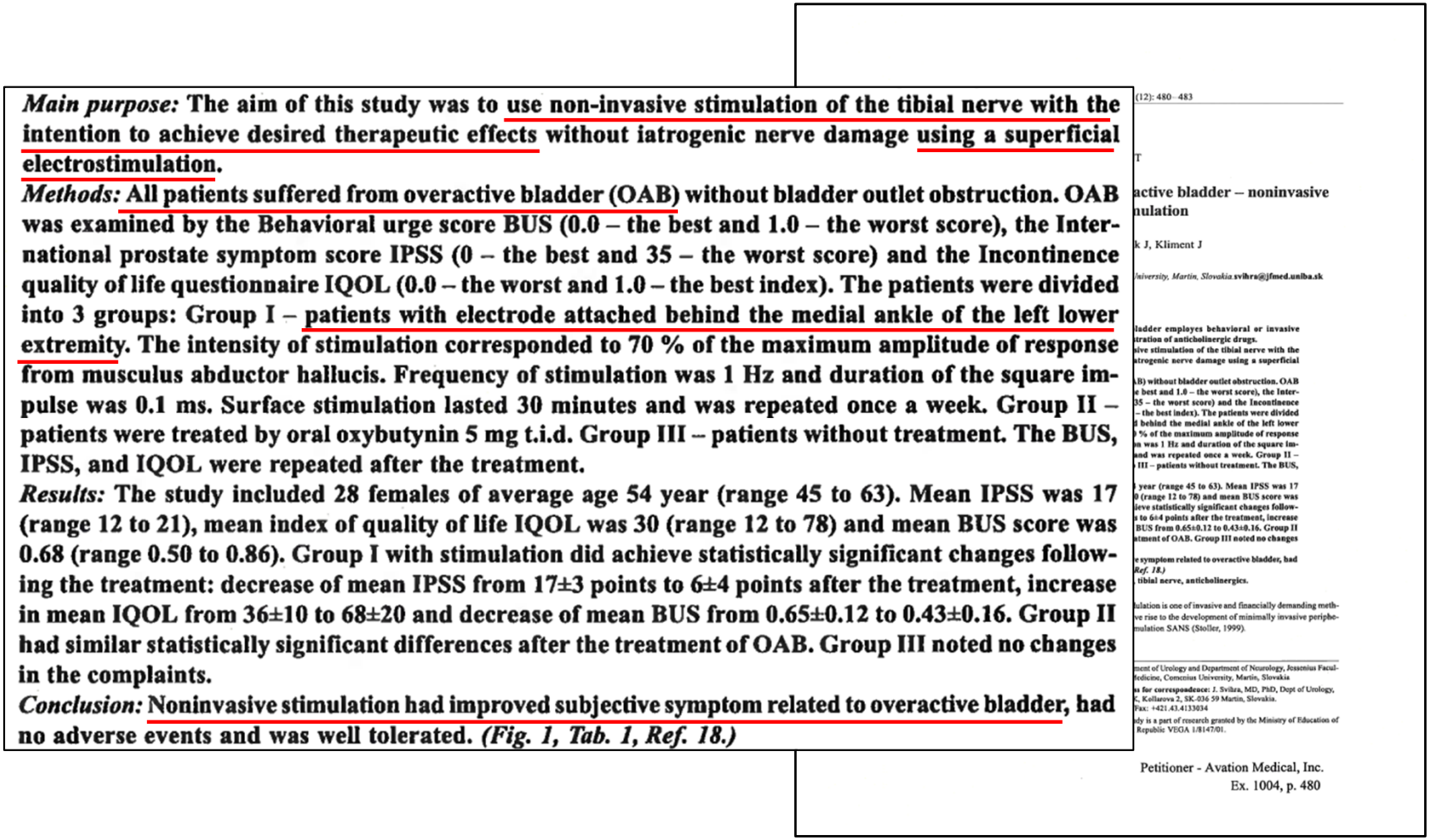
Address for correspondence: J. Svihra, MD, PhD, Dept of Urology, JLF UK, Kollarova 2, SK-036 59 Martin, Slovakia.
Phone/Fax: +421.43.4133034

The study is a part of research granted by the Ministry of Education of Slovak Republic VEGA 1/8147/01.

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

Ex.1004 at 480; *see* Paper 2 at 21-44.

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

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niversity, Martin, Slovakia svihra@jfmed.uniba.sk

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Ref. 18.)
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mulation SANS (Stoller, 1999).

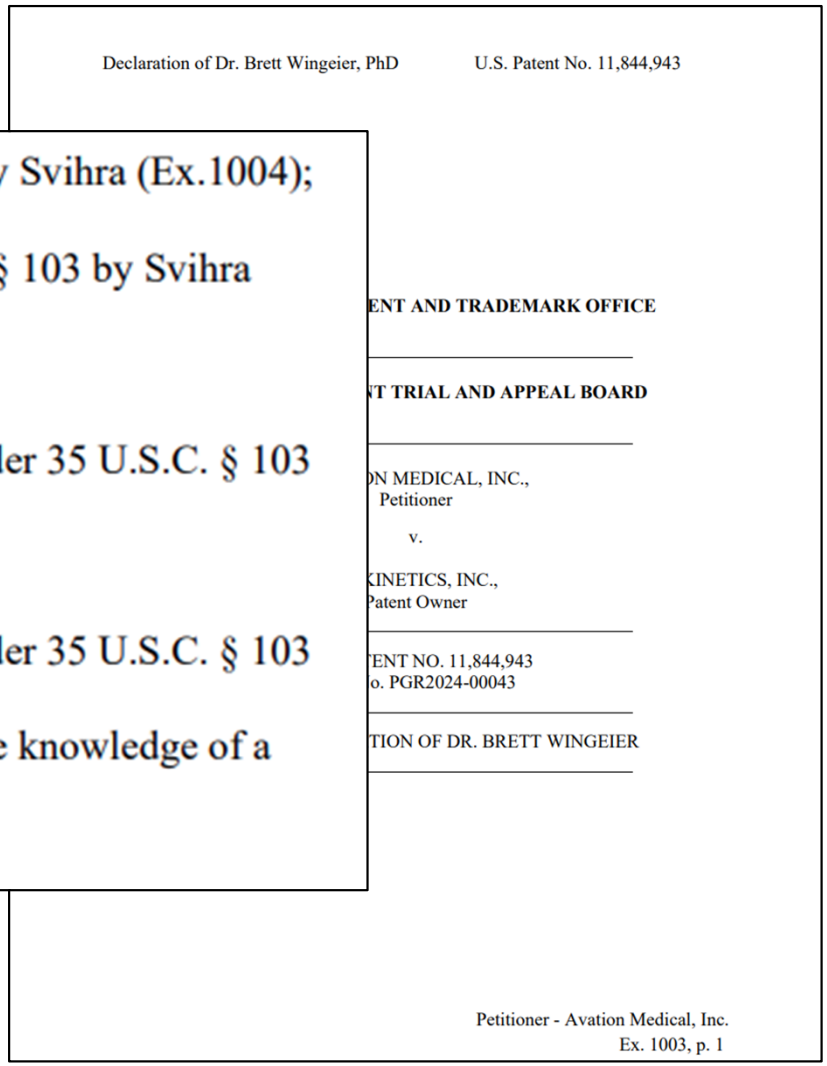
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dy is a part of research granted by the Ministry of Education of
Republic VEGA 1/8147/01.

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

See Paper 2 at 21-24 (citing Ex.1004 at 480).

