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On behalf of **Cala Health, Inc.**

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CALA HEALTH, INC.,
Petitioner,

v.

EMKINETICS INC.,
Patent Owner.

IPR 2023-00508
U.S. Patent 9,757,584

**PETITION FOR *INTER PARTES* REVIEW OF
U.S. PATENT 9,757,584**

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EXHIBIT LIST

Exhibit No.	Description
1001	U.S. Patent No. 9,757,584 (“the ’584 patent”)
1002	Declaration of John Laughlin
1003	CV of John Laughlin
1004	Excerpts from the ’584 Patent File History
1005	Fred E. Govier, et al., “Percutaneous Afferent Neuromodulation for the Refractory Overactive Bladder: Results of a Multicenter Study,” 165 J. UROLOGY 1193-1198 (April 2001) (“Govier”)
1006	U.S. Publication No. 2005/0171576 (“Williams”)
1007	U.S. Publication No. 2005/0182454 (“Gharib”)
1008	U.S. Publication No. 2009/0076565 to Surwit
1009	H.C. Klingler, et al., “Use of Peripheral Neuromodulation of the S3 Region for Treatment of Detrusor Overactivity: A Urodynamic-based Study,” UROLOGY 56:766-771, 2000 (“Klingler”)
1010	Michael R. Van Balken, et al., “Posterior Tibial Nerve Stimulation as Neuromodulative Treatment of Lower Urinary Track Dysfunction,” 166 J. UROLOGY 914-918 (September 2001) (“Van Balken”)
1011	Declaration of Rachel J. Watters regarding Van Balken (Ex. 1010)
1012	Declaration of Rachel J. Watters regarding Govier (Ex. 1005)
1013	Declaration of Sylvia D. Hall-Ellis, Ph.D. regarding Klingler (Ex. 1009)
1014	Cornell MARC record for Klingler (Ex. 1009)
1015	OCLC MARC record for Klingler (Ex. 1009)
1016	Library of Congress Authorities

Exhibit No.	Description
1017	Curriculum Vitae of Sylvia D. Hall-Ellis, Ph.D.
1018	Evaluation of Automatic Class III Designation – UroSurge Percutaneous SANS (Stoller Afferent Nerve Stimulator) Device
1019-1021	RESERVED
1022	Excerpts of File History for U.S. Patent No. 11,224,742 (the '742 patent)

Cala Health, Inc. (“Petitioner”) requests *inter partes* review of claims 1-8 of U.S. Patent No. 9,757,584 (“the ’584 patent,” Ex. 1001), purportedly owned by EMKinetics Inc. (“Patent Owner”).

I. SUMMARY OF THE ISSUES PRESENTED

The claims of the '584 patent recite methods of treating an overactive bladder by passing an electrical current along the tibial nerve or a branch of that nerve. The claimed methods recite only a few steps, specifically: (1) placing an electrode patch or transcutaneous electrode [green] on the patient's skin near the ankle, (2) inserting a percutaneous electrode [blue] into the patient's skin in proximity to the tibial nerve [red], (3) coupling the electrode patch (or transcutaneous electrode) and percutaneous electrode to a controller unit [yellow], and (4) activating the controller unit so current pulses flow along the tibial nerve between the electrode patch and percutaneous electrode.

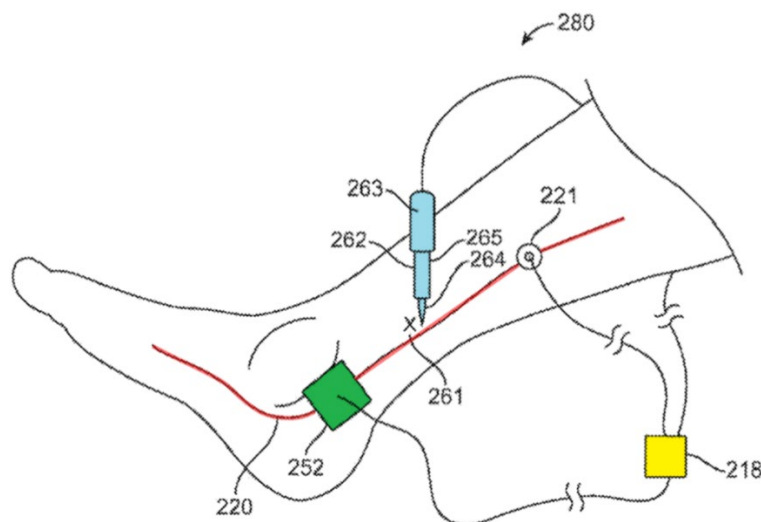


FIG. 27

The claimed methods were well known and had been implemented in many studies as of October 2, 2006, the earliest claimed priority date for the '584 patent. For example, Govier (Ex. 1005), published in 2001, discloses the results of a multicenter study of treatments for overactive bladder. As illustrated in Govier's Figure 3 below, Govier discloses the method of the '584 patent, including the steps of: (1) placing an electrode patch or transcutaneous electrode [green] on the patient's skin near the ankle, (2) inserting a percutaneous electrode [blue] into the patient's skin in proximity to the tibial nerve, (3) coupling the electrode patch and the percutaneous electrode to a controller unit [yellow], and (4) activating the controller unit so current pulses flow along the tibial nerve between the electrode patch and the percutaneous electrode.

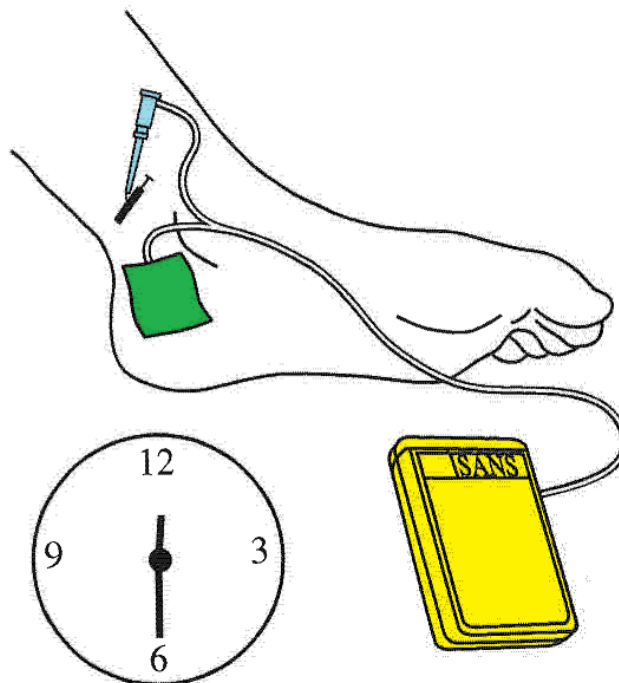
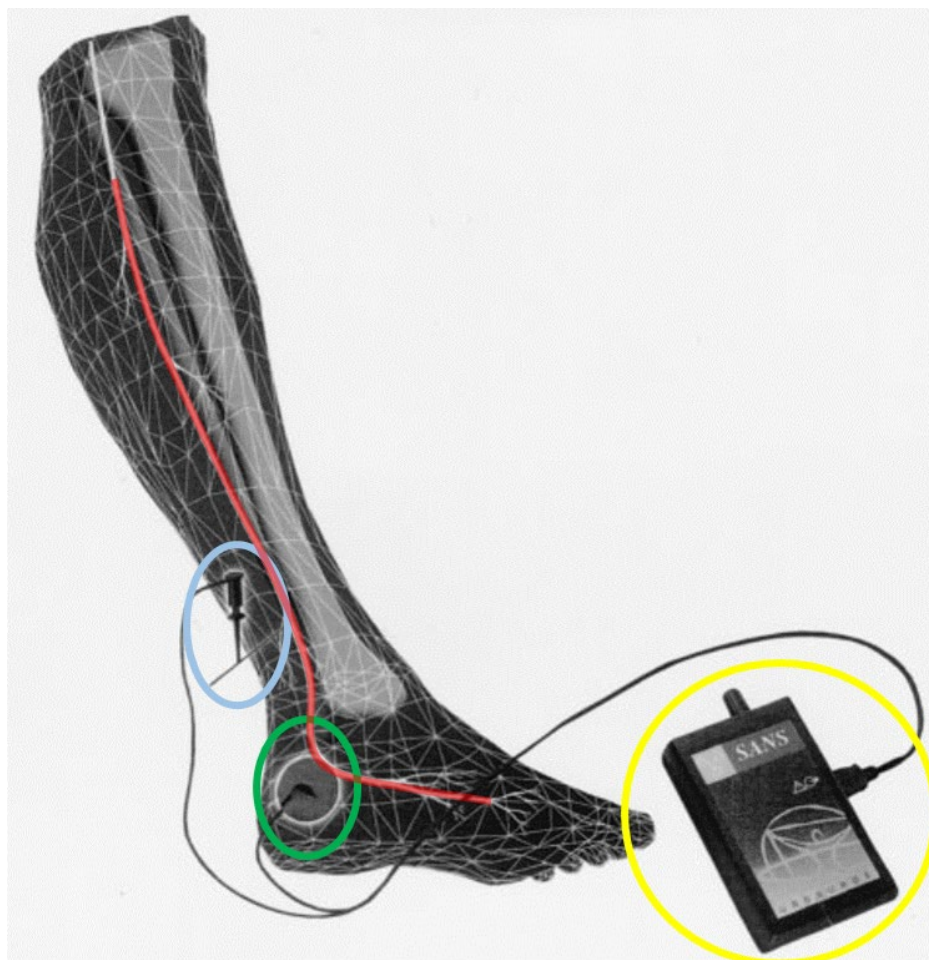


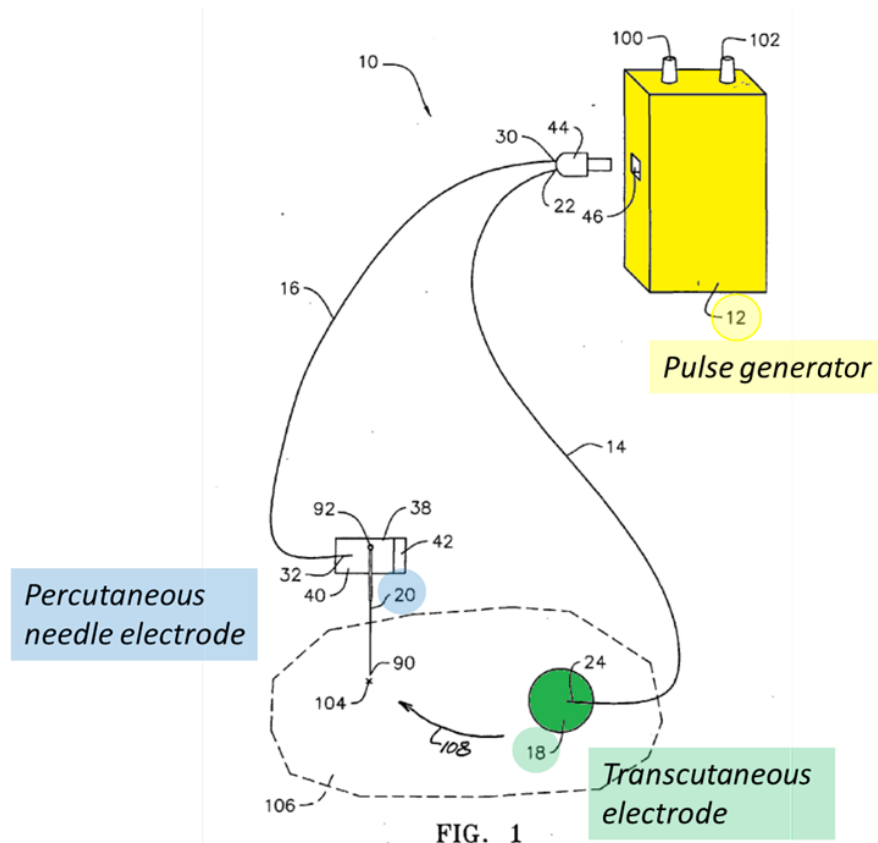
FIG. 3. Attach electrode and lead wire by placing electrode on same leg as needle near arch of foot. Connect grabber plug to needle on handle portion just above insertion point. Patient will control stimulation at comfortable level for 30 minutes.

Similarly, Klingler, published in 2000, describes the results of a study to treat overactive bladder by stimulating the tibial nerve. As illustrated by Klingler's Figure 1 below, Klingler discloses the method claimed in the '584 patent, including the steps of: (1) placing an electrode patch or transcutaneous electrode [green circle] on the patient's skin near the ankle, (2) inserting a percutaneous electrode [blue circle] into the patient's skin in proximity to the tibial nerve [red], (3) coupling the electrode patch and the percutaneous electrode to a controller unit [yellow], and (4) activating the controller unit so current pulses flow along the tibial nerve between the electrode patch and the percutaneous electrode.



Likewise, Van Balken, published in 2001, describes the results of a study to treat overactive bladder by stimulating the tibial nerve. Van Balken describes the method claimed in the '584 patent, including the steps of: (1) placing a “stick on electrode” on the patient’s skin “near the arch of the foot,” (2) inserting a “34 gauge stainless steel needle” into the patient’s skin in proximity to the tibial nerve, (3) electrically coupling the stick on electrode and needle electrode to a “low voltage (9 volts) Urosurge stimulator,” and (4) activating the stimulator so current pulses flow along the tibial nerve between the electrode patch and the needle electrode.

The patent literature also disclosed the methods claimed in the '584 patent. For example, Williams, published August 4, 2005, discloses “an electro-nerve stimulation apparatus” that is “particularly suited for the treatment of urinary incontinence.” As illustrated in Williams’s Figure 1 below, Williams discloses the method of the '584 patent, including the steps of: (1) placing a transcutaneous electrode [green] on the patient’s skin near the ankle, (2) inserting a percutaneous needle electrode [blue] into the patient’s skin in proximity to the tibial nerve, (3) coupling the transcutaneous electrode and needle electrode to a controller unit [yellow], and (4) activating the controller unit so current pulses flow along the tibial nerve between the transcutaneous electrode and the needle electrode.



These prior art publications establish that the claimed method was known and disclosed before the earliest claimed priority date of the '584 patent. Unfortunately, the journal articles were not before the Examiner during prosecution. Because the prior art anticipates or renders obvious the claimed methods, claims 1-8 of the '584 patent should be cancelled.

II. THE PARTIES

Petitioner is a bioelectronics medicine company that has developed neuromodulation therapies that have transformed the standard of care for chronic disease. Petitioner's Cala Trio product is currently the only non-invasive, drug free treatment that addresses the root cause of essential tremor with electrical

stimulation. The Cala Trio has received significant praise in the industry, including being named a GOLD WINNER of the 2020 Edison Awards in the Diagnostic & Disease Treatment category. Petitioner is currently developing additional neuromodulation therapies for a host of chronic diseases in the fields of neurology, cardiology, urology, and psychiatry.

In contrast, Patent Owner does not appear to commercially practice the '584 patent.

III. THE '584 PATENT

A. Overview of the '584 Patent

The '584 patent issued on September 12, 2017, and claims priority through a series of continuation and continuations-in-part applications to U.S. Provisional Patent Application No. 60/848,720 filed October 2, 2006.

The majority of the '584 patent relates to “systems and/or methods for electromagnetic induction therapy,” which is not the focus of the claims. (Ex. 1001, abstract.) However, a smaller segment of the patent describes methods for treating ailments by providing “electrical energy” to a target nerve. (*Id.*, 8:33-37.) For example, the '584 patent describes an energy emitting system 280 that

“includes one or more percutaneous electrode needles 262 [blue]¹ coupled to a controller 218 [yellow] and having an end insertable into a subject’s body in proximity to [a] target nerve.” (*Id.*, 27:55-59, Fig. 27.) “The percutaneous electrode needle 262 is inserted through the skin at a location and to a depth that brings the tip in close proximity to the target nerve to be stimulated.” (*Id.*, 27:67-28:3.)

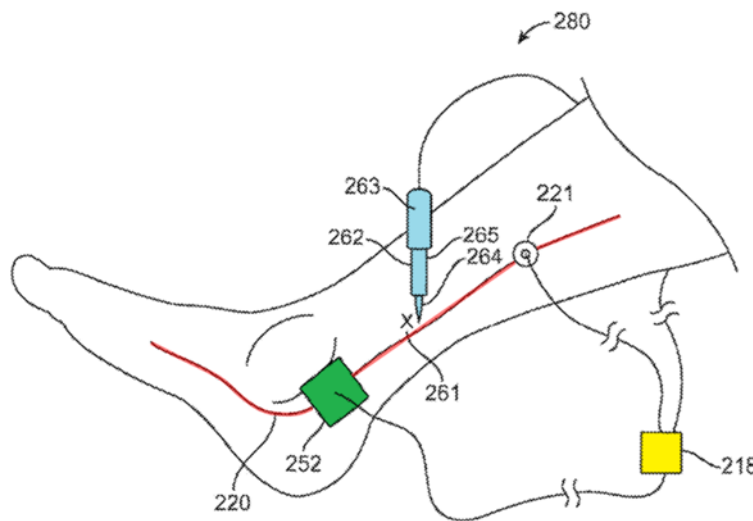


FIG. 27

(*Id.*, Fig. 27.)

“The percutaneous electrode needle 262 is inductively coupled to conductive microneedle patch 252 [green].” (*Id.*, 27:61-63.) The “patch can include at least one electrode” and “may optionally be attached to various other materials or adhesive materials.” (*Id.*, 28:62-66.) While Figure 27 specifically illustrates a

¹ All color and colored labels have been added by Petitioner unless otherwise noted.

“microneedle patch,” the ’584 patent discloses that the microneedles are optional. (See e.g., *id.*, 28:66-29:2 (“An array of microneedles *may* be deposited on a surface of the electrode....”).) The “microneedle patch 252 is placed on a first portion of a patient’s body, for example a foot, ankle, or leg, in proximity to posterior tibial nerve 220 [red above] within the first portion of the patient’s body and downstream or distal to a selected stimulation site 261.” (*Id.*, 27:63-67.)

In use, the “controller 218 is activated and a current passes through microneedle patch 252 and traverses the internal stimulation site 261 by passing from microneedle patch 252 to the internal percutaneous electrode needle 262....” (*Id.*, 28:4-7.) The ’584 patent discloses that the described stimulating devices may have various indications, including treating overactive bladder. (*Id.*, 41:59-42:14.)

B. Prosecution History of the ’584 Patent

Patent Owner filed the application for the ’584 patent on February 29, 2016. In a Non-Final Office Action, the Examiner rejected the claims as being either anticipated or rendered obvious by U.S. Publication No. 2009/0076565 to Surwit. (Ex. 1004, 70-72; Ex. 1008.) The Non-Final Office Action also identified double-patenting rejections of the pending claims vis-à-vis U.S. Patent No. 9,387,338, which is the parent of the ’584 patent. (*Id.*, 72-73.)

In response to the Non-Final Office Action, Patent Owner admitted that “Surwit discloses a device which ‘is a combination of electrode and generator

components including a 34 gauge needle 4 cm in length, surface electrode, lead wires and a hand held electrical generator.” (*Id.*, 57.) However, Patent Owner argued, “Surwit does not disclose current ‘passing between the electrode patch and the percutaneous electrode.” (*Id.*) Patent Owner claimed, “nowhere does Surwit disclose the relationship between the needle and the surface electrode, let alone that current passes between the surface electrode and the needle.” (*Id.*)

The Examiner subsequently allowed the claims without comment. (*Id.*, 21-27.) However, as explained below, the prior art cited in this Petition discloses a current that passes between a surface electrode and percutaneous needle to stimulate the tibial nerve.

C. Priority

The '584 patent's earliest claimed priority date is October 2, 2006. The references relied on by Petitioner herein were published over one year before the earliest claimed priority date and, therefore, qualify as prior art under 35 U.S.C. §102(b). However, Petitioner reserves the right to contest the actual priority date of the '584 patent's claims should the priority date become relevant in the future.

D. Level of Ordinary Skill in the Art

A person of ordinary skill in the art (“POSITA”) at the time of the claimed invention would have had an undergraduate degree in the field of biomedical engineering, or a related engineering discipline, and at least two years of

experience in the design and/or analysis of biomedical devices. Additional work experience could serve as a substitute for an engineering degree. (Ex. 1002, ¶23.)

IV. CLAIM CONSTRUCTION

A claim subject to *inter partes* review “shall be construed using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. §282(b), including construing the claim in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent.” 37 C.F.R. §42.100(b). Petitioner believes that no claim terms require express construction to resolve the challenges in this Petition. *See Consolidated Patent Trial Practice Guide* at 44 (November 2019); *see also Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017). However, Petitioner reserves the right to respond to any claim construction issues raised by Patent Owner. *See id.* For this proceeding only, Petitioner assumes the claims are not invalid under 35 U.S.C. §112, but reserves the right to contest validity under §112 in other proceedings.

V. STATEMENT OF PRECISE RELIEF REQUESTED

A. Grounds

Petitioner requests cancellation of claims 1-8 of the '584 patent as follows:

Ground 1: Claims 1-8 are anticipated under 35 U.S.C. §102(b) by Govier.

