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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.

IPR2023-00511
U.S. Patent 9,387,338

**PETITION FOR *INTER PARTES* REVIEW OF
U.S. PATENT 9,387,338**

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EXHIBIT LIST

Exhibit No.	Description
1001	U.S. Patent No. 9,387,338 (“the ’338 patent”)
1002	Declaration of John Laughlin
1003	CV of John Laughlin
1004	Excerpts from the ’338 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	RESERVED
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	U.S. Patent Publication No. 2005/0261559 (“Mumford”)
1020	U.S. Patent 6,662,052 (“Sarwal”)
1021	U.S. Patent 7,283,866 to Mumford et al.
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. 9,387,338 (“the ’338 patent,” Ex. 1001), purportedly owned by EMKinetics Inc. (“Patent Owner”).

I. SUMMARY OF THE ISSUES PRESENTED

The claims of the ’338 patent recite methods of treating incontinence by passing an electrical current along the tibial 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 a stimulation site, (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 including a pulse generator [yellow], and (4) activating the pulse generator so current pulses flow along the tibial nerve between the electrode patch and percutaneous electrode.

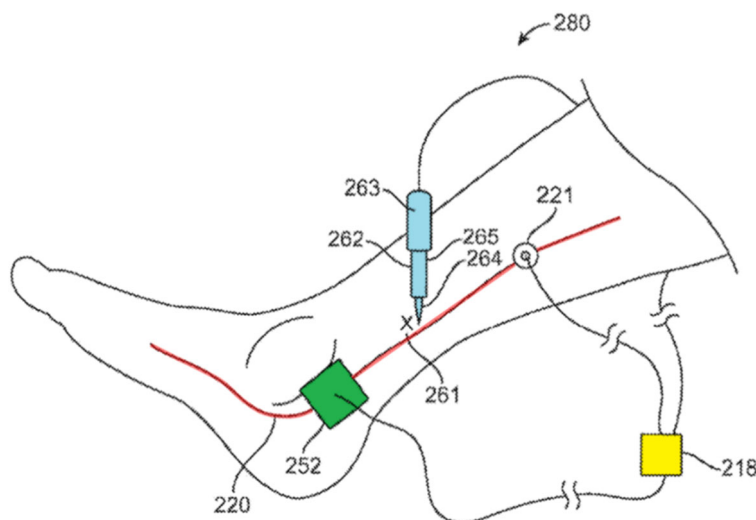


FIG. 27

The claimed methods were well known and had been implemented in numerous studies as of October 2, 2006, the earliest claimed priority date for the '338 patent. For example, Govier (Ex. 1005), published in 2001, discloses a multicenter study for treating overactive bladder and incontinence. As illustrated in Govier's Figure 3 below, Govier discloses the method of the '338 patent, including the steps of: (1) placing an electrode patch or transcutaneous electrode [green] on the patient's skin near a stimulation site, (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 including a pulse generator [yellow], and (4) activating the pulse generator so current pulses flow along the tibial nerve between the electrode patch and the percutaneous electrode.

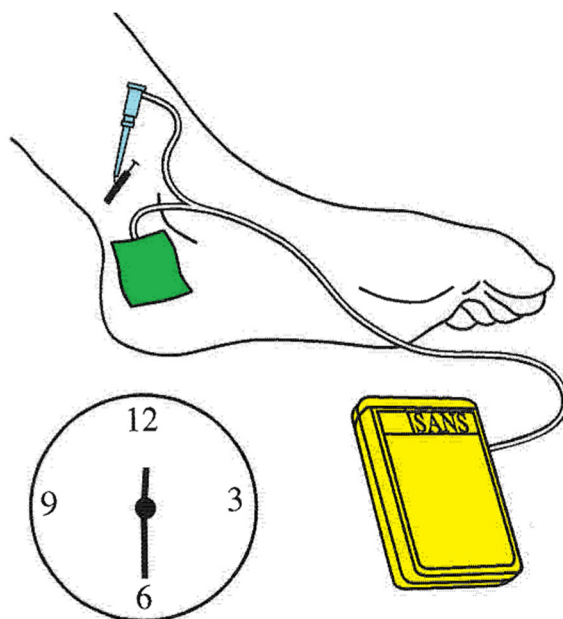
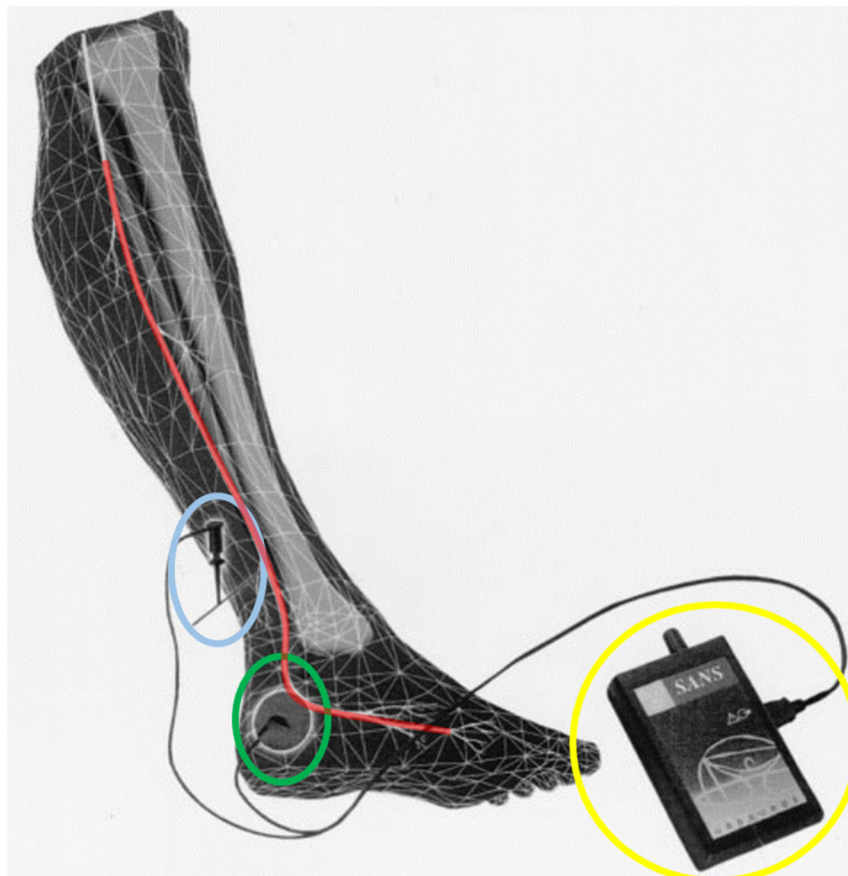


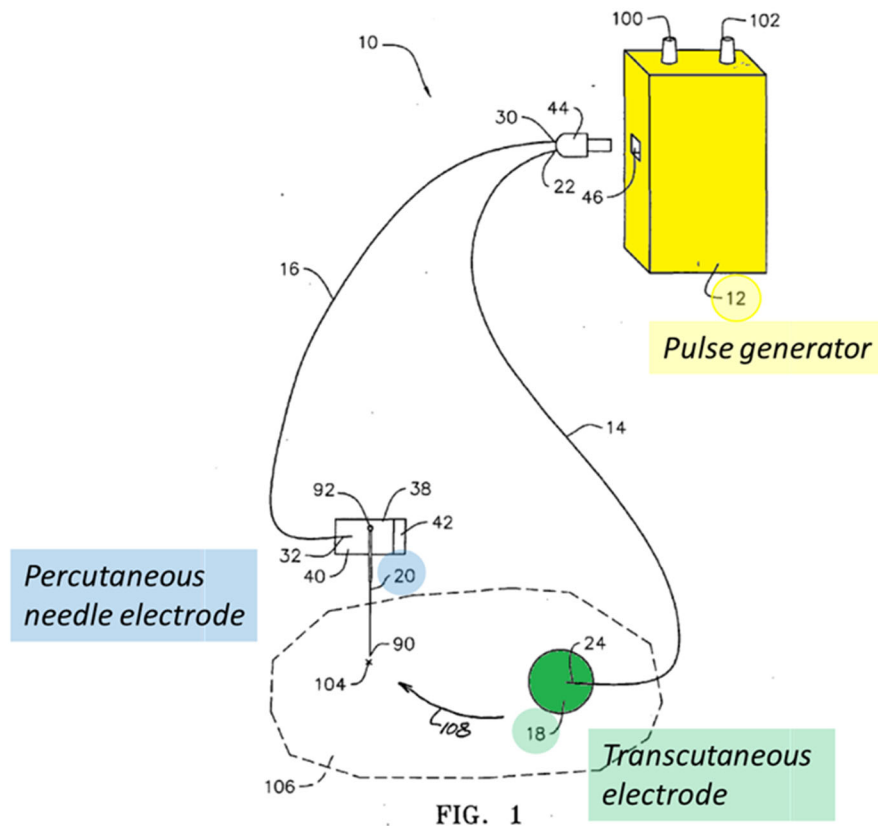
FIG. 3. Attach electrode and lead wire by placing electrode on same leg as needle near arch of foot. Connect grabber plug to needle on handle portion just above insertion point. Patient will control stimulation at comfortable level for 30 minutes.

Similarly, Klingler, published in 2000, describes a study to treat overactive bladder and incontinence by stimulating the tibial nerve. As illustrated Klingler's Figure 1 below, Klingler discloses the method claimed in the '338 patent, including the steps of: (1) placing an electrode patch or transcutaneous electrode [green circle] on the patient's skin near a stimulation site, (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 including a pulse generator [yellow], and (4) activating the pulse generator so current pulses flow along the tibial nerve between the electrode patch and the percutaneous electrode.



Likewise, Van Balken, published in 2001, describes a study to treat overactive bladder and incontinence by stimulating the tibial nerve. Van Balken describes the method claimed in the '338 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 '338 patent. For example, Williams, published August 4, 2005, discloses “[a]n 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 '338 patent, including the steps of: (1) placing a transcutaneous electrode [green] on the patient’s skin near a stimulation site, (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 including a pulse generator [yellow], and (4) activating the pulse generator 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 '338 patent. Unfortunately, the journal publications were not before the Examiner during prosecution. Because the prior art anticipates or renders obvious the claimed methods, claims 1-8 of the '338 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 '338 patent.

III. THE '338 PATENT

A. Overview of the '338 Patent

The '338 patent issued on July 12, 2016, 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 '338 patent relates to “systems and/or methods for electromagnetic induction therapy,” which is not the focus of the claims. (Ex. 1001, abstract.) However, a segment of the patent describes methods for treating ailments by providing “electrical energy” to a target nerve. (*Id.*, 8:18-22.) For example, the '338 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.*, 27:1-5, 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.*, 27:13-16.)

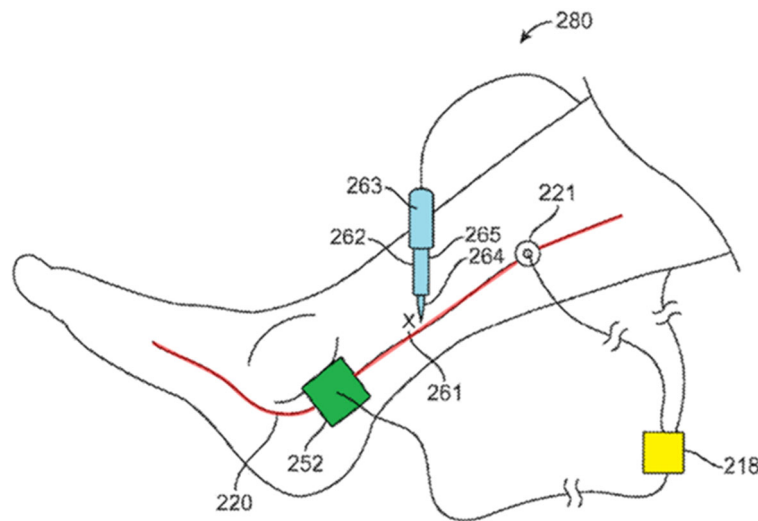


FIG. 27

(*Id.*, Fig. 27.)

“The percutaneous electrode needle 262 is inductively coupled to conductive microneedle patch 252 [green].” (*Id.*, 27:7-9.) The “patch can include at least one electrode” and “may optionally be attached to various other materials or adhesive materials.” (*Id.*, 28:7-14.) While Figure 27 specifically discloses a “microneedle

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

patch,” the ’338 patent discloses that the microneedles are optional. (*See e.g., id.*, 28:11-14 (“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.*, 27:17-20.) The ’338 patent discloses that the described stimulating devices may be used to treat a long list of indications, including overactive bladder. (*Id.*, 40:41-63.)

The ’338 patent also generically states, “In various variations described herein, housings, conductive coils, microneedle patches, energy emitting apparatus, energy generators, or electrode needles may be connected, coupled, wirelessly connected or coupled or otherwise in communication with each other, controllers or sensors, using a variety of methods or techniques known in the art.” (*Id.*, 35:1-7.) However, the patent does not provide further detail regarding how the wireless connections between a controller and electrode patch or needle would function.

B. Prosecution History of the '338 Patent

Patent Owner filed the application for the '338 patent on April 1, 2015. The initial claims recited a method of treating migraines involving non-invasive electrical stimulation of the occipital nerve or a branch of that nerve. (Ex. 1004, 245-246.) The Examiner rejected the original claims as obvious over the prior art. (*Id.*, 108-113.) Patent Owner subsequently amended the claims to recite a method for treating “incontinence” by stimulating the tibial nerve. (*Id.*, 95-97.) Patent Owner argued that the cited prior art did not teach or suggest placing an electrode near the tibial nerve to treat incontinence. (*Id.*, 98.) The Examiner subsequently allowed the amended claims without further rejection. (*Id.*, 68-74.) 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 and treat incontinence.

C. Priority

The '338 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 or were filed for and published before the earliest claimed priority date and, therefore, qualify as prior art under 35 U.S.C. §§102(a)-(b) and (e). However, Petitioner reserves the right to contest the actual priority date of the '338 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 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 a formal degree and vice versa. (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 '338 patent as follows:

Ground 1: Claims 1-3 and 6 are anticipated under 35 U.S.C. §102(b) (“§102(b)”) by Govier.

Ground 2: Claims 1-3 and 6 are obvious under 35 U.S.C. §103 (“§103”) over Govier in view of Williams.

Ground 3: Claims 1-3 and 6 are anticipated under §102(b) by Williams.

Ground 4: Claims 1-3 and 6 are obvious under §103 over Williams in view of Govier.

Grounds 5-6: Claims 4-5 and 7-8 are obvious under §103 over Govier in view of Mumford or Govier in view of Williams and Mumford.

Grounds 7-8: Claims 4-5 and 7-8 are obvious under §103 over Williams in view of Mumford or Williams in view of Govier and Mumford.

Grounds 9-10: Claims 4-5 and 7-8 are obvious under §103 over Govier in view of Sarwal or Govier in view of Williams and Sarwal.

Grounds 11-12: Claims 4-5 and 7-8 are obvious under §103 over Williams in view of Sarwal or Williams in view of Govier and Sarwal.

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

B. Status of References as Prior Art

The relied-upon references, with the exception of Mumford, are prior art under 35 U.S.C. §102(b) because each published more than one year before the '338 patent's earliest claimed priority date (October 2, 2006). Govier published by April 2001; Williams published on August 4, 2005; and Sarwal issued on December 9, 2003. 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.

Mumford qualifies as prior art under at least 35 U.S.C. §§102(a) and 102(e) because Mumford was filed on August 18, 2000 and published on November 24, 2005.