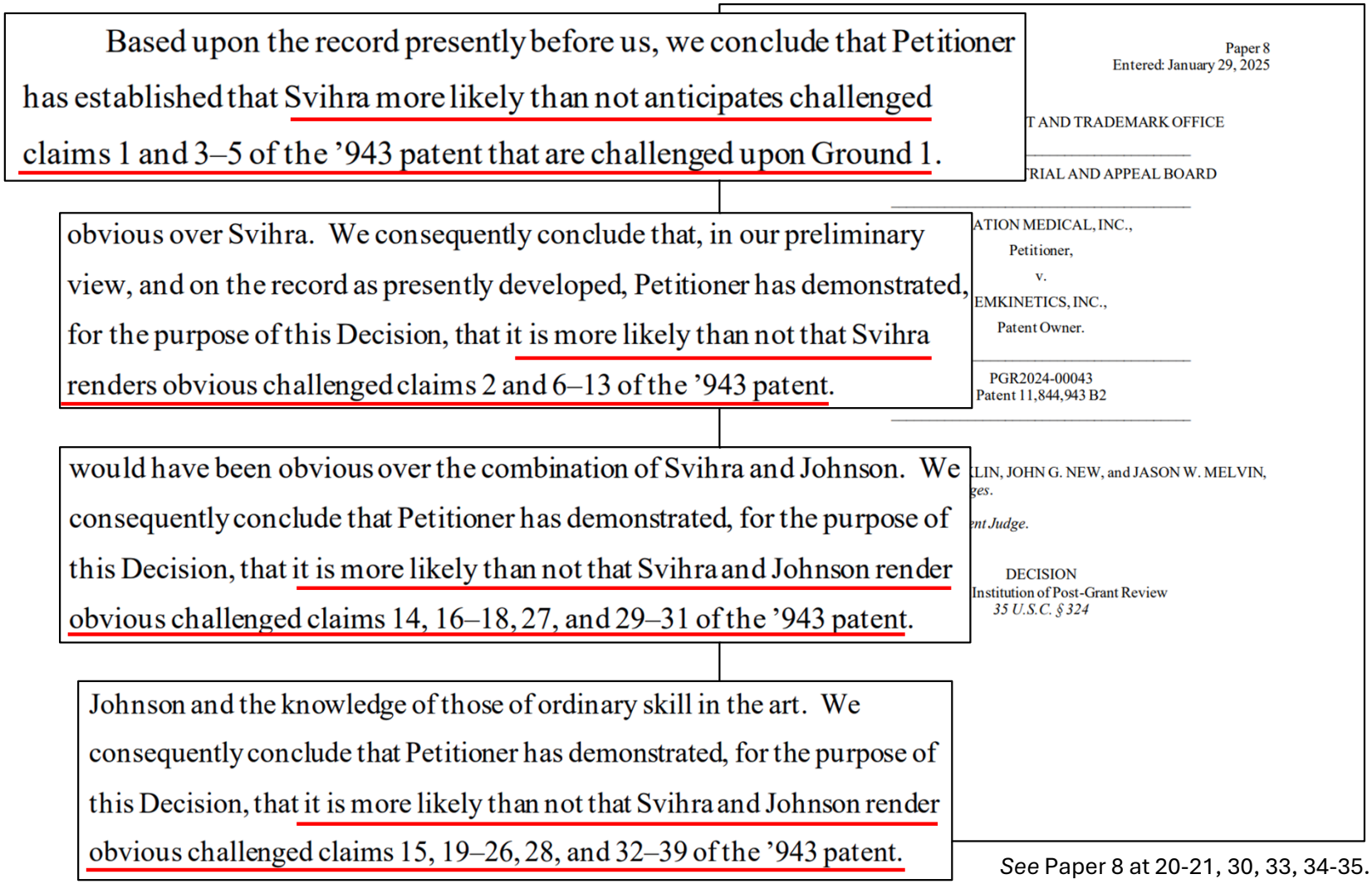
Dr. Wingeier Confirms Svihra Discloses All Elements

- Claims 1 and 3-5 are anticipated under 35 U.S.C. § 102 by Svihra (Ex.1004);
- Claims 2 and 6-13 are rendered obvious under 35 U.S.C. § 103 by Svihra (Ex.1004) in view of the knowledge of a POSA;
- Claims 14, 16-18, 27, and 29-31 are rendered obvious under 35 U.S.C. § 103 by Svihra (Ex.1004) in view of Johnson (Ex.1007);
- Claims 15, 19-26, 28, and 32-39 are rendered obvious under 35 U.S.C. § 103 by Svihra (Ex.1004) in view of Johnson (Ex.1007) and the knowledge of a POSA;



See Ex.1003 at ¶ 274.

Petitioner's Svihra Grounds 1-4 and Board's Findings on Institution Are Undisputed by Patent Owner



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

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

would have been obvious over the combination of Svihra and Johnson. We consequently conclude that Petitioner has demonstrated, for the purpose of this Decision, that it is more likely than not that Svihra and Johnson render obvious challenged claims 14, 16–18, 27, and 29–31 of the '943 patent.

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

Paper 8
Entered: January 29, 2025

T AND TRADEMARK OFFICE

RIAL AND APPEAL BOARD

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

PGR2024-00043
Patent 11,844,943 B2

LIN, JOHN G. NEW, and JASON W. MELVIN,
ges.

ent Judge.

DECISION
Institution of Post-Grant Review
35 U.S.C. § 324

See Paper 8 at 20-21, 30, 33, 34-35.

Grounds 5-8: Amarenco (Ex.1005) Invalidates the Challenged Claims



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DOI: 10.1097/01.ju.0000067446.17576.bd

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 ±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.[5] Chronic electrical stimulation of perineal skin/sacral dermatomes was used to manage urge incontinence and many studies have had good and consistent results.[4,6–8] 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.[9,10] 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.[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.

Accepted for publication January 17, 2003.