Ground 2: Claims 1-8 are unpatentable under 35 U.S.C. §103 as obvious over Govier in view of Williams.

Ground 3: Claims 1-2, 4-6, and 8 are anticipated under 35 U.S.C. §102(b) by Williams.

Ground 4: Claims 1-8 are rendered obvious under 35 U.S.C. §103 by Williams in view of Govier.

Grounds 5-6: Claims 3 and 7 are rendered obvious under 35 U.S.C. §103 by Govier in view of Gharib or, alternatively, over Govier in view of Williams and Gharib.

Grounds 7-8: Claims 3 and 7 are rendered obvious under 35 U.S.C. §103 by Williams in view of Govier or, alternatively over Williams in view of Govier and Gharib.

Additional support is included in the Declaration of John Laughlin (Ex. 1002).

B. Status of References as Prior Art

The relied-upon references are prior art under 35 U.S.C. §102(b) because each reference published more than one year before the '584 patent's earliest claimed priority date (October 2, 2006). Govier published by April 2001; Williams published on August 4, 2005; and Gharib published on August 18, 2005. Petitioner

also relies upon Klingler, published by December 2000, and Van Balken, published by September 2001, as representative of the state of the prior art.

Documentary evidence and the testimony of a qualified librarian with the University of Wisconsin-Madison General Library System establishes that Govier was catalogued, searchable, and accessible to relevant members of the public within two or three weeks of March 19, 2001. (Ex. 1012, pp. 2-3.) Information on the face of Govier is consistent with and, thus, corroborates the documentary evidence and librarian testimony, including the following: (1) the date “April 2001” is printed on both the cover of the journal and the title page of the article within the journal, (2) the title page of the article includes a 2001 copyright date and states that the article was accepted for publication on October 13, 2000, and (3) all of the references cited in Govier pre-date 2001. (Ex. 1005, 1193, 1198.)

Documentary evidence and the testimony of a qualified librarian establishes that Klingler was catalogued, searchable, and accessible to relevant members of the public on or shortly after November 28, 2000. (Ex. 1013 ¶¶40-46 (citing Exs. 1014-1016).) Information on the face of Klingler is consistent with and, thus, corroborates the documentary evidence and librarian testimony, including the following: (1) the date “November 2000” is printed on the cover of the journal, (2) the title page of the article includes a 2000 copyright date and states that the article

was submitted on February 18, 2000 and accepted on June 8, 2000, and (3) all of the references cited in Klingler pre-date 2000. (Ex. 1009, cover, 766, 770-771.)

Documentary evidence and the testimony of a qualified librarian with the University of Wisconsin-Madison General Library System establishes that Van Balken was catalogued, searchable, and accessible to relevant members of the public within two or three weeks of August 16, 2001. (Ex. 1011, pp. 2-3.) Information on the face of Van Balken is consistent with and, thus, corroborates the documentary evidence and librarian testimony, including the following: (1) the date “September 2001” is printed on both the cover of the journal and the title page of the article within the journal, (2) the title page of the article includes a 2001 copyright date and states that the article was accepted for publication on March 9, 2001, and (3) all of the references cited in Van Balken pre-date 2001. (Ex. 1010, 914, 918.)

Govier, Van Balken, Klingler, and Williams constitute analogous art because the references are from the same field of endeavor as the ’584 patent, e.g., neurostimulation to treat various ailments, including overactive bladder and urinary urge incontinence. *Unwired Planet, LLC v. Google Inc.*, 841 F.3d 995, 1000 (Fed. Cir. 2016); Ex. 1002, ¶39. The references are also reasonably pertinent to a particular problem the ’584 inventors were addressing, e.g., treatment of

various ailments, including overactive bladder and urinary urge incontinence, via electrical stimulation of nerves, including the tibial nerve. *Id.*

Gharib also constitutes analogous art because it discloses the same methods of stimulating a nerve and detecting a muscular response as described in the '584 patent. (Ex. 1002, ¶39.) Gharib is reasonably pertinent to a particular problem addressed by the '584 patent (e.g., the need to assess nerve stimulation by assessing a muscular response), is in the same field of endeavor as the '584 patent (neurostimulation), and uses similar technology (e.g., stimulation electrodes, muscular sensors, and a control unit) to the '584 patent. *Id.* Therefore, a POSITA is presumed to have been aware of these references. *In re Nilssen*, 851 F.2d 1401, 1403 (Fed. Cir. 1988).

C. Majority of the Cited Art Was Not Before the Examiner

Govier, Klingler, Van Balken, and Gharib were not before the Examiner during prosecution. Williams was identified in an IDS along with hundreds of other references. (Ex. 1004, 122). However, the Examiner never applied Williams and no evidence suggests that the Examiner considered Williams in combination with any other references. As shown herein, Williams anticipates or renders obvious the challenged claims. Therefore, the Examiner erred in allowing the challenged claims over Williams.

The Examiner’s error is confirmed by the prosecution history of a related patent application, U.S. Patent No. 11,224,742 (the ’742 patent, Ex. 1022). The ’742 patent is the child of the ’584 patent. During prosecution of the ’742 patent, PO proposed substantially similar claims to the challenged claims herein. (Ex. 1022, 363-364.) The Examiner of the ’742 patent, who was different than the Examiner of the ’584 patent, rejected several of the claims under pre-AIA 35 U.S.C. 102(b) “as being anticipated by Williams et al. (US 2005/0171576, hereinafter ‘Williams’) as evidenced by Eini et al. (US 6,432,037, hereinafter ‘Eini’). (*Id.*, 192-193.) PO subsequently acquiesced to the rejection by cancelling or substantially amending the rejected claims. (*Id.*, 177-182.)

VI. SPECIFIC PROPOSED GROUNDS FOR REJECTION

A. Grounds 1-2: Claims 1-8 Are Anticipated By Govier Or Rendered Obvious By Govier Combined With Williams

1. Overview of Govier

Govier discloses the results of a “multicenter clinical trial that was undertaken to determine the safety and efficacy of percutaneous peripheral afferent nerve stimulation for treatment of refractive overactive bladder and/or pelvic floor dysfunction.” (Ex. 1005, 1193.) Fifty-three patients with overactive bladders were treated. (*Id.*) The “[p]atients received weekly percutaneous electrical stimulations via a 34 gauge needle [blue] placed near the tibial nerve 3 finger breadths above

the ankle” and an “electrocardiogram ground pad” [green] “placed over the medial aspect of the calcaneus.” (*Id.*, 1193-94.)

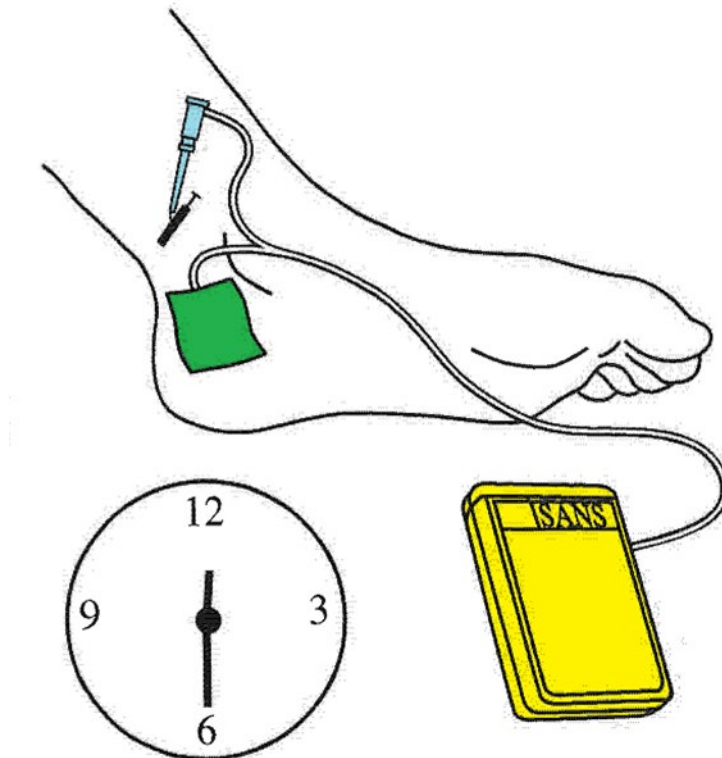


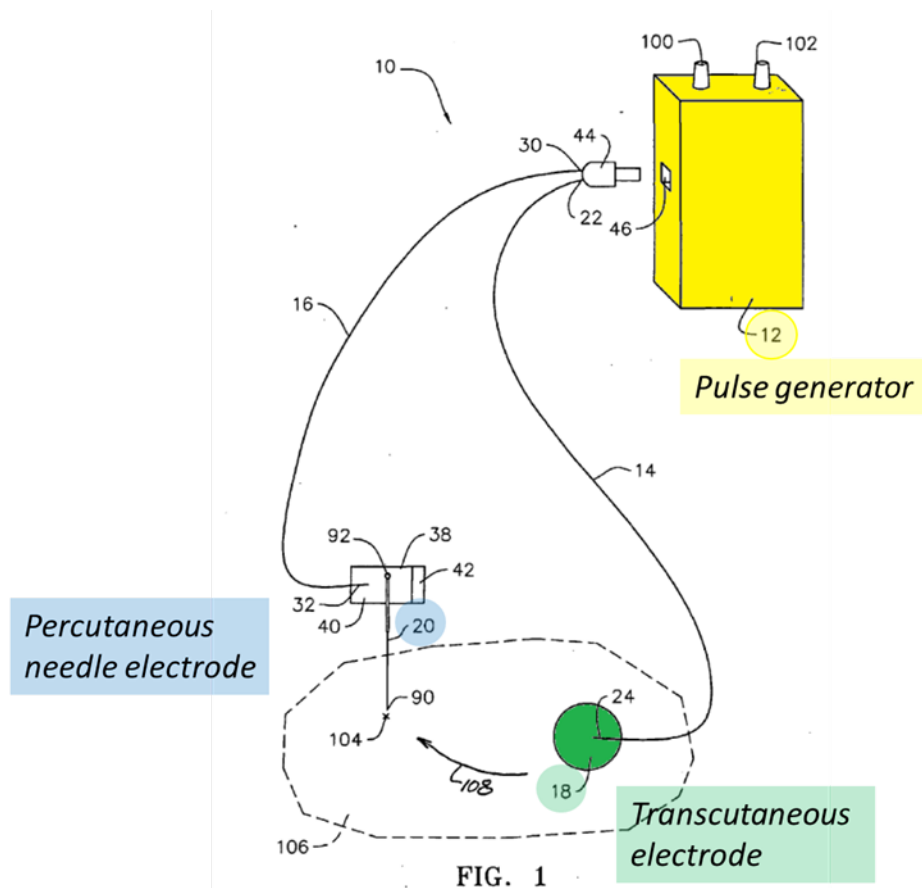
FIG. 3. Attach electrode and lead wire by placing electrode on same leg as needle near arch of foot. Connect grabber plug to needle on handle portion just above insertion point. Patient will control stimulation at comfortable level for 30 minutes.

A “stimulator” [yellow] was “connected to the needle and the ipsilateral ground pad” and “[s]timulation was titrated from 0 to 10 mA with fixed pulse 200 microseconds at frequency 20 Hz.” (*Id.*, 1194.) Once activated, the physician confirmed proper needle placement by observing the muscular response of the patient’s toes. (*Id.* (“Proper needle placement was confirmed with great toe flexion and/or fanning or plantar toe flexion of ipsilateral digits 2 through 5.”).) “The stimulator was left with the patient controlling the power setting for 30 minutes” and the “[t]herapeutic sessions were once a week for 12 weeks.” (*Id.*) Govier’s

treatment method resulted in treatment success for 71% of the patients. (*Id.*, 1193, 1196.) Govier concluded, “[p]ercutaneous peripheral afferent nerve stimulation offers a safe, minimally invasive and effective treatment for managing refractive overactive bladder and/or pelvic floor dysfunction.” (*Id.*, 1193.)

2. Overview of Williams

Williams discloses an electro-nerve stimulation apparatus that includes “a pulse generator [yellow], a first electrically conductive, insulated lead wire, a second electrically conductive, insulated lead wire, an electrically conductive transcutaneous electrode [green] and an electrically conductive percutaneous needle electrode [blue].” (Ex. 1006, abstract, [0006]; *see also id.*, claims 1, 24 (reciting same).)



(*Id.*, Fig. 1.)

“In use, the transcutaneous electrode is adhered to the patient's skin distal from the desired internal stimulation site.” (*Id.*, abstract; *see also id* [0007], [00028].) “The percutaneous needle electrode is inserted through the skin in proximity to the desired internal stimulation site.” (*Id.*, abstract; *see also id.*, [0007], [0030].) The pulse generator, which is electrically coupled to the transcutaneous electrode and percutaneous needle electrode via lead wires, “is activated to pass current pulses between the transcutaneous electrode and the

percutaneous needle electrode through the internal stimulation site.” (*Id.*, abstract; *see also id.*, [0007], [0031]-[0032], claim 24.)

Williams discloses, “the apparatus and system 10 of the present invention is particularly suited for the treatment of urinary urge incontinence.” (*Id.*, [0037].) In order to treat urinary urge incontinence, Williams discloses that the “percutaneous needle electrode 20 is inserted into the patient’s skin in proximity to the tibial nerve cephalic to the medial malleolus.” (*Id.*) Generally speaking, “the medial malleolus” is the bony protrusion sticking out of the inside of the foot and forms part of the ankle. (Ex. 1002, ¶48.) Williams further discloses that the “transcutaneous electrode is adhered to the patient’s skin distal to the percutaneous needle electrode.” (Ex. 1006, [0037].) In this case, “distal” refers to an area below the needle electrode (or nearer the bottom of the foot). (Ex. 1002, ¶48; *see also* Ex. 1001, 27:63-67, Fig. 27 (describing patch 252 as being “distal to a selected stimulation site 261”).)

3. Independent Claim 1

Claim 1 is anticipated by Govier or rendered obvious by Govier in combination with Williams. The preamble of claim 1 recites “[a] method.” If the preamble is limiting, Govier discloses “a method.” (Ex. 1002, ¶55.) Govier discloses a method of treating “overactive bladder” using electrical stimulation of the “tibial nerve.” (Ex. 1005, 1193.)

a. **Limitation [A1]: “applying an electrode patch to the skin such that the electrode patch is disposed on an outer surface of the skin”**

Govier discloses this limitation, or renders this limitation obvious in combination with Williams. (Ex. 1002, ¶¶56-65.) Govier discloses applying an “electrocardiogram ground pad” [green] to the outer surface of the patient’s skin over the center of the heel bone (i.e., “medial aspect of the calcaneus”). (Ex. 1005, 1194.) The “electrocardiogram ground pad” is the “electrode patch” required by claim 1. (Ex. 1002, ¶¶57-60.)

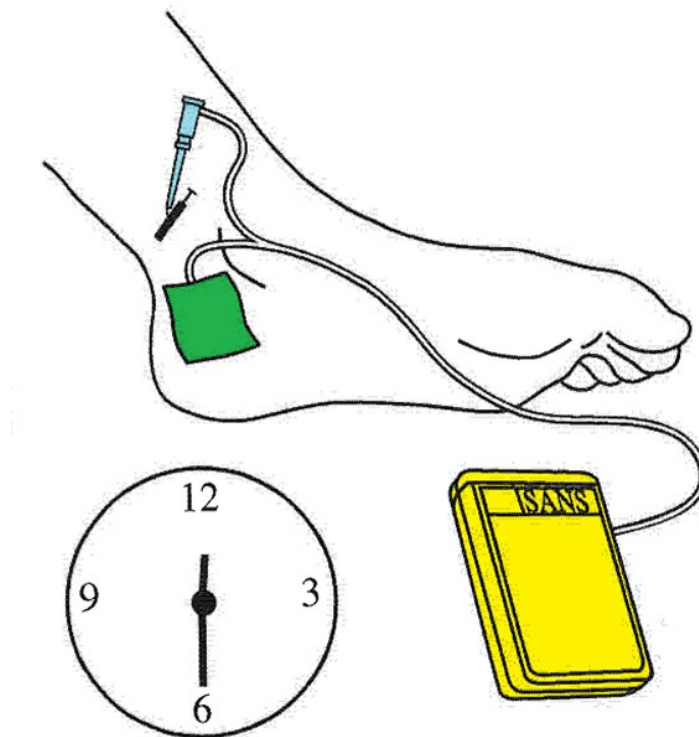
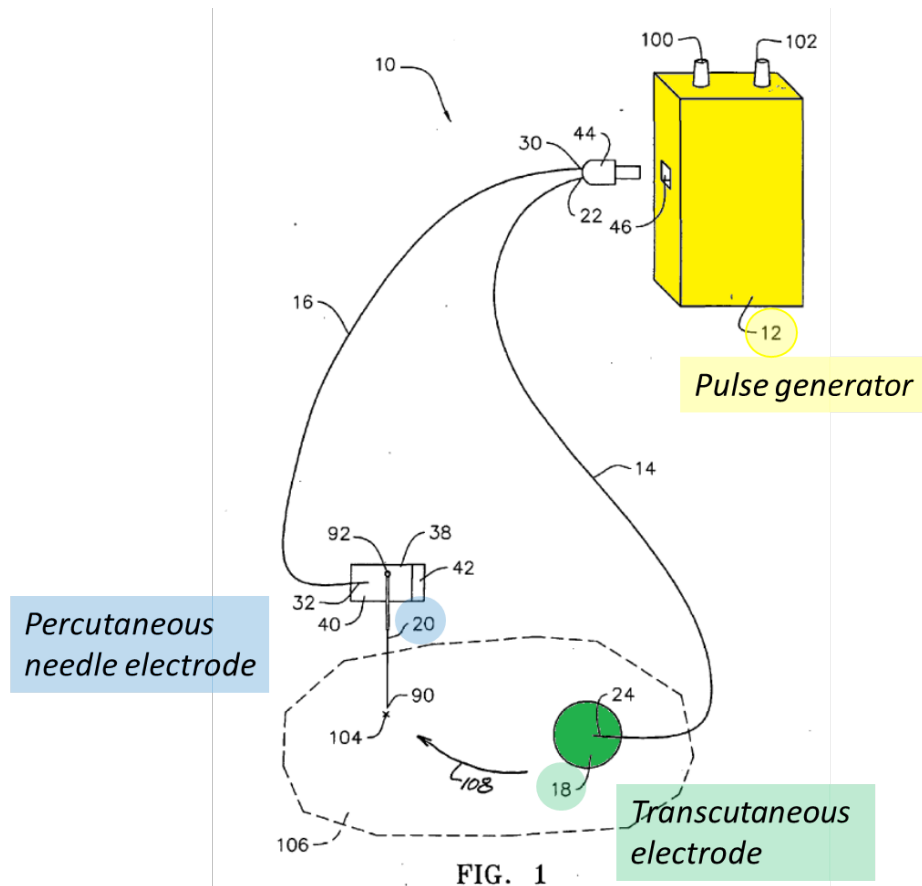


FIG. 3. Attach electrode and lead wire by placing electrode on same leg as needle near arch of foot. Connect grabber plug to needle on handle portion just above insertion point. Patient will control stimulation at comfortable level for 30 minutes.

Figure 3 (above) confirms that the electrocardiogram ground pad is an “electrode patch” because the caption to Figure 3 refers to the ground pad as an “electrode”

and the figure depicts the ground pad as a square patch. (*See* Ex. 1005 (“FIG. 3. Attach electrode and lead wire by placing electrode on same leg as needle near arch of foot.”); Ex. 1002, ¶58.) Govier further confirms that electrocardiogram type electrodes, like the patch shown in Figure 3, were well known in the art as of Govier’s publication. (*See* Ex. 1005, 1193 (describing 1983 study that created “electrical stimulation via a stick on electrocardiogram type electrode with foam backing”).)

If Govier does not disclose this limitation, it renders the limitation obvious in combination with Williams. (Ex. 1002, ¶¶61-65.) Williams discloses an “electro-nerve stimulation apparatus” for treating “urinary urge incontinence.” (Ex. 1006, abstract, [0037].) Like Govier, Williams’s “electro-nerve stimulation system compris[es] a pulse generator [yellow] electrically coupled by first and second electrically conductive insulated lead wires to an electrically conductive transcutaneous electrode [green] and an electrically conductive percutaneous needle electrode [blue], respectively.” (*Id.*, [0006]; *see also id.*, [0023], claims 1, 24, Fig. 1.)



(*Id.*, Fig. 1.) Williams discloses, “the transcutaneous electrode...is positioned and adhered to the patient’s skin distally proximate the stimulation site.” (*Id.*, [0007]; *see also id.*, [0004] (defining a “transcutaneous electrode” as “an electrode which does not penetrate the surface of the skin”).) Williams explains that “[o]ne face of the transcutaneous electrode includes an electrically conductive medical grade adhesive to removably adhere the electrode to the patient’s skin near the desired stimulation site” and, as shown above, the electrode is in the form of a round patch. (*Id.*, [0006], Fig. 1.) Thus, Williams discloses the “electrode patch” required by claim 1. (Ex. 1002, ¶¶61-62.)

