

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CALA HEALTH, INC.,
Petitioner,

v.

EMKINETICS INC.,
Patent Owner.

U.S. Patent 9,387,338

**DECLARATION OF JOHN LAUGHLIN IN SUPPORT OF
PETITION FOR *INTER PARTES* REVIEW OF
U.S. PATENT 9,387,338**

TABLE OF CONTENTS

	Page No.
I. EXPERIENCE AND QUALIFICATIONS.....	3
II. SUMMARY OF OPINIONS	4
III. LEGAL BACKGROUND	5
A. Applicable Legal Standards	5
B. Secondary Considerations	9
C. Person of Ordinary Skill in the Art	10
IV. THE '338 PATENT	11
A. Overview of the '338 Patent.....	11
1. The Specification	11
2. The Claims	13
B. The Priority Date of the '338 Patent	15
C. Claim Construction	15
V. TECHNOLOGY BACKGROUND.....	15
A. Govier.....	16
B. Klingler.....	18
C. Van Balken.....	19
D. Williams	20
E. Mumford.....	22

TABLE OF CONTENTS

(*cont'd*)

	Page No.
F. Sarwal	23
VI. CLAIMS 1-8 OF THE '338 PATENT ARE UNPATENTABLE	25
A. Claims 1-3 and 6 Are Anticipated By Govier Or Rendered Obvious By Govier Combined With Williams	25
1. Independent Claim 1	25
a. Preamble – “A method”	25
b. “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”	26
i. Govier Anticipates.....	26
ii. Govier and Williams Render Obvious	29
c. “the electrode patch is electrically coupled with a controller unit”	33
d. “the controller unit including a pulse generator”	35
i. Govier Anticipates.....	35
ii. Govier and Williams Render Obvious	36
e. “electrically coupling a percutaneous electrode to the controller unit”	40

TABLE OF CONTENTS

(*cont'd*)

	Page No.
f. “the percutaneous electrode having an end for inserting in proximity to a tibial nerve of the patient”	42
g. “inserting the end of the percutaneous electrode into the skin in proximity to the tibial nerve of the patient”	44
h. “activating the pulse generator such that current pulses flow along the tibial nerve by passing between the electrode patch and the percutaneous electrode”	45
i. Govier Anticipates.....	45
ii. Govier and Williams Render Obvious	47
i. “the current pulses configured to treat incontinence”	49
2. Independent Claim 2	50
a. Preamble – “A method”	50
b. “positioning a transcutaneous electrode on skin of a patient in proximity to a tibial nerve”	50
i. Govier Anticipates.....	51
ii. Govier and Williams Render Obvious	53
c. “inserting an end of a percutaneous needle electrode through the skin in proximity to the tibial nerve”	56

TABLE OF CONTENTS

(*cont'd*)

	Page No.
d. “the percutaneous needle electrode including a wire disposed opposite the end”	58
e. “securing a controller unit to the transcutaneous electrode such that the controller unit is electrically coupled to the transcutaneous electrode”	60
f. “the controller unit including a pulse generator”	61
g. “connecting the wire of the percutaneous needle electrode to the controller unit for electrically coupling the percutaneous needle electrode to the controller”	62
h. “activating the pulse generator such that current pulses flow along the tibial nerve by passing between the transcutaneous electrode and the percutaneous needle electrode”	65
i. Govier Anticipates.....	65
ii. Govier and Williams Render Obvious	66
i. “the current pulses configured to treat incontinence”	67
3. Dependent Claim 3 - “wherein the electrode patch is placed on an ankle of the patient”	67
4. Dependent Claim 6 - “wherein the transcutaneous electrode is placed on an ankle of the patient”	70

TABLE OF CONTENTS

(cont'd)

	Page No.
B. Claims 1-3 and 6 Are Anticipated By Williams Or Rendered Obvious By Williams Combined With Govier.....	72
1. Independent Claim 1	72
a. Preamble – “A method”	72
b. “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”	72
c. “the electrode patch is electrically coupled with a controller unit”	76
d. “the controller unit including a pulse generator”	77
e. “electrically coupling a percutaneous electrode to the controller unit”	77
f. “the percutaneous electrode having an end for inserting in proximity to a tibial nerve of the patient”	79
g. “inserting the end of the percutaneous electrode into the skin in proximity to the tibial nerve of the patient”	80
h. “activating the pulse generator such that current pulses flow along the tibial nerve by passing between the electrode patch and the percutaneous electrode”	81
i. Williams Anticipates	81

TABLE OF CONTENTS **(cont'd)**

	Page No.
ii. Williams and Govier Render Obvious	84
i. “the current pulses configured to treat incontinence”	84
2. Independent Claim 2	84
a. Preamble – “A method”	85
b. “positioning a transcutaneous electrode on skin of a patient in proximity to a tibial nerve”	85
c. “inserting an end of a percutaneous needle electrode through the skin in proximity to the tibial nerve”	88
d. “the percutaneous needle electrode including a wire disposed opposite the end”	90
e. “securing a controller unit to the transcutaneous electrode such that the controller unit is electrically coupled to the transcutaneous electrode”	91
f. “the controller unit including a pulse generator”	92
g. “connecting the wire of the percutaneous needle electrode to the controller unit for electrically coupling the percutaneous needle electrode to the controller”	92
h. “activating the pulse generator such that current pulses flow along the tibial nerve by	

TABLE OF CONTENTS

(*cont'd*)

	Page No.
passing between the transcutaneous electrode and the percutaneous needle electrode”	93
i. “the current pulses configured to treat incontinence”	95
3. Dependent Claim 3 - “wherein the electrode patch is placed on an ankle of the patient”	95
4. Dependent Claim 6 - “wherein the transcutaneous electrode is placed on an ankle of the patient”	96
C. Claims 4-5 and 7-8 are Obvious over Govier in Combination With Mumford or Govier in Combination With Williams and Mumford	97
1. Introduction to Claims 4-5 and 7-8.....	97
2. Dependent Claim 4 - “wherein the controller unit communicates wirelessly with the electrode patch”	101
3. Dependent Claim 5 - “wherein the controller unit communicates wirelessly with the percutaneous electrode”	108
4. Dependent Claim 7 - “wherein the controller unit communicates wirelessly with the transcutaneous electrode”	112
5. Dependent Claim 8 - “wherein the controller unit communicates wirelessly with the percutaneous needle electrode”	112

TABLE OF CONTENTS
(cont'd)

	Page No.
D. Claims 4-5 and 7-8 are Obvious over Williams in Combination With Mumford or Williams in Combination With Govier and Mumford.....	113
E. Claims 4-5 and 7-8 are Obvious over Govier in Combination With Sarwal or Govier in Combination With Williams and Sarwal	113
1. Dependent Claim 4 - “wherein the controller unit communicates wirelessly with the electrode patch”	113
2. Dependent Claim 5 - “wherein the controller unit communicates wirelessly with the percutaneous electrode”	118
3. Dependent Claim 7 - “wherein the controller unit communicates wirelessly with the transcutaneous electrode”	118
4. Dependent Claim 8 - “wherein the controller unit communicates wirelessly with the percutaneous needle electrode”	119
F. Claims 4-5 and 7-8 are Obvious over Williams in Combination With Sarwal or Williams in Combination With Govier and Sarwal	119
VII. CONCLUSION	119

I, John Laughlin, declare as follows:

1. I am making this declaration at the request of Cala Health, Inc. (“Petitioner”). I understand that Petitioner will submit this Declaration as Exhibit 1002 in support of a Petition for Inter Partes Review against U.S. Patent No. 9,387,338 (“the ’338 patent”). While I understand that the Petition may rely on and incorporate portions of my analysis set forth in this Declaration, the analysis set forth in this Declaration is my own independent analysis. I have not been provided, and I have not reviewed, the Petition or any portion of the Petition.

2. I am being compensated for my work in this matter and I am being reimbursed at cost for my expenses. My compensation in no way depends upon the outcome of this proceeding.

3. In preparing this Declaration, I considered the following materials:

Exhibit No.	Description
1001	U.S. Patent No. 9,387,338 (“the ’338 patent”)
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”)

Exhibit No.	Description
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”)
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.

I. EXPERIENCE AND QUALIFICATIONS

4. My experience and qualifications are summarized in my *curriculum vitae*, a copy of which is provided as Exhibit 1003.