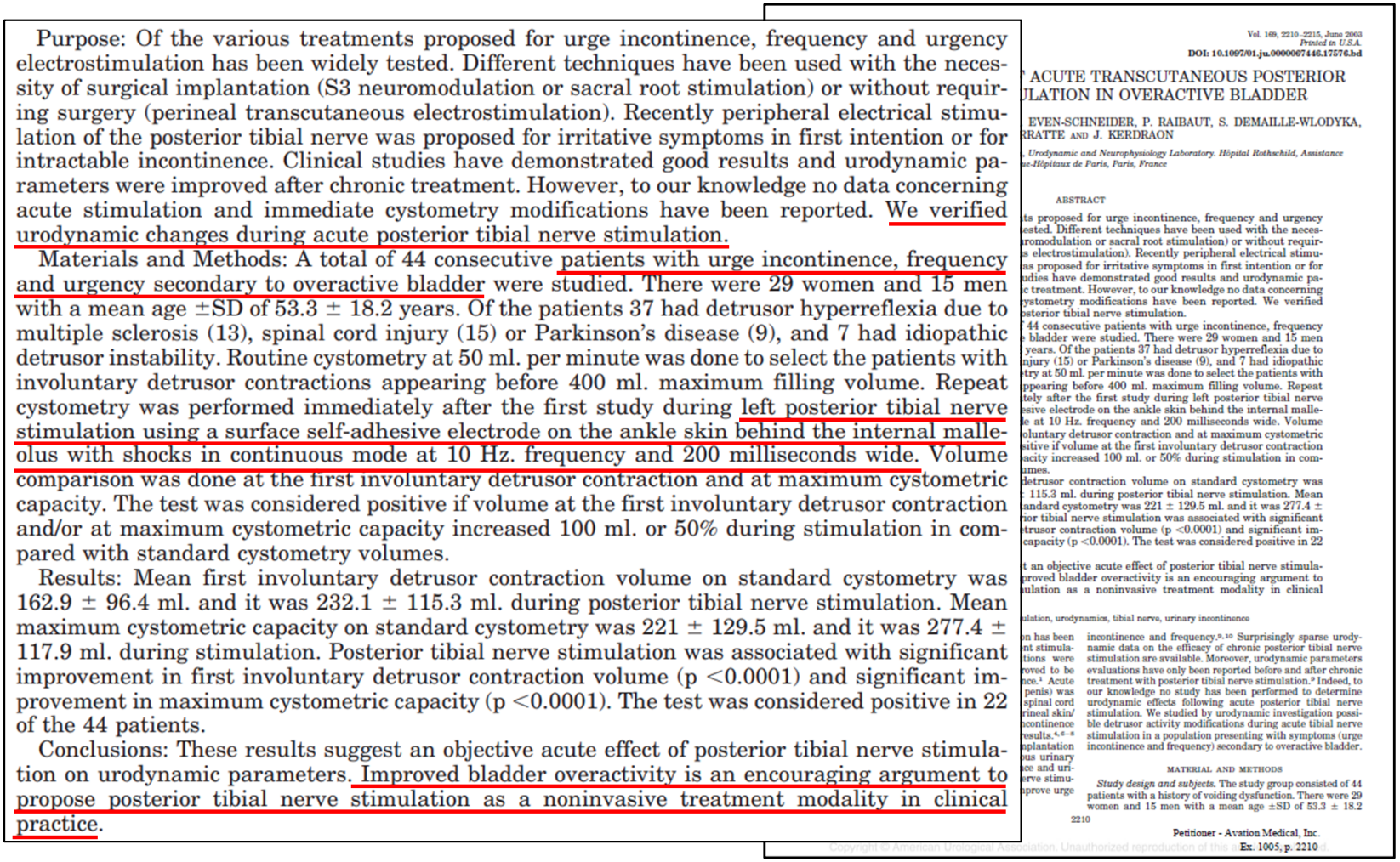
MATERIAL AND METHODS

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 ±SD of 53.3 ± 18.2

Petitioner - Avation Medical, Inc.
Ex. 1005, p. 2210
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Ex.1005 at 2210; *see* Paper 2 at 44-65.

Amarenco 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 ±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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Printed in U.S.A.
DOI: 10.1097/01.ju.0000067446.17576.bd

ACUTE TRANSCUTANEOUS POSTERIOR
ULATION IN OVERACTIVE BLADDER

EVEN-SCHNEIDER, P. RAIBAUT, S. DEMAILLE-WLODYKA,
RRATTE AND J. KERDRAON

Urodynamic and Neurophysiology Laboratory. Hôpital Rothschild, Assistance
se-Hôpitaux de Paris, Paris, France

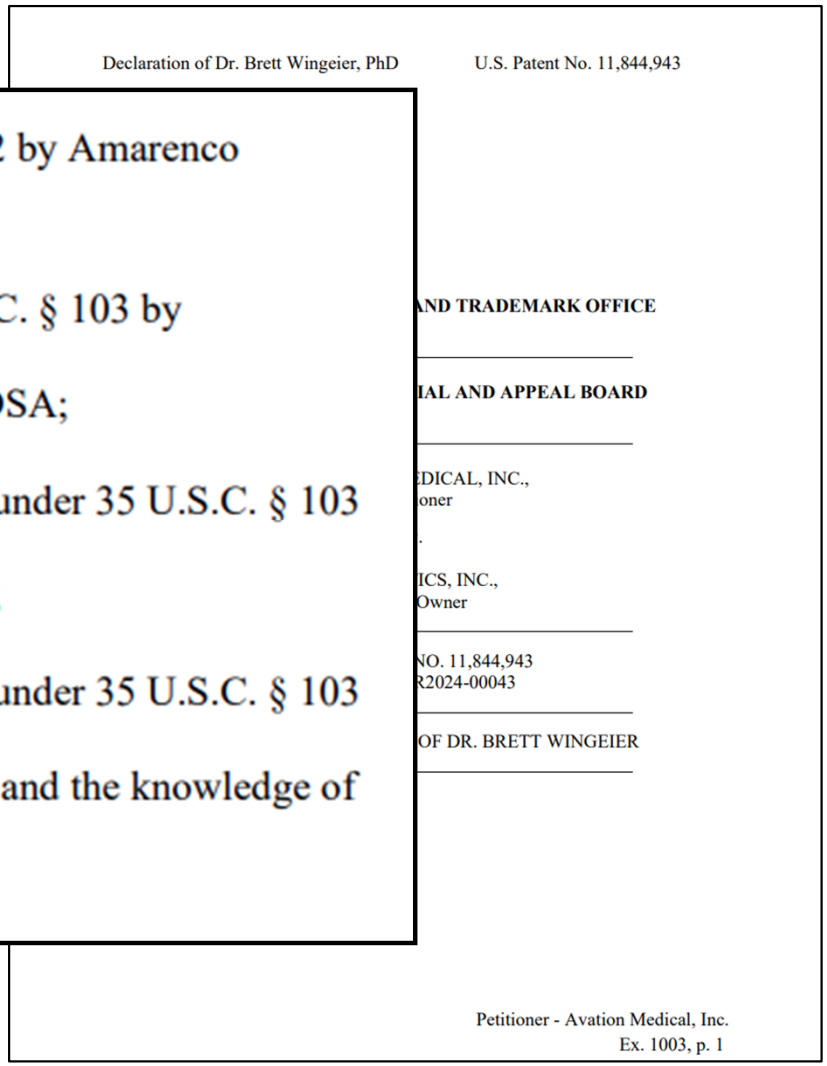
ABSTRACT

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See Paper 2 at 44-65 (citing Ex.1005 at 2210).

Dr. Wingeier Confirms Amarenco Discloses All Elements

- Claims 1-3 and 5 are anticipated under 35 U.S.C. § 102 by Amarenco (Ex.1005);
- Claims 4 and 6-13 are rendered obvious under 35 U.S.C. § 103 by Amarenco (Ex.1005) in view of the knowledge of a POSA;
- Claims 14-16, 18, 27-29, and 31 are rendered obvious under 35 U.S.C. § 103 by Amarenco (Ex.1005) in view of Johnson (Ex.1007);
- Claims 17, 19-26, 30, and 32-39 are rendered obvious under 35 U.S.C. § 103 by Amarenco (Ex.1005) in view of Johnson (Ex.1007) and the knowledge of a POSA;



See Ex.1003 at ¶ 274.