A POSITA would have been motivated to combine Williams’s electrode patch with Govier’s system. (*Id.*, ¶¶63-65.) Govier and Williams describe similar two-electrode systems (including an electrode patch and needle electrode) used to treat similar problems (e.g., urinary incontinence). (Ex. 1005, abstract; Ex. 1006, [0037].) A POSITA would have found the substitution of Williams’s known electrode patch for the ground pad in Govier a simple substitution of one known element for another to obtain predictable results. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007). This combination of familiar elements according to known methods would have been obvious because it yields predictable results, specifically the ability to stimulate the tibial nerve to treat overactive bladder. *Id.* at 416. Moreover, Govier at least includes a teaching, suggestion, or motivation to use an electrode patch (*see e.g.*, Ex. 1005, Fig. 3 (referencing electrode)) that would have led a POSITA to modify Govier to include Williams’s electrode patch. *Id.* at 418-419.

A POSITA would have expected success in substituting Williams’s transcutaneous electrode for Govier’s ground pad because the electrode and ground pad are used for the same purpose in both references (i.e., for creating a current path along the tibial nerve). (Ex. 1005, 1194; Ex. 1006, [0032], [0037].) Williams discloses, “the current pulses generated by the pulse generator 12 will flow from the transcutaneous electrode 18 to the percutaneous needle electrode 20....” (Ex.

1006, [0027].) Likewise, current pulses flow between Govier’s electrocardiogram ground pad and percutaneous needle. (Ex. 1002, ¶64.) Thus, as in Govier, Williams’s electrode facilitates the flow of current pulses along the stimulation site. (*Id.*)

Additionally, Govier’s ground pad and Williams’s transcutaneous electrode share similar connections to their respective stimulator/pulse generator. Govier’s Figure 3 illustrates that the ground pad is connected to the stimulator with a lead wire. (Ex. 1005, 1194, Fig. 3.) Similarly, Williams discloses that a “first lead wire 14” electrically couples the transcutaneous electrode to the pulse generator. (Ex. 1006, [0024].) Thus, a POSITA would not have expected any problems in substituting Williams’s transcutaneous electrode for Govier’s electrocardiogram ground pad. (Ex. 1002, ¶65.)

b. Limitation [A2]: “the electrode patch is electrically coupled with a controller unit”

Govier discloses this limitation. (Ex. 1002, ¶¶66-70.) Govier discloses: “A stimulator was then connected to...the ipsilateral² ground pad (fig. 3).” (Ex. 1005, 1194.) Govier’s stimulator [yellow] is the “controller unit” required by claim 1. (Ex. 1002, ¶¶67-70.)

² “Ipsilateral” indicates that the ground pad is on the same side of the foot as the needle, as illustrated in Figure 3. (Ex. 1002, ¶67.)

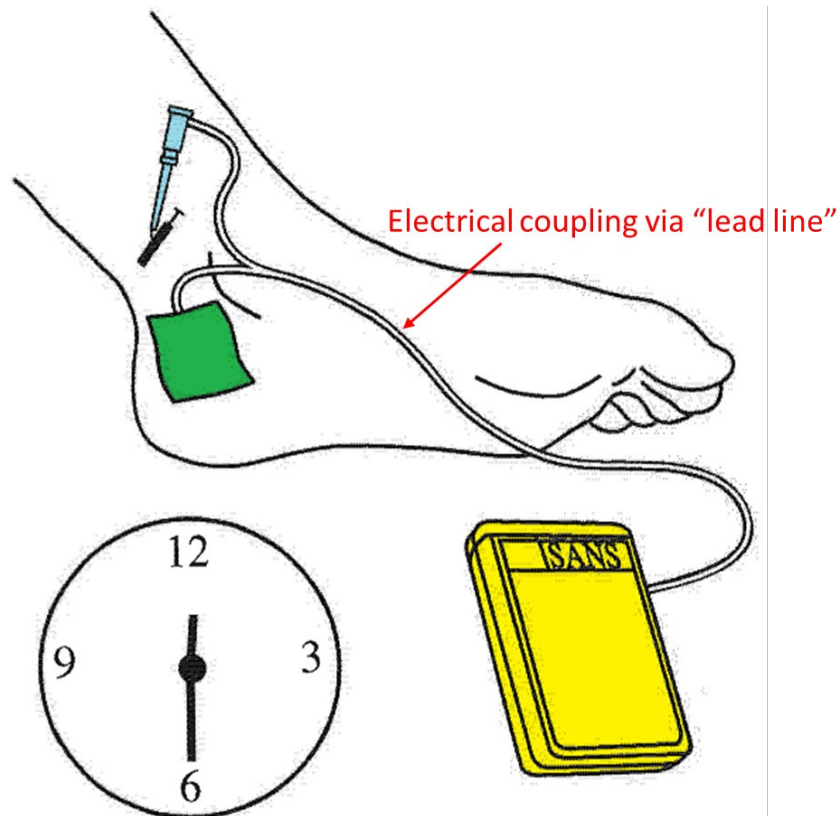


FIG. 3. Attach electrode and lead wire by placing electrode on same leg as needle near arch of foot. Connect grabber plug to needle on handle portion just above insertion point. Patient will control stimulation at comfortable level for 30 minutes.

Govier discloses that the stimulator was electrically coupled to the electrocardiogram ground pad (electrode patch) through a “lead wire” and permitted the user to generate and control (i.e., titrate) the electrical signals applied to the tibial nerve “from 0 to 10 mA. with fixed pulse 200 microseconds at frequency 20 Hz.” (Ex. 1005, 1194-1195.) Govier further discloses that the patients also used the stimulator unit to control “the power setting for 30 minutes.” (*Id.*, 1194; *see also id.*, 1195 (“Patient will control stimulation at comfortable level for 30 minutes.”).)

The '584 patent does not use the term “controller unit” in the specification. However, the patent repeatedly refers to a “controller” that generates, and may be used to vary, current flow. (*See e.g.*, Ex. 1001, abstract, 5:57-60, 6:18-20, 28:4-21; Ex. 1002, ¶¶70.) As discussed above, this is the function of Govier’s stimulator. Thus, Govier discloses an electrode patch that is electrically coupled with a controller unit.

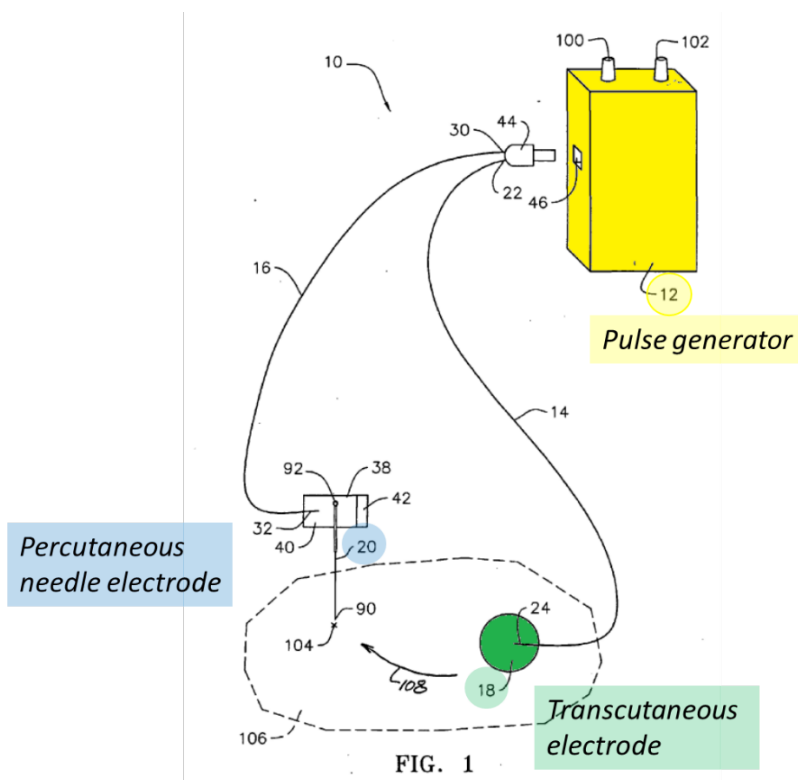
c. **Limitation [A3]: “the controller unit including a pulse generator”**

Govier discloses this limitation, or renders this limitation obvious in combination with Williams. (Ex. 1002, ¶¶71-78.) Govier discloses that the stimulator is a “Sans device” made by UroSurge. (Ex. 1005, 1194.) The UroSurge Sans device was well known in the field for providing “electrical stimulation to the peripheral nerves associated with pelvic floor function.” (Ex. 1018, 1; Ex. 1009, 767.) The device included a “needle electrode, surface electrode, external **pulse generator**, and lead wire assembly (which connects all three).” (Ex. 1018, 1 (emphasis added).)

Govier confirms that the stimulator (Sans device) included a pulse generator. Govier discloses that the stimulator delivered pulsed stimulation: “[s]timulation was titrated from 0 to 10 mA., with fixed **pulse** 200 microseconds at frequency 20 Hz.” (Ex. 1005, 1194 (emphasis added).) A POSITA would have understood that

the stimulator must include a “pulse generator” in order to generate the described pulses. (Ex. 1002, ¶73.) Thus, Govier discloses this limitation.

If Govier does not disclose this limitation, it renders the limitation obvious in combination with Williams. (Ex. 1002, ¶¶74-78.) As discussed above (*supra* §VI.A.2), Williams discloses an “electro-nerve stimulation apparatus” for treating “urinary urge incontinence” that includes “a pulse generator [yellow]”:



(Ex. 1006, abstract, [0006], [0023], [0037], Fig. 1, claims 1, 24.) Williams’s “pulse generator 12 is preferably a small hand-held, battery operated pulse generator that produces small electrical current pulses, preferably between 1-10 mA, which pass between the transcutaneous electrode 18 and the percutaneous needle electrode 20.” (*Id.*, [0031].) Williams specifically identifies a commercially-available pulse

generator and explains that those skilled in the art would know how to modify the pulse generator for use with the preferred embodiment. (*Id.*) Williams also discloses that the patient uses the pulse generator to control the current pulses. (*Id.*) Thus, Williams discloses the “pulse generator” required by claim 1. (Ex. 1002, ¶¶74-75.)

A POSITA would have been motivated to substitute Williams’s pulse generator for Govier’s stimulator. (Ex. 1002, ¶¶76-77.) Govier and Williams each describe commercially-available pulse generators (or stimulators) having a percutaneous needle and electrode patch for electrically stimulating the tibial nerve. (Ex. 1005, 1193-94; Ex. 1006, [0031], [0037].) Govier’s Sans-type stimulator and Williams’s pulse generator each create current pulses between 1-10 mA. (Ex. 1005, 1194; Ex. 1006, [0031].) A POSITA would have found it obvious to try either commercially-available pulse generator with Govier’s system given these similarities. (Ex. 1002, ¶76.) Further, the substitution of Williams’s known pulse generator for Govier’s stimulator would have been nothing more than a simple substitution of one known element for another to obtain predictable results. *KSR*, 550 U.S. at 417; Ex. 1002, ¶77. Moreover, Govier includes a teaching, suggestion, or motivation to use a pulse generator (*see e.g.*, Ex. 1005, 1194 (referencing a “fixed pulse”)) that would have led a POSITA to modify Govier to include Williams’s pulse generator. *KSR*, 550 U.S. at 418-19. Further, Govier and

Williams disclose a finite number of identified, predictable solutions for generating a current pulse with a reasonable expectation of success (*e.g.*, Sans device by UroSurge and pulse generator by Finetech-Medical). A POSITA would have been motivated to select from these finite, commercially-available devices to produce the current pulses. (Ex. 1002, ¶77.)

A POSITA would have expected success in substituting Williams’s pulse generator for Govier’s stimulator because the pulse generator and stimulator are used for the same purpose in both references. (*Id.*, ¶78.) Williams discloses that the “pulse generator” produces “current pulses, preferably between 1-10 mA, which pass between the transcutaneous electrode 18 and the percutaneous needle electrode 20.” (Ex. 1006, [0031].) Similarly, Govier discloses that the simulator is used to titrate the stimulation “from 0 to 10 mA. with fixed pulse 200 microseconds at frequency 20 Hz.” (Ex. 1005, 1194.) Moreover, both devices had a proven track record and, as Williams explained, if any small modifications were necessary to use the stimulator/generator with Govier’s system, such modifications would have been within the skill level of a POSITA. (*See* Ex. 1006, [0031] (“Those skilled in the art would readily appreciate how to make such modifications” “to achieve the functionality and desired features of the present invention.”).) Thus, Govier in combination with Williams renders this limitation obvious.

d. **Limitation [B1]: “electrically coupling a percutaneous electrode to the controller unit”**

Govier discloses this limitation. (Ex. 1002, ¶¶79-83.) Govier describes a study where “[p]atients received weekly percutaneous electrical stimulations via a 34 gauge needle [blue] placed near the tibial nerve 3 finger breadths above the ankle.” (Ex. 1005, 1193; *see also id.*, 1194 (“A 34 gauge, solid stainless steel needle was advanced through the skin....”).) The 34-gauge needle is the “percutaneous electrode” required by claim 1 because, for example, Govier discloses that the electrical stimulation is supplied via the needle and the needle penetrates the patient’s skin. (Ex. 1002, ¶80.)

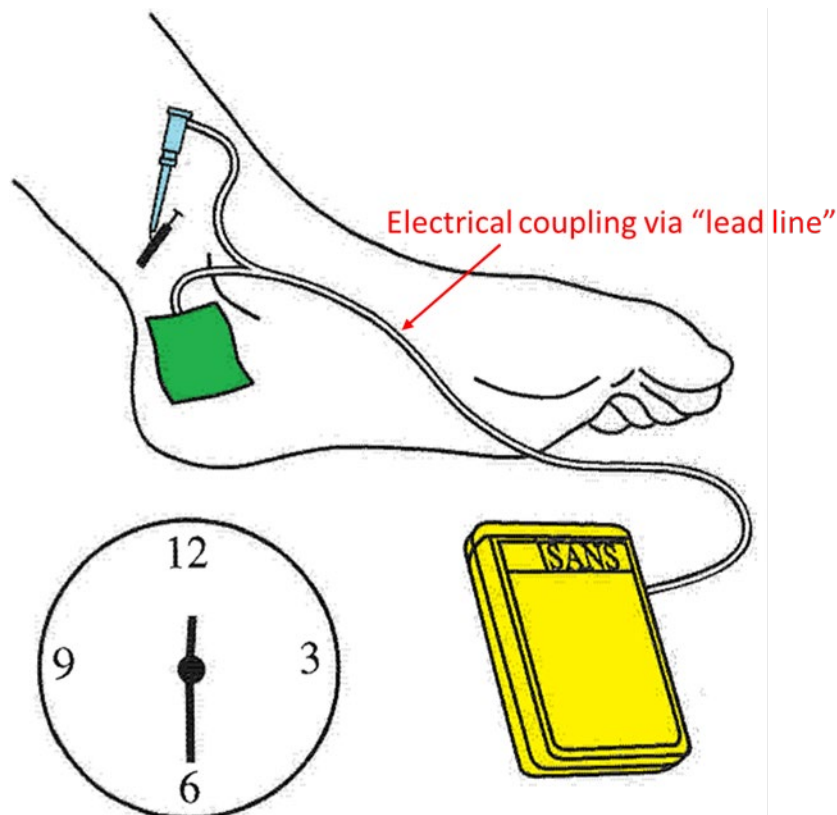


FIG. 3. Attach electrode and lead wire by placing electrode on same leg as needle near arch of foot. Connect grabber plug to needle on handle portion just above insertion point. Patient will control stimulation at comfortable level for 30 minutes.

Govier states that the stimulator is “connected to the needle” and, as shown in Figure 3 (above), a lead wire extends from the needle to the stimulator. (Ex. 1005, 1194-95; *see id.*, 1195 (“Connect grabber plug to needle on handle portion just above insertion point.”).) Govier further states that the user can vary the electrical stimulation using the stimulator and that proper needle placement is confirmed based on observed toe flexion. (*Id.*, 1194.) Based on these descriptions, a POSITA would have understood that the needle is “electrically coupled” to the stimulator (i.e., controller unit). (Ex. 1002, ¶81.)

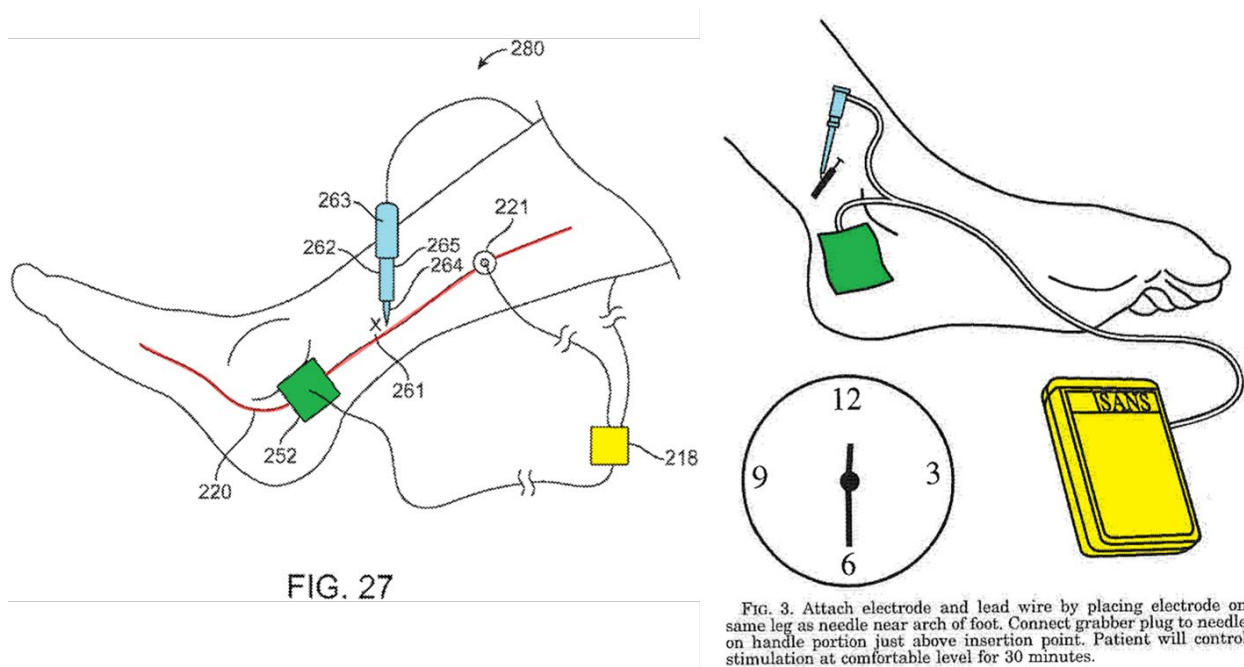
Moreover, the ’584 patent confirms that Govier’s needle is a “percutaneous electrode.” (*Id.*, ¶¶82-83.) The only percutaneous electrodes disclosed in the ’584 patent that are electrically coupled to a controller unit are percutaneous electrode needles (e.g., percutaneous electrode needle 262), like Govier’s percutaneous needle. (Ex. 1001, 27:55-28:3, Fig. 27.) Thus, if the ’584 patent discloses this limitation, then so does Govier. (*Id.*)

e. **Limitation [B2]: “the percutaneous electrode having an end for inserting in proximity to a tibial nerve, or a branch thereof, of the patient”**

Govier discloses this limitation. (Ex. 1002, ¶¶84-86.) Govier discloses placing the percutaneous needle electrode “near the tibial nerve 3 finger breadths above the ankle.” (Ex. 1005, 1193; *see also id.*, 1194 (“This point was about 1 finger breadth posterior from the edge of the tibia.”).) The needle was “advanced

through the skin with the aid of an overlying plastic cylinder that was 3 mm. shorter than the needle.” (*Id.*, 1194.) “Once the skin was pierced the cylinder was removed, and the needle was advanced approximately 3 to 4 cm. posterior to the tibia....” (*Id.*)

A side-by-side comparison of the embodiments in the ’584 patent (left) and Govier (right) illustrates that the percutaneous electrodes [blue] in both references are inserted at approximately the same location near the tibial nerve.



(Ex. 1001, 27:53-28:3, Fig. 27; Ex. 1005, 1195 (Fig. 3); Ex. 1002, ¶¶85-86.) Thus, if the ’584 patent discloses this limitation, Govier does too.

f. **Limitation [C]: “inserting the end of the percutaneous electrode into the skin in proximity to the tibial nerve, or a branch thereof, of the patient”**

Govier discloses this limitation. (Ex. 1002, ¶¶87-89.) As discussed in the previous section, Govier discloses placing a percutaneous needle electrode “near the tibial nerve 3 finger breadths above the ankle.” (Ex. 1005, 1193; *see also id.*, 1194 (“This point was about 1 finger breadth posterior from the edge of the tibia.”).) Govier further discloses: “A 34 gauge, solid stainless steel needle was advanced through the skin with the aid of an overlying plastic cylinder that was 3 mm. shorter than the needle. Once the skin was pierced the cylinder was removed, and the needle was advanced approximately 3 to 4 cm. posterior to the tibia.” (*Id.*, 1194.)