5. I earned a bachelor of science from Texas A&M University in 1993 and obtained a master of engineering degree from Texas A&M University in 1995. I am a member of the National Academy of Forensic Engineers, the National Society of Professional Engineers, the Texas Society of Professional Engineers, and the Human Factors and Ergonomics Society.

6. I spent 17 years working in the field of biomedical engineering with special experience in the field of neuroelectrical engineering.

7. From 1996-1997, I worked as a clinical research engineer for Cyberonics, Inc. where I worked on a NeuroCybernetic prosthesis. From 1997 to 2005, I worked as a senior forensic biomedical engineer for Rimkus Consulting Group performing forensic analyses. From 2005 to 2007, I was a principal field clinical engineer for Advanced Bionics Corporation where I led clinical trials investigating novel neurostimulation therapies for incontinence, migraine, and erectile dysfunction. I also worked on spinal cord stimulation therapies and chronic pain.

8. I worked as a senior field clinical engineer for EnteroMedics, Inc. from 2007-2009 where I focused on neuromodulation systems for treating obesity

and other diseases. In 2009, I formed the Laughlin Engineering Firm where I have consulted on a variety of engineering projects, including Class III medical devices. My list of publications is appended to my *curriculum vitae*, a copy of which is provided as Exhibit 1003. Relevant to this matter, I published two papers involving studies on neurostimulation techniques. *See* Ex. 1003.

II. SUMMARY OF OPINIONS

9. In view of the discussion below, it is my opinion that claims 1-8 of the '338 patent are unpatentable for the following reasons:

Govier-Based Grounds

- Claims 1-3 and 6 are anticipated by Govier;
- Claims 1-3 and 6 are rendered obvious by Govier in combination with Williams;
- Claims 4-5 and 7-8 are rendered obvious by Govier in combination with Mumford;
- Claims 4-5 and 7-8 are rendered obvious by Govier in combination with Williams and Mumford;
- Claims 4-5 and 7-8 are rendered obvious by Govier in combination with Sarwal; and
- Claims 4-5 and 7-8 are rendered obvious by Govier in combination with Williams and Sarwal.

Williams-Based Grounds

- Claims 1-3 and 6 are anticipated by Williams;
- Claims 1-3 and 6 are rendered obvious by Williams in combination with Govier;
- Claims 4-5 and 7-8 are rendered obvious by Williams in combination with Mumford;
- Claims 4-5 and 7-8 are rendered obvious by Williams in combination with Govier and Mumford;
- Claims 4-5 and 7-8 are rendered obvious by Williams in combination with Sarwal; and
- Claims 4-5 and 7-8 are rendered obvious by Williams in combination with Govier and Sarwal.

III. LEGAL BACKGROUND

A. Applicable Legal Standards

10. I have been asked to provide my opinion as to whether certain claims of the '338 patent are anticipated and/or would have been obvious to a person of ordinary skill in the art at the time of the alleged invention, in view of the prior art.

11. I am an engineer by training and profession. The opinions I am expressing in this report involve the application of my training and technical

knowledge and experience to the evaluation of certain prior art with respect to the '338 patent.

12. Although I have been involved as a technical expert in patent matters before, I am not an expert in patent law. Therefore, the attorneys from Knobbe, Martens, Olson & Bear, LLP have provided me with guidance as to the applicable patent law in this matter. The paragraphs below express my understanding of how I must apply legal principles relating to patent validity in my analysis.

13. It is my understanding that in determining whether a patent claim is anticipated by or obvious in view of the prior art, the Patent Office construes the claim by giving the claim its ordinary and customary meaning ascribed to it by a person of ordinary skill in the art at the time of the invention, consistent with the specification and prosecution history. I also understand that in reading the claim, I must not import limitations from the specification into the claim terms; in other words, I must not narrow the scope of the claim terms by implicitly adding disclosed limitations that have no express basis in the claims.

14. It is my understanding that a claim is “anticipated” if a prior art reference describes, either expressly or inherently, each limitation of the claim. I understand that this description must be recognizable to a person of ordinary skill in the art at the time of the alleged invention.

15. It is my understanding that a claim is “obvious” if the claimed subject matter as a whole would have been obvious to a person of ordinary skill in the art at the time of the alleged invention. I also understand that an obviousness analysis takes into account the scope and content of the prior art, the differences between the claimed subject matter and the prior art, and the level of ordinary skill in the art at the time of the invention.

16. In determining the scope and content of the prior art, it is my understanding that a reference is considered appropriate (e.g., analogous) prior art if it falls within the field of the inventor’s endeavor. In addition, a reference is prior art if it is reasonably pertinent to the particular problem with which the inventor was involved. A reference is reasonably pertinent if it logically would have commended itself to an inventor’s attention in considering the problem. If a reference relates to the same problem as the claimed invention, that supports use of the reference as prior art in an obviousness analysis.

17. To assess the differences between prior art and the claimed subject matter, it is my understanding that the law requires the claimed invention to be considered as a whole. This “as a whole” assessment requires showing that one of ordinary skill in the art at the time of invention, confronted by the same problems as the inventor and with no knowledge of the claimed invention, would have selected the elements from the prior art and combined them in the claimed manner.

18. It is my further understanding that the law recognizes several rationales for combining references or modifying a reference to show obviousness of claimed subject matter. Some of these rationales include: combining prior art elements according to known methods to yield predictable results; simple substitution of one known element for another to obtain predictable results; a predictable use of prior art elements according to their established functions; applying a known technique to a known device (method or product) ready for improvement to yield predictable results; choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success; and some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

19. I understand that a prior art reference may also suggest a limitation of the claims. In that case, even if the prior art reference does not explicitly disclose the limitation, the motivation to modify the prior art reference to include the limitation may exist within the prior art reference itself. Thus, the limitation would have been obvious over that prior art reference alone. This is the case if a person of ordinary skill in the art would have had a simple design choice or a finite number of identified, predictable solutions, for example, and if the modification furthers the goals of the prior art reference.

20. I further understand that the obviousness analysis must be performed from the perspective of a person of ordinary skill in the art at the time of the alleged invention. This is to avoid using impermissible hindsight in the analysis. The claims of the patent must not be used to provide a road map for obviousness; instead, the claims would have been obvious if a person of ordinary skill in the art would have been motivated to combine the teachings of the prior art to arrive at the claimed invention and had a reasonable expectation of success in doing so.

B. Secondary Considerations

21. I also understand that an obviousness analysis must consider whether there are additional factors that would indicate that the invention would not have been obvious. I understand that these factors are sometimes called “secondary considerations.” These factors include whether there was: (i) a long-felt need in the industry; (ii) any unexpected results; (iii) skepticism of the invention; (iv) a teaching away from the invention; (v) commercial success; (vi) praise by others for the invention; and (vii) copying by other companies. I am not aware of any evidence that would suggest that the claims of the ’338 patent would have been non-obvious. To the extent Patent Owner submits such evidence during the course of the *inter partes* review, I may provide my opinion on such evidence if asked to do so by counsel.

C. Person of Ordinary Skill in the Art

22. It is my understanding that when interpreting the claims of the '338 patent, I must do so based on the perspective of a person of ordinary skill in the art at the relevant priority date. As discussed below, I understand the earliest possible priority date to be October 2, 2006.

23. The '338 patent describes the use of well-known neuromodulation methods. Based on my review of the specification and claims of the '338 patent, it is my opinion that a person of ordinary skill in the art would be a person having a degree in the field of biomedical engineering, or a related engineering discipline, and at least two years of experience in the design and/or analysis of biomedical devices. Additional work experience could serve as a substitute for an engineering degree.

24. I am able to make this assessment because in the late 1990s and 2000s, I was familiar with design and operation principles common in the neuromodulation field as explained in my CV and discussed herein. The engineers that I worked with during the late 1990s and 2000s had the requisite knowledge to perform the methods described in the claims of the '338 patent. Because I have worked with and supervised biomedical engineers, I know very well what their capabilities were in the late 1990s and 2000s, how those engineers would interpret

and understand the claims of the '338 patent, and how they would understand the disclosures in the prior art discussed herein.