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 and (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 and (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 and (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, Williams, and Sarwal constitute analogous art because the references are from the same field of endeavor as the '338 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 '338 inventors were addressing, e.g., treatment of various ailments, including overactive bladder and urinary incontinence, via electrical stimulation of nerves, including the tibial nerve. *Id.*

Mumford also constitutes analogous art because it discloses the same methods of stimulating a nerve as the '338 patent. (Ex. 1002, ¶40.) Mumford is reasonably pertinent to a particular problem addressed by the '338 patent (e.g., the need to efficiently stimulate a nerve), is in the same field of endeavor as the '338 patent (neurostimulation), and uses similar technology (e.g., stimulation electrodes and a control unit) as the '338 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, Mumford, and Sarwal were not before the Examiner during prosecution. Williams was identified in an IDS along with hundreds of other references. (Ex. 1004, 160). 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 grandchild of the '338 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 '338 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 1-3 and 6 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.) 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.)

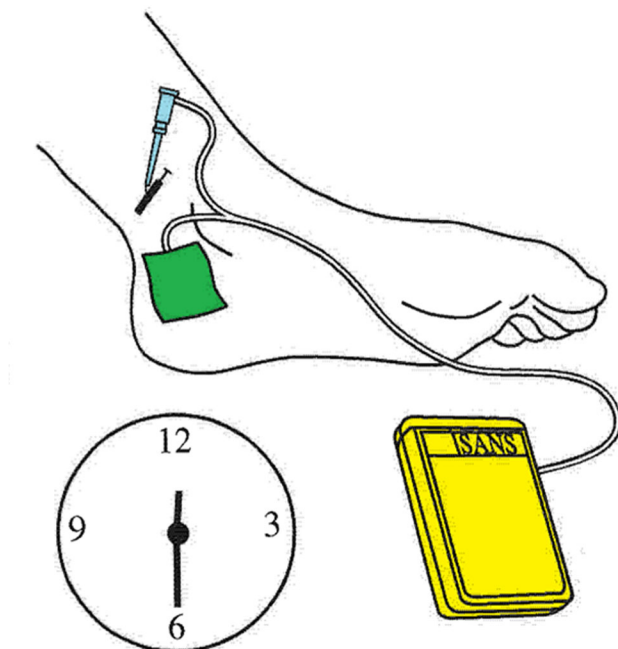
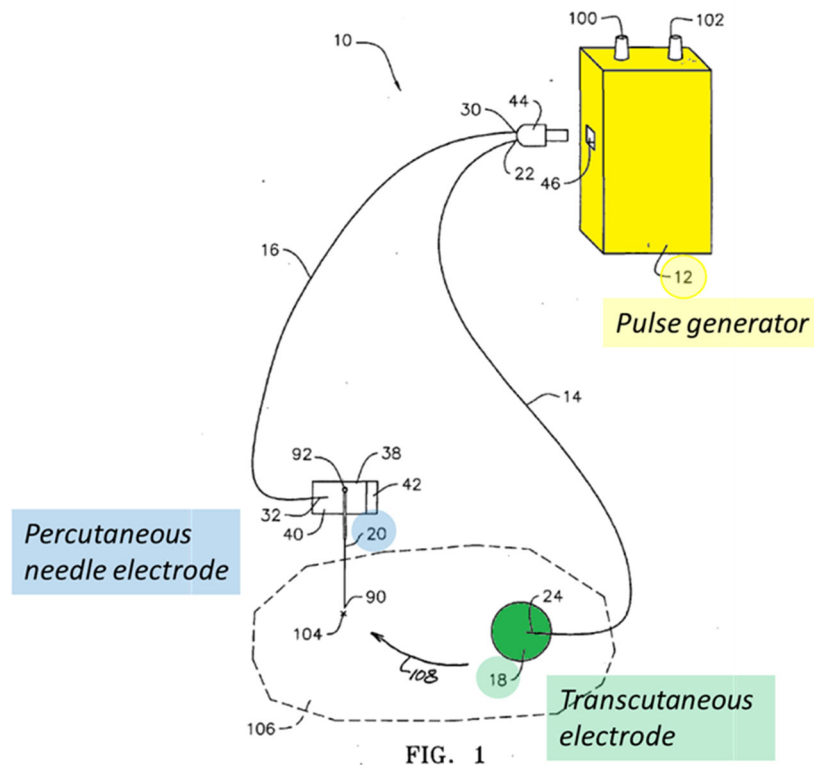


FIG. 3. Attach electrode and lead wire by placing electrode on same leg as needle near arch of foot. Connect grabber plug to needle on handle portion just above insertion point. Patient will control stimulation at comfortable level for 30 minutes.

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.*) “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].)



(*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].)

Williams discloses that 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 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, ¶49.) 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 arch of the foot). (Ex. 1002, ¶49; *see also* Ex. 1001, 27:9-13, 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 with Williams. (Ex. 1002, ¶¶56-101.) The preamble of claim 1 recites “[a] method.” Govier discloses a method of treating “overactive bladder” using electrical stimulation of the “tibial nerve.” (*Id.*, ¶58; Ex. 1005, 1193.)

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

Govier discloses this limitation, or renders this limitation obvious with Williams. (Ex. 1002, ¶¶59-68.) Govier discloses applying an “electrocardiogram ground pad” [green] to the outer surface of the patient’s skin near the anklebone (i.e., “medial aspect of the calcaneus”). (Ex. 1005, 1194.) Govier’s “electrocardiogram ground pad” is the “electrode patch” required by claim 1. (Ex. 1002, ¶¶60-63.) The area around the patient’s anklebone is in proximity to the tibial nerve, a stimulation site of a patient. (*Id.*)

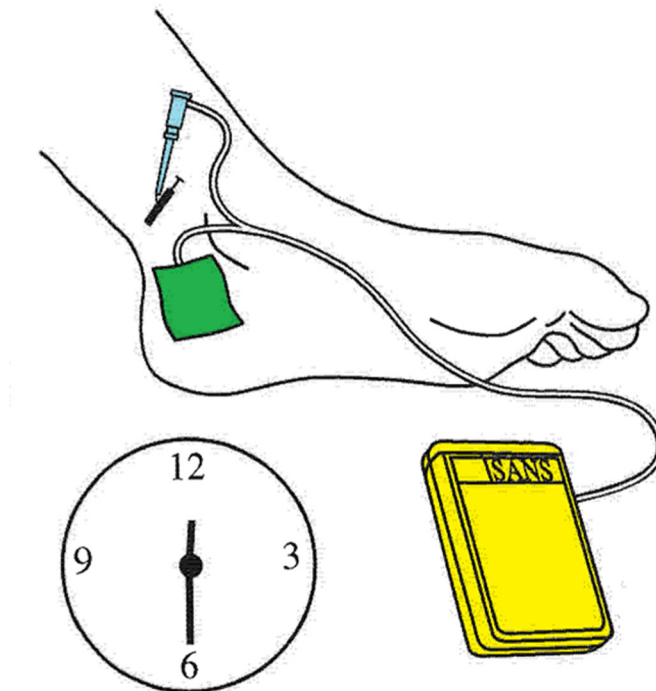
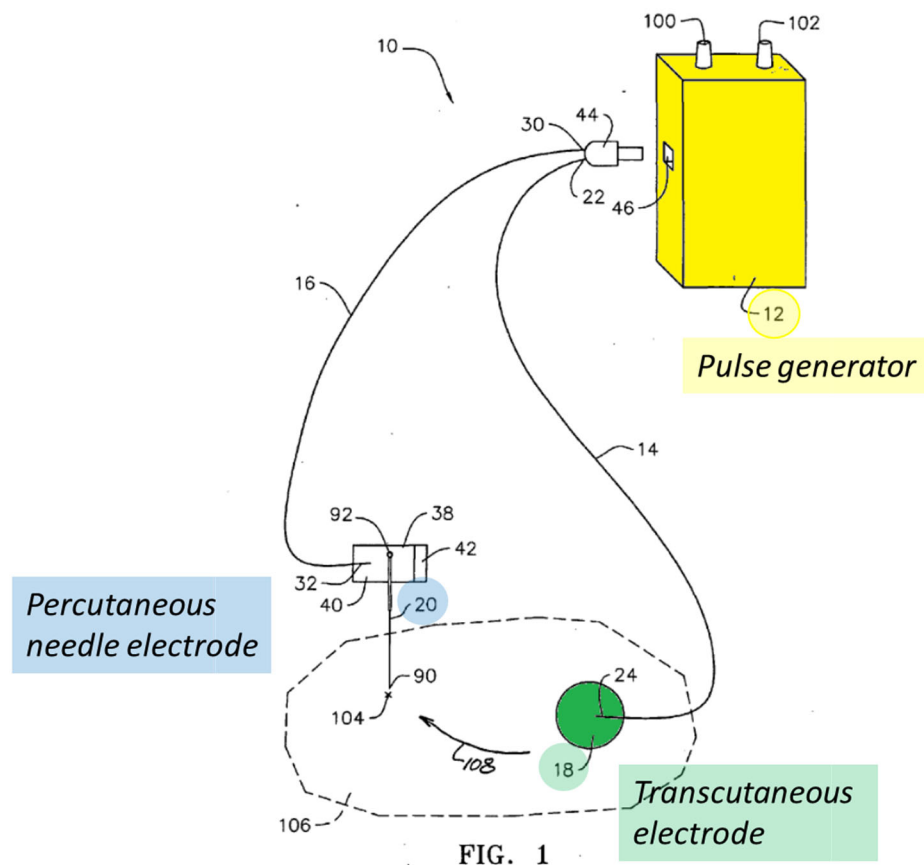


FIG. 3. Attach electrode and lead wire by placing electrode on same leg as needle near arch of foot. Connect grabber plug to needle on handle portion just above insertion point. Patient will control stimulation at comfortable level for 30 minutes.

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

the figure illustrates the ground pad as a square patch. Govier further confirms that electrocardiogram type electrodes, like the above patch, were well known in the art as of Govier’s publication. (*See* Ex. 1005, 1193 (describing 1983 study of “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, ¶¶64-68.) 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], [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”).) 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, the electrode is a round patch. (*Id.*, [0006], Fig. 1.) Thus, Williams also discloses the “electrode patch” required by claim 1.

A POSITA would have been motivated to combine Williams’s electrode patch with Govier’s system. (Ex. 1002, ¶¶66-68.) Govier and Williams describe similar systems used to treat similar problems (e.g., urinary incontinence). (Ex. 1005, abstract; Ex. 1006, [0037]; Ex. 1002, ¶¶66-68, 79.) A POSITA would have found the substitution of Williams’s known electrode patch for Govier’s ground pad 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 does no more than yield predictable results. *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., generating a current along the tibial nerve). (Ex. 1005, 1194; Ex. 1006, [0032], [0037]; Ex. 1002, ¶¶67-68.) 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, ¶67.)

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 ground pad is connected to the stimulator with a lead wire. (Ex. 1005, 1194, Fig. 3.) Similarly, Williams’s transcutaneous electrode is electrically coupled to the pulse generator by a “first lead wire 14.” (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, ¶¶68.)

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

Govier discloses this limitation. (Ex. 1002, ¶¶69-73.) 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, ¶¶70-73.)

² “Ipsilateral” means the ground pad is on the same side of the foot as the needle, as illustrated in Figure 3. (Ex. 1002, ¶70.)

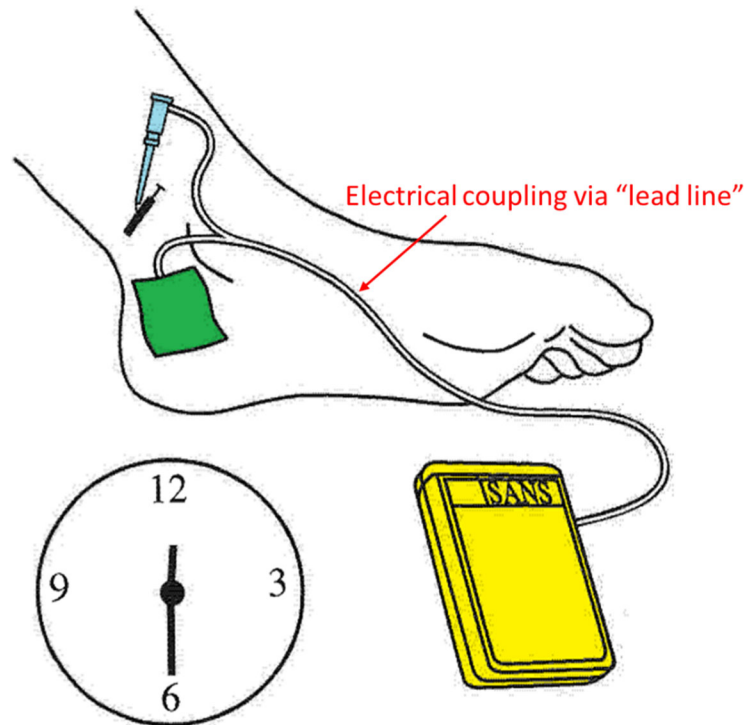


FIG. 3. Attach electrode and lead wire by placing electrode on same leg as needle near arch of foot. Connect grabber plug to needle on handle portion just above insertion point. Patient will control stimulation at comfortable level for 30 minutes.

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 current 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 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 '338 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. (*See e.g.*, Ex. 1001, abstract, 5:57-60, 6:18-20, 28:4-21.) As

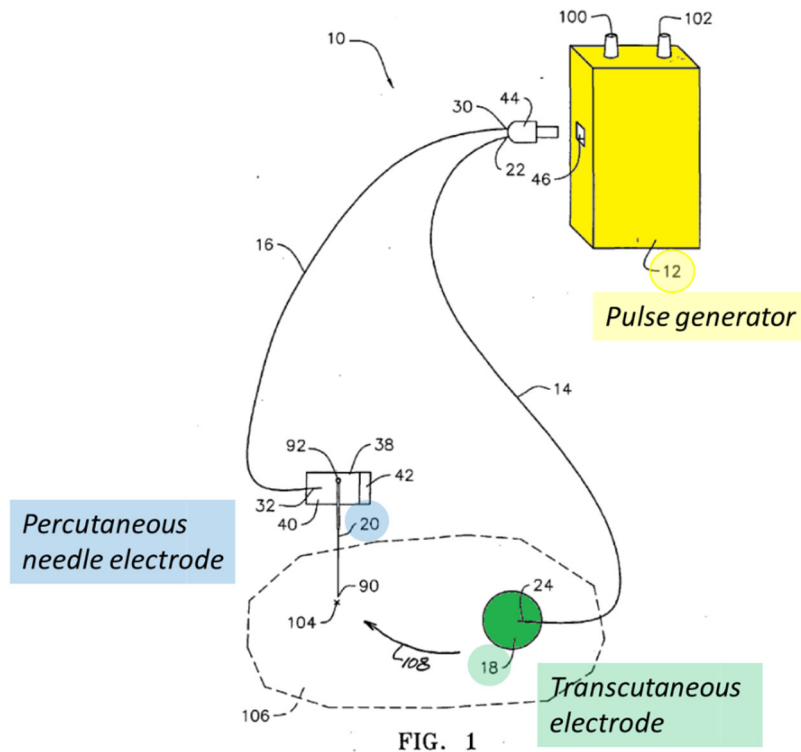
discussed above, this is the function of Govier’s stimulator. Thus, Govier discloses this limitation.

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

Govier discloses this limitation, or renders this limitation obvious with Williams. (Ex. 1002, ¶¶74-81.) Govier’s 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 the “electrode needles, surface electrode, external *pulse generator*, and lead wire assembly (which connects all three).” (Ex. 1018, 1 (emphasis added).)

Govier confirms that its stimulator included a pulse generator by disclosing 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 Govier’s stimulator must include a “pulse generator” in order to generate the described pulses. (Ex. 1002, ¶76.) Thus, Govier discloses this limitation.