As shown in the previous section, a side-by-side comparison of the embodiments in the ’584 patent (above left) and Govier (above right) illustrates that the percutaneous electrodes [blue] in both references are inserted at approximately the same location near the tibial nerve. (Ex. 1001, 27:53-28:3, Fig. 27; Ex. 1005, 1195 (Fig. 3); Ex. 1002, ¶¶85-86.) Thus, if the ’584 patent discloses this limitation, Govier does too.

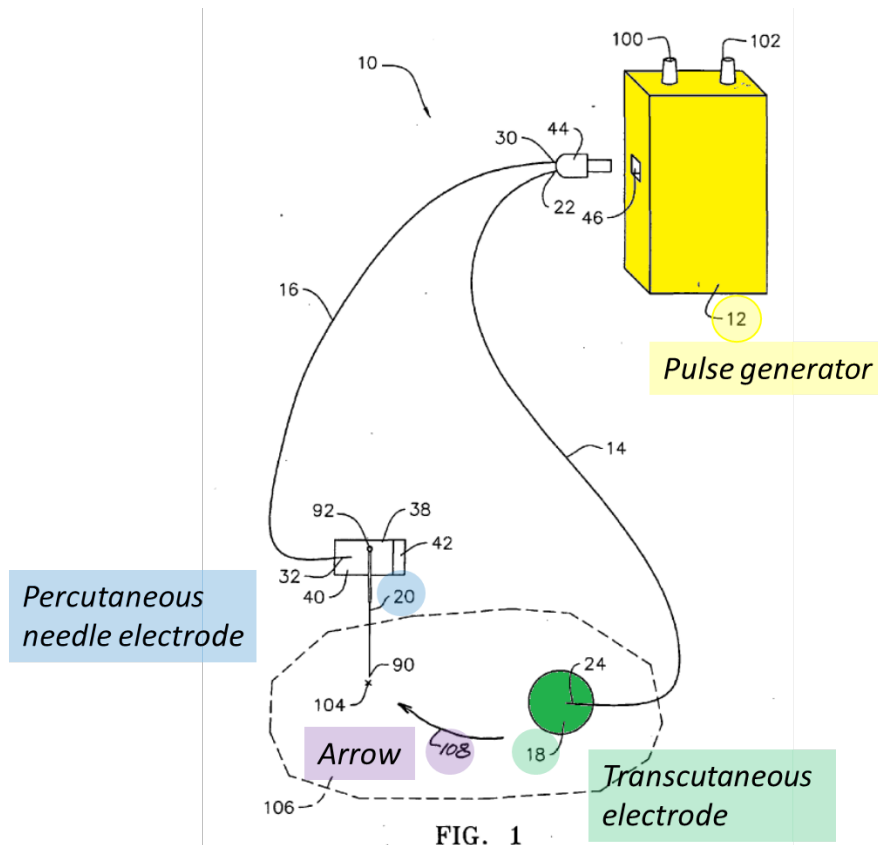
g. **Limitation [D]: “activating the pulse generator such that current pulses flow along the tibial nerve, or branch thereof, by passing between the electrode patch and the percutaneous electrode”**

Govier discloses this limitation, or renders this limitation obvious in combination with Williams. (Ex. 1002, ¶¶90-96.) Govier discloses a study “to determine the safety and efficacy of percutaneous peripheral afferent nerve stimulation for treatment” employing “weekly percutaneous electrical stimulations via a 34 gauge needle placed near the tibial nerve....” (Ex. 1005, 1193.) Govier explains that a stimulator (pulse generator) was connected to a percutaneous needle (percutaneous electrode) and electrocardiogram ground pad (electrode patch) and activated so that “[s]timulation was titrated from 0 to 10 mA. with fixed pulse 200 microseconds at frequency 20 Hz.” (*Id.*, 1194.) Govier further discloses that the patient would control the current pulses using the stimulator for 30 minutes. (*Id.*)

Govier also discloses that “[p]roper needle placement was confirmed with great toe flexion and/or fanning or plantar toe flexion of ipsilateral digits 2 through 5.” (Ex. 1005, 1194.) These toe behaviors indicated to the doctor that the current pulses were passing along the tibial nerve and between the percutaneous needle and electrode patch. (Ex. 1002, ¶92.) Thus, based on these disclosures, a POSITA would have understood that activation of the stimulator (pulse generator) caused current pulses to pass between the percutaneous needle and electrode patch along the tibial nerve. (*Id.*)

Claim 1 does not require the current pulses to flow in a specific direction (e.g., *from* ground pad to percutaneous electrode). Rather, the claim merely requires the current pulses to pass “*between* the electrode patch and the percutaneous electrode” and, thus, Govier discloses this limitation. Govier’s stimulator is electrically coupled to the ground pad and needle in Govier’s Figure 3 to permit the current to flow between the two electrodes. (Ex. 1002, ¶93.) Without either electrode (ground pad or needle), a current would not flow along the tibial nerve as described. (*Id.*)

However, if the Board determines that claim 1 requires the current pulses to flow from the electrode patch to the percutaneous needle, then Govier in combination with Williams renders this limitation obvious. (*Id.*, ¶¶94-96.) Williams discloses that the “pulse generator 12 is activated to generate current pulses.” (Ex. 1006, [0032].) Williams further discloses, “The current pulses from the pulse generator 12 traverse the internal stimulation site 104 by passing from the transcutaneous electrode 18 [electrode patch, green] to the percutaneous needle electrode 20 [percutaneous electrode, blue] as indicated by the arrow 108 [purple].” (*Id.*, [0032], Fig. 1.)



(*Id.*, Fig. 1.) As explained previously, Williams discloses that one of the stimulation sites is the tibial nerve. (*Id.*, [0037].)

A POSITA would have been motivated to use Williams’s method in Govier’s system, and expected success in doing so, due to the structural similarities between the systems, as previously explained. (*Supra* §§VI.A.3.a, c; Ex. 1002, ¶95.) Moreover, both references describe similar configurations for the percutaneous needle and transcutaneous needle or ground pad. Specifically, Govier illustrates positioning the ground pad distal to the needle. (Ex. 1005, Fig. 3; Ex. 1002, ¶95.) Williams also discloses, “The transcutaneous electrode is adhered to the patient’s skin distal to the percutaneous needle electrode.” (Ex. 1006, [0037].)

For this additional reason, a POSITA would have expected success in using Williams’s stimulation method in Govier.

Additionally, a POSITA would have understood that current pulses could move in only two directions using the systems described in Govier or Williams: (1) electrode patch to percutaneous electrode or (2) percutaneous electrode to electrode patch. (Ex. 1002, ¶96.) A POSITA would have found it obvious to use either finite option. (*Id.*) A POSITA would have understood that the flow path of the current in Govier could be switched by toggling the electrode that is positive, and the electrode that is negative, as desired. (*Id.*) This toggling could have been accomplished by something as simple as switching the lead wires. (*Id.*) Thus, a POSITA would have expected success in transmitting current pulses in either direction. (*Id.*) In fact, the ’584 patent confirms that the current could pass through either the electrode patch or electrode needle, stating: “Optionally, a current may be passed from the controller 218 through microneedle patch 252 and for [sic] from the controller 218 through percutaneous electrode needle 262, traversing the internal stimulation site as the current passes between the patch and needle.” (Ex. 1001, 28:17-21; Ex. 1002, ¶96.)

h. Limitation [E]: “the current pulses configured to treat overactive bladder”

Govier discloses this limitation. (Ex. 1002, ¶¶97-98.) Govier discloses that the described study “was undertaken to determine the safety and efficacy of

percutaneous peripheral afferent nerve stimulation for treatment of refractive overactive bladder and/or pelvic floor dysfunction.” (Ex. 1005, 1193.) Govier concludes that the “study confirms the safety and efficacy of afferent peripheral nerve stimulation for patients with refractive overactive bladders and pelvic floor dysfunction.” (*Id.*, 1198.)

For the reasons above, Govier anticipates claim 1 or renders claim 1 obvious in combination with Williams.

4. Dependent Claim 2

Claim 2 depends from claim 1 and further recites: “wherein inserting the end of the percutaneous electrode comprises inserting the end near or at an ankle of the patient.” Govier discloses this limitation. (Ex. 1002, ¶¶99-101.)

As shown in Figure 3 (below), Govier discloses inserting the end of the percutaneous needle (i.e., percutaneous electrode) [blue] near or at an ankle of the patient. (*Id.*; *see also* Ex. 1005, 1194 (“the needle was advanced approximately 3 to 4 cm. posterior to the tibia and, if advanced further, would traverse anterior to the fibula.”)).

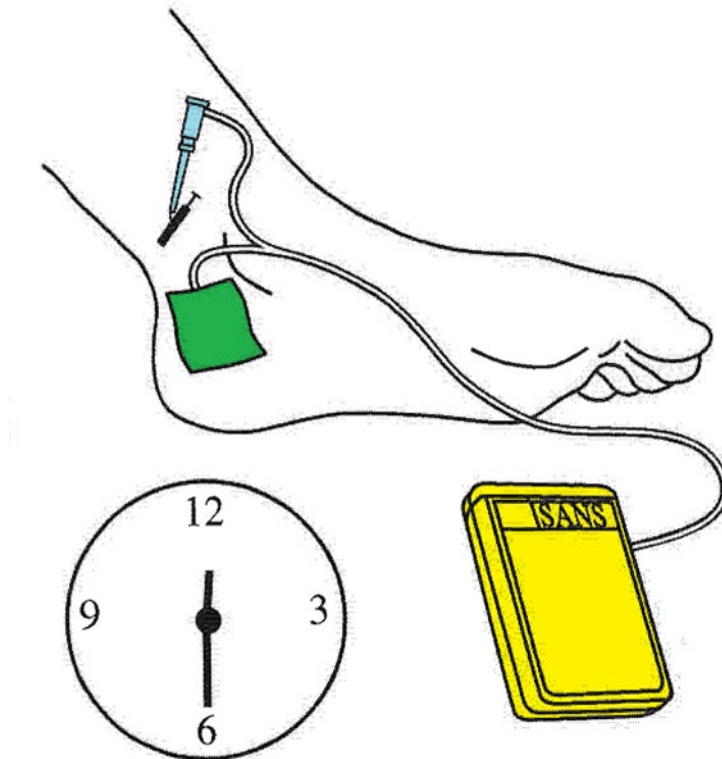


FIG. 3. Attach electrode and lead wire by placing electrode on same leg as needle near arch of foot. Connect grabber plug to needle on handle portion just above insertion point. Patient will control stimulation at comfortable level for 30 minutes.

(*Id.*, Fig. 3.)

5. Dependent Claim 3

Claim 3 depends from claim 1 and recites: “further comprising detecting a muscular response caused by an electrical conduction or stimulation of a nerve, muscle, or body tissue.” Govier discloses this limitation. (Ex. 1002, ¶¶102-105.)

Govier discloses that once the electrical stimulation of the tibial nerve begins, the doctor detects a muscular response by observing the patient’s toes to determine if the needle is in the proper location. (See Ex. 1005, 1194 (“Proper needle placement was confirmed with great toe flexion and/or fanning or plantar toe flexion of ipsilateral digits 2 through 5.”).) Gharib confirms that visually

monitoring a patient’s muscular response was a well-known and “generally effective” method for determining the proximity of an electrode needle to a nerve. (Ex. 1007, [0005]-[0006]; *see also* Ex. 1009, 767 (“Proper stimulation was identified by great toe flexion and/or plantar flexion of digits two to five.”).) Gharib explains that the “muscular response is...typically...a shake or ‘twitch’” and that when the muscular response is observed, “the needle is considered to be near the nerve coupled to the responsive muscle.” (*Id.*, [0005].) Thus, observing the flexion or fanning of the toes is an example of detecting a muscular response and, therefore, Govier satisfies this limitation. (Ex. 1002, ¶¶103-104.)

The muscular response detected in Govier (i.e., toe flexion or fanning) is consistent with the ’584 patent. For example, the ’584 patent discloses, “the electrical current may [sic] varied by the logic controller both on the basis of an input provided by the one or more sensors and also an input provided by the patient according to a ***muscular response she has perceived, for example, the twitching of a toe*** after application of the magnetic field.” (Ex. 1001, 9:28-35 (emphasis added); *see also id.*, 11:48-53.) Thus, simple visual observation of a patient, as described in Govier, is a method of detecting a muscular response. While the ’584 patent also describes “sensors” for detecting a muscular response (*see id.*, 6:11-15), claim 3 does not require a sensor (or other hardware), and the specification does not require use of a sensor.

6. Dependent Claim 4

Claim 4 depends from claim 1 and recites: “wherein activating the pulse generator comprises activating for a duration of about 30 minutes per week to treat the patient.” Govier discloses this limitation. (Ex. 1002, ¶¶106-107.)

Govier discloses, “The stimulator [pulse generator] was left with the patient controlling the power setting for 30 minutes. Therapeutic sessions were once a week for 12 weeks.” (Ex. 1005, 1194; *see also* Ex. 1010, 915 (“Patients underwent 12 weekly outpatient treatment sessions, each lasting for 30 minutes.”).)

7. Independent Claim 5

Claim 5 is anticipated by Govier or rendered obvious by Govier in combination with Williams. The preamble of claim 5 recites “[a] method.” If the preamble is limiting, Govier discloses this limitation. (Ex. 1002, ¶109.) Govier discloses a method of treating “overactive bladder” with electrical stimulation of the “tibial nerve.” (Ex. 1005, 1193.)

a. Limitation [A]: “positioning a transcutaneous electrode on skin of a patient in proximity to a tibial nerve, or a branch thereof”

Govier discloses this limitation, or renders this limitation obvious in combination with Williams. (Ex. 1002, ¶¶110-117.) Govier discloses applying an “electrocardiogram ground pad” [green] to the outer surface of the patient’s skin near the heel bone (i.e., calcaneus). (Ex. 1005, 1194.) The “electrocardiogram

ground pad” is the “transcutaneous electrode” required by claim 1. (Ex. 1002, ¶¶111-114.)

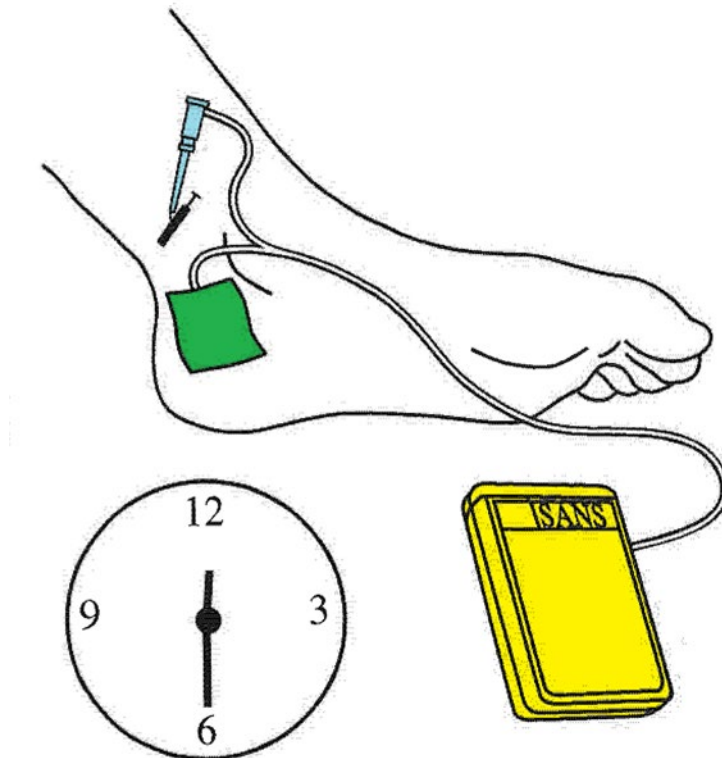
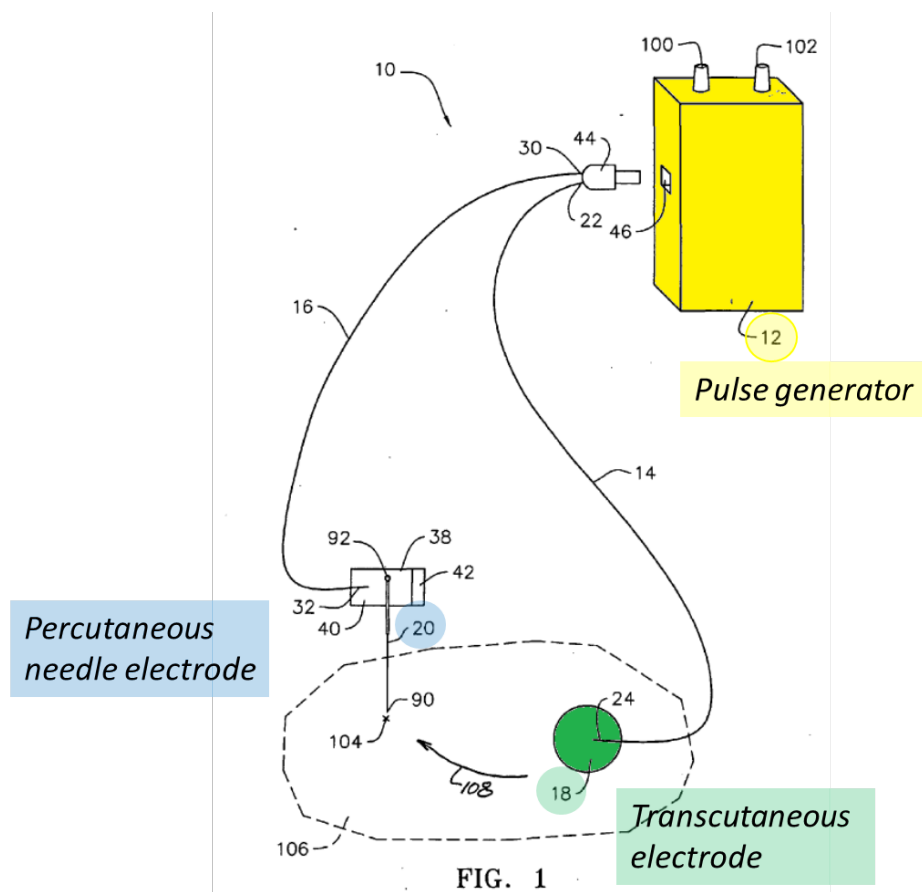


FIG. 3. Attach electrode and lead wire by placing electrode on same leg as needle near arch of foot. Connect grabber plug to needle on handle portion just above insertion point. Patient will control stimulation at comfortable level for 30 minutes.

Figure 3 (above) confirms that the electrocardiogram ground pad is a “transcutaneous electrode” because the caption to Figure 3 refers to the ground pad as an “electrode,” and Govier confirms that the ground pad is “placed over” the patient’s skin. (See Ex. 1005, 1194 (“An electrocardiogram ground pad was placed over the medial aspect of the calcaneus.”).) Govier further confirms that electrocardiogram type electrodes, like the transcutaneous electrode shown in Figure 3, were well known in the art as of Govier’s publication. (See *id.*, 1193

(describing 1983 study that created “electrical stimulation via a stick on electrocardiogram type electrode with foam backing”).)

If Govier does not disclose this limitation, it renders the limitation obvious in combination with Williams. (Ex. 1002, ¶¶115-117.) Like Govier, Williams’s “electro-nerve stimulation system compris[es] a pulse generator [yellow] electrically coupled by first and second electrically conductive insulated lead wires to an electrically conductive transcutaneous electrode [green] and an electrically conductive percutaneous needle electrode [blue], respectively.” (Ex. 1006, [0006], [0023], Fig. 1.)



(*Id.*, Fig. 1.) Williams discloses, “the transcutaneous electrode...is positioned and adhered to the patient’s skin distally proximate the stimulation site.” (*Id.*, [0007]; *see also id.*, [0004] (defining a “transcutaneous electrode” as “an electrode which does not penetrate the surface of the skin”); Ex. 1002, ¶116.) Williams explains that “[o]ne face of the transcutaneous electrode includes an electrically conductive medical grade adhesive to removably adhere the electrode to the patient’s skin near the desired stimulation site” and, as shown above, the electrode is in the form of a round patch. (Ex. 1006, [0006], Fig. 1.) Thus, Williams discloses the “transcutaneous electrode” required by claim 1.

A POSITA would have been motivated to substitute Williams’s transcutaneous electrode for Govier’s ground pad, and expected success in doing so, for the reasons presented in claim 1. (*Supra* §VI.A.3.a; Ex. 1002, ¶¶61-65.)

b. Limitation [B1]: “inserting an end of a percutaneous needle electrode through the skin in proximity to the tibial nerve, or a branch thereof”

Govier discloses this limitation. (Ex. 1002, ¶¶118-121.) Govier describes a study where “[p]atients received weekly percutaneous electrical stimulations via a 34 gauge needle [blue] placed near the tibial nerve 3 finger breadths above the ankle.” (Ex. 1005, 1193; *see also id.*, 1194 (“A 34 gauge, solid stainless steel needle was advanced through the skin....”).) The 34-gauge needle is the

“percutaneous electrode” required by claim 1 because, for example, Govier discloses that the electrical stimulation is supplied via the needle. (Ex. 1002, ¶119.)