25. In my opinion, as set forth in more detail below, a person having ordinary skill in the art at the time of the invention would have considered the devices and methods claimed in the '338 patent to be anticipated by and/or obvious in view of the prior art.

IV. THE '338 PATENT

A. Overview of the '338 Patent

1. The Specification

26. 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 ('338 patent) at abstract. However, a portion of the patent describes methods for treating ailments by providing “electrical energy” to a target nerve. *Id.* at 8:18-22. In a specific embodiment, the '338 patent describes an energy emitting system 280 that “includes one or more percutaneous electrode needles 262 [blue] coupled to a controller 218 [yellow] and having an end insertable into a subject’s body in proximity to [a] target nerve.” *Id.* at 27:1-5, Figure 27. This embodiment is illustrated in Figure 27 below. “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.* at 27:13-16.

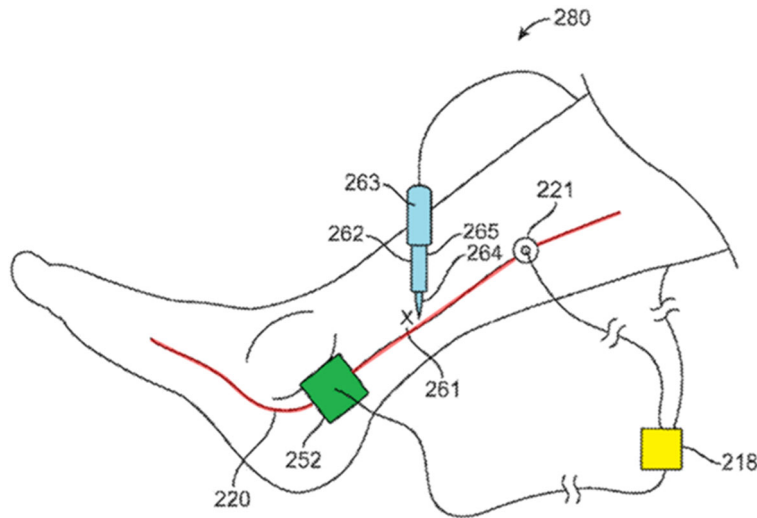


FIG. 27

'338 Patent – Figure 27

27. “The percutaneous electrode needle 262 is inductively coupled to conductive microneedle patch 252 [green].” *Id.* at 27:7-9. The “patch can include at least one electrode” and “may optionally be attached to various other materials or adhesive materials.” *Id.* at 28:10-11. While Figure 27 specifically discloses a “microneedle patch,” the ’338 patent discloses that the microneedles are optional. *See e.g., id.* at 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.* at 27:9-13.

28. 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 the microneedle patch 252 to the internal percutaneous electrode needle 262....” *Id.* at 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 and urinary incontinence. *Id.* at 17:4-52, 40:41-63.

2. The Claims

29. The ’338 patent includes 8 claims. I offer opinions regarding all of the claims (claims 1-8) in this Declaration. Claims 1 and 2 are independent claims.

Claim 1 recites:

A method, comprising:
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 and the electrode patch is electrically coupled with a controller unit, the controller unit including a pulse generator;
electrically coupling a percutaneous electrode having an end for inserting in proximity to a tibial nerve of the patient to the controller unit;
inserting the end of the percutaneous electrode into the skin in proximity to the tibial nerve of the patient; and
activating the pulse generator such that current pulses flow along the tibial nerve by passing between the electrode patch and the percutaneous electrode, the current pulses configured to treat incontinence.

30. Independent claim 2 recites:

A method, comprising:
positioning a transcutaneous electrode on skin of a patient in proximity to a tibial nerve;
inserting an end of a percutaneous needle electrode through the skin in proximity to the tibial nerve, the percutaneous needle electrode including a wire disposed opposite the end;

securing a controller unit to the transcutaneous electrode such that the controller unit is electrically coupled to the transcutaneous electrode, the controller unit including a pulse generator,

connecting the wire of the percutaneous needle electrode to the controller unit for electrically coupling the percutaneous needle electrode to the controller; and

activating the pulse generator such that current pulses flow along the tibial nerve by passing between the transcutaneous electrode and the percutaneous needle electrode, the current pulses configured to treat incontinence.

31. Dependent claim 3 recites:

The method of claim 1, wherein the electrode patch is placed on an ankle of the patient.

32. Dependent claim 4 recites:

The method of claim 1, wherein the controller unit communicates wirelessly with the electrode patch.

33. Dependent claim 5 recites:

The method of claim 1, wherein the controller unit communicates wirelessly with the percutaneous electrode.

34. Dependent claim 6 recites:

The method of claim 2, wherein the transcutaneous electrode is placed on an ankle of the patient.

35. Dependent claim 7 recites:

The method of claim 2, wherein the controller unit communicates wirelessly with the transcutaneous electrode.

36. Dependent claim 8 recites:

The method of claim 2, wherein the controller unit communicates wirelessly with the percutaneous needle electrode.

B. The Priority Date of the '338 Patent

37. For purposes of this Declaration, I have been asked to assume that the '338 patent's priority date is October 2, 2006. However, my opinions would not change if the priority date of the '338 patent were between 2007 and 2009.

C. Claim Construction

38. I understand that I should give the claim language its ordinary and customary meaning as understood by a person of ordinary skill in the art at the time of filing (October 2006) and in accordance with the specification and prosecution history. I have applied this standard in my analysis.

V. TECHNOLOGY BACKGROUND

39. The methods claimed in the '338 patent were well known by October 2006 and described in various printed publications. 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 incontinence. 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 incontinence, via electrical stimulation of nerves, including the tibial nerve.

40. Mumford also constitutes analogous art because it discloses the same methods of stimulating a nerve as the '338 patent. 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.

A. Govier

41. Govier (published in 2001) 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 (Govier) p. 1193 (Abstract). A total of 53 patients with overactive bladders were treated. *Id.* Patients received weekly percutaneous electrical stimulations via a 34 gauge needle placed near the tibial nerve 3 finger breadths above the ankle.” *Id.* “An electrocardiogram ground pad was placed over the medial aspect of the calcaneus. A stimulator was then connected to the needle and the ipsilateral ground pad (fig. 3). Stimulation was titrated from 0 to 10 mA with fixed pulse 200 microseconds at frequency 20 Hz.” *Id.* at p. 1194. “The stimulator was left with the patient controlling the power setting for 30 minutes. Therapeutic sessions were once a week for 12 weeks.” *Id.* The conclusions of Govier include that “[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.* at p. 1193 (Abstract).

42. 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.