If Govier does not disclose this limitation, it renders the limitation obvious in combination with Williams. (Ex. 1002, ¶¶77-81.) Williams discloses an “electro-nerve stimulation apparatus” for treating “urinary urge incontinence” that includes “a pulse generator [yellow]”:



(*Supra* §VI.A.2; Ex. 1006, abstract, [0006], [0023], [0037], Fig. 1.) 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 identifies a commercially-available pulse generator and explains that those skilled in the art would know how to make the necessary modifications to use the pulse generator with Williams’s preferred electrodes. (*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, ¶78.)

A POSITA would have been motivated to substitute Williams’s pulse generator for Govier’s stimulator. (Ex. 1002, ¶¶79-81.) 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, ¶79.) 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, ¶80. 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. Additionally, Govier and Williams disclose a finite number of identified, predictable solutions for generating current pulses with a reasonable expectation of success (*e.g.*, UroSurge Sans device and Finetech-Medical pulse generator). A POSITA would have been motivated to use either commercially-available device to produce the current pulses. (Ex. 1002, ¶¶79-80.)

A POSITA would have expected success in substituting Williams’s pulse generator for Govier’s stimulator because the devices are used for the same purpose in both references. (Ex. 1002, ¶81.) 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.) Both devices were commercially available and, as Williams explained, if any modifications were necessary to make the stimulator/generator compatible 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, ¶¶82-86.) 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.) 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, ¶¶83-86.)

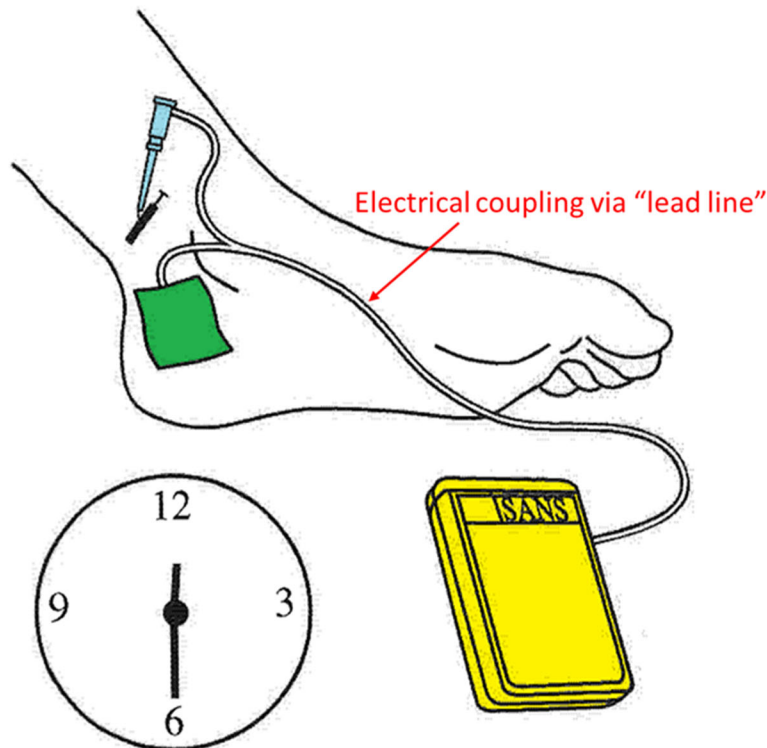


FIG. 3. Attach electrode and lead wire by placing electrode on same leg as needle near arch of foot. Connect grabber plug to needle on handle portion just above insertion point. Patient will control stimulation at comfortable level for 30 minutes.

Govier states that the stimulator is “connected to the needle” and, as shown 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 with the stimulator. (*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, ¶¶83-86.)

Moreover, the '338 patent confirms that Govier's needle is a "percutaneous electrode." (Ex. 1002, ¶85.) The only percutaneous electrodes disclosed in the '338 patent that are electrically coupled to a controller unit are percutaneous electrode needles (e.g., percutaneous electrode needle 262). (Ex. 1001, 27:55-28:3, Fig. 27.) Thus, if the '338 patent discloses this limitation, so does Govier.

e. **Limitation [B2]: "the percutaneous electrode having an end for inserting in proximity to a tibial nerve of the patient"**

Govier discloses this limitation. (Ex. 1002, ¶¶87-89.) 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 '338 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.

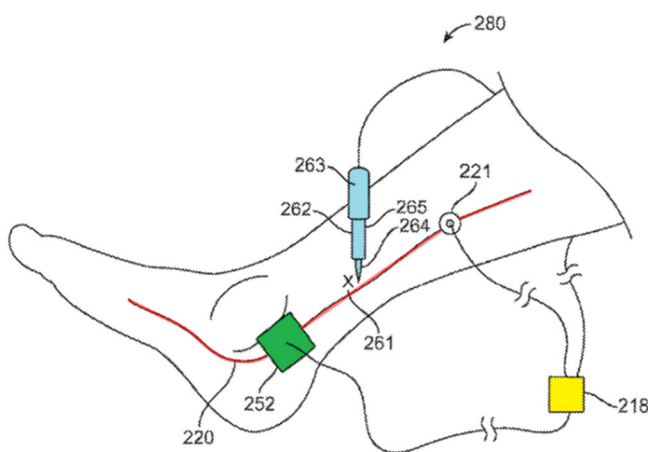


FIG. 27

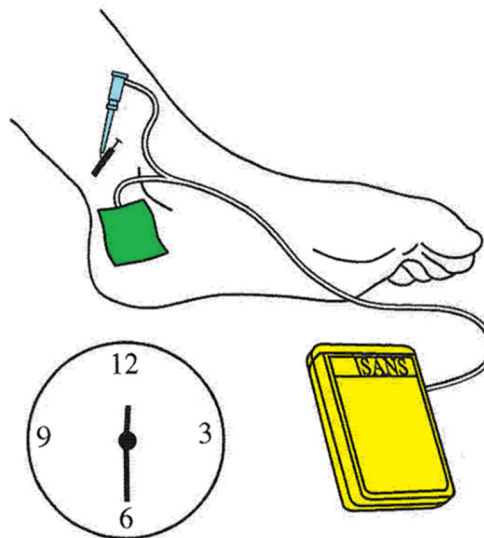


FIG. 3. Attach electrode and lead wire by placing electrode on same leg as needle near arch of foot. Connect grabber plug to needle on handle portion just above insertion point. Patient will control stimulation at comfortable level for 30 minutes.

(Ex. 1001, 27:53-28:3, Fig. 27; Ex. 1005, 1195 (Fig. 3); Ex. 1002, ¶89.) Thus, if the '338 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 of the patient”**

Govier discloses this limitation. (Ex. 1002, ¶¶90-92.) 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.”); *supra* §VI.A.3.e.)

As shown in the previous section, a comparison of the embodiments in the '338 patent (above left) and Govier (above right) illustrates that the percutaneous electrodes [blue] 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, ¶89.) Thus, if the '338 patent discloses this limitation, Govier does too.

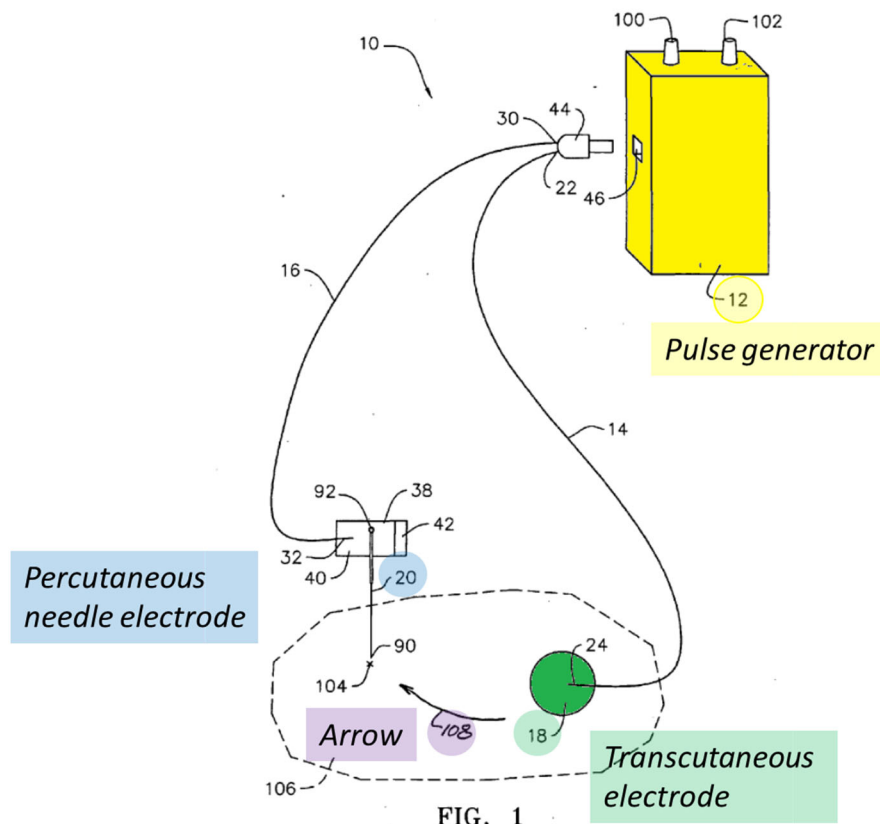
g. **Limitation [D]: “activating the pulse generator such that current pulses flow along the tibial nerve by passing between the electrode patch and the percutaneous electrode”**

Govier discloses this limitation or renders this limitation obvious with Williams. (Ex. 1002, ¶¶93-99.) Govier discloses “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 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.” (Ex. 1005, 1194.) Flexion or fanning of the toes indicates that the current pulses were passing along the tibial nerve and between the percutaneous needle and electrode patch. (Ex. 1002, ¶95.) 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 percutaneous electrode” and, thus, Govier discloses this limitation. Govier’s stimulator is electrically coupled to the ground pad and needle to permit the current to flow between the two electrodes. (Ex. 1002, ¶96.) Without current flow between both electrodes (ground pad or needle), a current would not flow along the tibial nerve as described. (*Id.*)

However, if 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.*, ¶¶97-99.) 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. (Ex. 1002, ¶¶66-68, 79-81, 98.) Moreover, both references describe a similar orientation 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.) Similarly, Williams 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. (Ex. 1002, ¶98.)

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, ¶99.) 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 switch 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 ’338 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, ¶99.)

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

Govier discloses this limitation. (Ex. 1002, ¶¶100-101.) 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 explains that a “predominant symptom” of overactive bladder includes “urge incontinence.” (*Id.*) Govier concludes that the study resulted in “a 35% reduction or improvement in daytime and nighttime urge incontinence or leak episodes during the 12-week treatment.” (*Id.*, 1193, 1198.) Thus, Govier’s current pulses were configured to treat incontinence.

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

4. Independent Claim 2

Claim 2 is anticipated by Govier or rendered obvious by Govier in combination with Williams. (Ex. 1002, ¶¶102-135.) The preamble of claim 2 recites “[a] method.” Govier discloses a method of treating “overactive bladder” with electrical stimulation of the “tibial nerve.” (*Id.*, ¶103; Ex. 1005, 1193.)

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

Govier discloses this limitation, or renders it obvious with Williams. (Ex. 1002, ¶104-112.) 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, ¶¶105-108.)

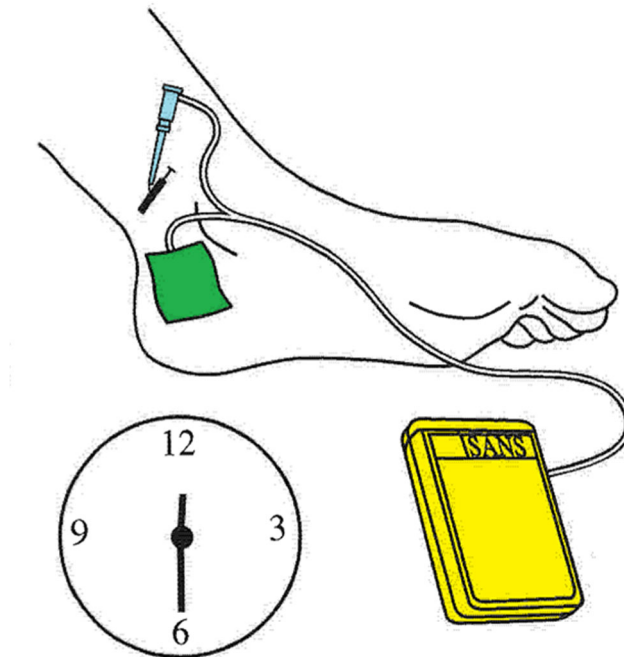
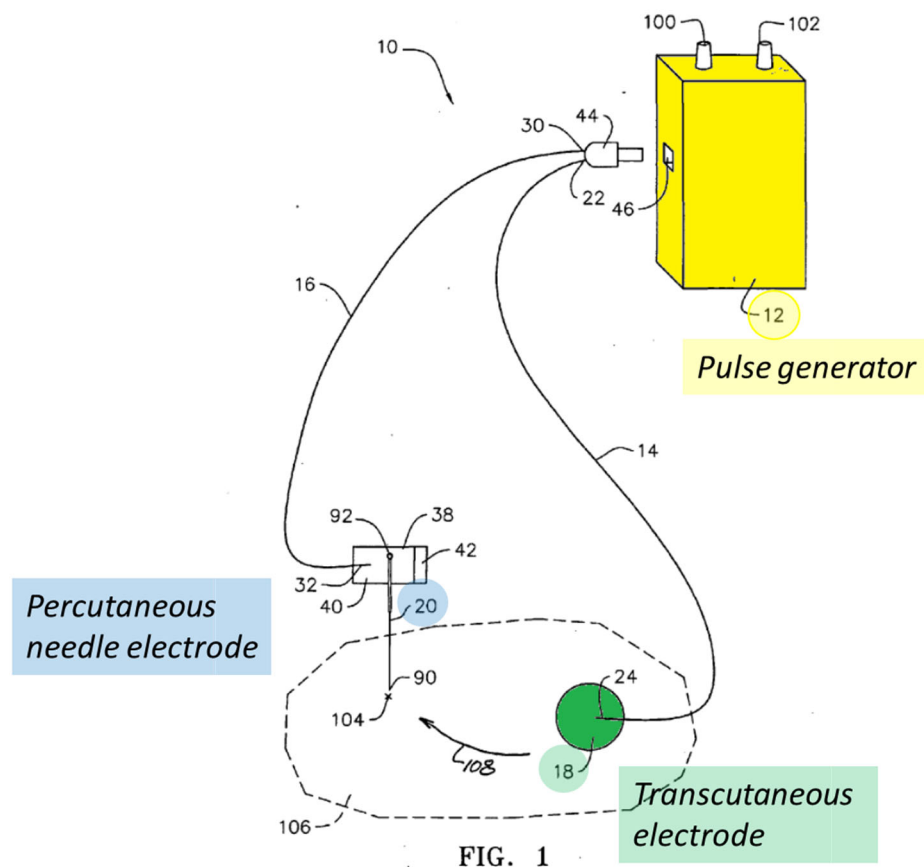


FIG. 3. Attach electrode and lead wire by placing electrode on same leg as needle near arch of foot. Connect grabber plug to needle on handle portion just above insertion point. Patient will control stimulation at comfortable level for 30 minutes.

Figure 3 (above) confirms that the electrocardiogram ground pad is a “transcutaneous electrode” because Figure 3’s caption 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 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, ¶¶109-112.) 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”).) 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 a round patch. (*Id.*, [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.)

b. Limitation [B1]: "inserting an end of a percutaneous needle electrode through the skin in proximity to the tibial nerve"

Govier discloses this limitation. (Ex. 1002, ¶¶113-116.) 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 needle electrode" required by claim 2 because, for example, Govier discloses that the electrical stimulation is supplied via the needle and the needle penetrates the patient's skin. (Ex. 1002, ¶¶114-116.)