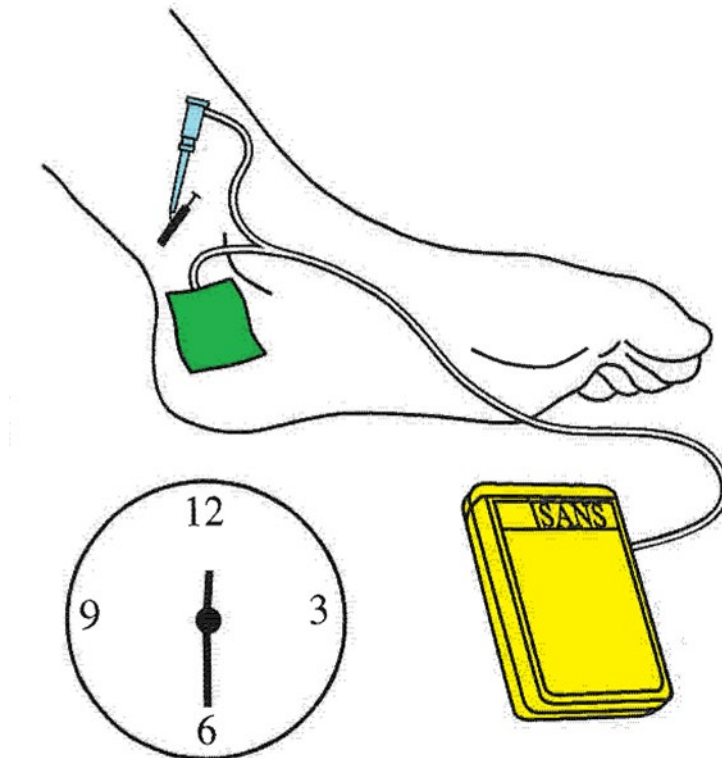


FIG. 3. Attach electrode and lead wire by placing electrode on same leg as needle near arch of foot. Connect grabber plug to needle on handle portion just above insertion point. Patient will control stimulation at comfortable level for 30 minutes.

(Ex. 1005, Fig. 3.)

Govier discloses placing the percutaneous needle electrode “near the tibial nerve 3 finger breadths above the ankle.” (*Id.*, 1193; *see also id.*, 1194 (“This point was about 1 finger breadth posterior from the edge of the tibia.”).) The needle was “advanced through the skin with the aid of an overlying plastic cylinder that was 3 mm. shorter than the needle.” (*Id.*, 1194.) “Once the skin was pierced the cylinder was removed, and the needle was advanced approximately 3 to 4 cm. posterior to the tibia....” (*Id.*)

A side-by-side comparison of the embodiments in the '584 patent (left) and Govier (right) illustrates that the percutaneous electrodes [blue] in both references are inserted at approximately the same location near the tibial nerve.

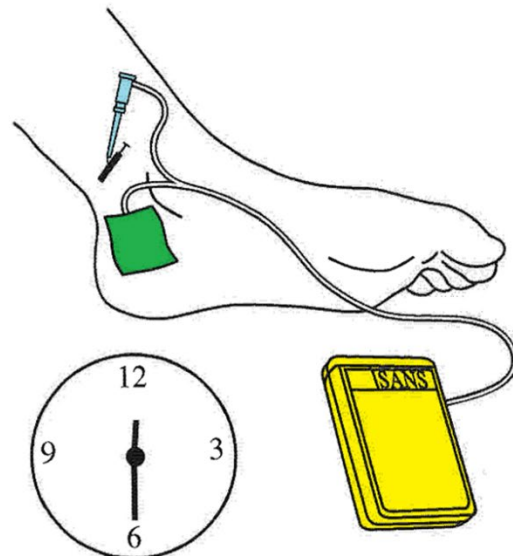
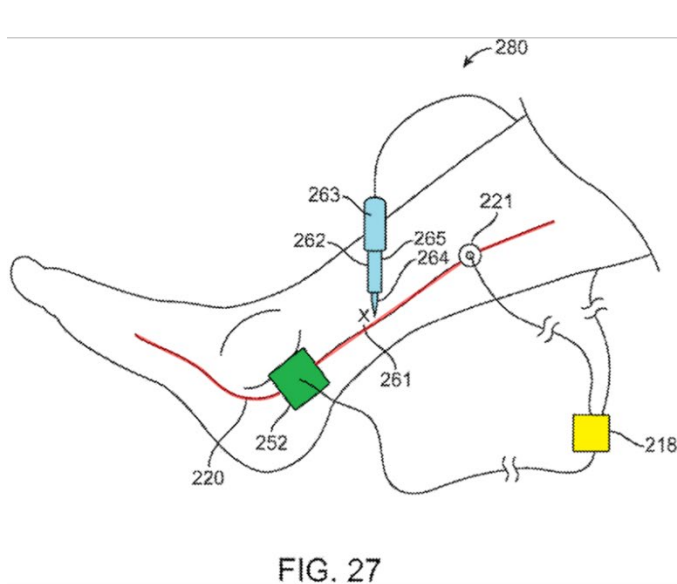


FIG. 3. Attach electrode and lead wire by placing electrode on same leg as needle near arch of foot. Connect grabber plug to needle on handle portion just above insertion point. Patient will control stimulation at comfortable level for 30 minutes.

(Ex. 1001, 27:53-28:3, Fig. 27; Ex. 1005, 1195 (Fig. 3); Ex. 1002, ¶121.) Thus, if the '584 patent discloses this limitation, Govier does too.

c. **Limitation [B2]: “the percutaneous needle electrode including a wire disposed opposite the end”**

Govier discloses this limitation. (Ex. 1002, ¶¶122-123.) As shown in Figure 3 (below), Govier’s percutaneous needle includes a wire disposed at the end opposite from the portion of the needle inserted into the patient:

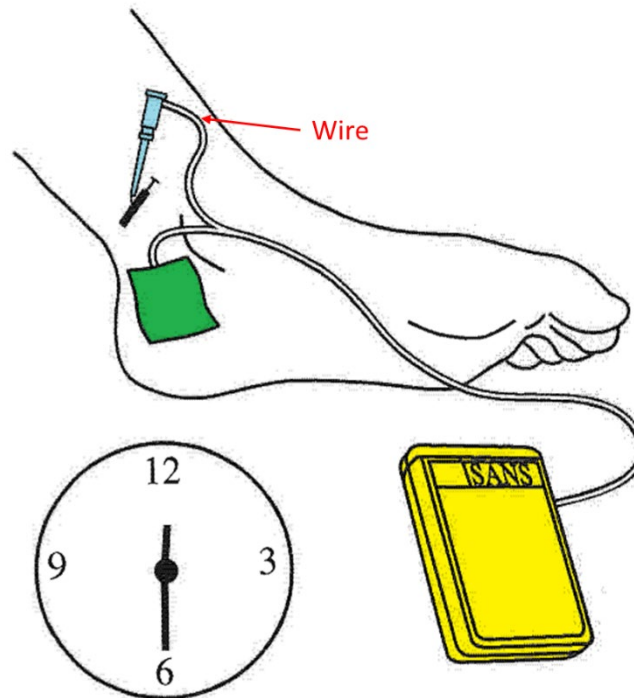


FIG. 3. Attach electrode and lead wire by placing electrode on same leg as needle near arch of foot. Connect grabber plug to needle on handle portion just above insertion point. Patient will control stimulation at comfortable level for 30 minutes.

(Ex. 1005, 1195; *see also id.*, 1194 (“A stimulator was then connected to the needle and the ipsilateral ground pad (fig. 3).”))

d. **Limitation [C1]: “securing a controller unit to the transcutaneous electrode such that the controller unit is electrically coupled to the transcutaneous electrode”**

Govier discloses this limitation. (Ex. 1002, ¶¶124-127.) Govier discloses: “A stimulator was then connected to...the ipsilateral ground pad (fig. 3).” (Ex. 1005, 1194.) Govier’s stimulator [yellow] is the “controller unit” required by claim 5. (Ex. 1002, ¶¶67-70, 125.)

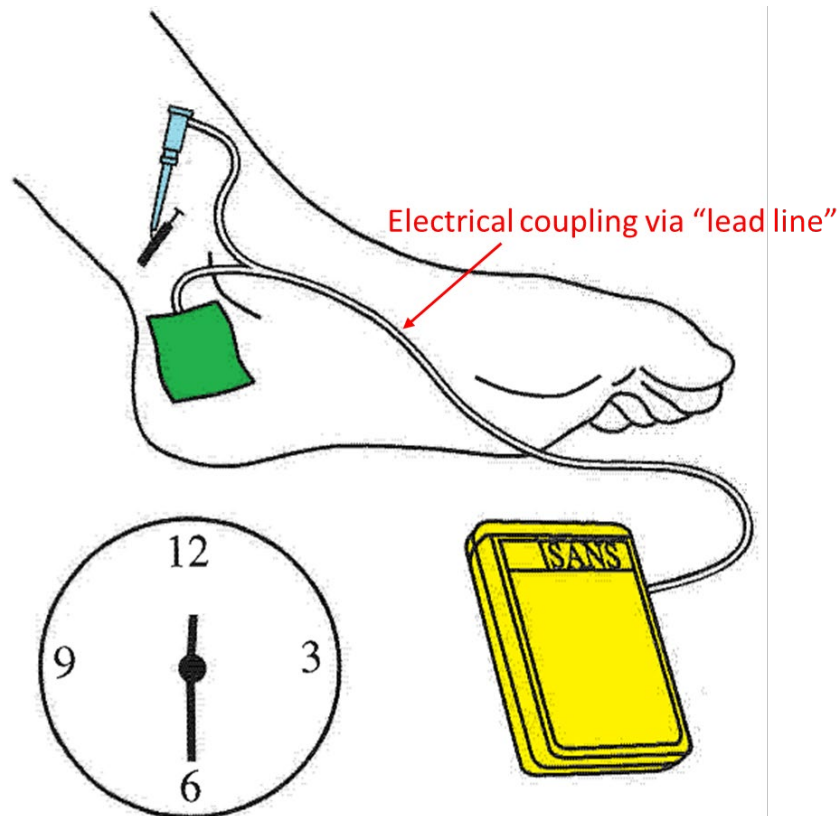


FIG. 3. Attach electrode and lead wire by placing electrode on same leg as needle near arch of foot. Connect grabber plug to needle on handle portion just above insertion point. Patient will control stimulation at comfortable level for 30 minutes.

Govier discloses that the stimulator was electrically coupled to the electrocardiogram ground pad (electrode patch) through a “lead wire” and permitted the user to generate and control (i.e., titrate) the electrical signals applied to the tibial nerve “from 0 to 10 mA with fixed pulse 200 microseconds at frequency 20 Hz.” (Ex. 1005, 1194-1195.) Govier further discloses that the patients also used the stimulator unit to control “the power setting for 30 minutes.” (*Id.*, 1194; *see also id.*, 1195 (“Patient will control stimulation at comfortable level for 30 minutes.”).)

As explained in claim 1, the '584 patent does not use the term “controller unit” in the specification. However, the patent repeatedly refers to a “controller” that generates, and may be used to vary, current flow. (*See e.g.*, Ex. 1001, abstract, 5:57-60, 6:18-20, 28:4-21.) As discussed above, this is the function of Govier’s stimulator. Thus, Govier satisfies this limitation. (Ex. 1002, ¶¶124-127.)

e. **Limitation [C2]: “the controller unit including a pulse generator”**

This limitation also appeared in claim 1. (*Supra* §VI.A.3.c.) Govier discloses this limitation, or renders the limitation obvious in view of Williams, for the reasons previously provided. (*Id.*)

f. **Limitation [D]: “connecting the wire of the percutaneous needle electrode to the controller unit for electrically coupling the percutaneous needle electrode to the controller”**

Govier discloses this limitation. (Ex. 1002, ¶¶129-133.) Govier describes a study where “[p]atients received weekly percutaneous electrical stimulations via a 34 gauge needle [blue] placed near the tibial nerve 3 finger breadths above the ankle.” (Ex. 1005, 1193; *see also id.*, 1194 (“A 34 gauge, solid stainless steel needle was advanced through the skin....”).) The 34-gauge needle is the “percutaneous electrode” required by claim 1 because, for example, Govier discloses that the electrical stimulation is supplied via the needle and the needle penetrates the patient’s skin. (Ex. 1002, ¶¶80-83, 130.)

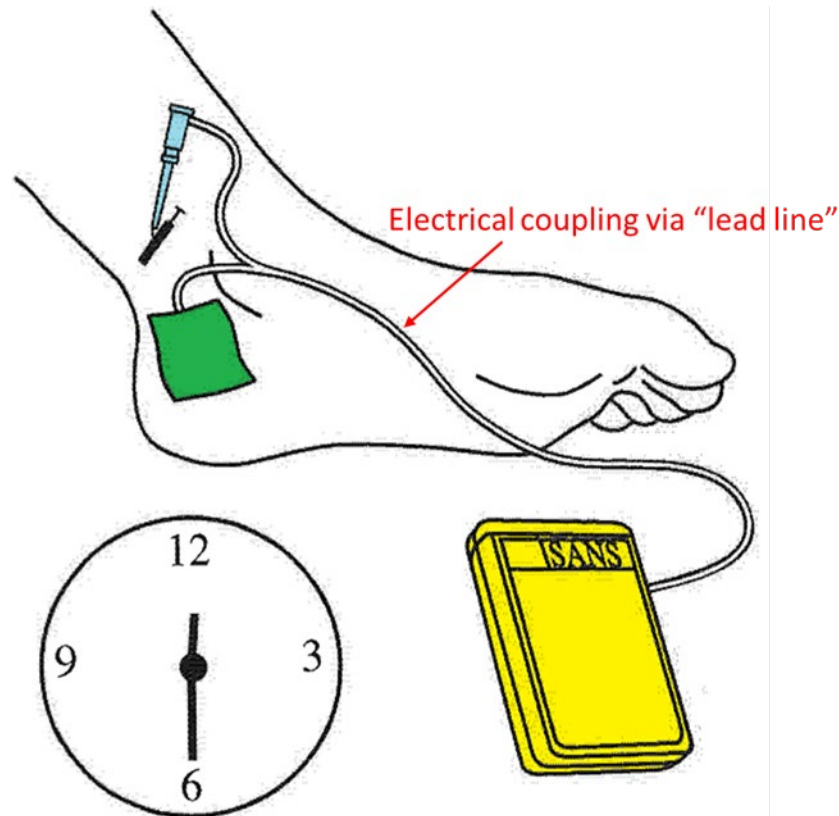


FIG. 3. Attach electrode and lead wire by placing electrode on same leg as needle near arch of foot. Connect grabber plug to needle on handle portion just above insertion point. Patient will control stimulation at comfortable level for 30 minutes.

Govier states that the stimulator is “connected to the needle” and, as shown in Figure 3 (above), a lead wire extends from the needle to the stimulator. (Ex. 1005, 1194-95; *see also id.*, 1195 (“Connect grabber plug to needle on handle portion just above insertion point.”).) Govier further states that the user can vary the electrical stimulation using the stimulator and that proper needle placement is confirmed based on observed toe flexion. (*Id.*, 1194.) Based on these descriptions, a POSITA would have understood that the needle electrode is “electrically coupled” to the stimulator (i.e., controller unit). (Ex. 1002, ¶131.)

Moreover, Govier's needle is a "percutaneous" needle electrode. (Ex. 1002, ¶132.) Govier discloses that the needle is "advanced through the skin" and that "[o]nce the skin was pierced...the needle was advanced approximately 3 to 4 cm. posterior to the tibia and, if advanced further, would traverse anterior to the fibula." (Ex. 1005, 1194.)

g. **Limitation [E]: "activating the pulse generator such that current pulses flow along the tibial nerve, or a branch thereof, by passing between the transcutaneous electrode and the percutaneous needle electrode"**

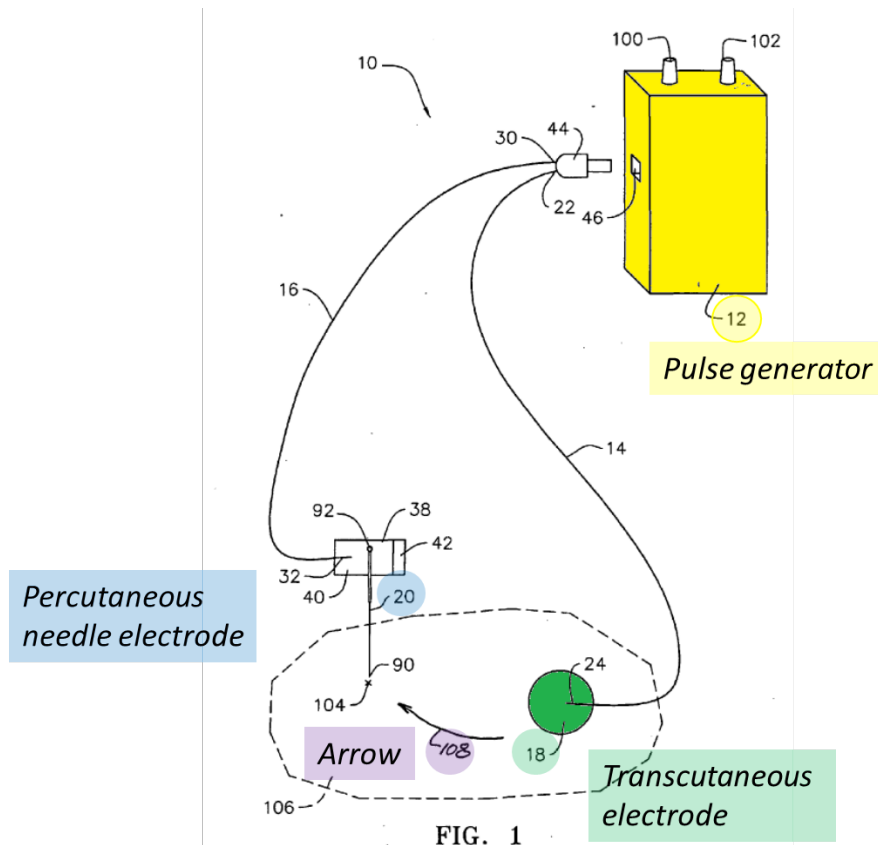
Govier discloses this limitation, or renders this limitation obvious in combination with Williams. (Ex. 1002, ¶¶134-139.) Govier discloses a study "to determine the safety and efficacy of percutaneous peripheral afferent nerve stimulation for treatment" employing "weekly percutaneous electrical stimulations via a 34 gauge needle placed near the tibial nerve...." (Ex. 1005, 1193.) Govier explains that a stimulator (pulse generator) was connected to a percutaneous needle (percutaneous needle electrode) and electrocardiogram ground pad (transcutaneous electrode) and activated so that "[s]timulation was titrated from 0 to 10mA. with fixed pulse 200 microseconds at frequency 20 Hz." (*Id.*, 1194.) Govier further discloses that the patient would control the current pulses using the stimulator for 30 minutes. (*Id.*)

Govier also discloses, "Proper needle placement was confirmed with great toe flexion and/or fanning or plantar toe flexion of ipsilateral digits 2 through 5."

(*Id.*, 1194.) Flexion or fanning of the toes indicated that the current pulses were passing along the tibial nerve and between the percutaneous needle electrode and transcutaneous electrode. (Ex. 1002, ¶92.) Thus, based on these disclosures, a POSITA would have understood that activation of the stimulator (pulse generator) caused current pulses to pass between the percutaneous needle electrode and transcutaneous electrode along the tibial nerve. (*Id.*)

As in Claim 1, Claim 5 does not require the current pulses to flow in a specific direction (e.g., *from* ground pad to percutaneous electrode). (*Supra* §VI.A.3.g.) Rather, the claim merely requires the current pulses to pass “*between* the transcutaneous electrode and percutaneous needle electrode” and, thus, Govier discloses this limitation.

However, if claim 1 requires the current pulses to flow from the transcutaneous electrode to the percutaneous needle electrode, then Govier, in combination with Williams, renders the limitation obvious. (*Id.*) As explained in claim 1, Williams discloses, “The current pulses from the pulse generator 12 traverse the internal stimulation site 104 by passing from the transcutaneous electrode 18 [electrode patch, green] to the percutaneous needle electrode 20 [percutaneous electrode, blue] as indicated by the arrow 108 [purple].” (Ex. 1006, [0032], Fig. 1; *supra* §VI.A.3.g.)



(Ex. 1006, Fig. 1.) Williams discloses that one of the stimulation sites is the tibial nerve. (*Id.*, [0037].)

A POSITA would have been motivated to use Williams’s method in Govier’s system, and expected success in doing so, for the reasons set forth in claim 1. (*Supra* §VI.A.3.g; Ex. 1002, ¶¶63-65, 76-78, 95-96.)

h. Limitation [F]: “the current pulses configured to treat overactive bladder”

This limitation also appears in claim 1. (*Supra* §VI.A.3.h.) Govier discloses this limitation for the reasons previously stated. (*Id.*)

8. Dependent Claim 6

Claim 6 depends from claim 5 and recites: “wherein inserting an end of the percutaneous needle electrode comprises inserting the end near or at an ankle of the patient.” Govier discloses this limitation. (Ex. 1002, ¶¶141-143.)