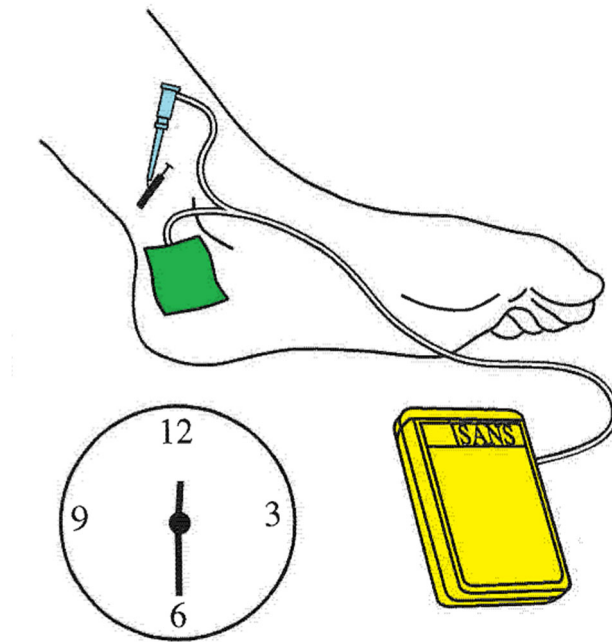


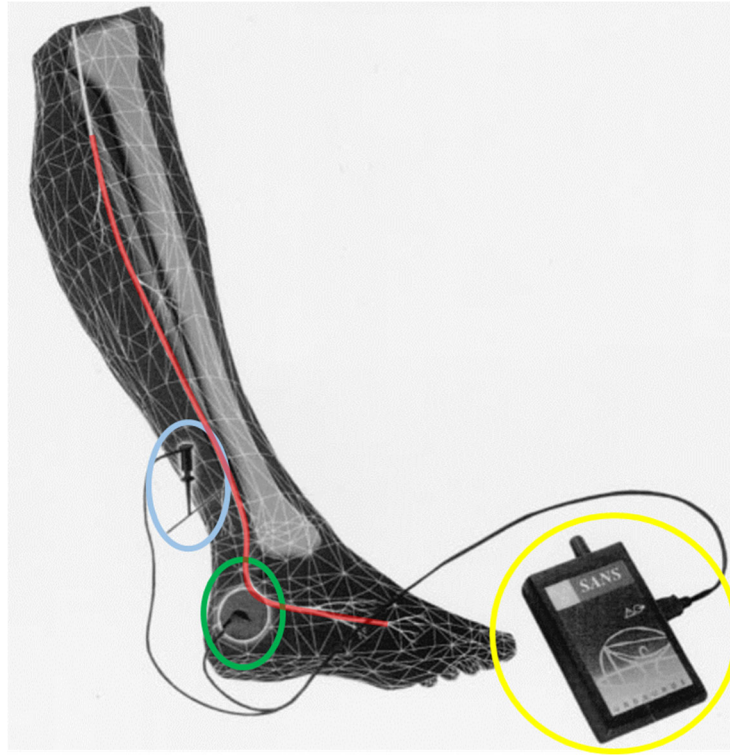
FIG. 3. Attach electrode and lead wire by placing electrode on same leg as needle near arch of foot. Connect grabber plug to needle on handle portion just above insertion point. Patient will control stimulation at comfortable level for 30 minutes.

Govier – Figure 3

B. Klingler

43. Klingler (published in 2000) disclosed a similar method of peripheral neuromodulation of posterior tibial nerves to treat patients with urgency-frequency syndrome due to an overactive bladder. Klingler describes stimulating the posterior tibial nerves with the Stoller Afferent Nerve Stimulator (SANS), which was attached to a 34-gauge needle and a neutral surface electrode positioned at or near the ankle. Ex. 1009 (Klingler) at p. 766 (Abstract) and p. 767 (description of Figure 1).

44. 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.



Klingler – Figure 1

C. Van Balken

45. Similarly, Van Balken (published in 2001) describes posterior tibial nerve stimulation as a neuromodulative treatment of patients with symptoms of bladder overactivity. Ex. 1010 (Van Balken) at p. 914 (Title, Abstract). The treatment method in Van Balken is disclosed as follows:

A 34 gauge stainless steel needle is inserted approximately 3 to 4 cm., about 3 fingerbreadths cephalad to the medial malleolus, between the posterior margin of the tibia and soleus muscle. A stick on electrode is placed on the same leg near the arch of the foot. The needle and electrode are connected to a low voltage (9 volts) Urosurge stimulator (Urosurge, Coralville, Iowa) with an adjustable pulse intensity of 0 to 10 mA., a fixed pulse width of 200 microseconds and a frequency of 20 Hz.

Id. at p. 915.

46. 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.

D. Williams

47. Williams (a patent application that published on August 4, 2005) describes an electro-nerve stimulation apparatus that includes “a pulse generator, a first electrically conductive, insulated lead wire, a second electrically conductive, insulated lead wire, an electrically conductive transcutaneous electrode and an electrically conductive percutaneous needle electrode.” Ex. 1006 (Williams) at Abstract. “Connected to one end of the first and second lead wires is a connector for electrically coupling with the pulse generator. The transcutaneous electrode is operably connected to the other end of the first lead wire. An electrically conductive adaptor is secured to the other end of the second lead wire for electrically coupling to the terminal end of the percutaneous needle electrode.” *Id.*

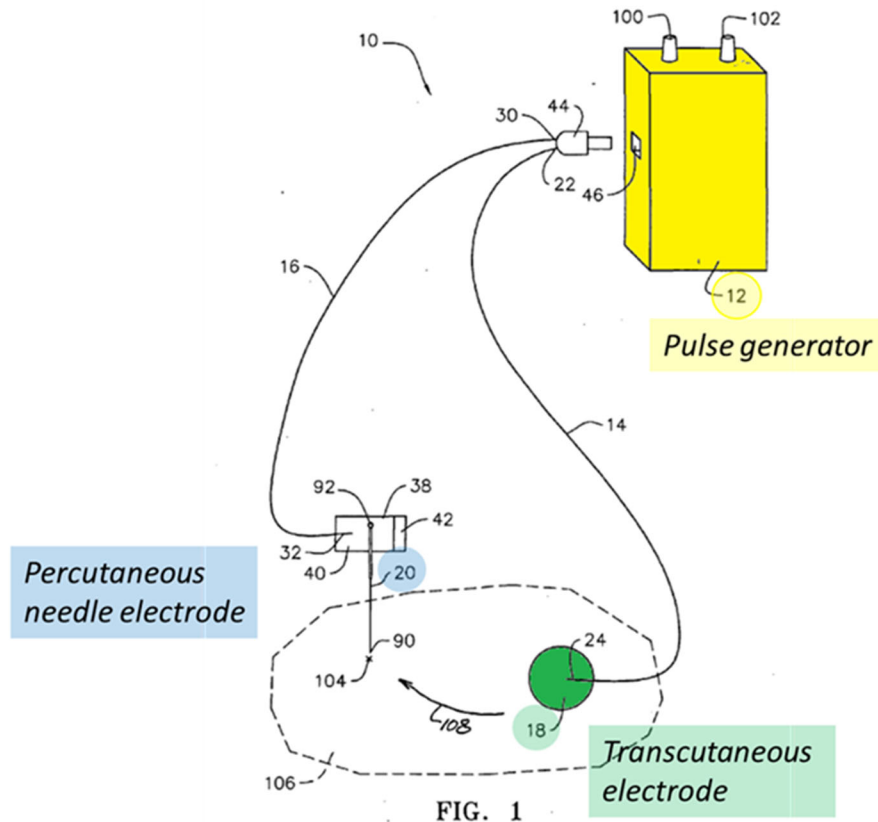
48. “In use, the transcutaneous electrode is adhered to the patient's skin distal from the desired internal stimulation site. The percutaneous needle electrode

is inserted through the skin in proximity to the desired internal stimulation site. The pulse generator is activated to pass current pulses between the transcutaneous electrode and the percutaneous needle electrode through the internal stimulation site.” *Id.*

49. Williams teaches that the apparatus and system disclosed in Williams is “particularly suited for the treatment of urinary urge incontinence” and that the “percutaneous needle electrode 20 is inserted into the patient’s skin in proximity to the tibial nerve cephalic to the medial malleolus” and the “transcutaneous electrode is adhered to the patient’s skin distal to the percutaneous needle electrode.” *Id.* at [0037]. The medial malleolus is the bony protrusion sticking out of the inside of the foot and forms a part of the ankle, as would have been understood by a person of ordinary skill in the art. “Distal” refers to an area below the needle electrode (or nearer the bottom of the foot).

50. 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.



Williams – Figure 1

E. Mumford

51. 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 (Mumford) at [0006]; *see also id.* at [0028]-[0038] (describing Figure 1), claim 1.)