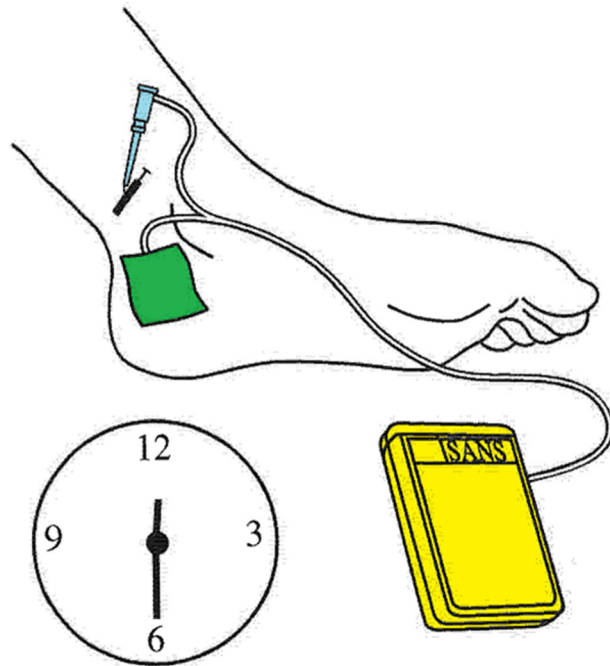


FIG. 3. Attach electrode and lead wire by placing electrode on same leg as needle near arch of foot. Connect grabber plug to needle on handle portion just above insertion point. Patient will control stimulation at comfortable level for 30 minutes.

Govier discloses 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 ’338 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.

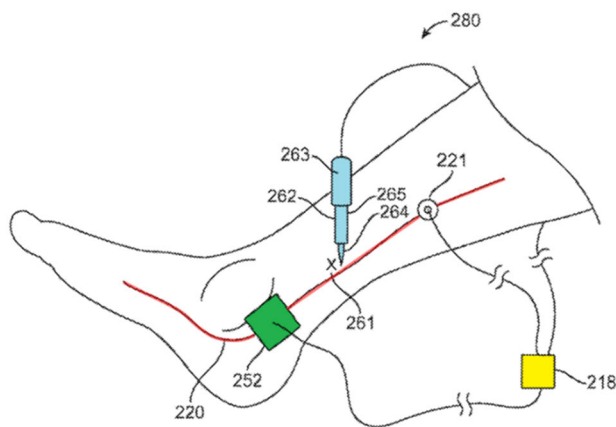


FIG. 27

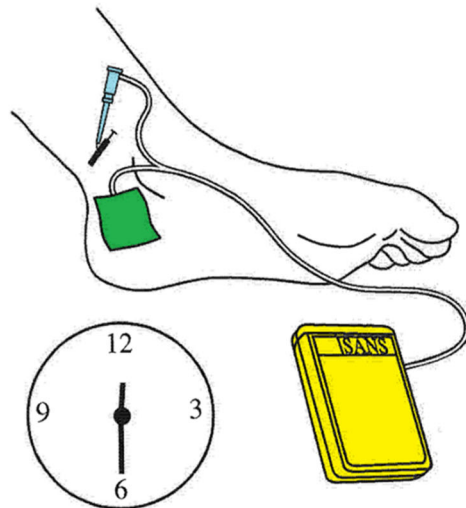


FIG. 3. Attach electrode and lead wire by placing electrode on same leg as needle near arch of foot. Connect grabber plug to needle on handle portion just above insertion point. Patient will control stimulation at comfortable level for 30 minutes.

(Ex. 1001, 27:53-28:3, Fig. 27; Ex. 1005, 1195 (Fig. 3); Ex. 1002, ¶116.) Thus, if the '338 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, ¶¶117-118.) As shown in Figure 3, Govier's percutaneous needle includes a wire disposed at the end opposite from the portion of the needle inserted into the patient:

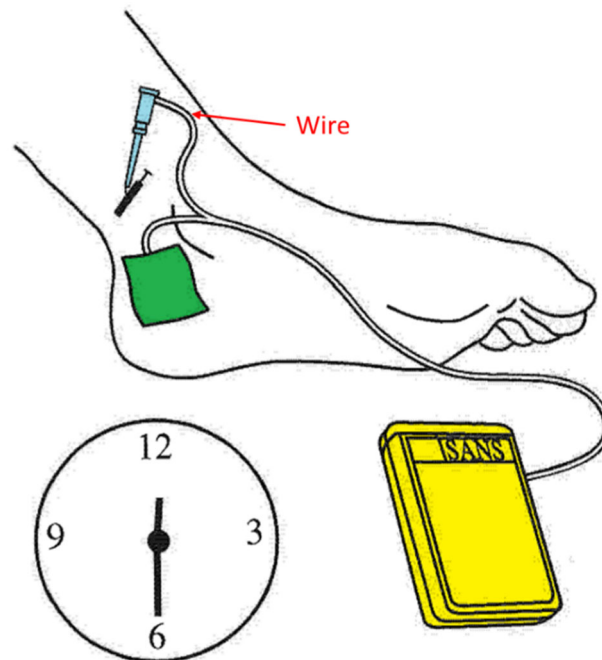


FIG. 3. Attach electrode and lead wire by placing electrode on same leg as needle near arch of foot. Connect grabber plug to needle on handle portion just above insertion point. Patient will control stimulation at comfortable level for 30 minutes.

(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, ¶¶119-122.) 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, ¶¶71-73, 120.)

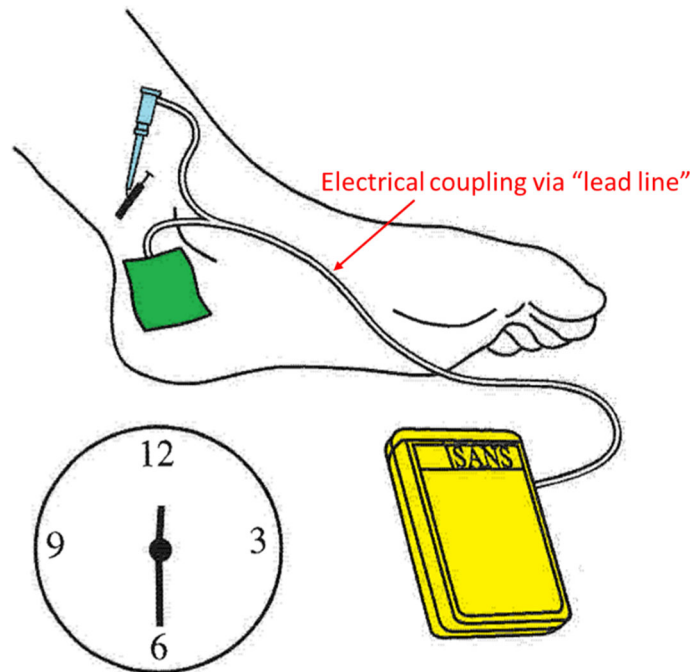


FIG. 3. Attach electrode and lead wire by placing electrode on same leg as needle near arch of foot. Connect grabber plug to needle on handle portion just above insertion point. Patient will control stimulation at comfortable level for 30 minutes.

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 a comfortable level for 30 minutes.”).)

As explained with respect to claim 1, the ’338 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, ¶122.)

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, ¶¶124-128.) 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.) The 34-gauge needle is the “percutaneous needle electrode” required by claim 2 because, for example, Govier discloses that the electrical stimulation is supplied via the needle and the needle penetrates the patient’s skin. (Ex. 1002, ¶125.)

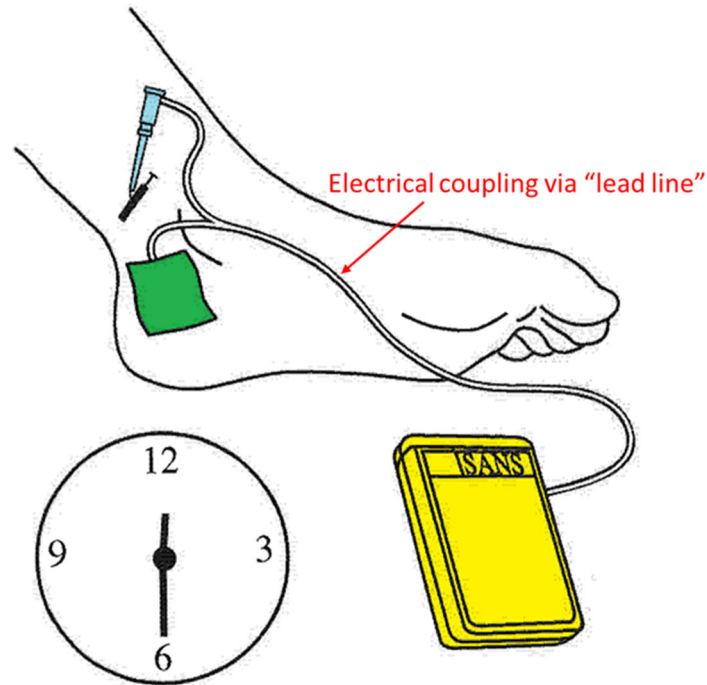


FIG. 3. Attach electrode and lead wire by placing electrode on same leg as needle near arch of foot. Connect grabber plug to needle on handle portion just above insertion point. Patient will control stimulation at comfortable level for 30 minutes.

Govier states that the stimulator is “connected to the needle” and, as shown 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, ¶¶126-128.)

Moreover, Govier’s needle is a “percutaneous” needle electrode. (Ex. 1002, ¶127.) 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 by passing between the transcutaneous electrode and the percutaneous needle electrode”

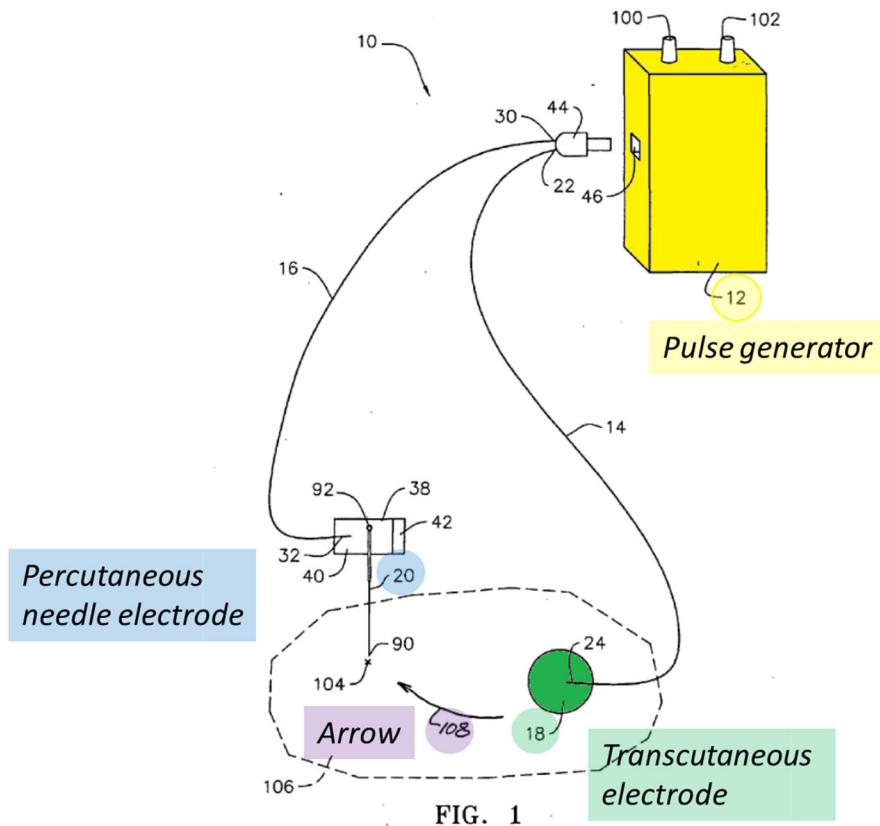
Govier discloses this limitation or renders this limitation obvious with Williams. (Ex. 1002, ¶¶129-134.) Govier discloses a study “to determine the safety and efficacy of percutaneous peripheral afferent nerve stimulation treatment” employing “weekly percutaneous electrical stimulations via a 34 gauge 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.” (Ex. 1005, 1194.) These toe behaviors indicated that the current pulses were passing along the tibial nerve and between the percutaneous needle electrode and transcutaneous electrode. (Ex. 1002, ¶131.) 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.) 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.*) 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.)



(*Id.*, 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.)

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

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

5. Dependent Claim 3

Claim 3 depends from claim 1 and further recites: “wherein the electrode patch is placed on an ankle of the patient.” Govier discloses this limitation or renders it obvious with Williams. (Ex. 1002, ¶136-139.)

As shown in Figure 3 (below), Govier discloses applying an “electrocardiogram ground pad” [green] to the outer surface of the patient’s skin near the heel bone (i.e., calcaneus) and on the ankle [red]. (Ex. 1005, 1194; Ex. 1002, ¶137.)

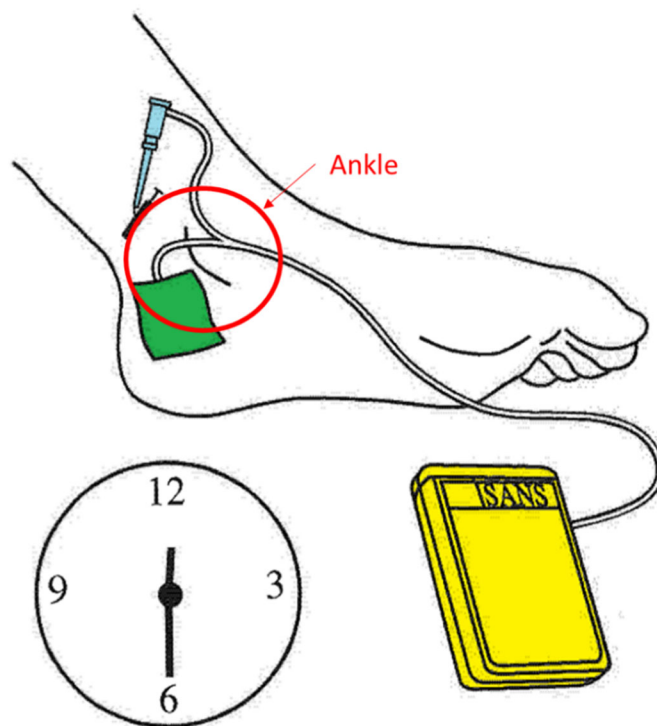


FIG. 3. Attach electrode and lead wire by placing electrode on same leg as needle near arch of foot. Connect grabber plug to needle on handle portion just above insertion point. Patient will control stimulation at comfortable level for 30 minutes.

(*Id.*, Fig. 3.) The “electrocardiogram ground pad” is the “electrode patch” required by claim 1. (*Supra* §VI.A.3.a.)

Williams also describes placing a transcutaneous electrode on an ankle of the patient. (Ex. 1002, ¶138.) Williams discloses adhering the transcutaneous electrode to the patient's skin distal to the percutaneous electrode needle. (Ex. 1006, [0037].) The percutaneous electrode needle “is inserted into the patient's skin in proximity to the tibial nerve cephalic to the medial malleolus.” (*Id.*) Based on these descriptions, a POSITA would have understood that the transcutaneous electrode is placed on an ankle of the patient because it is distal to the needle, which is placed just above the anklebone, and must be placed along the tibial nerve, which runs past the anklebone. (*See e.g.*, Ex. 1009, Fig. 3 (picturing tibial nerve); Ex. 1002, ¶¶138-139.)