As shown in Figure 3 (below), Govier discloses inserting the end of the percutaneous needle (i.e., percutaneous needle electrode) [blue] near or at an ankle of the patient. (Ex. 1005, Fig. 3; *see also id.*, 1194 (“the needle was advanced approximately 3 to 4 cm. posterior to the tibia and, if advanced further, would traverse anterior to the fibula.”)).

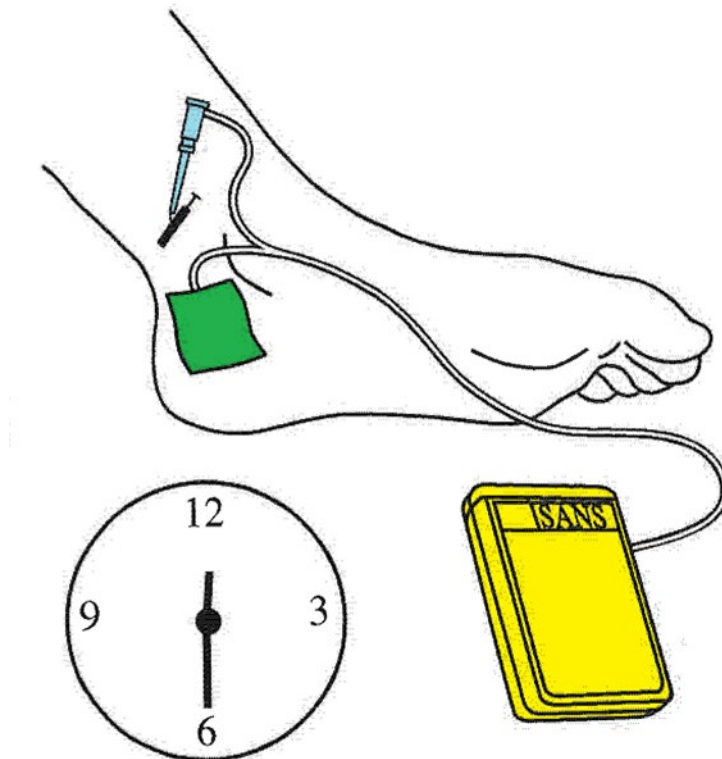


FIG. 3. Attach electrode and lead wire by placing electrode on same leg as needle near arch of foot. Connect grabber plug to needle on handle portion just above insertion point. Patient will control stimulation at comfortable level for 30 minutes.

(*Id.*, Fig. 3.)

9. Dependent Claim 7

Claim 7 depends from claim 5 and recites: “further comprising detecting a muscular response caused by an electrical conduction or stimulation of a nerve, muscle, or body tissue.” This is the same limitation from claim 3, and Govier discloses this limitation for the reasons previously presented. (*Supra* §VI.A.5.)

10. Dependent Claim 8

Claim 8 depends from claim 5 and recites: “wherein activating the pulse generator comprises activating for a duration of about 30 minutes per week to treat the patient.” This is the same limitation from claim 4, and Govier discloses this limitation for the reasons previously presented. (*Supra* §VI.A.6.)

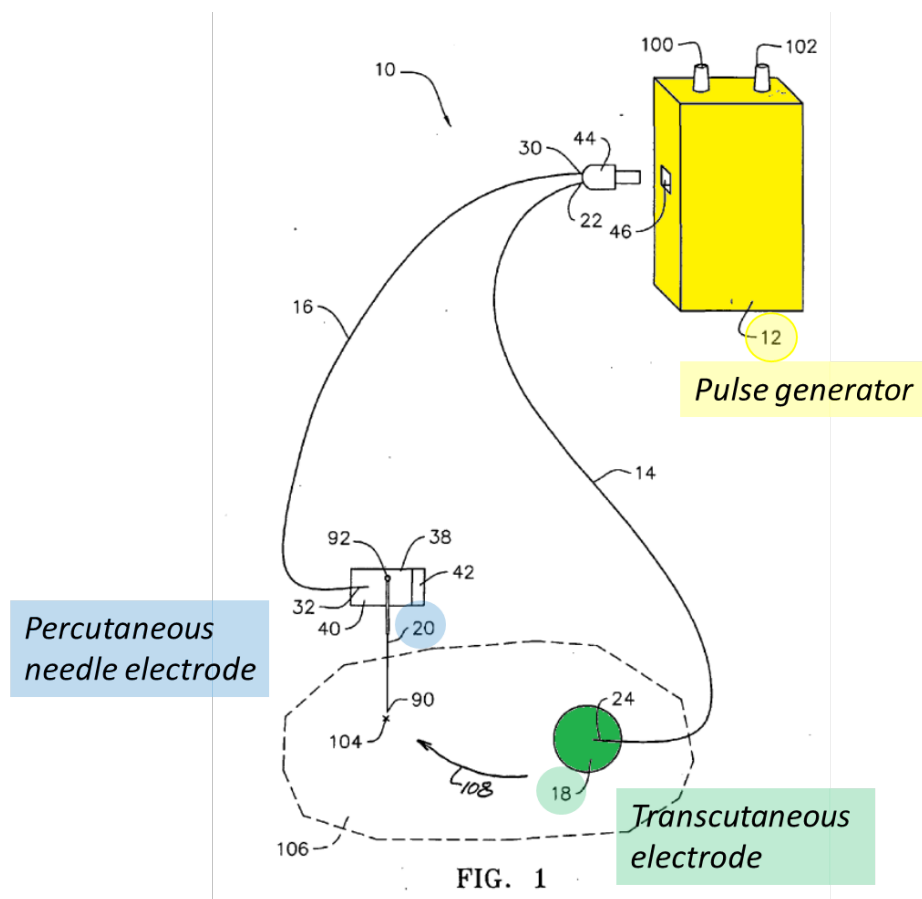
B. Grounds 3-4: Claims 1-8 Are Anticipated By Williams Or Rendered Obvious By Williams Combined With Govier

1. Independent Claim 1

Claim 1 is anticipated by Williams or rendered obvious by Williams in combination with Govier. (Ex. 1002, ¶¶145-171.) The preamble of claim 1 recites “[a] method.” If the preamble is limiting, Williams discloses this limitation. (*Id.*, ¶¶146-147.) Williams discloses methods of using “electro-nerve stimulation systems utilizing transcutaneous and percutaneous electrodes” to treat “urinary urge incontinence.” (Ex. 1006, [0002], [0037].)

a. **Limitation [A1]: “applying an electrode patch to the skin such that the electrode patch is disposed on an outer surface of the skin”**

Williams discloses this limitation. (Ex. 1002, ¶¶148-152.) Williams’s “electro-nerve stimulation system compris[es] a pulse generator [yellow] electrically coupled by first and second electrically conductive insulated lead wires to *an electrically conductive transcutaneous electrode [green]* and an electrically conductive percutaneous needle electrode [blue], respectively.” (Ex. 1006, [0006], [0023] (emphasis added); *see also id.*, claims 1-2, 24-25.)

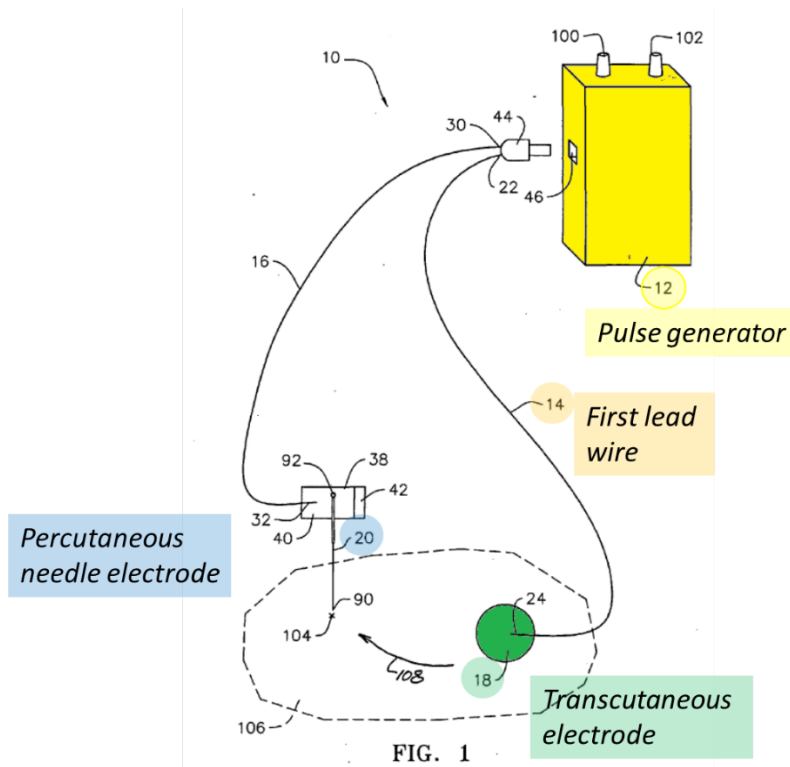


(*Id.*, Fig. 1.)

Williams’s “transcutaneous electrode” is the “electrode patch” required by claim 1. (Ex. 1002, ¶¶150-152.) Williams states, “the transcutaneous electrode...is positioned and adhered to the patient’s skin distally proximate the stimulation site.” (Ex. 1006., [0007]; *see also id.*, [0004] (defining a “transcutaneous electrode” as “an electrode which does not penetrate the surface of the skin”).) Williams explains that “[o]ne face of the transcutaneous electrode includes an electrically conductive medical grade adhesive to removably adhere the electrode to the patient’s skin near the desired stimulation site.” (*Id.*, [0006], Fig. 1.) As shown in Figure 1 above, the transcutaneous electrode is a round patch.

b. Limitation [A2]: “the electrode patch is electrically coupled with a controller unit”

Williams discloses this limitation. (Ex. 1002, ¶¶153-155.) Williams discloses that a “pulse generator” is “electrically coupled...to an electrically conductive transcutaneous electrode.” (Ex. 1006, [0006]; *see also id.*, [0024] (describing electrical coupling of elements), claims 1, 24.) The “transcutaneous electrode” is the “electrode patch” required by claim 1. (*Supra* §VI.B.1.a.) Williams specifically describes a “first lead wire 14” [orange] that “electrically couples” the pulse generator 12 to the transcutaneous electrode 18. (Ex. 1006, [0024].)



Williams further discloses that “[t]he preferred pulse generator 12 includes a first dial 100 used for selecting the desired current pulse for treatment” and “a second dial 102 for setting the desired treatment time.” (*Id.*, [0031].) Williams’s pulse generator (including the dials) is the “controller unit” required by claim 1 at least because it allows the user to control the stimulation and current pulses. (Ex. 1002, ¶155; *see also supra* §VI.A.3.b (describing use of “controller unit” in ’584 patent).)

c. **Limitation [A3]: “the controller unit including a pulse generator”**

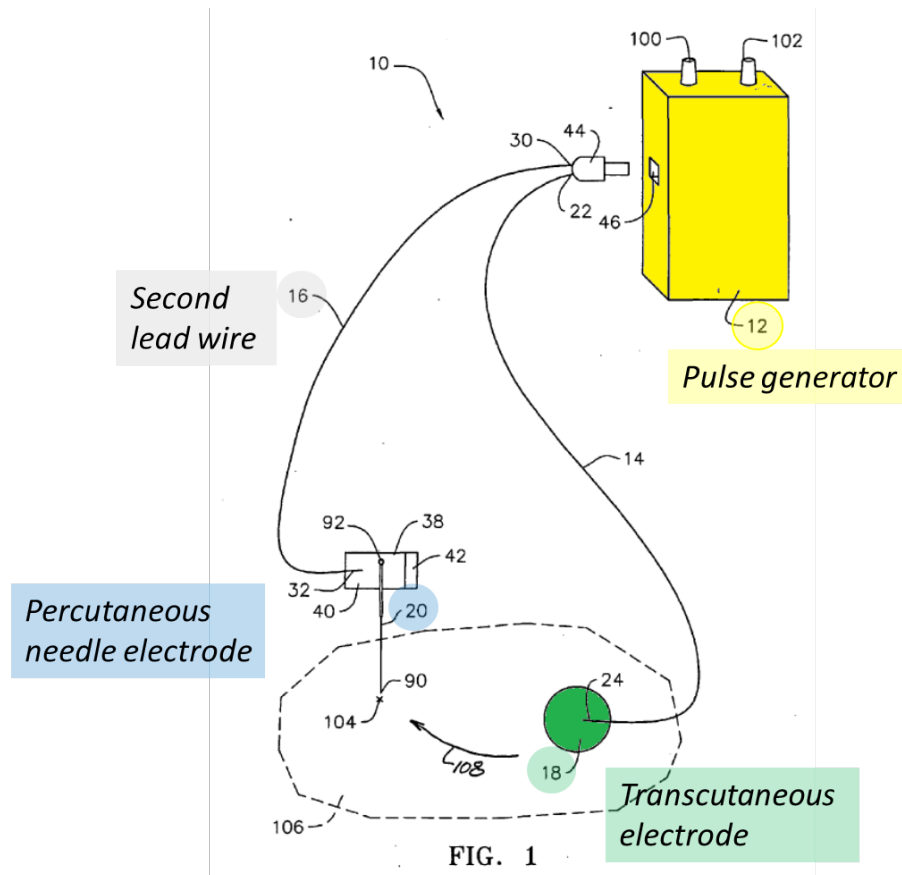
Williams discloses this limitation. (Ex. 1002, ¶¶156-157.) Williams discloses “an electro-nerve stimulation system comprising a *pulse generator*.” (Ex.

1006, [0006] (emphasis added).) Williams discloses that the “pulse generator 12 is activated to generate current pulses.” (*Id.*, [0032], Fig. 1.)

d. **Limitation [B1]: “electrically coupling a percutaneous electrode to the controller unit”**

Williams discloses this limitation. (Ex. 1002, ¶¶158-160.) Williams discloses “electro-nerve stimulation systems utilizing transcutaneous and *percutaneous electrodes*.” (Ex. 1006, [0002].) In the preferred embodiment, Williams discloses that the “percutaneous electrode” is “an electrically conductive percutaneous needle electrode 20.” (*Id.*, [0023].) The “percutaneous needle electrode 20 is inserted into the patient’s skin in proximity to the tibial nerve cephalic to the medial malleolus” to treat urinary incontinence. (*Id.*, [0037].)

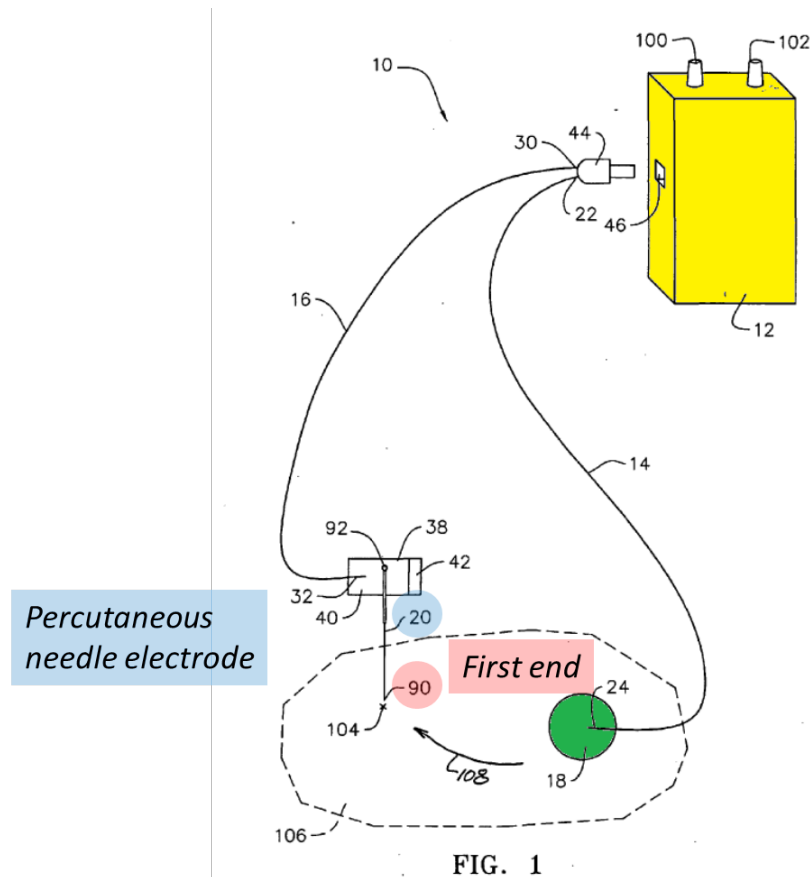
Williams also discloses that the “pulse generator” is “electrically coupled...to...an electrically conductive percutaneous needle electrode.” (Ex. 1006, [0006]; *see also id.*, claims 1, 24.) Williams describes a “second lead wire 16” [gray] that “electrically couples” the pulse generator 12 to the percutaneous needle electrode 20. (*Id.*, [0025]; *see also id.*, [0029] (describing connection between tape member 38 and electrode 20), [0032] (describing electrical coupling of pulse generator to electrode 20).)



(*Id.*, Fig. 1.)

- e. **Limitation [B2]: “the percutaneous electrode having an end for inserting in proximity to a tibial nerve, or a branch thereof, of the patient”**

Williams discloses this limitation. (Ex. 1002, ¶¶161-162.) Williams’s percutaneous electrode needle “includes a first end 90 [red] for insertion into the patient’s body in proximity to the preselected internal stimulation site....” (Ex. 1006, [0030].)



(*Id.*, Fig. 1.) Williams further discloses that the “percutaneous needle electrode 20 is inserted into the patient’s skin *in proximity to the tibial nerve* cephalic to the medial malleolus.” (*Id.*, [0037] (emphasis added).)

f. **Limitation [C]: “inserting the end of the percutaneous electrode into the skin in proximity to the tibial nerve, or a branch thereof, of the patient”**

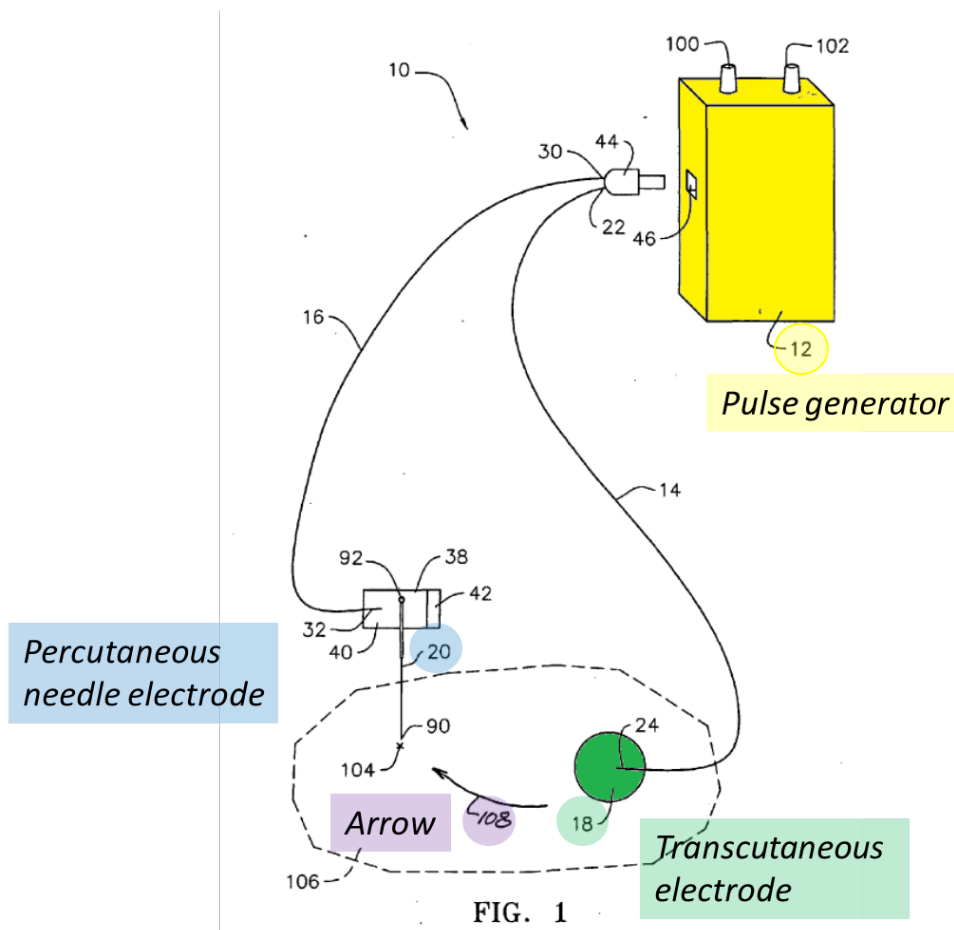
Williams discloses this limitation. (Ex. 1002, ¶163.) Williams states that the “percutaneous needle electrode 20 is inserted into the patient’s skin *in proximity to the tibial nerve* cephalic to the medial malleolus.” (*Id.*, [0037] (emphasis added); *supra* §VI.B.1.e.)