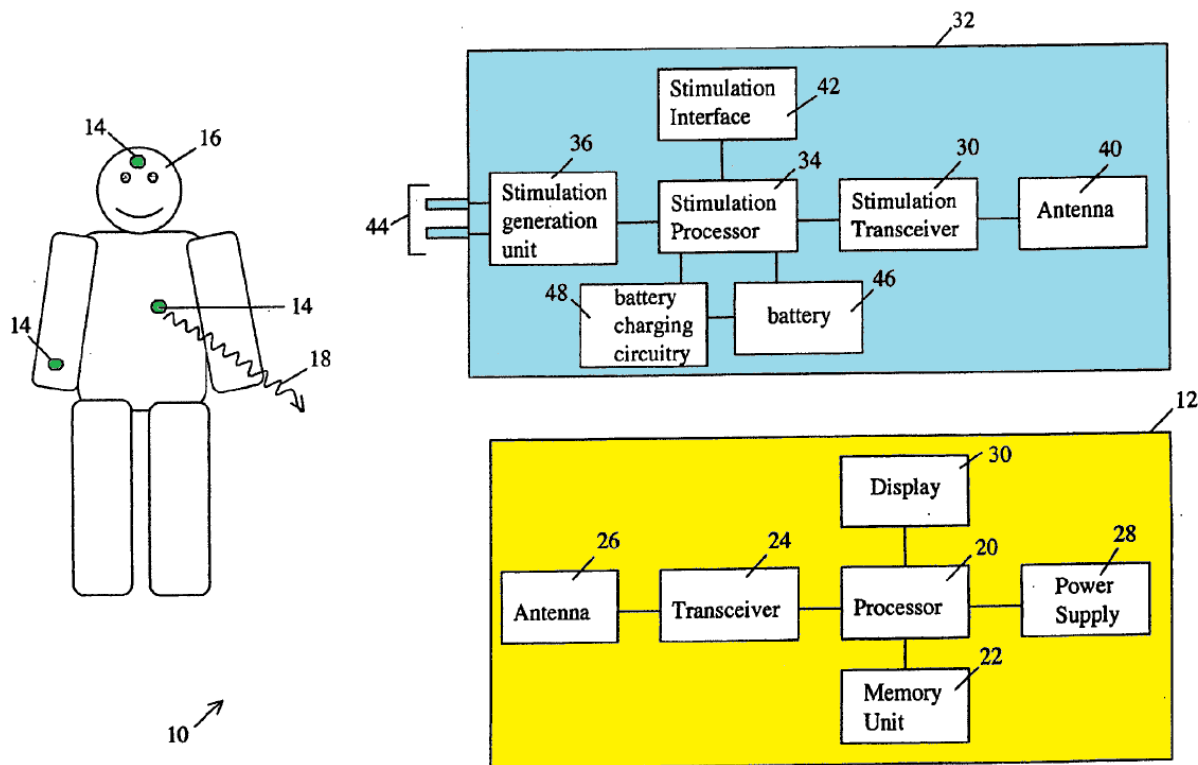


FIGURE 1

Mumford – Figure 1

52. 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.* at [0009].

F. Sarwal

53. Sarwal discloses a “system and method for remotely controlling the stimulation therapy for neurological, neuropsychiatric and urological disorders,” including “urinary incontinence.” Ex. 1020 (Sarwal) at 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.* at 7:4-61.

54. 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.* at 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.* at 11:14-17.

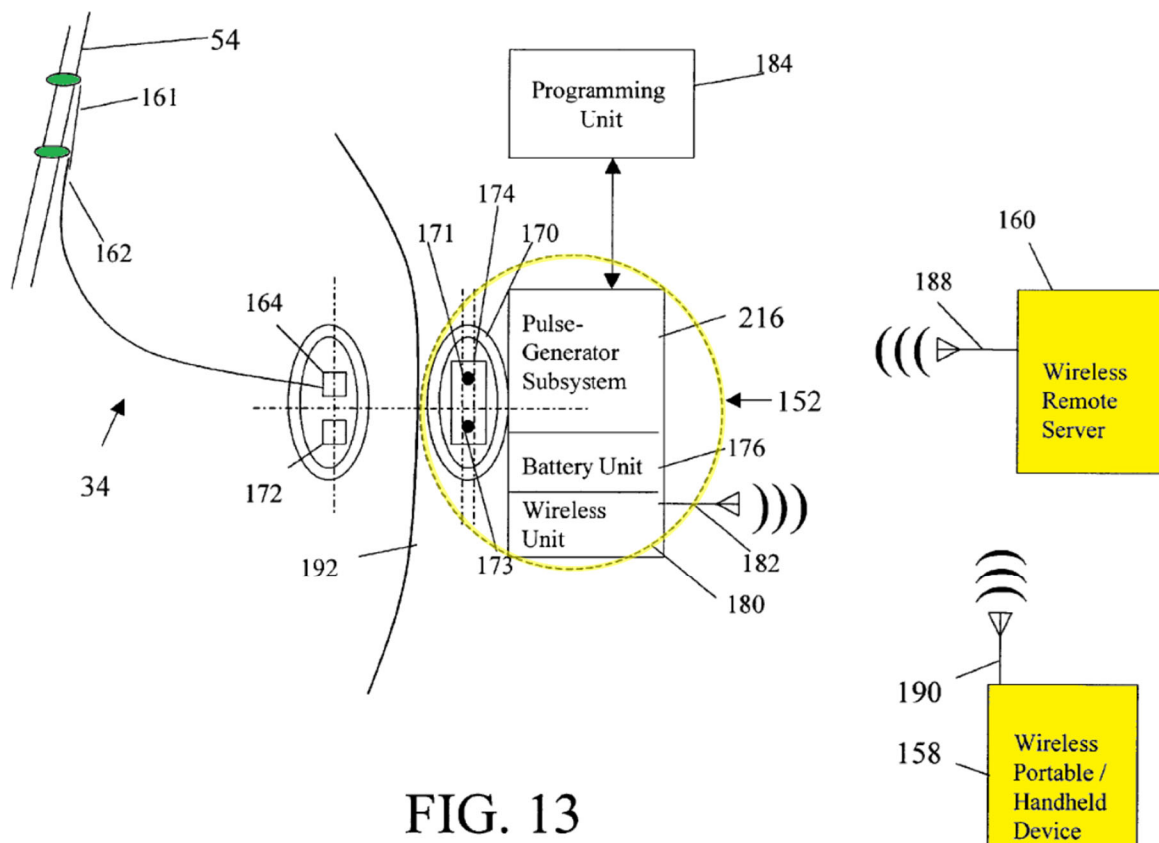


FIG. 13

Sarwal – Figure 13

55. 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.* at 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.* at 15:38-40. “The server in turn communicates these programs to the neurostimulator” (e.g., external stimulator 152). *Id.* at 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.* at 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.* at 11:14-19. Thus, Sarwal discloses wireless communication between a wireless remote server and external stimulator.

VI. CLAIMS 1-8 OF THE '338 PATENT ARE UNPATENTABLE

A. Claims 1-3 and 6 Are Anticipated By Govier Or Rendered Obvious By Govier Combined With Williams

1. Independent Claim 1

56. Independent Claim 1 is anticipated by Govier. To the extent Govier does not disclose each limitation of claim 1, claim 1 is also rendered obvious by Govier in combination with Williams.

a. Preamble – “A method”

57. The preamble of claim 1 recites “[a] method.”

58. Govier discloses “a method.” Govier discloses a method of treating “overactive bladder” using electrical stimulation of the “tibial nerve.” Ex. 1005 (Govier) at p. 1193 (Abstract).

b. **“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”**

59. Claim 1 next recites “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. If Govier does not disclose this limitation, Govier in combination with Williams renders this limitation obvious.

i. **Govier Anticipates**

60. Govier discloses applying an “electrocardiogram ground pad” [green] to the outer surface of the patient’s skin over the center of the heel bone (i.e., “medial aspect of the calcaneus”). Ex. 1005 (Govier) at 1194. The area around the patient’s heel and ankle bones is in proximity to the tibial nerve, a stimulation site of a patient. A person of ordinary skill in the art would have understood that the “electrocardiogram ground pad” is an “electrode patch,” as required by claim 1.

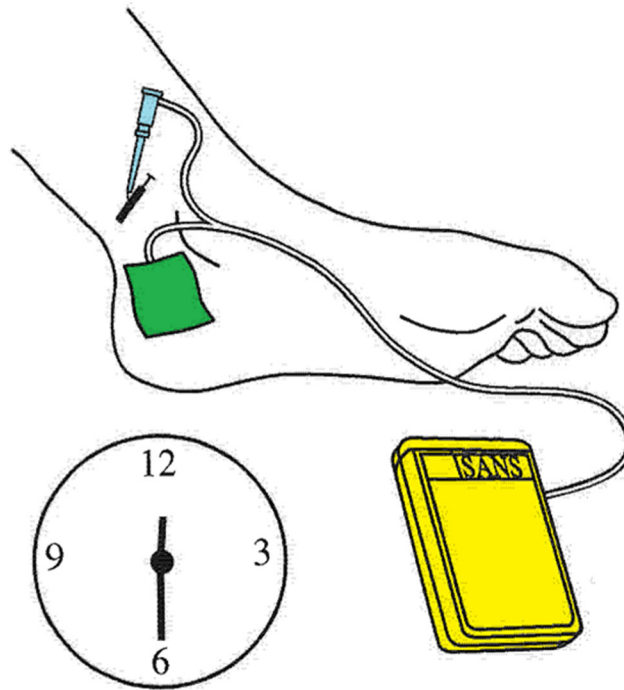


FIG. 3. Attach electrode and lead wire by placing electrode on same leg as needle near arch of foot. Connect grabber plug to needle on handle portion just above insertion point. Patient will control stimulation at comfortable level for 30 minutes.