Moreover, if Govier and Williams do not disclose placing the electrode patch on the ankle, a POSITA would have found it obvious to do so because there are a finite number of locations where the patch could be placed to stimulate the tibial nerve. (*Id.*)

6. Dependent Claim 6

Claim 6 depends from claim 2 and further recites: “wherein the transcutaneous electrode is placed on an ankle of the patient.” Govier discloses this limitation, or renders it obvious with Williams. (Ex. 1002, ¶¶140-143.) This limitation is the same as the limitation in claim 3 except it replaces “electrode

patch” with “transcutaneous electrode.” Govier discloses this limitation, or renders it obvious with Williams, for the reasons previously expressed. (*Supra* VI.A.5.)

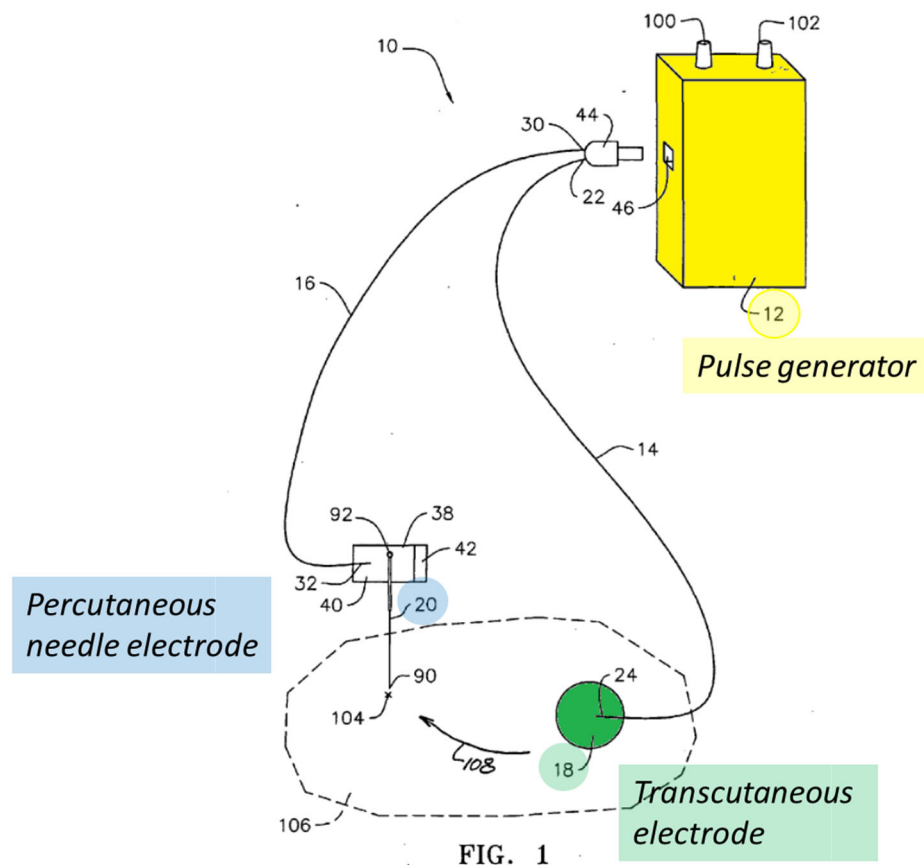
B. Ground 3-4: Claims 1-3 And 6 Are Anticipated By Williams Or Rendered Obvious By Williams Combined With Govier

1. Independent Claim 1

Claim 1 is anticipated by Williams, or rendered obvious by Williams with Govier. (Ex. 1002, ¶¶144-170.) The preamble of claim 1 recites “[a] method.” Williams discloses methods of using “electro-nerve stimulation systems utilizing transcutaneous and percutaneous electrodes” to treat “urinary urge incontinence.” (*Id.*, ¶146; Ex. 1006, [0002], [0037].)

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

Williams discloses this limitation. (Ex. 1002, ¶¶147-151.) 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 (emphasis added).)



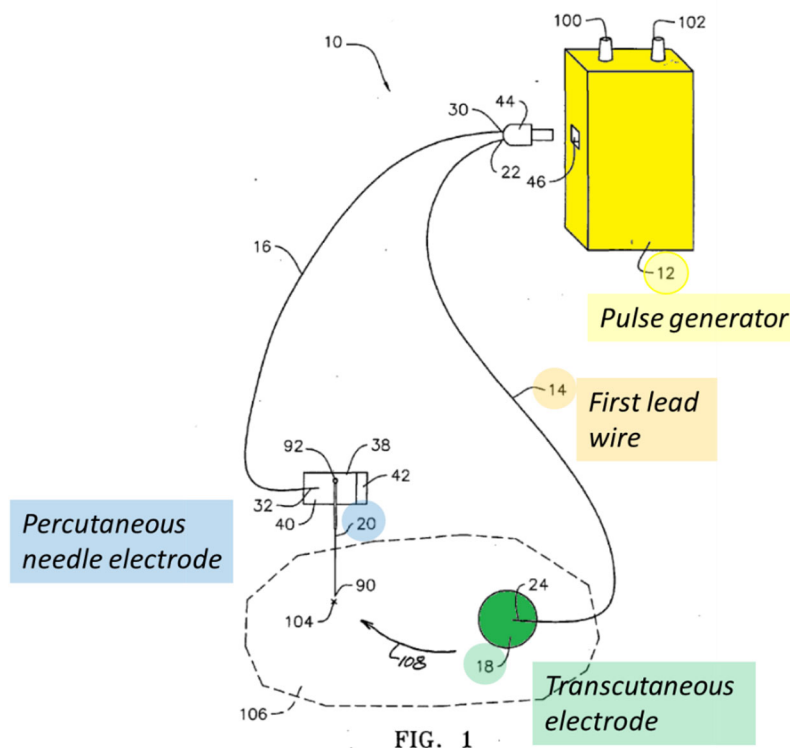
(*Id.*, Fig. 1.)

Williams’s “transcutaneous electrode” is the “electrode patch” required by claim 1. (Ex. 1002, ¶¶149-151.) 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, ¶¶152-154.) 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).) 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 because it allows the user to control the stimulation and current pulses. (Ex. 1002, ¶154; *see also supra* VI.A.3.b (describing use of “controller unit” in ’338 patent).)

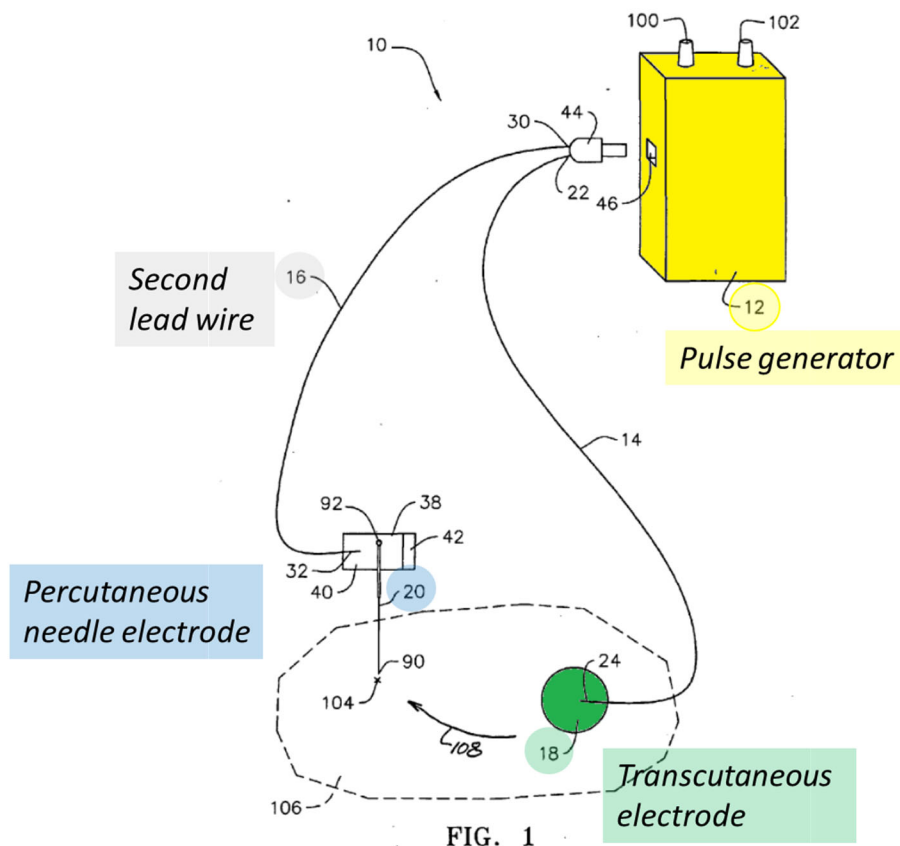
c. **Limitation [A3]: “the controller unit including a pulse generator”**

Williams discloses this limitation. (Ex. 1002, ¶¶155-156.) 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, ¶¶157-159.) 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].) 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); claims 1, 24.)



(*Id.*, Fig. 1.)

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

Williams discloses this limitation. (Ex. 1002, ¶¶160-161.) Williams’s percutaneous electrode needle “includes a first end 90 [red] for insertion into a patient’s body in proximity to the preselected internal stimulation site....” (Ex. 1006, [0030], Fig. 1.)

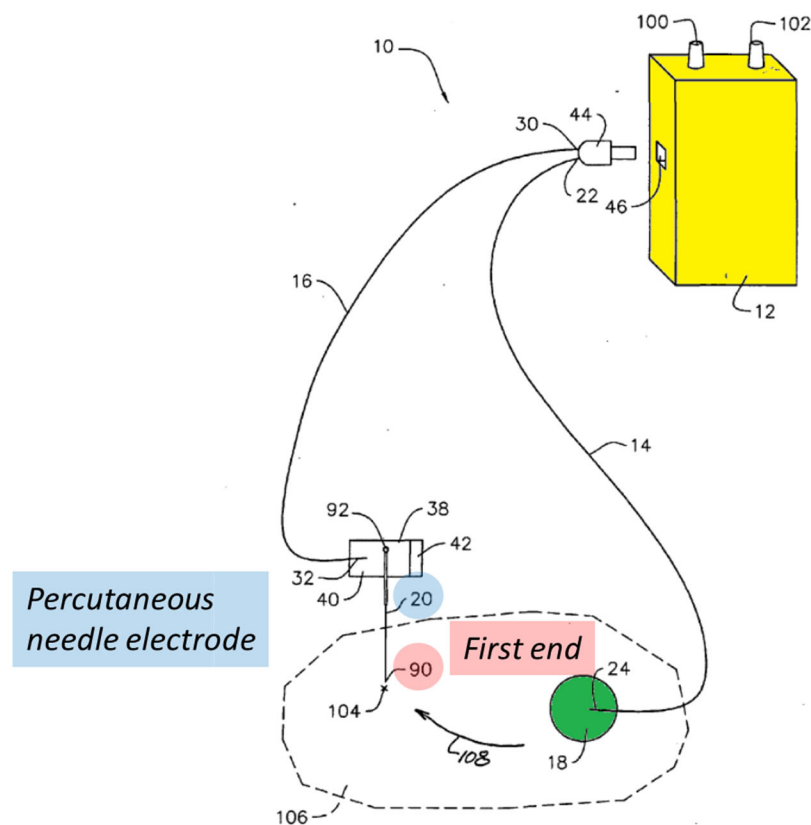


FIG. 1

(*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 of the patient”**

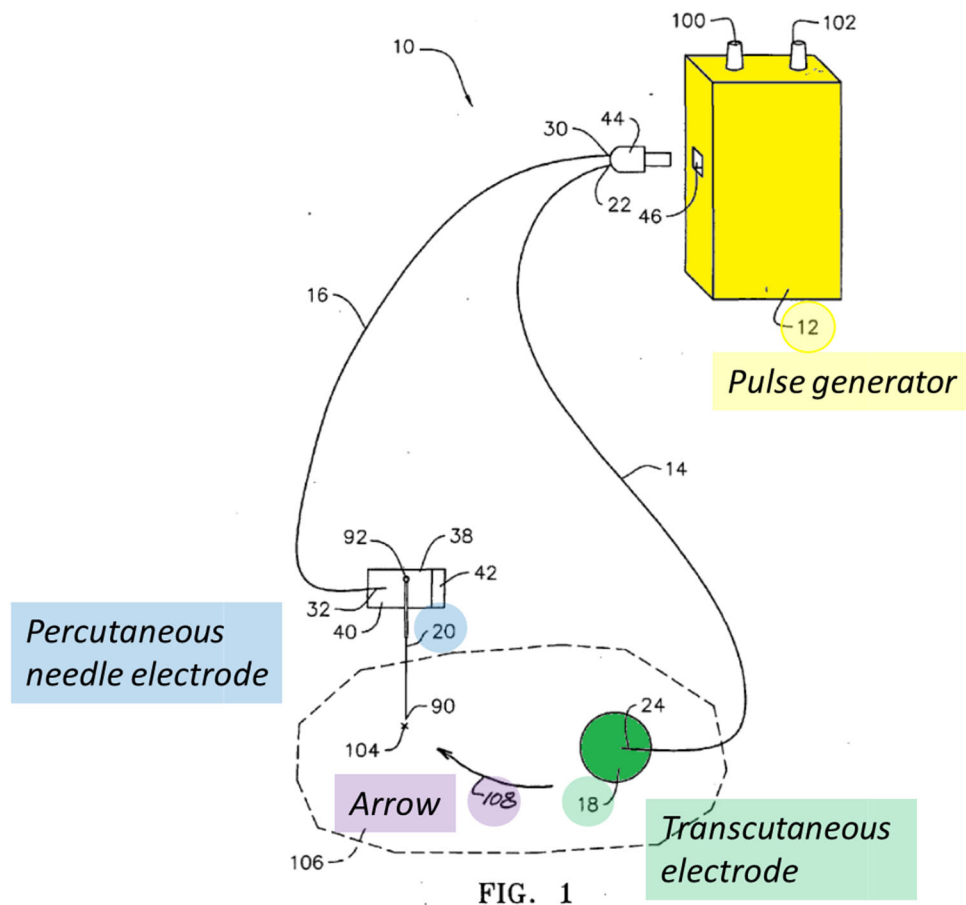
Williams discloses this limitation. (Ex. 1002, ¶162.) Williams states that the “percutaneous needle electrode 20 is inserted into the patient’s skin *in proximity to the tibial nerve* cephalic to the medial malleolus.” (Ex. 1006, [0037] (emphasis added); *supra* §VI.B.1.e.)

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

Williams discloses this limitation, or renders it obvious with Govier. (Ex. 1002, ¶¶163-168.) 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.*) In this embodiment, the current pulses flow along the tibial nerve by passing between the electrode patch and the percutaneous electrode. (Ex. 1002, ¶166.) Williams’s arrangement of components is the same as the arrangement described in the ’338 patent. (*Id.*; *see e.g.*, Ex. 1001, 26:66-27:16, 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 ’338 patent discloses this limitation, so does Williams.