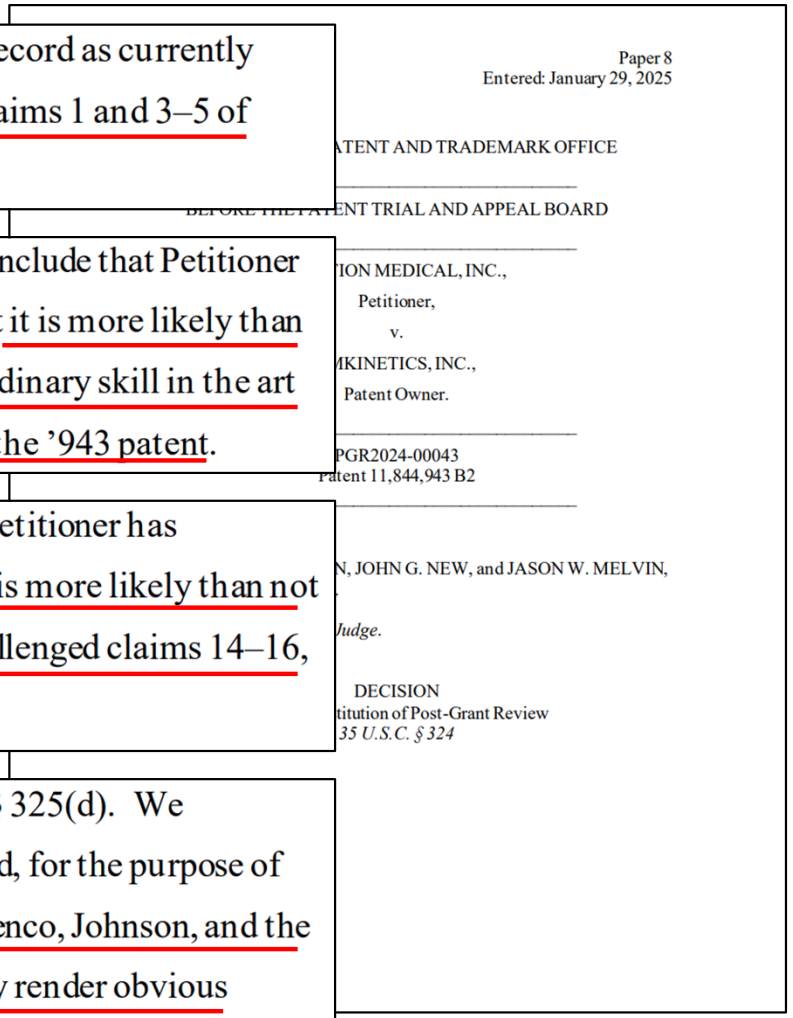
Petitioner's Amarenco Grounds 5-8 and Board's Findings on Institution Are Undisputed by Patent Owner

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

review under 35 U.S.C. § 325(d). We consequently conclude that Petitioner has demonstrated, for the purpose of this Decision, that it is more likely than not that Amarenco and the knowledge of a person of ordinary skill in the art likely render obvious challenged claims 4 and 6–13 of the '943 patent.

35 U.S.C. § 325(d). We consequently conclude that Petitioner has demonstrated, for the purpose of this Decision, that it is more likely than not that Amarenco and Johnson likely render obvious challenged claims 14–16, 18, 27–29, and 31 of the '943 patent.

deny institution of post-grant review under 35 U.S.C. § 325(d). We consequently conclude that Petitioner has demonstrated, for the purpose of this Decision, that it is more likely than not that Amarenco, Johnson, and the knowledge of a person of ordinary skill in the art likely render obvious challenged claims 17, 19–26, 30, and 32–39 of the '943 patent.


Paper 8
Entered: January 29, 2025

ATENT AND TRADEMARK OFFICE

ENT TRIAL AND APPEAL BOARD

ION MEDICAL, INC.,
Petitioner,
v.
MKINETICS, INC.,
Patent Owner.

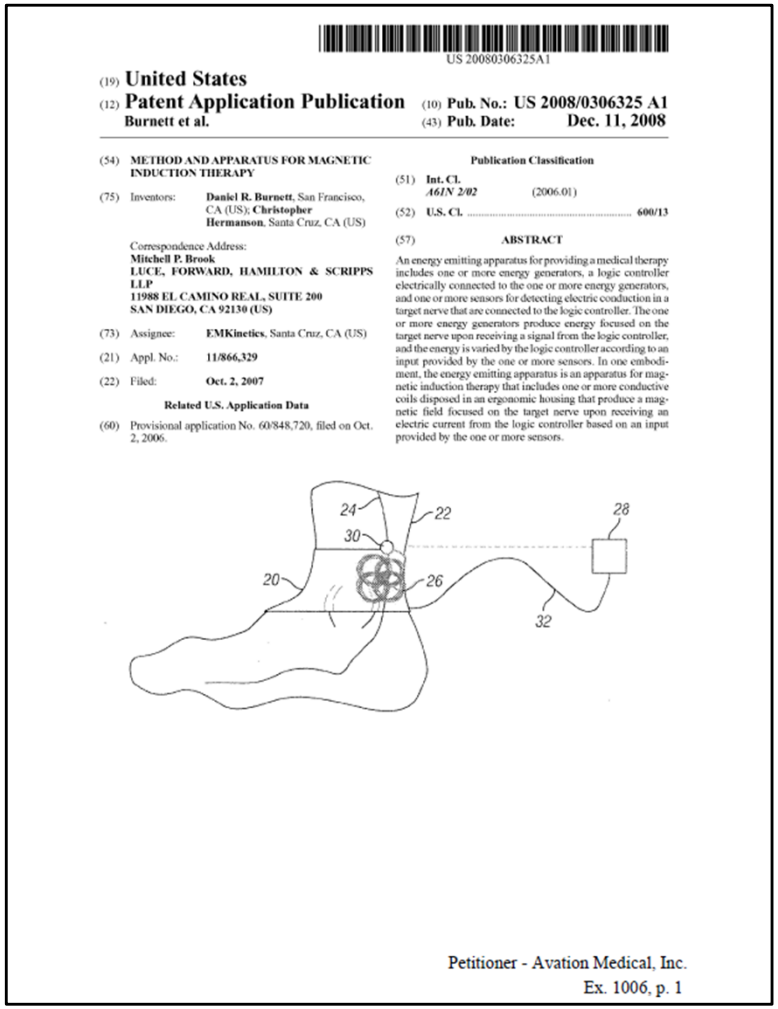
PGR2024-00043
Patent 11,844,943 B2

N, JOHN G. NEW, and JASON W. MELVIN,
Judge.

DECISION
titution of Post-Grant Review
35 U.S.C. § 324

See Paper 8 at 40, 44, 45, 46.

Grounds 9-10: Burnett (Ex.1006) Invalidates the Challenged Claims



US 20080306325A1

(19) **United States**

(12) **Patent Application Publication**
Burnett et al.

(10) **Pub. No.: US 2008/0306325 A1**
(43) **Pub. Date: Dec. 11, 2008**

(54) **METHOD AND APPARATUS FOR MAGNETIC INDUCTION THERAPY**

(75) Inventors: **Daniel R. Burnett**, San Francisco, CA (US); **Christopher Hermanson**, Santa Cruz, CA (US)

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(73) Assignee: **EMKinetics**, Santa Cruz, CA (US)

(21) Appl. No.: **11/866,329**

(22) Filed: **Oct. 2, 2007**

Related U.S. Application Data

(60) Provisional application No. 60/848,720, filed on Oct. 2, 2006.

Publication Classification

(51) **Int. Cl.**
A61N 2/02 (2006.01)

(52) **U.S. Cl.** **600/13**

(57) **ABSTRACT**

An energy emitting apparatus for providing a medical therapy includes one or more energy generators, a logic controller electrically connected to the one or more energy generators, and one or more sensors for detecting electric coduction in a target nerve that are connected to the logic controller. The one or more energy generators produce energy focused on the target nerve upon receiving a signal from the logic controller, and the energy is varied by the logic controller according to an input provided by the one or more sensors. In one embodiment, the energy emitting apparatus is an apparatus for magnetic induction therapy that includes one or more conductive coils disposed in an ergonomic housing that produce a magnetic field focused on the target nerve upon receiving an electric current from the logic controller based on an input provided by the one or more sensors.

Petitioner - Avation Medical, Inc.
Ex. 1006, p. 1

Ex.1006; *see* Paper 2 at 65-79.