- g. **Limitation [D]: “activating the pulse generator such that current pulses flow along the tibial nerve, or branch thereof, by passing between the electrode patch and the percutaneous electrode”**

Williams discloses this limitation. (Ex. 1002, ¶¶164-168.) Williams states:

The pulse generator 12 [yellow] is activated to generate current pulses. The current pulses from the pulse generator 12 traverse the internal stimulation site 104 by passing from the transcutaneous electrode 18 [green] to the percutaneous needle electrode 20 [blue] as indicated by the arrow 108 [purple].

(Ex. 1006, [0032].)



As discussed above, Williams discloses that one “internal stimulation site” is the tibial nerve. (*Id.*, [0037].) In this embodiment, the “percutaneous needle electrode 20 is inserted into the patient’s skin in proximity to the tibial nerve cephalic to the medial malleolus.” (*Id.*) Williams also teaches that the “transcutaneous electrode is adhered to the patient’s skin distal to the percutaneous needle electrode.” (*Id.*) This is the same arrangement of components described in the ’584 patent. (Ex. 1002, ¶¶167-168; *see e.g.*, Ex. 1001, 27:53-28:3, Fig. 27 (describing and illustrating placement of the electrode patch “downstream or distal to a selected stimulation site 261” and insertion of the electrode needle 262 “at a location and to a depth that brings the tip in close proximity to the target nerve to be stimulated”).) Thus, if the ’584 patent discloses this limitation, so does Williams.

h. Limitation [E]: “the current pulses configured to treat overactive bladder”

Williams discloses this limitation, or renders this limitation obvious in combination with Govier. (Ex. 1002, ¶¶169-171.) Williams discloses that the described system is “particularly suited for the treatment of urinary urge incontinence.” (Ex. 1006, [0037].) POSITAs in October 2006 often used the term “overactive bladder” and “urinary urge incontinence” interchangeably. (Ex. 1002, ¶170.) For example, Van Balken defines “overactive bladder” as “the urgency and frequency syndrome and/or *urge incontinence*.” (Ex. 1010, 914 (emphasis

added).) POSITAs commonly conflated “overactive bladder” and “urinary urge incontinence” because urge incontinence is a common symptom of an overactive bladder. (Ex. 1002, ¶170.) For example, Govier states that the “predominant symptoms” for overactive bladder include, “frequency, urgency, *urge incontinence* and pelvic pain.” (Ex. 1005, 1193 (emphasis added).) Based on this close relationship, a POSITA would have understood that Williams’s system is configured to treat overactive bladder. (Ex. 1002, ¶170.)

If Williams does not disclose this limitation, Williams in combination with Govier does. (Ex. 1002, ¶171.) Govier discloses the use of “percutaneous peripheral afferent nerve stimulation for treatment of refractive overactive bladder and/or pelvic floor dysfunction.” (Ex. 1005, 1193.) Govier discloses a system that is similar, if not identical, to the system described in Williams. (*See supra* §VI.A.1-2 (describing Govier and Williams).) Both systems include a pulse generator electrically coupled to a transcutaneous electrode and percutaneous needle electrode. (*Compare e.g.*, Ex. 1005, Fig. 3 *and* Ex. 1006, Fig. 1.) Both references also describe using the system to stimulate the tibial nerve. (Ex. 1005, 1195; Ex. 1006, [0037].) Moreover, Govier concludes that using these systems to stimulate the tibial nerve treats overactive bladder. (Ex. 1005, 1198.) Based on these disclosures, a POSITA would have found it obvious to use Williams’s system to treat overactive bladder. (Ex. 1002, ¶171.) Such a use would have merely been

the use of a known technique to treat a known problem using a prior art system.
KSR, 550 U.S. at 417-418.

2. Dependent Claim 2

Claim 2 depends from claim 1 and recites: “wherein inserting the end of the percutaneous electrode comprises inserting the end near or at an ankle of the patient.” Williams discloses this limitation. (Ex. 1002, ¶¶172-173.)

Williams states, the “percutaneous needle electrode 20 is inserted into the patient’s skin in proximity to the tibial nerve cephalic to the medial malleolus.” (Ex. 1006, [0037].) The medial malleolus is the anklebone on the inside of the leg. (Ex. 1002, ¶173.) Thus, Williams’s percutaneous needle electrode is inserted near or at an ankle of the patient.

3. Dependent Claim 3

Claim 3 depends from claim 1 and recites: “further comprising detecting a muscular response caused by an electrical conduction or stimulation of a nerve, muscle, or body tissue.” Williams in combination with Govier renders this limitation obvious. (Ex. 1002, ¶¶174-175.)

As explained in Grounds 1-2, Govier discloses that once the electrical stimulation of the tibial nerve begins, the doctor determines if the needle is properly positioned by observing the patient’s toes and detecting a muscular response. (*Supra* §VI.A.5.) A POSITA would have found it obvious to employ this

known method for assessing the needle's location when using Williams's system. (Ex. 1002, ¶175.) As discussed previously, Govier discloses a system that is similar, if not identical, to the system described in Williams. (*Supra* §VI.A.1-2.) As in Govier, Williams describes inserting a percutaneous needle electrode near the tibial nerve and activating a pulse generator to stimulate the nerve. (Ex. 1006, [0037].) Due to the substantial similarities between the systems described in Williams and Govier, a POSITA would have been motivated, and expected success, in using Govier's simple observation-based method for assessing the needle position by detecting a "muscular response" in the patient's toes. (Ex. 1002, ¶175.)

4. Dependent Claim 4

Claim 4 depends from claim 1 and further recites "wherein activating the pulse generator comprises activating for a duration of about 30 minutes per week to treat the patient." Williams in combination with Govier renders this limitation obvious. (Ex. 1002, ¶¶176-178.)

Govier discloses activating a pulse generator for a duration of 30 minutes per week to treat a patient. (*Supra* §VI.A.6.) A POSITA would have found it obvious to use this known treatment method when using Williams's system. (Ex. 1002, ¶¶177-178.) As discussed previously, Govier discloses a system that is similar, if not identical, to the system described in Williams. (*Supra* §VI.A.1-2.)

As in Govier, Williams describes activating a pulse generator to stimulate the tibial nerve. (Ex. 1006, [0037].) William discloses that the treatment time is “preferably in five minute increments” and set by the “second dial” 102 on the pulse generator. (*Id.*, [0031].)

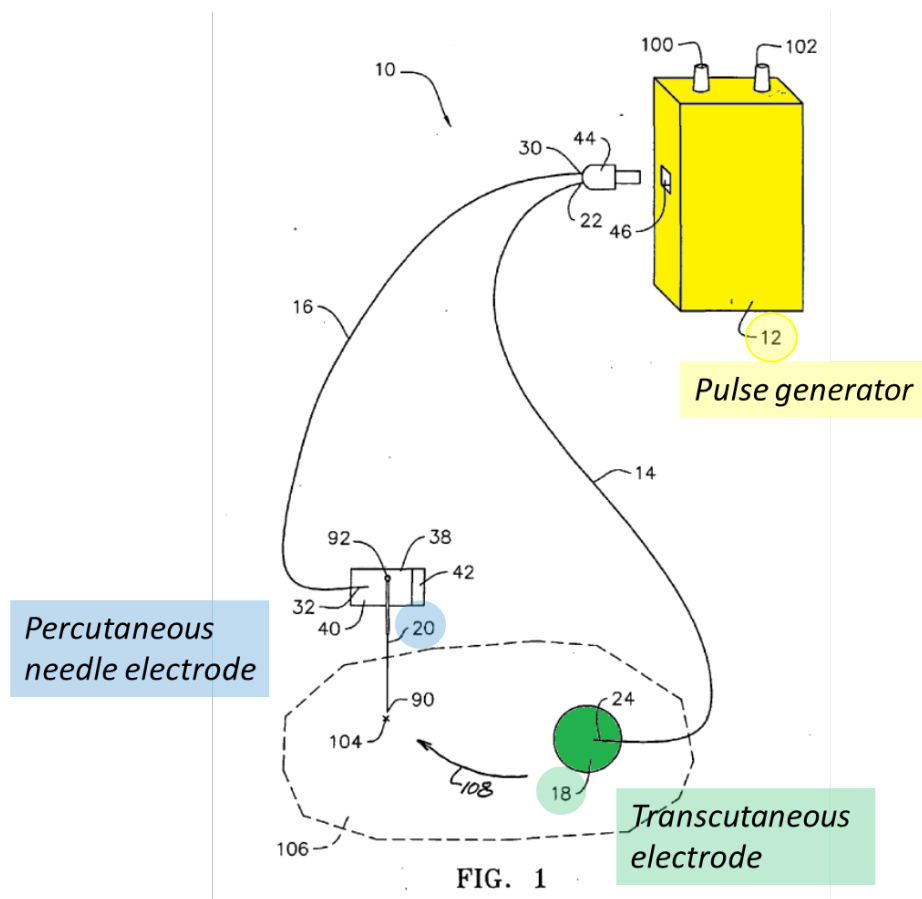
A POSITA would have recognized that only a finite number of reasonable treatment periods exist in five-minute increments and, therefore, would have found it obvious to try a treatment time of 30 minutes per week in view of the teachings in Govier. (Ex. 1002, ¶178.) Moreover, a POSITA would have been motivated to use the weekly 30-minute treatment described in Govier due to the similarities between the systems described in Govier and Williams. (*Supra* §VI.B.1.h.) A POSITA would have expected success in using the weekly 30-minute treatment because Govier discloses that the treatment was successful. (Ex. 1005, 1198.)

5. Independent Claim 5

Claim 5 is anticipated by Williams or rendered obvious by Williams in combination with Govier. (Ex. 1002, ¶¶179-199.) The preamble of claim 5 recites “[a] method.” If the preamble is limiting, Williams discloses this limitation. (*Id.*, ¶180.) Williams discloses methods of using “electro-nerve stimulation systems utilizing transcutaneous and percutaneous electrodes” to treat “urinary urge incontinence.” (Ex. 1006, [0002], [0037].)

a. **Limitation [A]: “positioning a transcutaneous electrode on skin of a patient in proximity to a tibial nerve, or a branch thereof”**

Williams discloses this limitation. (Ex. 1002, ¶¶181-184.) Williams’s “electro-nerve stimulation system compris[es] a pulse generator [yellow] electrically coupled by first and second electrically conductive insulated lead wires to *an electrically conductive transcutaneous electrode [green]* and an electrically conductive percutaneous needle electrode [blue], respectively.” (*Id.*, [0006], [0023], (emphasis added).)



(*Id.*, Fig. 1.)

Williams’s “transcutaneous electrode” satisfies claim 5. (Ex. 1002, ¶¶181-184.) Williams states, “the transcutaneous electrode...is positioned and adhered to the patient’s skin distally proximate the stimulation site.” (Ex. 1006, [0007]; *see also id.*, [0004] (defining a “transcutaneous electrode” as “an electrode which does not penetrate the surface of the skin”), claims 1-2, 24-25.) Williams explains, “One face of the transcutaneous electrode includes an electrically conductive medical grade adhesive to removably adhere the electrode to the patient’s skin near the desired stimulation site.” (*Id.*, [0006], Fig. 1.) As shown in Figure 1 above, the transcutaneous electrode is a round patch.

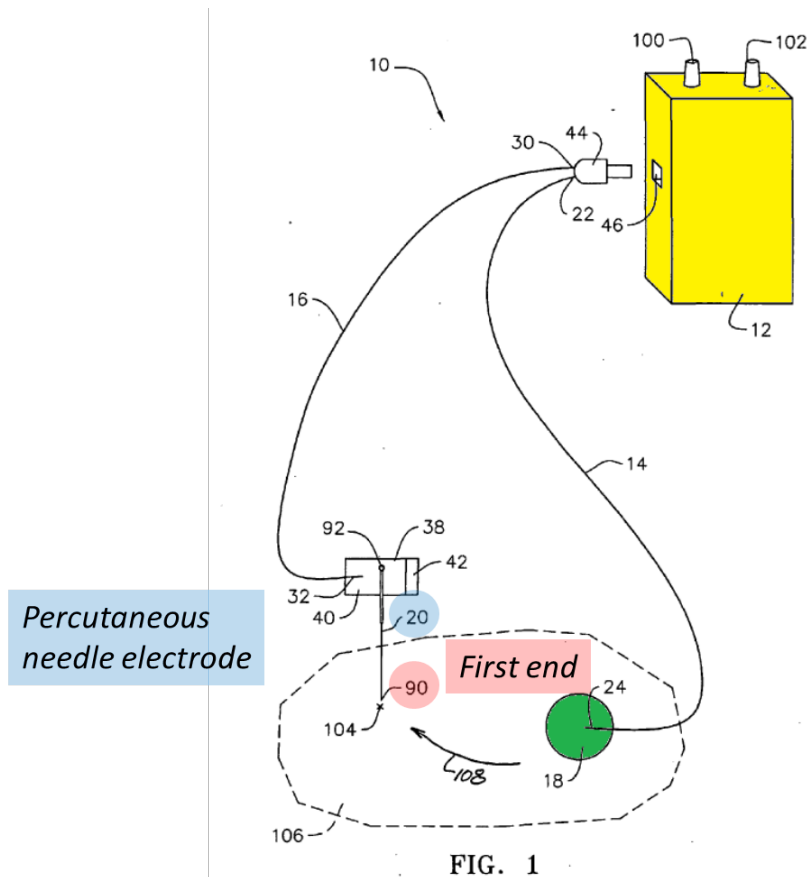
Williams also discloses positioning the transcutaneous electrode in proximity to the tibial nerve, or a branch thereof. (Ex. 1002, ¶184.) Williams discloses that the “transcutaneous electrode is adhered to the patient’s skin distal to the percutaneous needle electrode.” (Ex. 1006, [0037].) The “percutaneous needle electrode 20 is inserted into the patient’s skin in proximity to the tibial nerve cephalic to the medial malleolus.” (*Id.*) A POSITA would have understood that the transcutaneous electrode must be positioned in proximity to a tibial nerve, or a branch thereof, because the tibial nerve runs distally down the foot, which is where the transcutaneous electrode is located. (Ex. 1002, ¶184.) Moreover, a POSITA would have recognized that the transcutaneous electrode must be located in

proximity to the tibial nerve in order for the system to stimulate the tibial nerve.

(*Id.*)

b. **Limitation [B1]: “inserting an end of a percutaneous needle electrode through the skin in proximity to the tibial nerve, or a branch thereof”**

Williams discloses this limitation. (Ex. 1002, ¶¶185-186.) Williams discloses “electro-nerve stimulation systems utilizing transcutaneous and *percutaneous electrodes*.” (Ex. 1006, [0002].) In the preferred embodiment, Williams discloses that the “percutaneous electrode” is “an electrically conductive percutaneous needle electrode 20.” (*Id.*, [0023]; *see also id.*, claims 1, 24.) The percutaneous electrode needle “includes a first end 90 [red] for insertion into the patient’s body in proximity to the preselected internal stimulation site....” (Ex. 1006, [0030].)

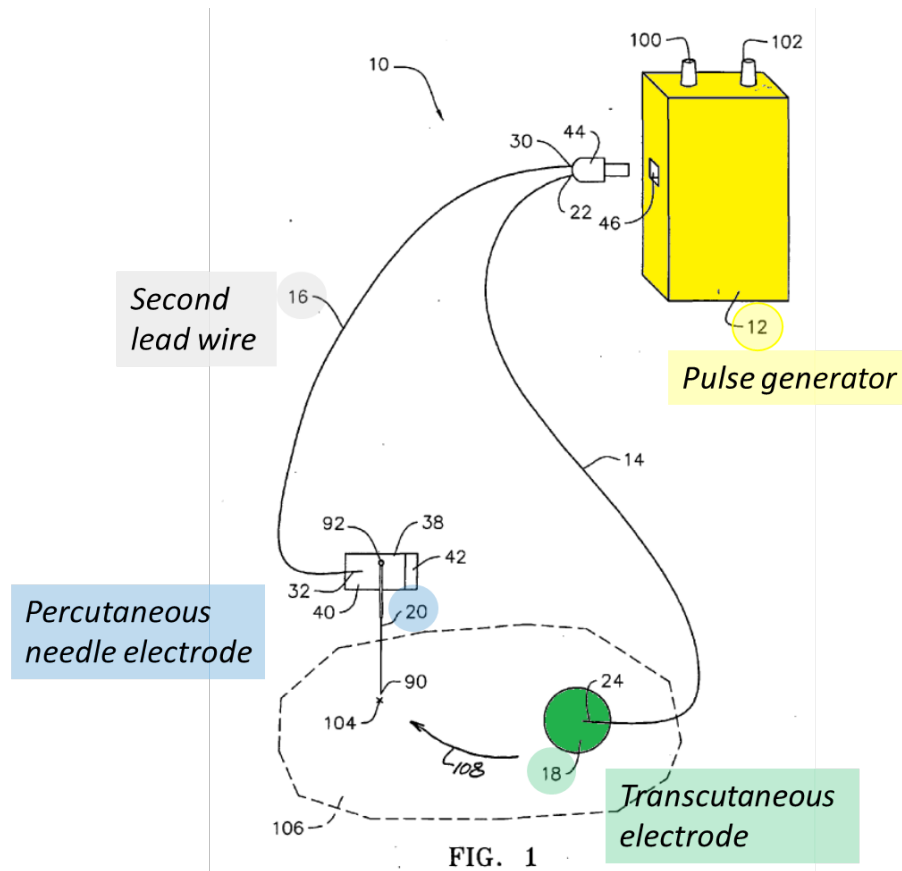


(*Id.*, Fig. 1.) Williams further discloses that the “percutaneous needle electrode 20 is inserted into the patient’s skin *in proximity to the tibial nerve* cephalic to the medial malleolus.” (*Id.*, [0037] (emphasis added).)

c. Limitation [B2]: “the percutaneous needle electrode including a wire disposed opposite the end”

Williams discloses this limitation. (Ex. 1002, ¶¶187-188.) Williams discloses a “second lead wire 16” [gray] at an end of the percutaneous needle electrode 20 that is opposite end 90. (Ex. 1006, [0025]; *see also id.*, claims 1, 24.) The second lead wire 16 “electrically couples” the percutaneous needle electrode 20 to the pulse generator 12. (*Id.*; *see also id.*, [0029] (describing connection

between tape member 38 and electrode 20), [0032] (describing electrical coupling of pulse generator to electrode 20).)

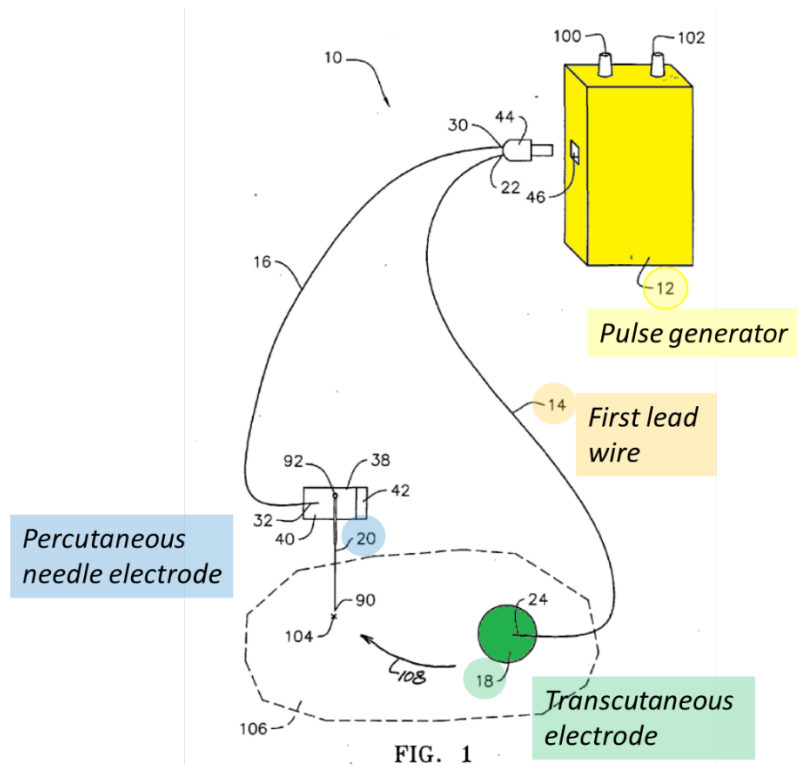


(*Id.*, Fig. 1.)

d. **Limitation [C1]: “securing a controller unit to the transcutaneous electrode such that the controller unit is electrically coupled to the transcutaneous electrode”**

Williams discloses this limitation. (Ex. 1002, ¶¶189-191.) Williams discloses that a “pulse generator” is “electrically coupled ... to an electrically conductive transcutaneous electrode.” (Ex. 1006, [0006]; *see also id.*, [0024] (describing electrical coupling of elements), claims 1, 24.) Williams specifically

describes a “first lead wire 14” [orange] that “electrically couples” the pulse generator 12 to the transcutaneous electrode 18. (*Id.*, [0024].)