Govier also discloses this limitation. (Ex. 1002, ¶168.) Govier describes a “clinical trial to determine the safety and efficacy of percutaneous tibial nerve stimulation for refractive overactive bladder and/or pelvic floor dysfunction.” (Ex. 1005, 1194.) Similar to Williams, Govier describes inserting a needle electrode near the tibial nerve and a ground pad distal of the needle electrode. (*Id.*; *supra* §VI.A.3.g.) A POSITA would have been motivated to use Williams’s system to produce current pulses that flow along the tibial nerve as described in Govier, and reasonably expected success in doing so, due to the similarities between the systems. (*Id.*)

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

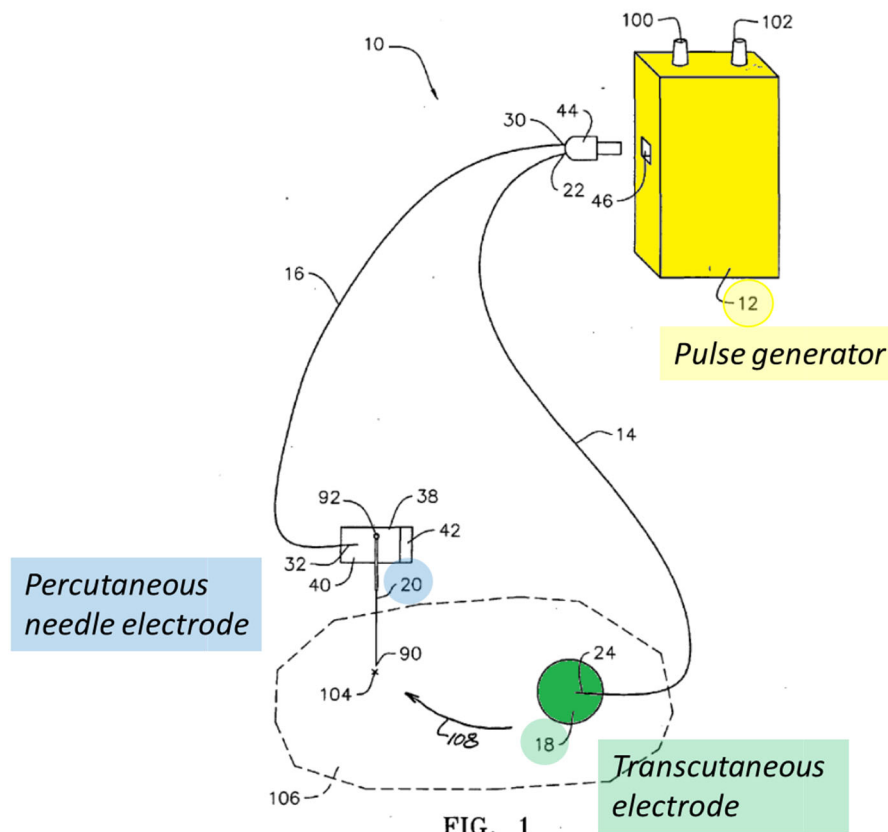
Williams discloses this limitation. (Ex. 1002, ¶¶169-170.) Williams discloses that the described system is “particularly suited for the treatment of urinary urge incontinence.” (Ex. 1006, [0037].)

2. Independent Claim 2

Claim 2 is anticipated by Williams, or rendered obvious by Williams in combination with Govier. (Ex. 1002, ¶¶171-191.) The preamble of claim 2 recites “[a] method.” Williams discloses methods of using “electro-nerve stimulation systems utilizing transcutaneous and percutaneous electrodes” to treat “urinary urge incontinence.” (*Id.*, ¶172; Ex. 1006, [0002], [0037].)

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

Williams discloses this limitation. (Ex. 1002, ¶¶173-176.) 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 (emphasis added).)

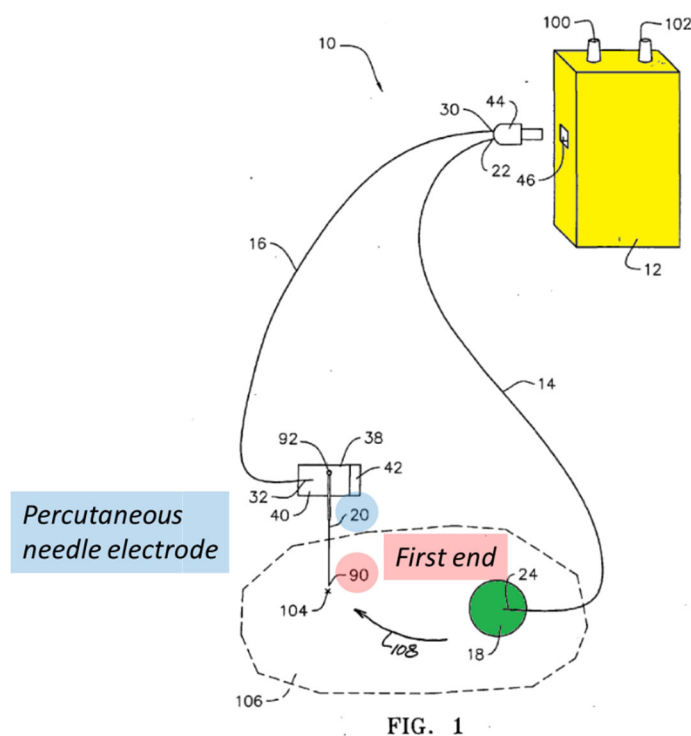


(*Id.*, Fig. 1.)

Williams’s “transcutaneous electrode” is the “electrode patch” required by claim 1. (Ex. 1002, ¶¶175-176.) 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 [B1]: “inserting an end of a percutaneous needle electrode through the skin in proximity to the tibial nerve”**

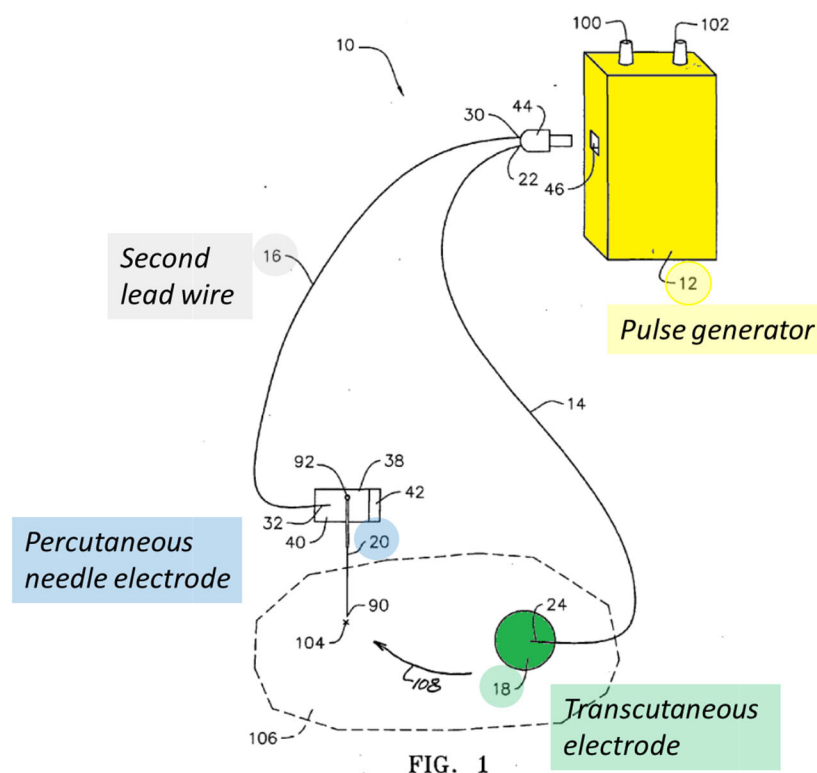
Williams discloses this limitation. (Ex. 1002, ¶¶177-178.) Williams discloses “electro-nerve stimulation systems utilizing transcutaneous and *percutaneous electrodes*.” (Ex. 1006, [0002].) In the preferred embodiment, Williams discloses that the “percutaneous electrode” is “an electrically conductive percutaneous needle electrode 20.” (*Id.*, [0023].) The percutaneous electrode needle “includes a first end 90 [red] for insertion into a patient’s body in proximity to the preselected internal stimulation site....” (*Id.*, [0030], Fig. 1.)



(*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”**

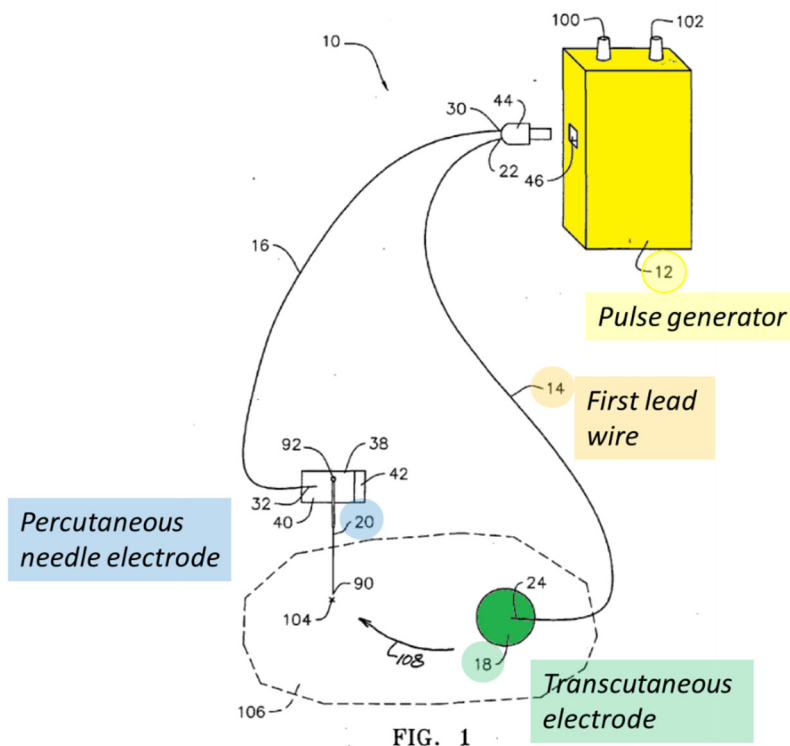
Williams discloses this limitation. (Ex. 1002, ¶¶179-180.) Williams discloses a “second lead wire 16” [gray] at an end of the percutaneous needle electrode 20 that is opposite end 90. (Ex. 1006, [0025].) The second lead wire 16 “electrically couples” the percutaneous needle electrode 20 to the pulse 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), claims 1, 24.)



(*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, ¶¶181-183.) 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).) 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

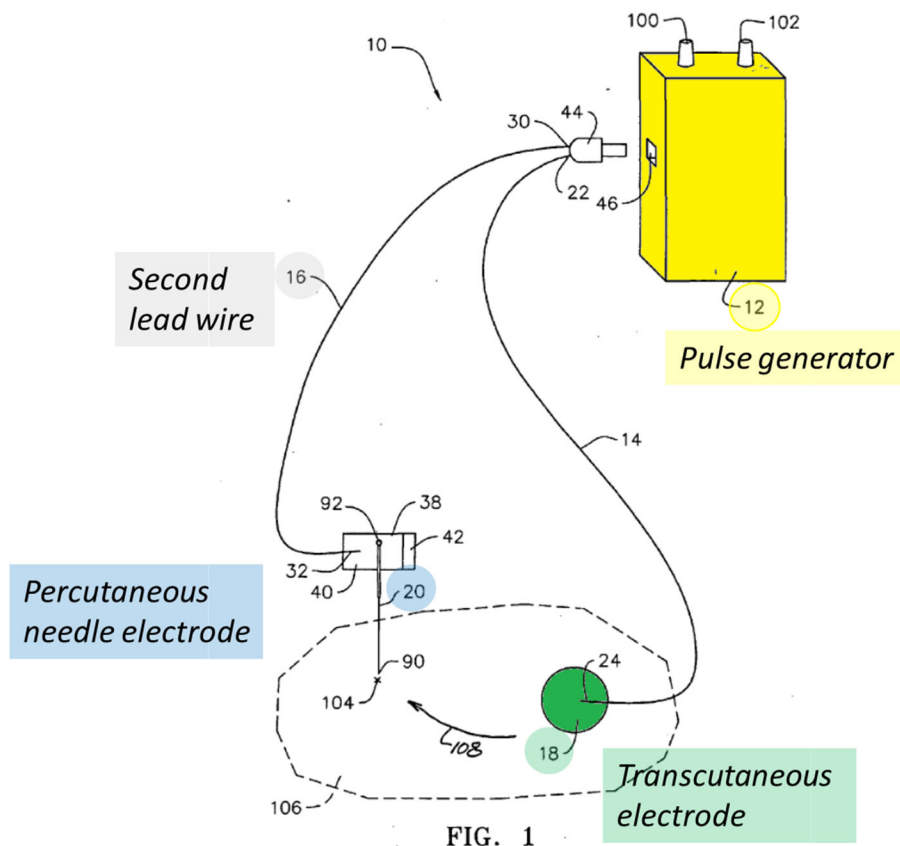
pulse generator (including the dials) is the “controller unit” required by claim 2 because it allows the user to control the stimulation and current pulses. (Ex. 1002, ¶¶154, 182-183; *see also supra* §VI.A.3.b (describing use of “controller unit” in ’338 patent).)

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, ¶¶185-186.) 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).)



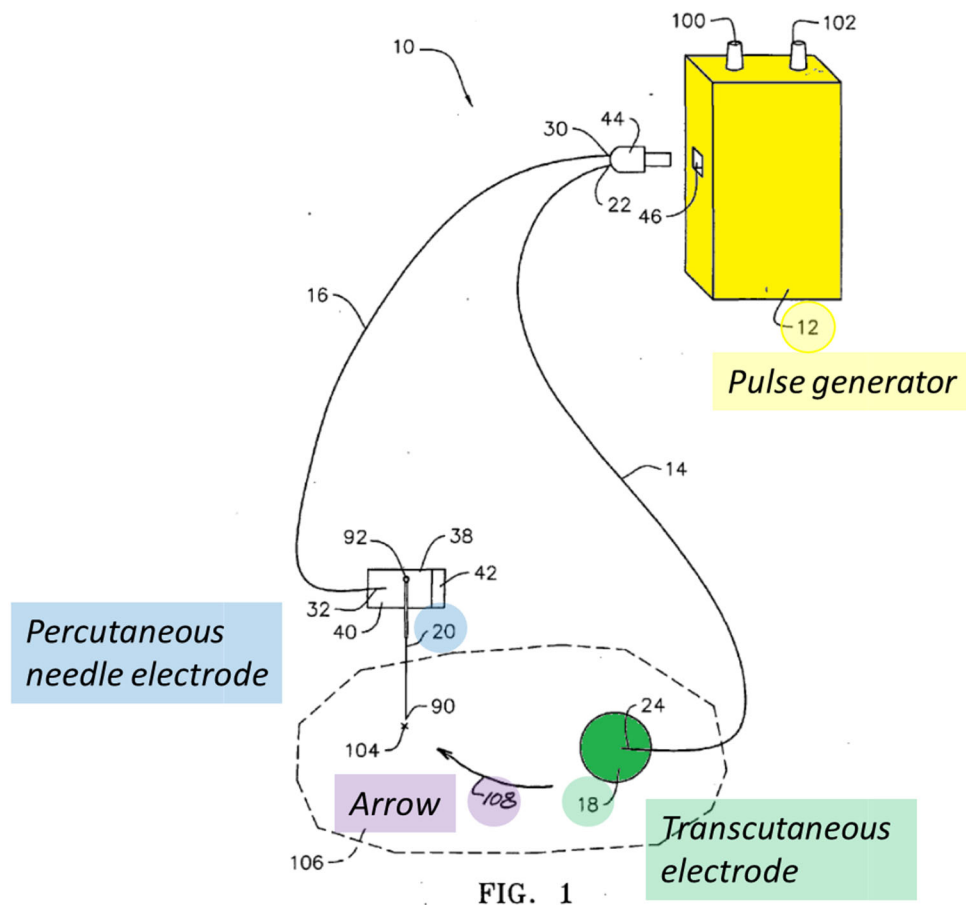
(*Id.*, Fig. 1.)

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

Williams discloses this limitation. (Ex. 1002, ¶¶187-190.) 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 ’338 patent. (Ex. 1002, ¶190; *see e.g.*, Ex. 1001, 27:53-3, 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 ’338 patent discloses this limitation, so does Williams.