Burnett Discloses All Elements

[0088] Still other embodiments of the invention are depicted in FIGS. **10** and **11**. In these embodiments, the source of energy for nerve stimulation is electrical energy that is dispensed through a percutaneous stimulator, such as a percutaneous needle **124**, or a transcutaneous stimulator, such as an electrode **126**. As shown in FIG. **10**, an electrical pulse controller **128** is electrically connected both to percutaneous needle **124** and to sensor **134**, to provide the desired feedback and modulate the power to percutaneous needle **134**. In the embodiment of FIG. **11**, electrical pulse controller **130** is connected both to electrode **126** and to sensor **136**, and performs a function similar to that of electrical pulse controller **128**. With these embodiments, nerve conduction may be detected at a site sufficiently distant from the site of stimulation, so to enable detection of nerve conduction despite the confounding interference from the direct electrical stimuli. Further, direct electrical stimulation of nerve and muscle may be tailored to provide optimal therapy and, in the case of electrode migration or other electrode malfunction, to report lack of stimulation of the bodily tissues. Still further, these embodiments enable a reduction in power requirement, because control of the signal is provided by the sensor to the signal generator loop.

US 20080306325A1

Publication (10) **Pub. No.: US 2008/0306325 A1**
(43) **Pub. Date: Dec. 11, 2008**

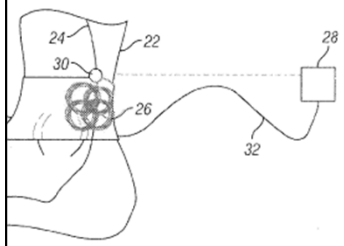
Publication Classification

(51) **Int. Cl.**
A61N 2/02 (2006.01)

(52) **U.S. Cl.** **600/13**

(57) **ABSTRACT**

An energy emitting apparatus for providing a medical therapy includes one or more energy generators, a logic controller electrically connected to the one or more energy generators, and one or more sensors for detecting electric conduction in a target nerve that are connected to the logic controller. The one or more energy generators produce energy focused on the target nerve upon receiving a signal from the logic controller, and the energy is varied by the logic controller according to an input provided by the one or more sensors. In one embodiment, the energy emitting apparatus is an apparatus for magnetic induction therapy that includes one or more conductive coils disposed in an ergonomic housing that produce a magnetic field focused on the target nerve upon receiving an electric current from the logic controller based on an input provided by the one or more sensors.

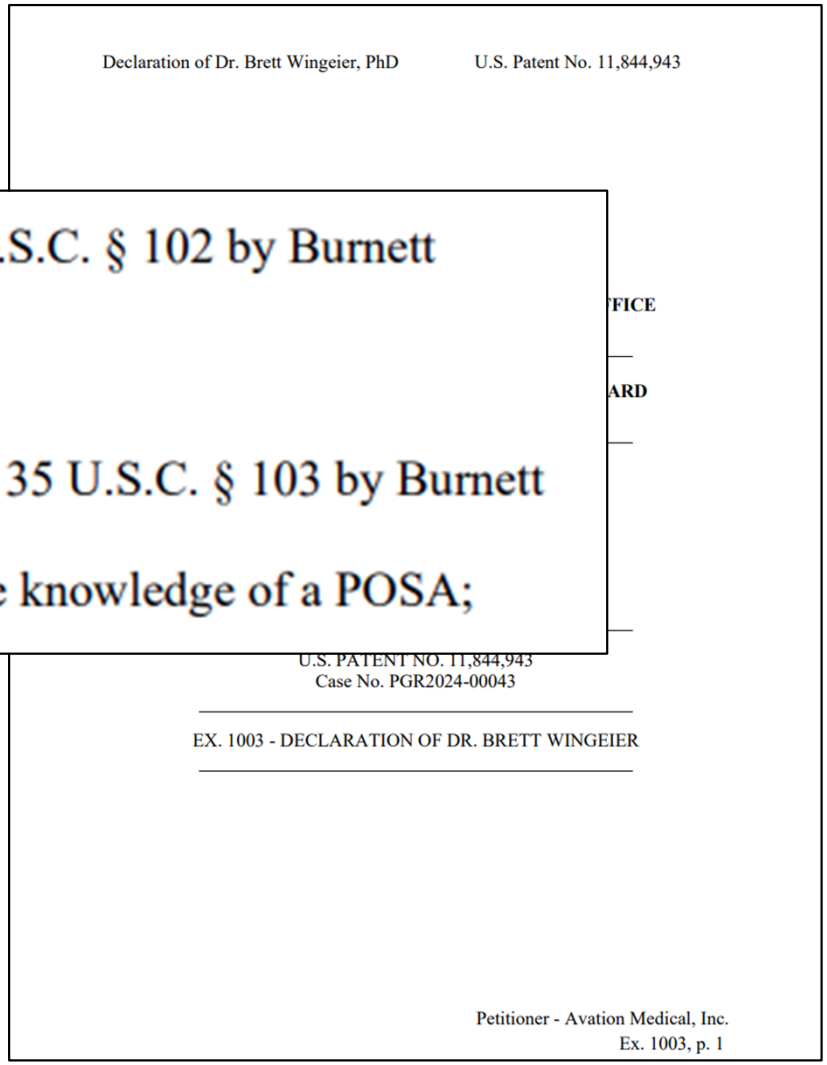


Petitioner - Avation Medical, Inc.
Ex. 1006, p. 1

See Paper 2 at 65-79 (citing Ex.1006 at [0088]).

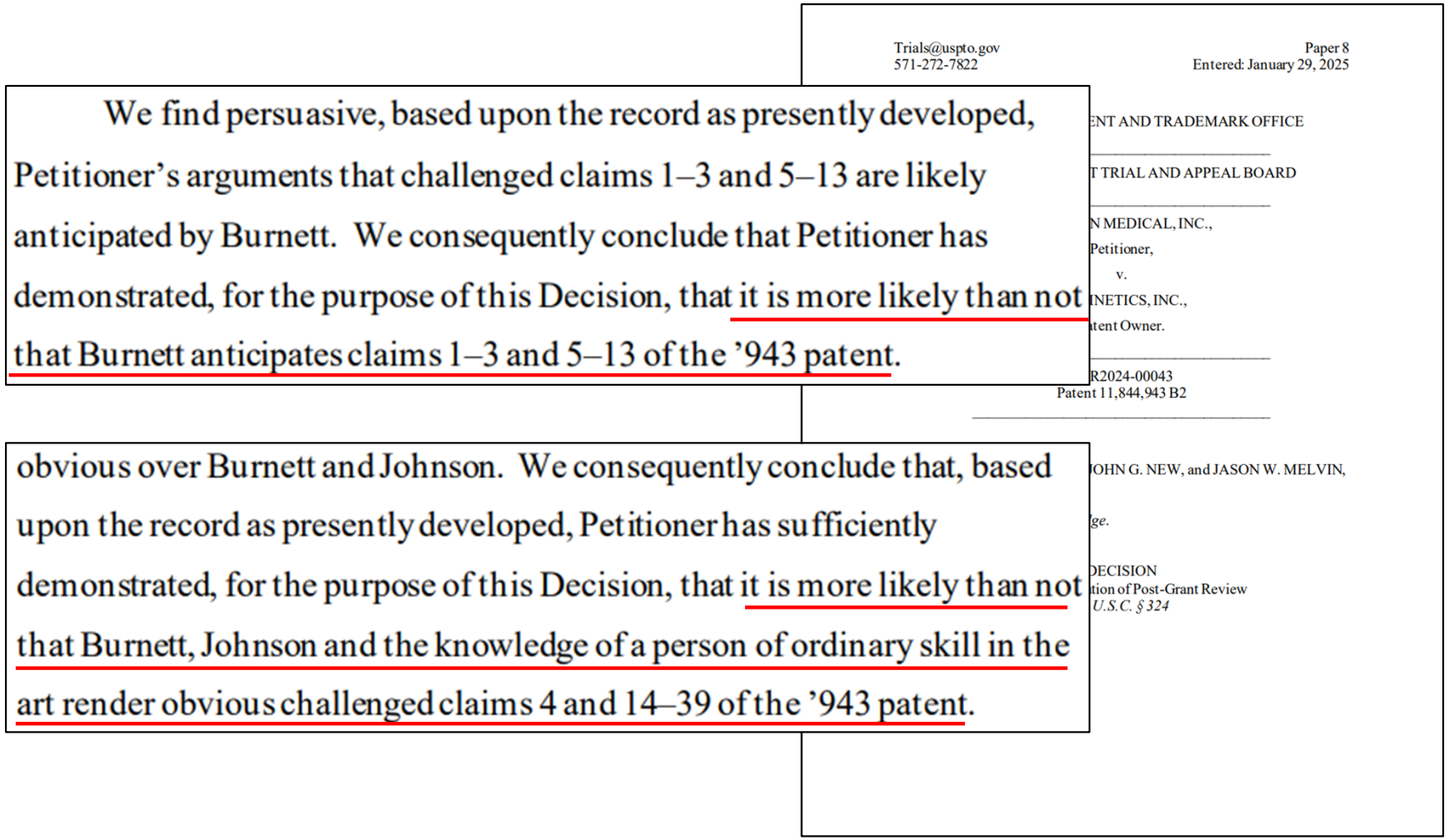
Dr. Wingeier Confirms Burnett Discloses All Elements