Govier – Figure 3

61. Figure 3 (above) confirms that the electrocardiogram ground pad is an “electrode patch” because the caption to Figure 3 refers to the ground pad as an “electrode” and the figure illustrates the ground pad as a square patch. The caption to Figure 3 specifically states: “FIG. 3. Attach electrode and lead wire by placing electrode on same leg as needle near arch of foot.” Govier further confirms that “electrocardiogram type electrodes,” like the patch shown in Figure 3, were well known in the art as of Govier’s publication. For example, Govier describes a study of “direct electrical stimulation of the tibial nerve” by McGuire et al. in 1983. Ex. 1005 (Govier) p. 1193 (right column). Govier states that the electrical stimulation

was provided by “a stick on electrocardiogram type electrode with foam backing.”

Id.

62. Moreover, it is my opinion that a person of ordinary skill in the art would have understood that the terms “ground pad” and “electrode,” as used in Govier, are synonymous or interchangeable with the term “electrode patch,” as claimed in the ’338 patent. I do not see any disclosure in Govier or the ’338 patent that would lead a person of ordinary skill in the art to conclude that the terms refer to different structures. Rather, as can be seen in the side-by-side comparison of the two figures below, the patch 252 in the ’338 patent (which a person of ordinary skill in the art would understand to be an “electrode patch” as claimed) and the electrode/ground pad of Govier are virtually identical in appearance and are positioned in virtually identical locations on an outer surface of the skin.

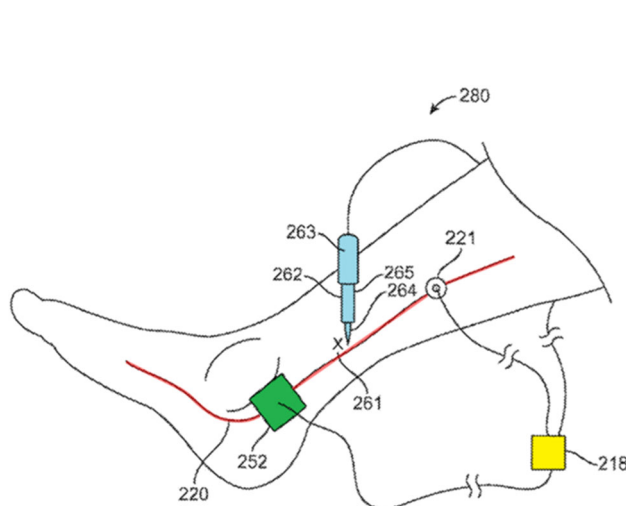
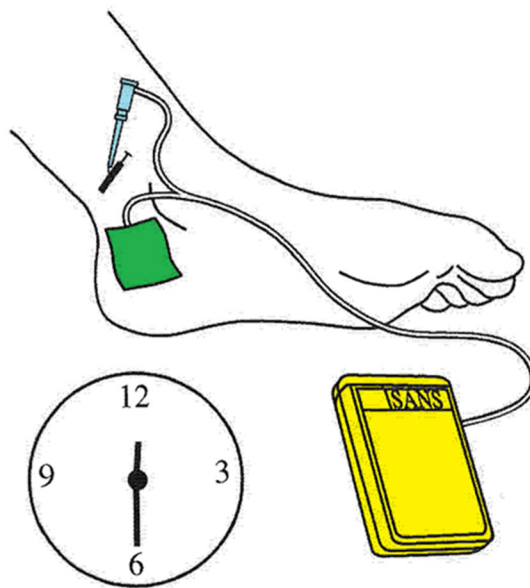


FIG. 27

'338 Patent - Figure 27

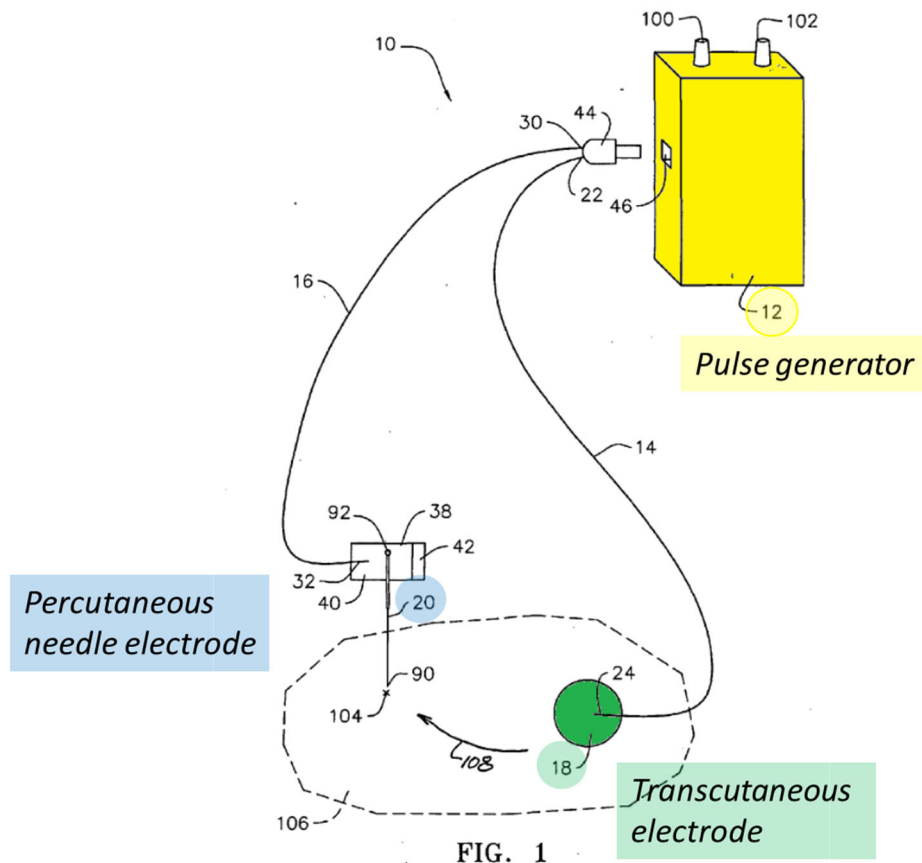


Govier - Figure 3

63. In addition, the '338 patent repeatedly refers to microneedle patches instead of electrode patches as used in Claim 1, including in connection with the examples describing current passing from a patch to an internal percutaneous electrode needle. For example, the '338 patent states that “microneedles may be attached, deposited, or arrayed on an electrode surface or patch in a variety of configurations and arrangements, depending on where the particular microneedle patch will be utilized and the treatment to be delivered.” Ex. 1001 ('338 Patent) at 20:26-30. A person of ordinary skill in the art would have understood that a microneedle patch is a type of electrode patch and that electrode patches with or without microneedles were both well-known and could be used interchangeably as of October 2006.

ii. Govier and Williams Render Obvious

64. If Govier does not disclose this limitation, it renders the limitation obvious in combination with Williams. Williams discloses an “electro-nerve stimulation apparatus” for treating “urinary urge incontinence.” Ex. 1006 (Williams) at 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.* at [0006], [0023], Fig. 1.



Williams - Figure 1

65. Williams discloses, “the transcutaneous electrode...is positioned and adhered to the patient’s skin distally proximate the stimulation site.” *Id.* at [0007]. Similarly, Williams states that a “transcutaneous electrode” is “an electrode which does not penetrate the surface of the skin.” *Id.* at [0004]. Williams explains that “[o]ne face of the transcutaneous electrode includes an electrically conductive medical grade adhesive to removably adhere the electrode to the patient’s skin near the desired stimulation site” and, as shown above, the electrode is in the form of a

round patch. *Id.* at [0006], Fig. 1. Thus, Williams discloses an “electrode patch,” as required by claim 1.