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

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

3. Dependent Claim 3

Claim 3 depends from claim 1 and further recites: “wherein the electrode patch is placed on an ankle of the patient.” Williams discloses this limitation. (Ex. 1002, ¶¶192-193.)

Williams’s “transcutaneous electrode” is the “electrode patch” required by claim 1. (Ex. 1002, ¶¶175-176.) 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”).) In a preferred embodiment, the “transcutaneous electrode is adhered to the patient’s skin distal to the percutaneous needle electrode,” which “is inserted into the patient’s skin in proximity to the tibial nerve cephalic to the medial malleolus.” (*Id.*, [0037].) Based on this description, a POSITA would have understood that the needle electrode

was inserted near the top of the anklebone (medial malleolus) and the transcutaneous electrode was placed over the lower portion of the ankle (i.e., distal the needle electrode). (Ex. 1002, ¶193.)

4. Dependent Claim 6

Claim 6 depends from claim 2 and further recites: “wherein the transcutaneous electrode is placed on an ankle of the patient.” Williams discloses this limitation. (Ex. 1002, ¶¶194-195.)

As explained in the previous section, a POSITA would have understood that the needle electrode was inserted near the top of the anklebone (medial malleolus) and the transcutaneous electrode (or electrode patch) was placed over the lower portion of the ankle (i.e., distal the needle electrode). (*Supra* §VI.B.3; Ex. 1002, ¶195.)

C. Grounds 5-6: Claims 4-5 and 7-8 are Obvious over Govier in view of Mumford or Govier in view of Williams and Mumford

1. Overview of Dependent Claims 4-5 and 7-8

Dependent claims 4-5 and 7-8 state that the “controller unit communicates wirelessly” with the electrode patch, transcutaneous electrode, percutaneous electrode, or percutaneous needle electrode. However, the dependent claims depend from claims 1 and 2, which also require the electrodes to be “electrically coupled” with the controller unit. Claim 2 establishes that an electrical coupling means a wire extends from the controller unit to the electrodes. (*See also* Ex. 1001,

16:34-38, Fig. 10 (illustrating that the “electrical pulse controller 128 is electrically connected to percutaneous needle 124” through a wire). Thus, claims 4-5 and 7-8 require a wired connection and wireless communication. (See Ex. 1002, ¶¶196-200 (further explaining reasons for such a connection).) As discussed below, the prior art discloses methods of adapting wired electrodes for wireless communication.

2. Overview of Mumford

Mumford discloses “a wireless physiological monitoring system that includes...at least one wireless sensor [green] and a monitoring device [yellow] which are linked to one another in a wireless fashion for measuring physiological signals from a patient for monitoring the patient.” (Ex. 1019, [0006]; *see also id.*, [0028]-[0038] (describing Figure 1), claim 1.)

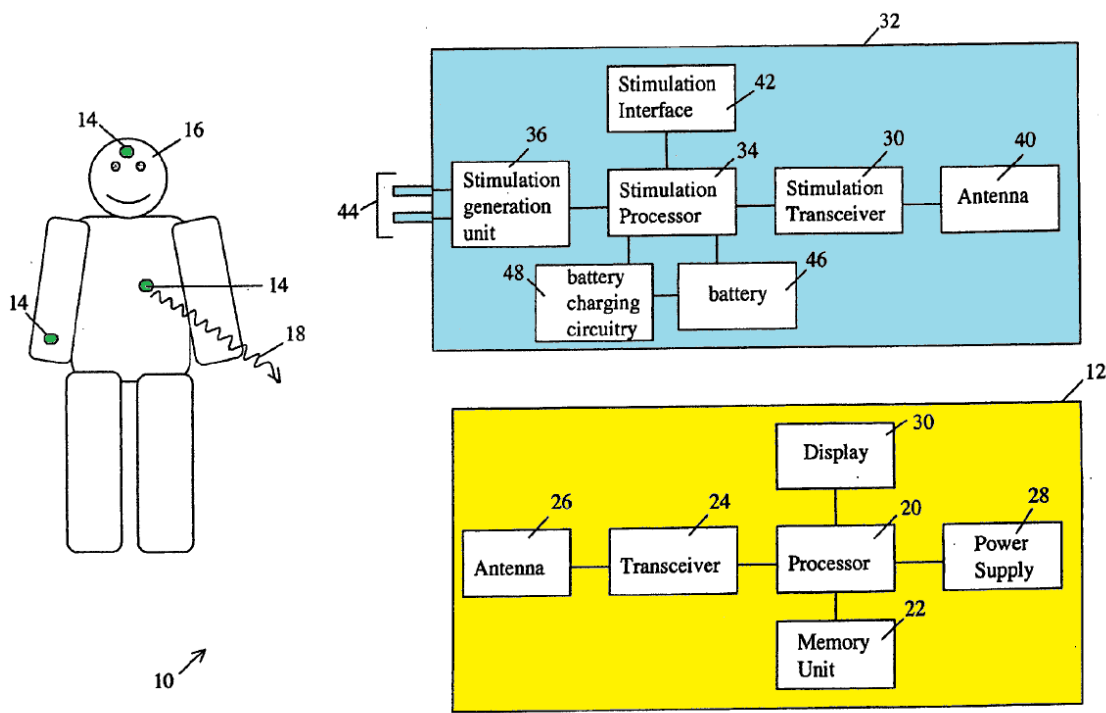


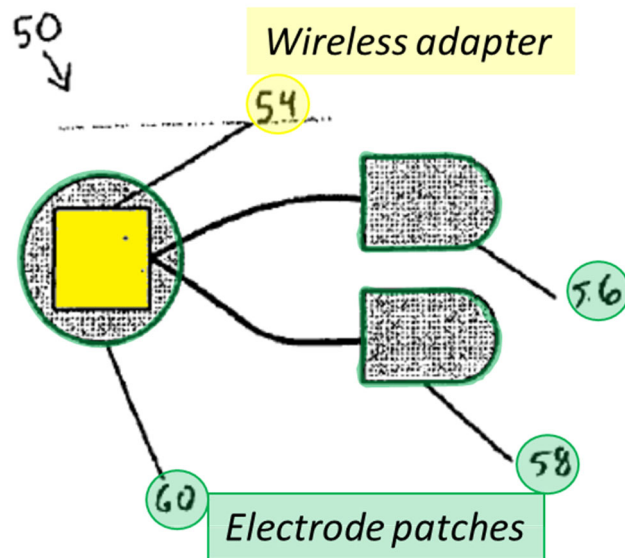
FIGURE 1

Mumford’s system “may also be used to perform diagnostic tests on the patient” and includes “a wireless stimulator [blue] that is synchronized with the wireless sensor for performing diagnostic tests such as nerve conduction velocity tests....” (*Id.*) Mumford discloses that the wireless communication may occur, for example, “according to the Bluetooth communication protocol.” (*Id.*, [0009].)

3. Dependent Claim 4

Claim 4 depends from claim 1 and further recites: “wherein the controller unit communicates wirelessly with the electrode patch.” Mumford discloses methods and devices for wirelessly communicating with electrodes and Govier in combination with Mumford, or Govier and Williams in combination with Mumford render this claim obvious. (Ex. 1002, ¶¶201-209.)

Mumford discloses, “the wireless sensor may be a wireless surface electrode assembly.” (Ex. 1019, [0007].) In a preferred embodiment, the wireless surface electrode assembly includes three conductive electrodes [green] and a wireless adapter 54 [yellow]. (*Id.*, [0040].) The electrodes also include “an adhesive portion” to attach the electrodes to the patient’s skin. (*Id.*, [0043].)



(*Id.*, Fig. 2a.) The wireless adapter 54 can be “snap-fit or friction-fit” to the electrode patch and includes the circuitry needed for the monitoring device to communicate wirelessly with the electrode. (*Id.*, [0050]-[0056], Fig. 4.) Mumford discloses that the monitoring device 12 [yellow in Figure 1 above] “sends commands via the transceiver 24 to the wireless sensors 14 to initiate monitoring or diagnostic tests and also to synchronize with the wireless sensors 14.” (Ex. 1019, [0030]; *see also id.*, [0059] (“During operation, the wireless sensors 14 are instructed by the monitoring device 12 to start and stop data transmission so that power and bandwidth are not wasted.”).) Mumford’s “transceiver 24 operates according to a suitable wireless communication protocol,” such as “the Bluetooth communication protocol.” (Ex. 1019, [0030]; *see also id.*, [0057]-[0062] (describing Bluetooth communication).) Thus, Mumford discloses a method of wirelessly communicating with an electrode patch. (Ex. 1002, ¶¶202-203.)

A POSITA would have been motivated to combine Mumford’s method of wireless communication (e.g., wireless adapter and Bluetooth protocol) with the electrodes in Govier and Williams for a number of reasons. (Ex. 1002, ¶¶204-209.) Mumford is analogous art to Govier and Williams because the references all disclose methods of stimulating a nerve in a patient using electrodes. (*See e.g.*, Ex. 1019, [0006], [0033], [0039]; Ex. 1005, 1193-94; Ex. 1006, [0007], [0037].)

Additionally, Mumford describes the disadvantages of wired connections between sensors and a controller unit, such as those disclosed in Govier and Williams. (Ex. 1019, [0004]-[0005].) For example, Mumford explains, “the cables are uncomfortable for the patient and limit the mobility of the patient.” (*Id.*) “The cables also make it difficult to perform any tests on the patient which require the patient to move.” (*Id.*) “Further, in some cases, the cables may be stiff and can easily become detached from the patient especially when the patient moves.” (*Id.*) Each of these disadvantages would have motivated a POSITA to modify Govier’s and Williams’s systems to include the wireless communication system disclosed in Mumford to eliminate at least some of the wires in the system. (Ex. 1002, ¶205.)

Additionally, Mumford discloses that the wireless communication is enabled by attaching simple wireless adapters to the electrodes and incorporating the Bluetooth protocol into a processor in the controller unit. (Ex. 1019, [0042].) Mumford explains that the “wireless adapter 54 can be reused and the

measurement module 52 [i.e., electrode] can be discarded.” (*Id.*) A POSITA would have been further motivated to use Mumford’s *reusable* wireless adapters because they would not significantly increase costs and may instead decrease costs by eliminating several cables. (Ex. 1002, ¶206.)

A POSITA would have found the substitution of Mumford’s wireless communication system for Govier’s or Williams’s wired system a simple substitution of one known element (i.e., wireless protocol) for another (i.e., wired protocol) to obtain predictable results. *KSR*, 550 U.S. at 417. This combination of known elements according to known methods would have been obvious because it does no more than yield predictable results (i.e., the ability to remotely control electrodes). *Id.* at 416. For these reasons, a POSITA would have been motivated to modify Govier and Williams’ systems to include Mumford’s wireless communication system. (Ex. 1002, ¶207.)

A POSITA would have had a reasonable expectation of success in combining Mumford’s wireless communication system with Govier and Williams because Mumford’s system uses a well-known wireless communication protocol, the Bluetooth protocol, which would have been available and well understood by POSITAs in 2006. (Ex. 1002, ¶¶208-209.) Moreover, Mumford specifically describes one way to use the Bluetooth protocol in combination with a controller unit and electrode, which would have given a POSITA increased confidence that

the system would work for its intended purpose. (*Id.*; Ex. 1019, [0057]-[0062].)

For these reasons, a POSITA would have found it obvious to combine a processor hosting the Bluetooth protocol with a pulse generator, such as the pulse generators described in Govier and Williams. (Ex. 1002, ¶208.) In fact, the '338 patent presumes that wireless communication protocols, including the Bluetooth protocol, were well known in 2006, stating that the described devices could communicate wirelessly “using a variety of methods or techniques *known in the art.*” (Ex. 1001, 35:1-7; *see also id.*, 15:43-49 (acknowledging Bluetooth known)); *Smith & Nephew, Inc. v. Rea*, 721 F.3d 1371, 1380-81 (Fed. Cir. 2013) (“[A]n unclaimed and undisclosed feature . . . cannot be the basis for finding [a] patent to be non-obvious over the prior art.”); *see also E.I. du Pont de Nemours & Co. v. Phillips Petroleum Co.*, 849 F.2d 1430, 1433 (Fed. Cir. 1988) (quoting *McCarty v. Lehigh Valley R. Co.*, 160 U.S. 110, 116, (1895) (“[N]o principle of law . . . would authorize us to read into a claim an element which is not present, for the purpose of making out a case of novelty”); *TorPharm, Inc. v. Ranbaxy Pharms., Inc.*, 336 F.3d 1322, 1331 (Fed. Cir. 2003) (“[N]onobviousness is assessed by reference to the claimed invention, and not by reference to properties that cannot ultimately be derived from the claims.”).

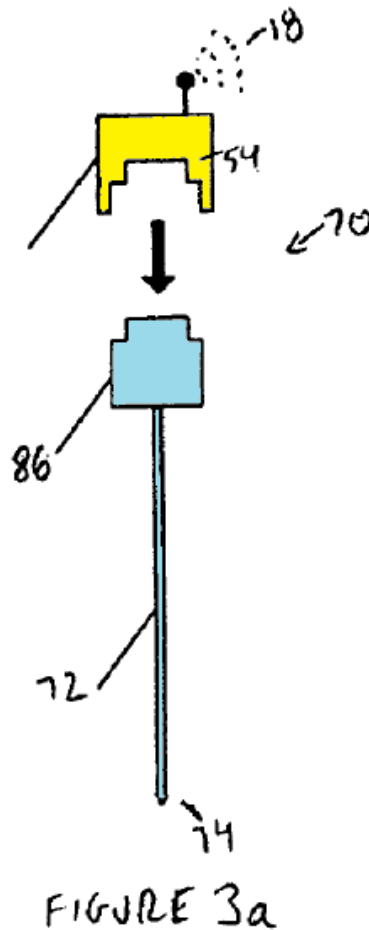
Additionally, Mumford discloses a simple method for wirelessly communicating with the electrodes through a wireless adapter. (Ex. 1019, [0043].)

Mumford explains that the wireless adapter can be “snap-fit” or “friction-fit” with the electrode, making the use of the device in medical setting simple and straightforward. (*Id.*, [0042].) For these reasons, a POSITA would have expected success in combining Mumford’s wireless communication system with the electrodes in Govier and Williams. (Ex. 1002, ¶209.)

4. Dependent Claim 5

Claim 5 depends from claim 1 and further recites: “wherein the controller unit communicates wirelessly with the percutaneous electrode.” Mumford discloses at least two methods for wirelessly communicating with a percutaneous electrode and Govier in combination with Mumford, or Govier and Williams in combination with Mumford render this claim obvious. (Ex. 1002, ¶¶210-215.)

First, Mumford discloses that the wireless sensor may also be a “wireless needle assembly 70.” (Ex. 1019, [0044].) The wireless needle assembly 70 includes a wireless adapter 54 and “a shaft with a needle tip 74 disposed at the end.” (*Id.*, [0045].)



(*Id.*, Fig. 3a.) Mumford explains that the wireless needle includes at least one electrode (referred to as a conductor). (*Id.*, [0045]-[0047], [0049]; *see also* Ex. 1021, 4:25-42, Fig. 1 (describing the needle as having electrodes).) Mumford’s wireless needle “is inserted into a desired measurement site on the patient” and, therefore, is a percutaneous electrode or percutaneous needle electrode. (Ex. 1019, [0048]; Ex. 1002, ¶211.)