- Claims 1-3 and 5-13 are anticipated under 35 U.S.C. § 102 by Burnett (Ex.1006);
- Claims 4 and 14-39 are rendered obvious under 35 U.S.C. § 103 by Burnett (Ex.1006) in view of Johnson (Ex.1007) and the knowledge of a POSA;



See Ex.1003 at ¶ 274.

Petitioner's Burnett Grounds 5-8 and Board's Findings on Institution Undisputed by Patent Owner



Trials@uspto.gov
571-272-7822

Paper 8
Entered: January 29, 2025

ENT AND TRADEMARK OFFICE

T TRIAL AND APPEAL BOARD

N MEDICAL, INC.,
Petitioner,
v.
INETICS, INC.,
tent Owner.

R2024-00043
Patent 11,844,943 B2

OHN G. NEW, and JASON W. MELVIN,

ge.

DECISION
tion of Post-Grant Review
U.S.C. § 324

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

obvious over Burnett and Johnson. We consequently conclude that, based upon the record as presently developed, Petitioner has sufficiently demonstrated, for the purpose of this Decision, that it is more likely than not that Burnett, Johnson and the knowledge of a person of ordinary skill in the art render obvious challenged claims 4 and 14–39 of the '943 patent.

See Paper 8 at 57, 60.

Claims 1-39 Lack Enablement

- "Enablement requires that the specification teach those in the art to ***make and use the invention without 'undue experimentation***.'" *In re Vaeck*, 947 F.2d 488, 495 (Fed. Cir. 1991).
- "Whether undue experimentation is needed is not a single, simple factual determination, but rather is ***a conclusion reached by weighing many factual considerations***." *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).
- "[W]here the specification teaches against a purported aspect of an invention, ***such a teaching 'is itself evidence that at least a significant amount of experimentation would have been necessary to practice the claimed invention***.'" *Liebel-Flarsheim Co. v. Medrad, Inc.*, 481 F.3d 1371, 1379 (Fed. Cir. 2007) (quoting *AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1244 (Fed. Cir. 2003)).

See Paper 2 at 79-80.

The '943 Patent's Specification Teaches Away from the Claimed Invention

- The '943 Patent teaches away from positioning electrical stimulator "near an ankle" of the patient:
  - "In contrast, ***utilizing an electrical stimulus*** having a frequency of about 5 Hz to about 60 Hz or greater ***to stimulate a target nerve or tissue through a non-glabrous skin surface (via an electrode positioned over the non-glabrous skin surface) is intolerable and painful, resulting in burns or injury, and thus making such a procedure impractical and not feasible***.

    For example, ***delivering electrical stimulation through a nonglabrous surface of the body, for example, by stimulating a site overlying a nerve near the medial malleolus to elicit a motor response of the abductor hallucis longus, generates a painful shock 81 to the patient***. While at a single pulse, such as in the use for EMG diagnostics, such electrical stimulation may be tolerable, as the frequency increases, ***the shocking sensation builds and quickly becomes painful and intolerable***."

    Ex.1001, 50:35-51:3 (emphasis added).

See Paper 2 at 80-81 (citing Ex.1001 at 50:35-51:3).

Skin "Near an Ankle" is Non-Glabrous

big toe. Moreover, a "glabrous" surface of the body is a smooth surface that is not typically covered by hair, such as the palm of the hand ("palmar surface") or bottom of the foot ("plantar surface"). A "non-glabrous" surface, by contrast, is a non-smooth surface of the body that may be covered by hair, such as the inner ankle.

272. Based on these statements in the patent specification, the patent clearly indicates that transdermal electrical stimulation therapy targeting nerves near the inner ankle through a non-glabrous skin surface should not be used because it is "painful and intolerable" to patients and such a procedure is "impractical and not feasible." This is, however, directly contrary to the claims, which all require positioning a noninvasive electrical stimulator "near an ankle" of the patient in order to target the posterior tibial nerve. *Id.*, cls. 1, 14, 27. Thus, in my opinion, the patent teaches against the claimed invention (*i.e.*, positioning a noninvasive electrical stimulator "near an ankle" of the patient in order to target the posterior tibial nerve) because the specification clearly indicates that transdermal electrical stimulation should ***not*** be applied to a non-glabrous skin surface such as "near an ankle."

NITED 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. 11,844,943
Case No. PGR2024-00043

EX. 1003 - DECLARATION OF DR. BRETT WINGEIER

See Paper 2 at 80-81 (citing Ex.1003 at ¶¶271-272.

Claims 1-39 of the ‘943 Patent Are Unpatentable

- Svihra is a prior art printed publication
- Amarenco is a prior art printed publication
- Burnett is prior art to the claims of the ’943 Patent
- ***The Board should find Petitioner has proven, by a preponderance of the evidence, that claims 1-39 of the ‘943 Patent are unpatentable***

Back-Up Slides

PGR Eligibility

The '943 Patent Is Eligible for PGR

- Patents described in AIA §3(n)(1) are eligible for PGR. *See* AIA §6(f)(2)(A), 125 Stat. at 311.
- According to §3(n)(1), 125 Stat. at 293, AIA patents include:

> any application for patent, and [] ***any patent*** issuing thereon, ***that contains or contained at any time***—
>
> (A) ***a claim to a claimed invention that has an effective filing date*** as defined in section 100(i) of title 35, United States Code, ***that is on or after the effective date [i.e., March 16, 2013]***; or
>
> (B) ***a specific reference*** under section 120, 121, or 365(c) of title 35, United States Code, ***to any patent or application that contains or contained at any time such a claim***.

See Paper 2 at 8; Paper 8 at 10.