66. A person of ordinary skill in the art would have been motivated to combine Williams’s electrode patch with Govier’s system. Govier and Williams describe similar systems used to treat similar problems (e.g., urinary incontinence). Ex. 1005 (Govier) at abstract; Ex. 1006 (Williams) at [0037]. For example, both systems include an electrode patch placed on the skin of the patient, a percutaneous needle inserted into the skin of the patient, and a controller unit that is electrically coupled to the electrodes and allows the user to control the pulsed stimulation to the electrodes. A person of ordinary skill in the art would have found the substitution of Williams’s known electrode patch for the ground pad in Govier a simple substitution of one known element for another to obtain predictable results. This combination of familiar elements according to known methods would have been obvious because it does no more than yield predictable results. Here, the predictable results are the application of electrical stimulation to the tibial nerve to treat urinary incontinence. Moreover, Govier at least includes a teaching, suggestion, or motivation to use an electrode patch (by referencing an “electrode” in the caption to Figure 3) that would have led a person of ordinary skill in the art to modify Govier to include Williams’s electrode patch.

67. A person of ordinary skill in the art 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, namely creating a current path along the tibial nerve. Ex. 1005 (Govier) at 1193-1194; Ex. 1006 (Williams) at [0032], [0037]. Williams discloses, “the current pulses generated by the pulse generator 12 will flow from the transcutaneous electrode 18 to the percutaneous electrode needle 20....” Ex. 1006 (Williams) at [0027]. Likewise, current pulses flow between Govier’s electrocardiogram ground pad and percutaneous needle. Thus, as in Govier, Williams’s electrode facilitates the flow of current pulses along the stimulation site.

68. Additionally, Govier’s ground pad and Williams’s transcutaneous electrode share similar connections to their respective stimulator/pulse generator. Govier’s Figure 3 illustrates that the ground pad is connected to the stimulator with a lead wire. Ex. 1005 (Govier) at 1195 (Fig. 3). Similarly, Williams discloses that a “first lead wire 14” electrically couples the transcutaneous electrode to the pulse generator. Ex. 1006 (Williams) at [0024]. Thus, a person of ordinary skill in the art would not have expected any problems in substituting Williams’s transcutaneous electrode for Govier’s electrocardiogram ground pad.

c. **“the electrode patch is electrically coupled with a controller unit”**

69. Claim 1 next recites “the electrode patch is electrically coupled with a controller unit.” Govier discloses this limitation.

70. Govier discloses: “A stimulator was then connected to...the ipsilateral ground pad (fig. 3).” Ex. 1005 (Govier) at 1194 (right column). I understand the term “ipsilateral” to mean that the ground pad is positioned on the same side of the foot as the needle, as illustrated in Figure 3.

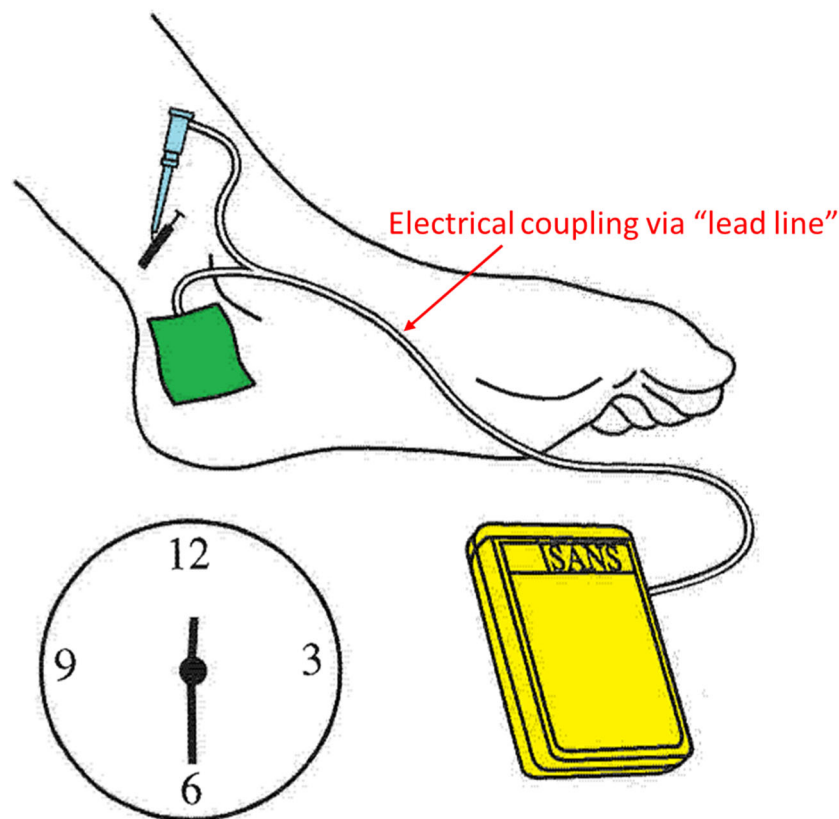


FIG. 3. Attach electrode and lead wire by placing electrode on same leg as needle near arch of foot. Connect grabber plug to needle on handle portion just above insertion point. Patient will control stimulation at comfortable level for 30 minutes.

Govier – Figure 3

71. Govier discloses that the stimulator was electrically coupled to the electrocardiogram ground pad (or the 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.” *Id.* at 1194-1195. Govier further discloses that the patients also used the stimulator unit to control “the power setting for 30 minutes.” *Id.* at 1194; *see also id.* at 1195 (“Patient will control stimulation at a comfortable level for 30 minutes.”).

72. Govier discloses that the stimulator is a Sans device provided by UroSurge in Coralville, Iowa, and that the stimulator provides stimulation with fixed pulse 200 microseconds at frequency 20 Hz, and that the stimulator was left with the patient controlling the power setting for 30 minutes. *Id.* at p. 1194.

73. I do not see the term “controller unit” used in the ’338 patent specification. However, the patent repeatedly refers to a “controller” that generates, and may be used to vary, current flow. *See e.g.*, Ex. 1001 (’338 patent) at abstract, 5:45-48, 6:6-8, 23:52-57, 24:2-8. As discussed above, this is the function of Govier’s stimulator. For these reasons, a person of ordinary skill in the art would have understood that Govier’s stimulator [yellow] is the “controller unit” required by claim 1.

d. **“the controller unit including a pulse generator”**

74. Claim 1 next recites “the controller unit including a pulse generator.” Govier discloses this limitation. If Govier does not disclose this limitation, then Govier in combination with Williams renders this limitation obvious.

i. **Govier Anticipates**

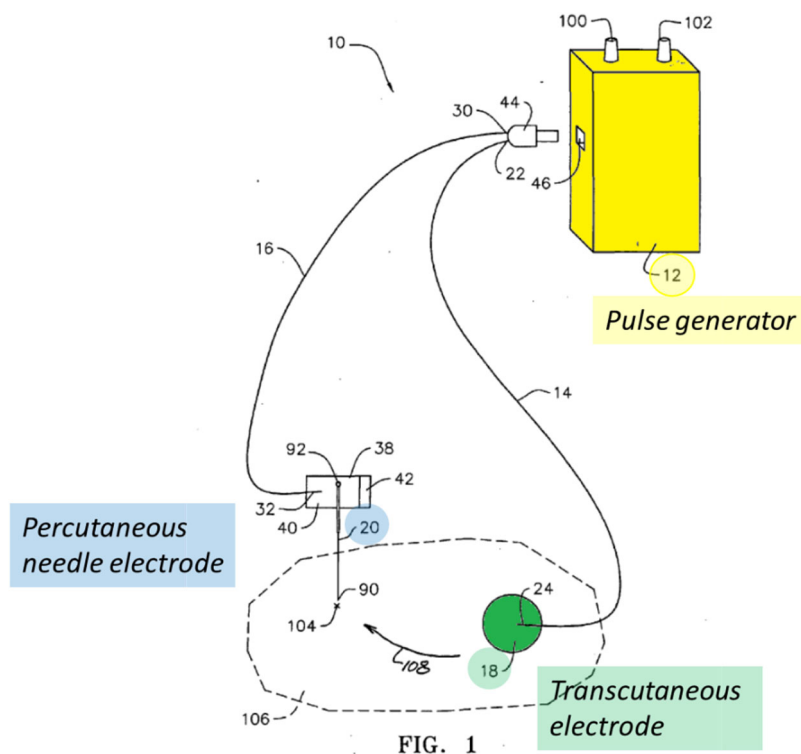
75. Govier discloses that the stimulator is a “Sans device” made by UroSurge. Ex. 1005 (Govier) at 1194. The UroSurge Sans device was well known in the field for providing “electrical stimulation to the peripheral nerves associated with pelvic floor function.” Ex. 2018 (UroSurge Sans FDA Approval) at 1; Ex. 1009 (Klingler) at 767 (using UroSurge Sans device). The Urosurge Sans device included the “electrode needles, surface electrode, external *pulse generator*, and lead wire assembly (which connects all three).” *Id.* (emphasis added). Further, I had experience with the UroSurge Sans device and can confirm that it included a pulse generator. While Govier refers to the UroSurge Sans device as a “stimulator,” persons of ordinary skill in the art in October 2006 often used the terms “stimulator” and “pulse generator” interchangeably.