As with the sensor electrodes discussed in claim 4, the wireless adapter 54 on the needle permits the monitoring device 12 to send “commands via the transceiver 24 to the wireless sensors 14 to initiate monitoring or diagnostic tests

and also to synchronize with the wireless sensors 14.” (*See e.g.*, Ex. 1019, [0030].) Mumford explains that the “transceiver 24 operates according to a suitable wireless communication protocol,” such as “the Bluetooth communication protocol.” (Ex. 1019, [0030]; *see also id.*, [0057]-[0062] (describing Bluetooth communication).)

Second, Mumford discloses a “wireless stimulator 32 [blue] for performing certain diagnostic tests on the patient 16 such as nerve conduction velocity tests.” (*Id.*, [0033].) The “wireless stimulator 32 is used to generate a stimulation current to create an action potential in a nerve of the patient 16.” (*Id.*) The wireless stimulator generates a stimulation current “when the stimulation transceiver 38 receives an appropriate command signal from the monitoring device 12 [yellow]....” (*Id.*, [0034]; *see also id.*, [0036] (“The stimulation interface 42 allows a medical practitioner to control the wireless stimulator.”).)

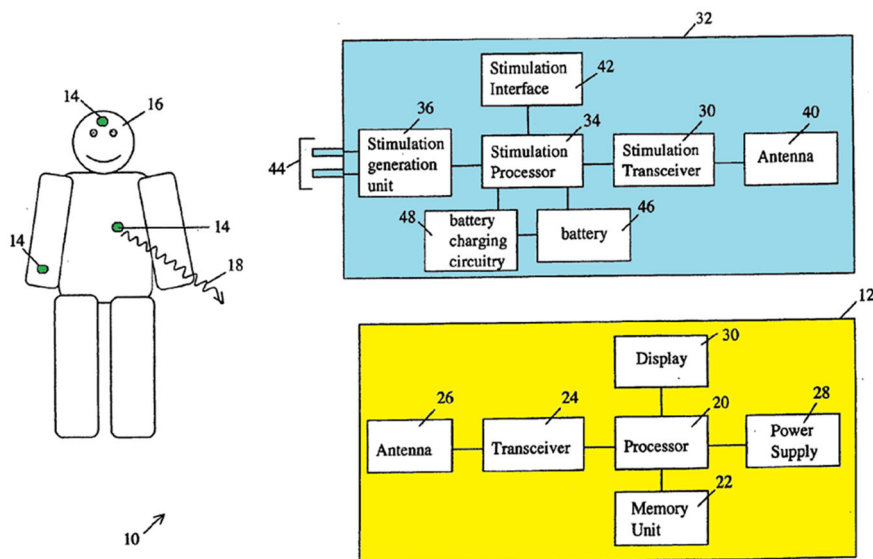


FIGURE 1

(*Id.*, Fig. 1.)

“During a diagnostic test, the two prongs 44 of the wireless stimulator 32 are applied to a test site on the skin of the patient 16 to stimulate the desired nerve.” (*Id.*, [0037].) Each prong is an electrode (e.g., cathode terminal and anode terminal). (*Id.*; Ex. 1002, ¶214.) Mumford further discloses that the wireless stimulator can also be equipped with adapter connections “to stimulate through smaller external electrodes or *needles* for cases in which the prongs 44 are not appropriate.” (Ex. 1019, [0037] (emphasis added).) Thus, Mumford discloses at least two examples of percutaneous needle electrodes that communicate wirelessly with a controller unit. (Ex. 1002, ¶214.)

A POSITA would have been motivated to, and expected success in, modifying Govier’s and Williams’s systems to include Mumford’s wireless needles and wireless communication protocols for the reasons provided in Claim 4. (*Supra* §VI.C.2.)

5. Dependent Claim 7

Claim 7 depends from claim 2 and further recites: “wherein the controller unit communicates wirelessly with the transcutaneous electrode.” Mumford discloses this limitation and Govier in combination with Mumford, or Govier and Williams in combination with Mumford render this claim obvious for the reasons provided in Claim 4. (*Supra* §VI.C.2.)

6. Dependent Claim 8

Claim 8 depends from claim 2 and further recites: “wherein the controller unit communicates wirelessly with the percutaneous needle electrode.” Mumford discloses this limitation and Govier in combination with Mumford, or Govier and Williams in combination with Mumford render this claim obvious for the reasons provided in Claims 4-5. (*Supra* §§VI.C.2-3.)

D. Grounds 7-8: Claims 4-5 and 7-8 are Obvious over Williams in view of Mumford or Williams in view of Govier and Mumford

A POSITA would have found claims 4-5 and 7-8 obvious over Williams in view of Mumford or Williams in view of Govier and Mumford for the reasons provided in the preceding sections. (*Supra* §§VI.C.2-5.)

E. Grounds 9-10: Claims 4-5 and 7-8 are Obvious over Govier in view of Sarwal or Govier in view of Williams and Sarwal

1. Overview of Sarwal

Sarwal discloses a “system and method for remotely controlling the stimulation therapy for neurological, neuropsychiatric and urological disorders,” including “urinary incontinence.” (Ex. 1020, Abstract, 1:17-23, 10:25-30, 13:16-47, Fig. 10B.) Sarwal explains that “wireless communication for medical stimulation devices” was well known by 2006 and identifies a number of prior art patents that disclose wireless communication devices. (*Id.*, 7:4-61.)

In one embodiment, Sarwal discloses an external stimulator 152 [yellow circle] having a pulse generator subsystem 216, a battery unit 176, and a wireless

unit (telemetry) 180. (*Id.*, 11:1-3. Fig. 13.) The external stimulator 152 is wirelessly coupled to an “implanted lead-receiver 34 [that] has a pair of electrodes 161, 162 [green] in contact with the nerve to be stimulated....” (*Id.*, 11:14-17.)

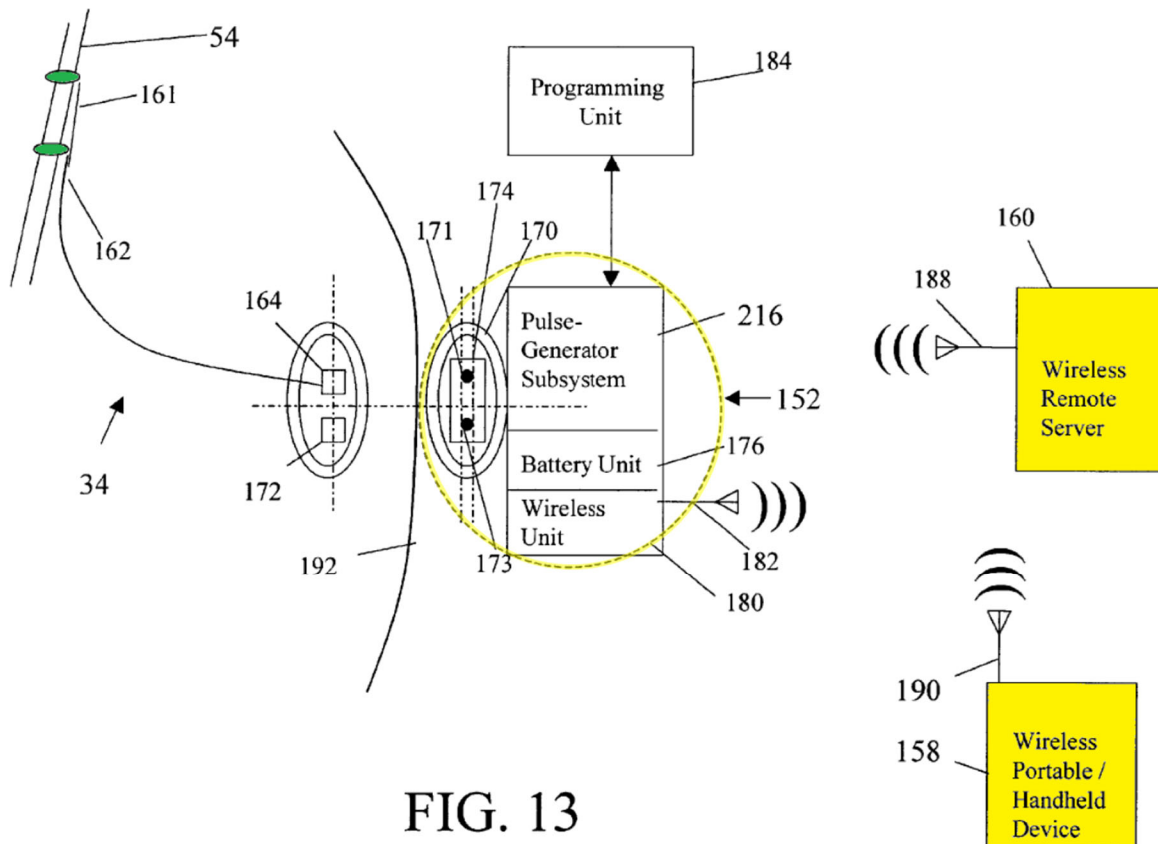


FIG. 13

(*Id.*, Fig. 13.)

In use, a physician provides instructions through a wireless remote server or wireless portable/handheld device [yellow], which are in wireless communication with the external stimulator 152. (*Id.*, 10:25-48, Fig. 10B.) For example, the physician can “set up long-term schedules of stimulation therapy for their patient population, through wireless communication with the server.” (*Id.*, 15:38-40.) “The server in turn communicates these programs to the neurostimulator” (e.g., external

stimulator 152). (*Id.*, 15:40-41.) The external stimulator then produces pulses through the pulse generator 216 and associated coil 170 based on the wirelessly received instructions. (*Id.*, 11:20-48.) The pulses cause a current to flow through implanted lead-receiver 34 and between the electrodes 161, 162 to stimulate the nerve. (*Id.*, 11:14-19; Ex. 1002, ¶55.) Thus, Sarwal discloses wireless communication between a wireless remote server and an external stimulator having a pulse generator and electrodes. (Ex. 1002, ¶55.)

2. Dependent Claim 4

Claim 4 depends from claim 1 and further recites: “wherein the controller unit communicates wirelessly with the electrode patch.” Sarwal discloses a controller unit that communicates wirelessly with a stimulator and Govier in combination with Sarwal, or Govier and Williams in combination with Sarwal render this claim obvious. (Ex. 1002, ¶¶219-225.)

Sarwal’s wireless remote server 160 (i.e., controller unit) wirelessly communicates with an external stimulator 152 having an “external (primary) coil 170” to induce a current that flows between electrodes 160, 161. (Ex. 1020, 10:49-60.) The external stimulator 152 includes “a patch 175 that connects to the skin 192.” (*Id.*, 10:54-58, Fig. 11.) The stimulator 152 also includes a “wireless unit (telemetry) 180 that “provides wireless communication with the wireless remote server 160 using the Wireless Application Protocol (WAP).” (*Id.*, 11:1-7, 14:35-

15:27, Fig. 20.) While Sarwal discloses that the external stimulator 152 generates a current through external coil 170, a POSITA would have recognized that the external stimulator could also create a current using electrodes, such as the electrode patch or needle electrodes described in Govier and Williams. (Ex. 1002, ¶220.)

A POSITA would have been motivated to combine Sarwal's wireless communication system, including the wireless unit and WAP protocol, with the systems in Govier and Williams for a number of reasons. (Ex. 1002, ¶¶221-225.) Sarwal is analogous art to Govier and Williams because the references all disclose methods of stimulating a nerve in a patient using electrodes to treat incontinence. (See e.g., Ex. 1020, 10:25-30, Fig. 10B; Ex. 1005, 1193-94; Ex. 1006, [0007], [0037].)

Additionally, Sarwal discloses that the wireless communication system permits the physician to beneficially control the stimulator or electrode. (Ex. 1020, 8:51-63.) Sarwal specifically cites the case of an Alzheimer's patients and the benefit that a physician could remotely program the stimulator to work for multiple weeks. (*Id.*)

A POSITA would have also been motivated to combine Sarwal's wireless communication system with the systems in Govier and Williams to address the disadvantages identified in Mumford. (Ex. 1019, [0004]-[0005]; Ex. 1002, ¶223.)

A POSITA would have found the substitution of Sarwal's wireless communication system with the wired systems in Govier and Williams a simple substitution of one known element (wireless unit and WAP protocol) for another (wired configuration) to obtain predictable results. *KSR*, 550 U.S. at 417; Ex. 1002, ¶224. This combination of known elements according to known methods would have been obvious because it does no more than yield predictable results (i.e., the ability to remotely control electrodes). *Id.* at 416. For these reasons, a POSITA would have been motivated to modify Govier's and Williams' systems to include Sarwal's wireless communication protocol. (Ex. 1002, ¶224.)

A POSITA would have had a reasonable expectation of success in combining Sarwal's wireless communication system with Govier and Williams because Sarwal's system uses a well-known wireless communication protocol, WAP, which would have been available and well understood by POSITAs in 2006. (Ex. 1002, ¶225.) Moreover, Sarwal expressly describes one way WAP could function with a controller unit and electrode, which would have given a POSITA increased confidence that the system would work for its intended purpose. (*Id.*; Ex. 1020, 14:35-15:27.) Further, as demonstrated by Mumford and Sarwal, small wireless units were well known in the art and could be easily integrated into electrodes for wireless communication. Additionally, a POSITA would have found it obvious to combine a processor hosting the WAP protocol with a pulse

generator, such as the pulse generators described in Govier and Williams, to enable wireless communication. (Ex. 1002, ¶225.) In fact, the '338 patent presumes that wireless communication protocols were well known in 2006, stating that the described devices could communicate wirelessly “using a variety of methods or techniques *known in the art*.” (Ex. 1001, 35:1-7); *see also* §VI.C.2 (collecting cases).

3. Dependent Claim 5

Claim 5 depends from claim 1 and further recites: “wherein the controller unit communicates wirelessly with the percutaneous electrode.” Sarwal discloses a controller unit that communicates wirelessly with an electrical coil and electrodes and Govier in combination with Sarwal, or Govier and Williams in combination with Sarwal render this claim obvious. (Ex. 1002, ¶¶226-227.)

A POSITA would have been motivated to, and reasonably expected success in, combining Sarwal’s wireless communication protocol with the system’s in Govier and Williams so that the controller unit could wirelessly communicate with the percutaneous needle electrode for the reasons expressed in claim 4. (*Supra* §VI.E.2.)

4. Dependent Claim 7

Claim 7 depends from claim 2 and further recites: “wherein the controller unit communicates wirelessly with the transcutaneous electrode.” Govier in

combination with Sarwal, or Govier and Williams in combination with Sarwal render this claim obvious for the reasons provided in Claim 4. (*Supra* §VI.E.2.)

5. Dependent Claim 8

Claim 8 depends from claim 2 and further recites: “wherein the controller unit communicates wirelessly with the percutaneous needle electrode.” Govier in combination with Sarwal, or Govier and Williams in combination with Sarwal render this claim obvious for the reasons provided in Claims 4-5. (*Supra* §VI.E.2-3.)

F. Grounds 11-12: Claims 4-5 and 7-8 are Obvious over Williams in view of Sarwal or Williams in view of Govier and Sarwal

A POSITA would have found claims 4-5 and 7-8 obvious over Williams in view of Sarwal or Williams in view of Govier and Sarwal for the reasons provided in the previous sections. (*Supra* §VI.E.2-5.)

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. 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. 9,757,584, which depends from the '338 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 BoxCalaHealth338@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: 949-760-0404 Facsimile: 949-760-9502

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 BoxCalaHealth338@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 '338 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 9,387,338,
exclusive of the parts exempted as provided in 37 C.F.R. §42.24(a), contains
13,982 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 9,387,338** and **EXHIBITS 1001-1022** are being served on January 23, 2023, via FedEx Priority Overnight to the correspondence address of record for the subject patent 9,387,338 found on the USPTO’s Patent Center webpage:

LEVINE BAGADE HAN LLP
2400 GENG ROAD, SUITE 120
PALO ALTO, CA 94303

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: January 23, 2023

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