The ‘943 Patent Is Eligible for PGR

- **The ‘943 Patent contains a specific reference to patents and/or applications that “contain[] or contained at any time” claims with an effective filing date after March 16, 2013:**
  - ‘669 Patent – contains claims (*e.g.*, claims 1 and 19) with effective filing date no earlier than March 30, 2017
  - ‘875 Application – contained claims (*e.g.*, originally-filed claims 1 and 21) with effective filing date no earlier than March 30, 2017
  - ‘706 Application – contained claims (*e.g.*, originally-filed claims 1, 11, and 12) with effective filing date no earlier than March 30, 2017
  - *See* Paper 2 at 9-13.
- **The ‘943 Patent contains claims with an effective filing date after March 16, 2013:**
  - No enablement for claims reciting “positioning a first portion of a patient’s body near an ankle relative to an electrical stimulator”
  - *See* Paper 2 at 13.

Patent Owner's Motion 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 Paper 23 at 2.
- **Consolidated Trial Practice Guide (Nov. 2019) at 73:**
  - "A party also ***may submit rebuttal evidence in support of its reply***."

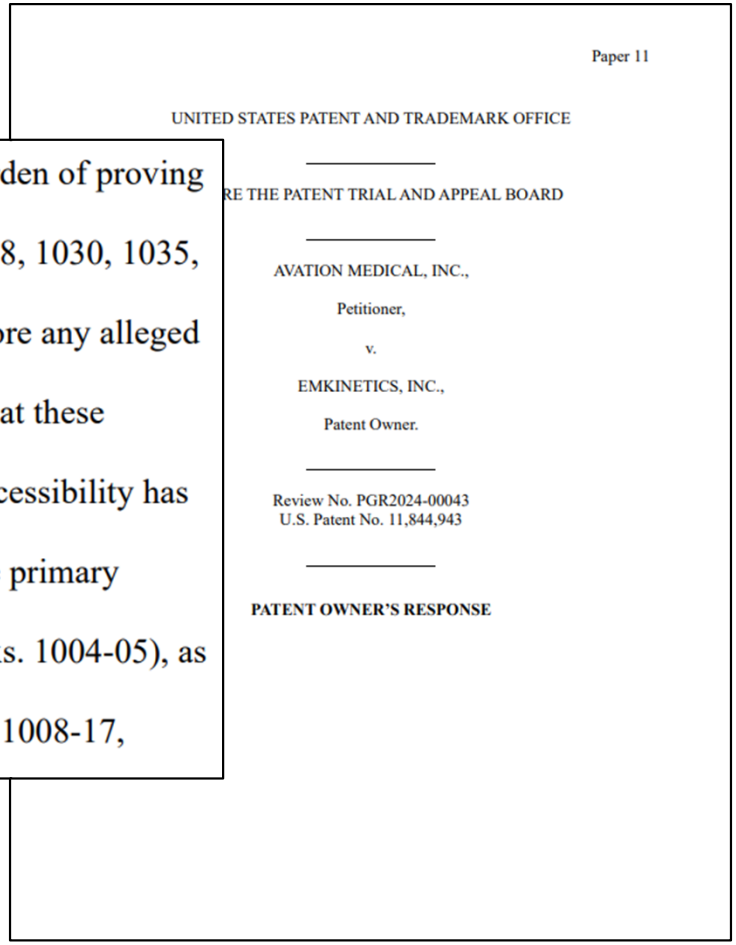
  See Paper 23 at 2.
- ***Hulu, LLC v. Sound View Innovations, LLC*, IPR2018-01039, Paper 29 at 14-15 (PTAB December 20, 2019) (precedential):**
  - ***"[S]ome limited opportunities exist for the petitioner to present new evidence later, including***: (1) in a reply to a patent owner preliminary response; (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 Paper 23 at 3.

Petitioner's Reply Evidence Properly Responded to Patent Owner Response

1. **Grounds 1-8 & 10.** 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) 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, for which public accessibility has not been established by a preponderance of the evidence, include the primary references on which Grounds 1-8 are based (Svihra & Amarenco, Exs. 1004-05), as well as the secondary references on which Ground 10 is based (Exs. 1008-17,



Paper 11

UNITED STATES PATENT AND TRADEMARK OFFICE

RE THE PATENT TRIAL AND APPEAL BOARD

AVATION MEDICAL, INC.,

Petitioner,

v.

EMKINETICS, INC.,

Patent Owner.

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

PATENT OWNER'S RESPONSE

See Paper 11 at 1.

Reply Evidence Is Not Supplemental Information

- **37 C.F.R. § 42.223:**
  - Relates to filing of "supplemental information," not reply evidence

  See Paper 23 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 Paper 23 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

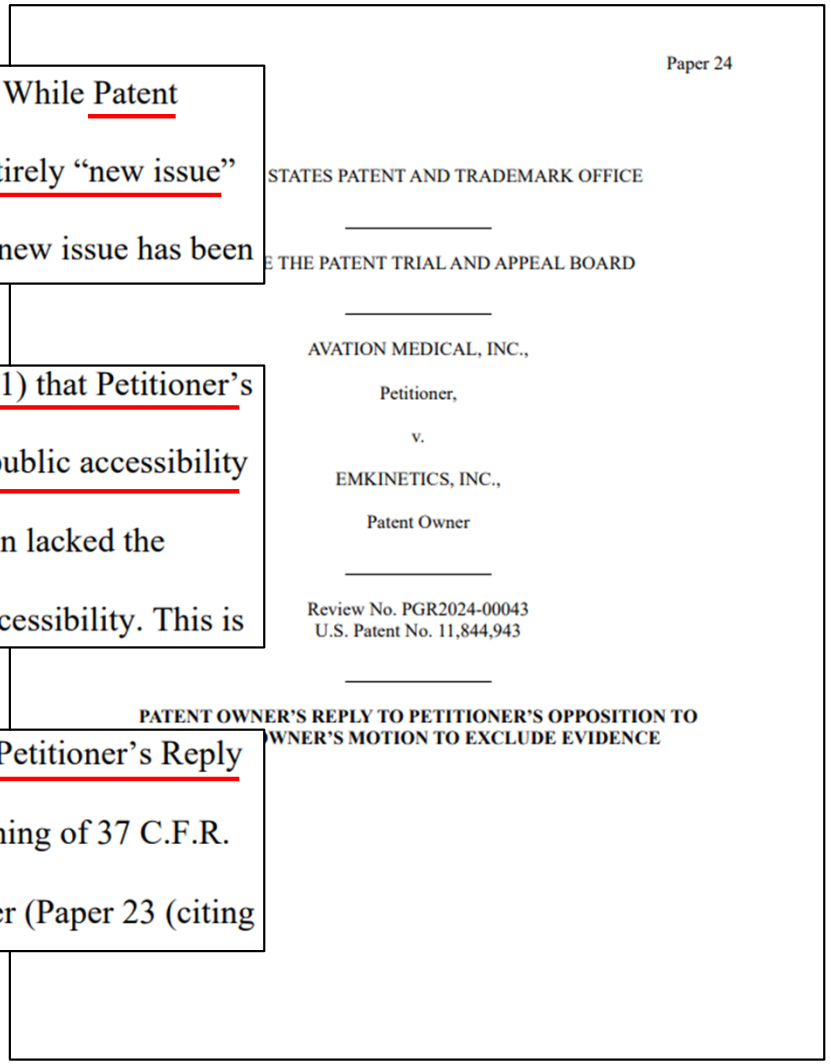
See Paper 24 at 2.

evidence. Rather, Patent Owner argued in its Response (Paper 11) that Petitioner's case-in-chief, *i.e.*, the Petition (Paper 2), failed to establish the public accessibility of numerous references, *e.g.*, certain relied-upon documents even lacked the hallmarks necessary to make out a *prima facie* case of public accessibility. This is

See Paper 24 at 3.

As discussed above, Patent Owner does *not* contend that Petitioner's Reply (Paper 12) 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 23 (citing

See Paper 24 at 4.