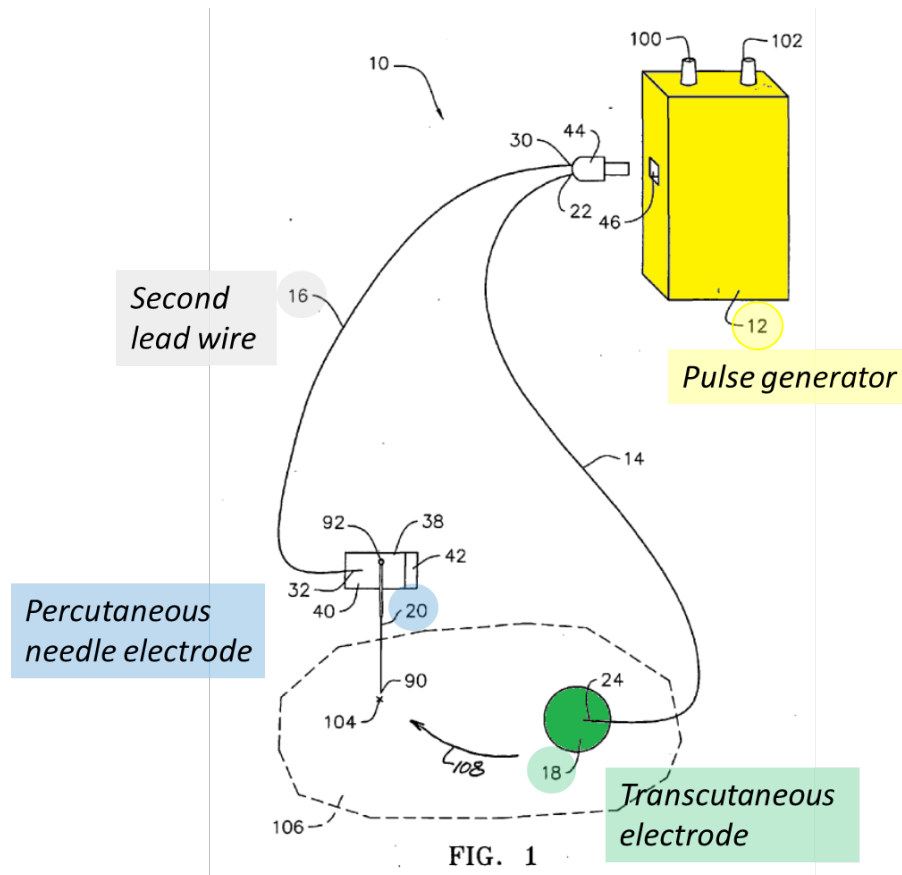
Williams further discloses that “[t]he preferred pulse generator 12 includes a first dial 100 used for selecting the desired current pulse for treatment” and “a second dial 102 for setting the desired treatment time.” (*Id.*, [0031].) Williams’s pulse generator (including the dials) is the “controller unit” required by claim 5 because it allows the user to control the stimulation and current pulses. (Ex. 1002, ¶¶70, 191; *see also supra* §VI.A.3.b (describing use of “controller unit” in ’584 patent).)

e. **Limitation [C2]: “the controller unit including a pulse generator”**

This limitation also appears in claim 1. (*Supra* §VI.B.1.c.) Williams discloses this limitation for the reasons previously presented. (*Id.*)

f. **Limitation [D]: “connecting the wire of the percutaneous needle electrode to the controller unit for electrically coupling the percutaneous needle electrode to the controller”**

Williams discloses this limitation. (Ex. 1002, ¶¶193-194.) Williams discloses that the “pulse generator” is “electrically coupled ... to ... an electrically conductive percutaneous needle electrode.” (Ex. 1006, [0006].) Williams describes a “second lead wire 16” [gray] that “electrically couples” the pulse generator 12 to the percutaneous needle electrode 20. (Ex. 1006, [0025]; *see also id.*, [0029] (describing connection between tape member 38 and electrode 20), [0032] (describing electrical coupling of pulse generator to electrode 20), claims 1, 24.)



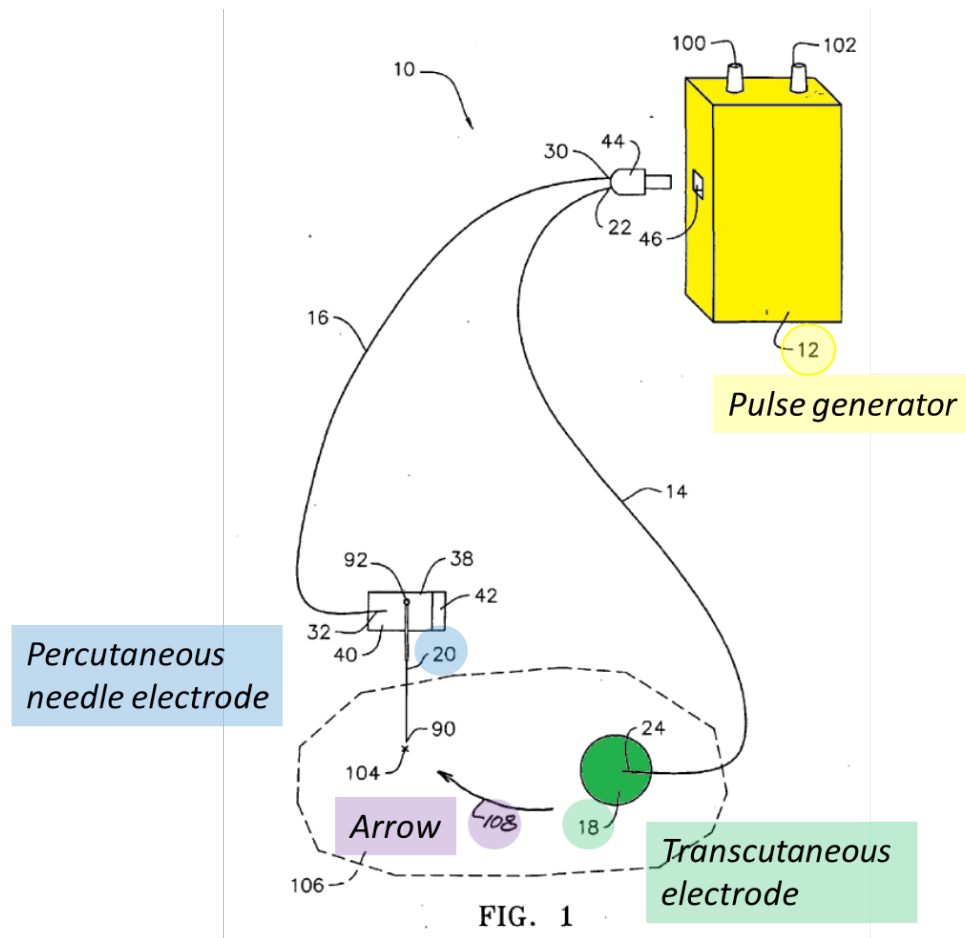
(*Id.*, Fig. 1.)

- g. **Limitation [E]: “activating the pulse generator such that current pulses flow along the tibial nerve, or a branch thereof, by passing between the transcutaneous electrode and the percutaneous needle electrode”**

Williams discloses this limitation. (Ex. 1002, ¶¶195-198.) Williams states:

The pulse generator 12 [yellow] is activated to generate current pulses. The current pulses from the pulse generator 12 traverse the internal stimulation site 104 by passing from the transcutaneous electrode 18 [green] to the percutaneous needle electrode 20 [blue] as indicated by the arrow 108 [purple].

(Ex. 1006, [0032].)



Williams discloses that one “internal stimulation site” is the tibial nerve. (*Id.*, [0037].) In this embodiment, the “percutaneous needle electrode 20 is inserted into the patient’s skin in proximity to the tibial nerve cephalic to the medial malleolus.” (*Id.*) Williams also teaches that the “transcutaneous electrode is adhered to the patient’s skin distal to the percutaneous needle electrode.” (*Id.*) This is the same arrangement of components described in the ’584 patent. (Ex. 1002, ¶¶197-198; *see e.g.*, Ex. 1001, 27:53-28:3, Fig. 27 (describing and illustrating placement of the electrode patch “downstream or distal to a selected stimulation

site 261” and insertion of the electrode needle 262 “at a location and to a depth that brings the tip in close proximity to the target nerve to be stimulated”).) Thus, if the ’584 patent discloses this limitation, so does Williams.

h. Limitation [F]: “the current pulses configured to treat overactive bladder”

This limitation also appears in claim 1. (*Supra* §VI.B.1.h.) Williams discloses this limitation, or renders this limitation obvious in combination with Govier, for the reasons previously presented. (*Id.*)

6. Dependent Claim 6

Claim 6 depends from claim 5 and further recites “wherein inserting an end of the percutaneous needle electrode comprises inserting the end near or at an ankle of the patient.” Williams discloses this limitation. (Ex. 1002, ¶¶200-201.)

Williams states, the “percutaneous needle electrode 20 is inserted into the patient’s skin in proximity to the tibial nerve cephalic to the medial malleolus.” (Ex. 1006, [0037].) The medial malleolus is the anklebone on the inside of the leg. (Ex. 1002, ¶201.) Thus, Williams’s percutaneous needle electrode is inserted near or at an ankle of the patient.

7. Dependent Claim 7

Claim 7 depends from claim 5 and recites: “further comprising detecting a muscular response caused by an electrical conduction or stimulation of a nerve, muscle, or body tissue.” This is the same limitation in claim 3. (*Supra* §VI.B.3.)

Williams discloses this limitation or renders this limitation obvious in combination with Govier for the reasons previously presented. (*Id.*)

8. Dependent Claim 8

Claim 8 depends from claim 5 and recites: “wherein activating the pulse generator comprises activating for a duration of about 30 minutes per week to treat the patient.” This is the same limitation in claim 4. (*Supra* §VI.B.4.) Williams in combination with Govier renders this limitation obvious for the reasons previously presented. (*Id.*)

C. Grounds 5-6: Claims 3 and 7 are obvious over Govier in view of Gharib or Govier in view of Williams and Gharib

1. Overview of Gharib

Gharib explains that prior art “systems and methods exist for monitoring nerves and nerve muscles.” (Ex. 1007, [0005].) Gharib continues:

One such system determines when a needle is approaching a nerve.

The system applies a current to the needle to evoke a muscular response. The muscular response is visually monitored, typically as a shake or “twitch.” When such a muscular response is observed by the user, the needle is considered to be near the nerve coupled to the responsive muscle.

(*Id.*) The described needle-based system is similar to the systems used in Govier and Williams and the observational approach to determine proper needle placement is also described in Govier. (*Supra* §VI.A.5; Ex. 1002, ¶205.)

While Gharib recognizes that the systems and methods described in Govier and Williams are “generally effective” for determining nerve proximity, the systems are “incapable of determining the direction of the nerve to the needle....” (Ex. 1007, [0006].) Thus, Gharib describes an improvement to the systems and methods in Govier and Williams that allows for greater accuracy in determining the proximity of a surgical instrument, such as a needle, to a nerve. (*Id.*, [0008]-[0009].)

Gharib’s improved system includes a surgical instrument, such as a needle, and a control unit “capable of delivering a stimulation signal, receiving and processing neuromuscular responses due to the stimulation signal, and identifying a relationship between the neuromuscular response and the stimulation signal.” (*Id.*, [0011].) Gharib’s “surgical instrument has at least one stimulation electrode electrically coupled to said control unit for transmitting the stimulation signal....” (*Id.*; *see also id.*, claim 1 (reciting “a control unit,” “receiving and processing neuromuscular responses,” “a surgical instrument having at least one stimulation electrode electrically coupled to said control unit”).) The system also includes electrodes “placed on the skin over the major muscle groups on the legs” to detect

the muscular response. (*Id.*, [0041].) Thus, Gharib describes methods of detecting a muscular response caused by stimulation of a nerve. (Ex. 1002, ¶207.)

2. Dependent Claim 3

Claim 3 depends from claim 1 and recites: “further comprising detecting a muscular response caused by an electrical conduction or stimulation of a nerve, muscle, or body tissue.” Gharib discloses this limitation and Govier in combination with Gharib, or Govier and Williams in combination with Gharib render this claim obvious. (Ex. 1002, ¶¶206-210.)

As explained above, Gharib discloses, “delivering a stimulation signal, *receiving and processing neuromuscular responses* due to the stimulation signal, and identifying a relationship between the neuromuscular response and the stimulation signal.” (Ex. 1007, [0011] (emphasis added).) In a preferred embodiment, Gharib discloses a system for “electrically stimulating nerves via one or more stimulation electrodes at the distal end of the surgical access component 24-28 while monitoring the EMG [i.e., muscular] responses of the muscle grounds innervated by the nerves.” (*Id.*, [0041]; *see also id.*, [0020] (“neuromuscular response (EMG)”).) The system monitors the EMG response “via 8 pairs of EMG electrodes 34 placed on the skin over the major muscle groups on the legs....” (*Id.*, [0041].) Gharib further discloses, “any of a variety of electrodes can be employed, including but not limited to needle electrodes.” (*Id.*, [0042].) Gharib provides

detailed algorithms to analyze the EMG (muscular) responses to determine “nerve proximity, nerve direction, and nerve pathology features...” (*Id.*, [0048].) Thus, Gharib discloses a method of detecting a muscular response caused by an electrical stimulation of a nerve, muscle, or body tissue. (Ex. 1002, ¶207.)

A POSITA would have been motivated to combine Gharib’s muscular response detection system with Govier, or Govier and Williams, for several reasons. (Ex. 1002 ¶¶208-210.) As explained above, Gharib specifically discloses improvements to systems like those disclosed in Govier and Williams. (*Supra* §VI.C.1.) Govier and Williams disclose methods for stimulating the tibial nerve with a percutaneous needle electrode. (Ex. 1005, 1194; Ex. 1006, [0037].) Govier discloses a method of determining the location of the needle electrode by observing the muscular response of the patient’s toes. (Ex. 1005, 1194.) Gharib discloses an improvement to such systems by including EMG electrodes placed on the patient’s skin to more accurately assess the muscular response. (Ex. 1007, [0005]-[0006].) Thus, Gharib provides a teaching, suggestion, and motivation to combine Gharib’s muscular response detection system with Govier, or Govier and Williams.

Additionally, Gharib’s muscular detection system is compatible with Gharib’s system. (Ex. 1002, ¶209.) Gharib discloses that the nerve stimulation may occur through a “needle,” which is the same way that Govier and Williams

stimulate the nerve. (*See e.g.*, Ex. 1007, [0041]-[0042]; Ex. 1005, 1194; Ex. 1006, [0037].) Gharib further discloses that the EMG response electrodes, which detect the muscular response, are electrically coupled to a “control unit.” (*See e.g.*, Ex. 1007, [0011].) Govier and Williams also disclose a “control” unit that is electrically coupled to the electrodes and may be used to activate and adjust the current pulses used to stimulate the nerve. (*See e.g.*, Ex. 1005, 1194; Ex. 1006, [0006].) Moreover, Gharib discloses that its “control unit” generates a stimulation current “comprised of monophasic pulses of 200 microsecond duration.” (Ex. 1007, [0048].) Govier’s control unit similarly generates a stimulation current “with fixed pulse 200 microseconds.” (Ex. 1005, 1194.) A POSITA would have expected success in combining Gharib’s muscular detection system with Govier, or Govier and Williams, due to all of these similarities. (Ex. 1002, ¶209.)

Moreover, the combination of Gharib with Govier (and Williams) applies a known technique (Gharib’s muscular response detection in response to electrical stimulation) to a known method (Govier’s and Williams’s electrical stimulation) that is ready for improvement and yields predictable results (a method for treating overactive bladder in which feedback regarding efficacy of treatment is received). (Ex. 1002, ¶210); *KSR*, 550 U.S. at 417.

For these reasons, Govier in combination with Gharib and/or Govier in combination with Williams and Gharib renders claim 3 obvious.

3. Dependent Claim 7

Claim 7 depends from claim 5 and recites. “further comprising detecting a muscular response caused by an electrical conduction or stimulation of a nerve, muscle, or body tissue.” This is the same limitation in claim 3. (*Supra* §VI.C.2.) Gharib discloses this limitation and Govier in combination with Gharib, or Govier and Williams in combination with Gharib render this claim obvious for the reasons previously presented. (*Id.*)

D. Grounds 7-8: Claims 3 and 7 are obvious over Williams in view of Gharib or Williams in view of Govier and Gharib

A POSITA would have found claims 3 and 7 obvious over Williams in view of Gharib or Williams in view of Govier and Gharib for the reasons provided in the previous sections. (*Supra* §VI.C.1-3.)

VII. SECONDARY CONSIDERATIONS

Secondary considerations should be evaluated, but do not control an obviousness conclusion, particularly where, as here, a strong *prima facie* showing of obviousness exists. *Leapfrog Enters., Inc. v. Fisher-Price, Inc.*, 485 F.3d 1157, 1162 (Fed. Cir. 2007); *Newell Cos. v. Kenney Mfg. Co.*, 864 F.2d 757, 768 (Fed. Cir. 1988). Petitioner is unaware of any evidence of secondary considerations, and any such evidence that Patent Owner may provide cannot possibly outweigh the strong *prima facie* case of obviousness. Petitioner reserves the right to respond to evidence of secondary considerations in due course.

VIII. MANDATORY NOTICES PURSUANT TO 37 C.F.R. §42.8(A)(1)

Pursuant to 37 C.F.R. §42.8(a)(1), the mandatory notices identified in 37 C.F.R. §42.8(b) are provided below as part of this Petition.

A. Real Party-In-Interest (37 C.F.R. §42.8(b)(1))

Cala Health, Inc. is the real party-in-interest for the instant Petition.

B. Related Matters (37 C.F.R. §42.8(b)(2))

Petitioner has also filed for *inter partes* review of U.S. Patent No. 9,387,338, which is the parent of the '584 patent.

C. Lead and Backup Counsel (37 C.F.R. §42.8(b)(3))

Petitioner provides the following designation of counsel, all of whom are included in Customer No. 20,995 identified in Petitioner's Power of Attorney.

Lead Counsel	Back-up Counsel
Joshua J. Stowell (Reg. No. 64,096) 2jys@knobbe.com BoxCalaHealth584@knobbe.com	William R. Zimmerman (<i>pro hac vice</i> admission request pending filing) 2wrz@knobbe.com
Knobbe, Martens, Olson, & Bear, LLP <u>Postal and Hand-Delivery Address:</u> 2040 Main St., 14th Floor Irvine, CA 92614 Telephone: 949-760-0404 Facsimile: 949-760-9502	Brian C. Barnes (Reg. No. 75,805) 2bcb@knobbe.com Knobbe, Martens, Olson, & Bear, LLP <u>Postal and Hand-Delivery Address:</u> 2040 Main St., 14th Floor Irvine, CA 92614 Telephone: 206-405-2000 Facsimile: 206-405-2001

D. Service Information (37 C.F.R. §42.8(b)(4))

Please direct all correspondence to lead counsel and back-up counsel at the addresses shown above. Petitioner also consents to electronic service by email to BoxCalaHealth584@knobbe.com.

IX. PAYMENT OF FEES PURSUANT TO 37 C.F.R. §42.103

The undersigned authorize the Office to charge the fee set forth in 37 C.F.R. §42.15(a) for this Petition to Deposit Account No. 11-1410. Review of 8 claims is requested. The undersigned further authorize payment for any additional fees that may be due to be charged to the above-referenced Deposit Account.

X. REQUIREMENTS FOR REVIEW UNDER 37 C.F.R. §42.104

Petitioner certifies that the '584 patent is available for *inter partes* review and that Petitioner is not barred or estopped from requesting *inter partes* review challenging the patent claims on the grounds identified herein.

XI. CONCLUSION

Petitioner has established a reasonable likelihood of prevailing in showing that at least one challenged claim is unpatentable, and therefore requests that the Board institute an *inter partes* review trial and cancel all challenged claims.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: January 23, 2023

By: /Joshua J. Stowell/

Joshua J. Stowell (Reg. No. 64,096)

Brian C. Barnes (Reg. No. 75,805)

Customer No. 20,995

Attorneys for Petitioner

CALA HEALTH, INC.

CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. §42.24(d), the undersigned certifies that the foregoing
PETITION FOR INTER PARTES REVIEW OF U.S. PATENT 9,757,584,
exclusive of the parts exempted as provided in 37 C.F.R. §42.24(a), contains
13,437 words and therefore complies with the type-volume limitations of 37 C.F.R.
§42.24(a).

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: January 23, 2023

By: /Joshua J. Stowell/

Joshua J. Stowell (Reg. No. 64,096)

Brian C. Barnes (Reg. No. 75,805)

Customer No. 20,995

Attorneys for Petitioner

CALA HEALTH, INC.

CERTIFICATE OF SERVICE

I hereby certify that, pursuant to 37 C.F.R. §42.105, a true and correct copy of the foregoing **PETITION FOR INTER PARTES REVIEW OF U.S. PATENT 9,757,584** and **EXHIBITS 1001-1018 and 1022** are being served on January 23, 2023, via FedEx Priority Overnight to the correspondence address of record for the subject patent 9,757,584 found on the USPTO's Patent Center webpage.

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KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: January 23, 2023

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