Paper 24

STATES PATENT AND TRADEMARK OFFICE

E THE PATENT TRIAL AND APPEAL BOARD

AVATION MEDICAL, INC.,

Petitioner,

v.

EMKINETICS, INC.,

Patent Owner

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

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

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 near an ankle relative to an electrical stimulator such that a posterior tibial nerve within the first portion of the body is directly targeted by the electrical stimulator;
  - [1.b] passing a current through the electrical stimulator; and
  - [1.c] delivering an electrical stimulus from the electrical stimulator to the posterior tibial nerve such that the posterior tibial nerve directly receives the electrical stimulation to treat overactive bladder or incontinence.
- **Claim 2**: The method of claim 1 wherein non-invasively positioning comprises positioning an electrode patch in communication with the electrical stimulator near an ankle of the patient.
- **Claim 3**: The method of claim 1 further comprising detecting a muscular response caused by an electrical conduction or stimulation of the posterior tibial nerve.
- **Claim 4**: The method of claim 1 wherein delivering the electrical stimulus comprises activating the electrical stimulator for a duration of about 30 minutes per week to treat the patient.
- **Claim 5**: The method of claim 1 further comprising displaying physiological parameters detected from the patient.
- **Claim 6**: The method of claim 1 further comprising detecting for a lack of presence of electrical conduction at a second portion of the patient's body distant from the first portion as an indicator of electrode migration from the first portion.
- **Claim 7**: The method of claim 6 wherein detecting for the presence of electrical conduction comprises detecting via an electrode patch positioned upon the second portion.
- **Claim 8**: The method of claim 1 further comprising detecting for a lack of presence of electrical conduction at a second portion of the patient's body distant from the first portion as an indicator of electrode malfunction from the first portion.
- **Claim 9**: The method of claim 8 wherein detecting for the presence of electrical conduction comprises detecting via an electrode patch positioned upon the second portion.
- **Claim 10**: The method of claim 1 further comprising detecting for a lack of presence of electrical conduction at a second portion of the patient's body distant from the first portion as an indicator of proper electrode placement upon the first portion.
- **Claim 11**: The method of claim 10 wherein detecting for the presence of electrical conduction comprises detecting via an electrode patch positioned upon the second portion.
- **Claim 12**: The method of claim 1 further comprising detecting for a lack of presence of electrical conduction through tissue at a second portion of the patient's body distant from the first portion as an indicator of electrode placement upon the first portion.
- **Claim 13**: The method of claim 12 wherein detecting for the presence of electrical conduction through tissue comprises detecting via an electrode patch positioned upon the second portion.

- **Claim 14**:
  - [14.p] A method of treating overactive bladder or incontinence, comprising:
  - [14.a] non-invasively positioning a first portion of a patient's body near an ankle relative to an electrical stimulator positioned within a sock worn upon a foot of the patient such that a posterior tibial nerve within the first portion of the body is directly targeted by the electrical stimulator;
  - [14.b] passing a current through the electrical stimulator; and
  - [14.c] delivering an electrical stimulus from the electrical stimulator to the posterior tibial nerve such that the posterior tibial nerve directly receives the electrical stimulation to treat overactive bladder or incontinence.
- **Claim 15**: The method of claim 14 wherein non-invasively positioning comprises positioning an electrode patch in communication with the electrical stimulator near an ankle of the patient.
- **Claim 16**: The method of claim 14 further comprising detecting a muscular response caused by an electrical conduction or stimulation of the posterior tibial nerve.
- **Claim 17**: The method of claim 14 wherein delivering the electrical stimulus comprises activating the electrical stimulator for a duration of about 30 minutes per week to treat the patient.
- **Claim 18**: The method of claim 14 further comprising displaying physiological parameters detected from the patient.
- **Claim 19**: The method of claim 14 further comprising detecting for a lack of presence of electrical conduction at a second portion of the patient's body distant from the first portion as an indicator of electrode migration from the first portion.
- **Claim 20**: The method of claim 19 wherein detecting for the presence of electrical conduction comprises detecting via an electrode patch positioned upon the second portion.
- **Claim 21**: The method of claim 14 further comprising detecting for a lack of presence of electrical conduction at a second portion of the patient's body distant from the first portion as an indicator of electrode malfunction from the first portion.
- **Claim 22**: The method of claim 21 wherein detecting for the presence of electrical conduction comprises detecting via an electrode patch positioned upon the second portion.
- **Claim 23**: The method of claim 14 further comprising detecting for a lack of presence of electrical conduction at a second portion of the patient's body distant from the first portion as an indicator of proper electrode placement upon the first portion.
- **Claim 24**: The method of claim 23 wherein detecting for the presence of electrical conduction comprises detecting via an electrode patch positioned upon the second portion.
- **Claim 25**: The method of claim 14 further comprising detecting for a lack of presence of electrical conduction through tissue at a second portion of the patient's body distant from the first portion as an indicator of electrode placement upon the first portion.
- **Claim 26**: The method of claim 25 wherein detecting for the presence of electrical conduction through tissue comprises detecting via an electrode patch positioned upon the second portion.

- **Claim 27**:
  - [27.p] A method of treating overactive bladder or incontinence, comprising:
  - [27.a] non-invasively positioning a first portion of a patient's body near an ankle relative to an electrical stimulator positioned upon a strap which is secured over a foot of the patient such that a posterior tibial nerve within the first portion of the body is directly targeted by the electrical stimulator;
  - [27.b] passing a current through the electrical stimulator; and
  - [27.c] delivering an electrical stimulus from the electrical stimulator to the posterior tibial nerve such that the posterior tibial nerve directly receives the electrical stimulation to treat overactive bladder or incontinence.
- **Claim 28**: The method of claim 27 wherein non-invasively positioning comprises positioning an electrode patch in communication with the electrical stimulator near an ankle of the patient.
- **Claim 29**: The method of claim 27 further comprising detecting a muscular response caused by an electrical conduction or stimulation of the posterior tibial nerve.
- **Claim 30**: The method of claim 27 wherein delivering the electrical stimulus comprises activating the electrical stimulator for a duration of about 30 minutes per week to treat the patient.
- **Claim 31**: The method of claim 27 further comprising displaying physiological parameters detected from the patient.
- **Claim 32**: The method of claim 27 further comprising detecting for a lack of presence of electrical conduction at a second portion of the patient's body distant from the first portion as an indicator of electrode migration from the first portion.
- **Claim 33**: The method of claim 32 wherein detecting for the presence of electrical conduction comprises detecting via an electrode patch positioned upon the second portion.
- **Claim 34**: The method of claim 27 further comprising detecting for a lack of presence of electrical conduction at a second portion of the patient's body distant from the first portion as an indicator of electrode malfunction from the first portion.
- **Claim 35**: The method of claim 34 wherein detecting for the presence of electrical conduction comprises detecting via an electrode patch positioned upon the second portion.
- **Claim 36**: The method of claim 27 further comprising detecting for a lack of presence of electrical conduction at a second portion of the patient's body distant from the first portion as an indicator of proper electrode placement upon the first portion.
- **Claim 37**: The method of claim 36 wherein detecting for the presence of electrical conduction comprises detecting via an electrode patch positioned upon the second portion.
- **Claim 38**: The method of claim 27 further comprising detecting for a lack of presence of electrical conduction through tissue at a second portion of the patient's body distant from the first portion as an indicator of electrode placement upon the first portion.
- **Claim 39**: The method of claim 38 wherein detecting for the presence of electrical conduction through tissue comprises detecting via an electrode patch positioned upon the second portion.