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

added). A person of ordinary skill in the art would have understood that the stimulator must include a “pulse generator” in order to generate the described pulses. Further, a person of ordinary skill in the art would have understood that it was conventional at the relevant time to use a pulse generator for applications that required the generation of a pulse for pulsed stimulation, such as Govier’s stimulator.

ii. Govier and Williams Render Obvious

77. Williams discloses an “electro-nerve stimulation apparatus” for treating “urinary urge incontinence” that includes “a pulse generator [yellow]”:



Williams – Figure 1

Ex. 1006 (Williams) at abstract, [0006], [0023], [0037], Fig. 1.

78. 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.* at [0031]. Williams specifically identifies a commercially-available pulse generator, the Finetech-Medical pulse generator, and explains that those skilled in the art would know how to make the necessary modifications to use that particular pulse generator with the preferred embodiment. *Id.* I agree with Williams that a person of ordinary skill in the art would have possessed the necessary skills and knowledge to adapt an existing pulse generator for use with a simple two-electrode system as described in Williams or Govier. Like Govier, Williams also discloses that the patient uses the pulse generator to control the current pulses. *Id.* Thus, a person of ordinary skill in the art would have understood that Williams discloses a “pulse generator,” as required by claim 1.

79. A person of ordinary skill in the art would have been motivated to substitute Williams’s pulse generator for Govier’s stimulator. 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 (Govier) at 1193-94; Ex. 1006 (Williams) at [0031], [0037]. Govier’s Sans-type stimulator and Williams’s pulse generator each create identical current

pulses between 1-10 mA. Ex. 1005 (Govier) at 1194; Ex. 1006 (Williams) at [0031]. A person of ordinary skill in the art would have found it obvious to try and use either commercially-available pulse generator with Govier's system given these similarities. In fact, the evidence shows that stimulators and pulse generators were well known in the art and a person of ordinary skill in the art would even consider the terms stimulator and pulse generator to be synonymous or interchangeable. *See, e.g.*, Ex. 1005 (Govier) at p. 1194, Ex. 1006 (Williams) at [0032], Ex. 1009 (Klingler) at p. 767, and Ex. 1010 (Van Balken) at p. 915. Further, as I discussed above, a person of ordinary skill in the art would have possessed the necessary skills and knowledge to adapt any commercially available pulse generator for use with a simple two-electrode system as claimed in the '338 patent.

80. It is my opinion that 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. Moreover, Govier includes a teaching, suggestion, or motivation to use a pulse generator (*see e.g.*, Ex. 1005 (Govier) at 1194 (referencing a "fixed pulse")) that would have led a person of ordinary skill in the art to modify Govier to include Williams's pulse generator. Govier and Williams also disclose a finite number of identified, predictable solutions for generating a current pulse with a reasonable

expectation of success (*e.g.*, Govier’s UroSurge Sans device and Williams’ Finetech-Medical pulse generator). A person of ordinary skill in the art would have been motivated to select from these finite, commercially-available devices to produce the current pulses.

81. A person of ordinary skill in the art would have expected success in substituting Williams’s pulse generator for Govier’s stimulator because the pulse generator and stimulator are used for the same purpose in both references. Williams discloses that the “pulse generator” produces “current pulses, preferably between 1-10 mA, which pass between the transcutaneous electrode 18 and the percutaneous electrode needle 20.” Ex. 1006 (Williams) at [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 (Williams) at 1194. Moreover, both devices had a proven track record and, as Williams explained, if any small modifications were necessary to make the stimulator/generator compatible with Govier’s system, such modifications would have been within the skill level of a person of ordinary skill in the art. *See* Ex. 1006 (“Williams”) at [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.

e. **“electrically coupling a percutaneous electrode to the controller unit”**

82. Claim 1 next recites “electrically coupling a percutaneous electrode to the controller unit.” Govier discloses this limitation.

83. Govier describes a study where “[p]atients received weekly percutaneous electrical stimulations via a 34 gauge needle [blue] placed near the tibial nerve 3 finger breadths above the ankle.” Ex. 1005 (Govier) at 1193; *see also id.* at 1194 (“A 34 gauge, solid stainless steel needle was advanced through the skin....”).) A person of ordinary skill in the art would have understood that the 34-gauge needle is a “percutaneous electrode,” as required by claim 1, because, for example, Govier discloses that the electrical stimulation is supplied via the needle and the needle is inserted through the patient’s skin.

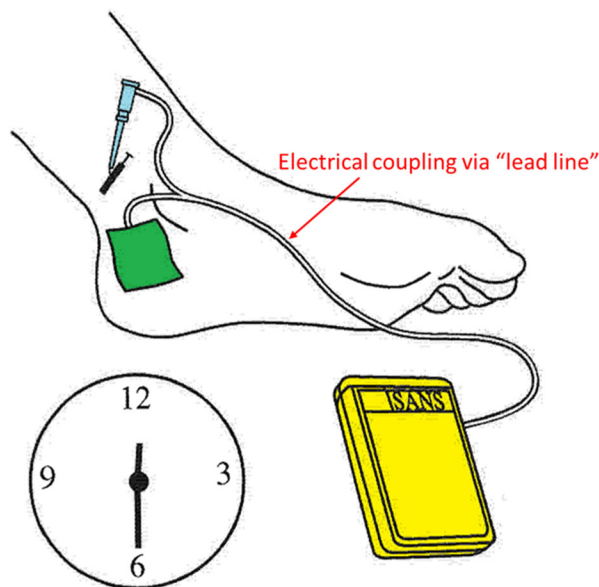


FIG. 3. Attach electrode and lead wire by placing electrode on same leg as needle near arch of foot. Connect grabber plug to needle on handle portion just above insertion point. Patient will control stimulation at comfortable level for 30 minutes.

Govier – Figure 3

84. Govier states that the stimulator is “connected to the needle” and, as shown in Figure 3 (above), a lead wire extends from the needle to the stimulator. *Id.* at 1194-95; *see also id.* at 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.* at 1194. Based on these descriptions, a person of ordinary skill in the art would have understood that the needle is “electrically coupled” to the stimulator (i.e., controller unit).

85. Moreover, the '338 patent confirms that Govier's needle is a “percutaneous electrode.” 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), like Govier's percutaneous needle. Ex. 1001 ('338 patent) at 26:66-27:16, Fig. 27.

86. Again, FIG. 27 of the '338 patent and FIG. 3 of Govier have been reproduced side-by-side below to show the similar configurations and positioning of the percutaneous electrode [blue] and the controller unit [yellow].

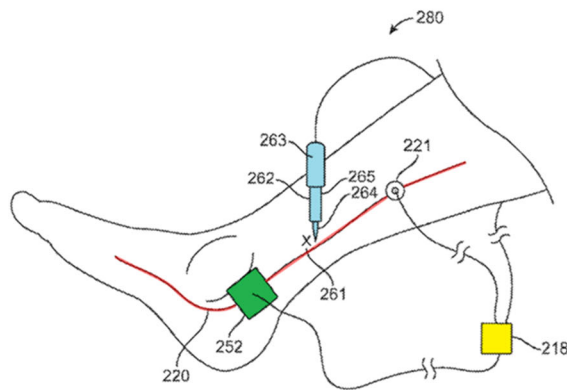
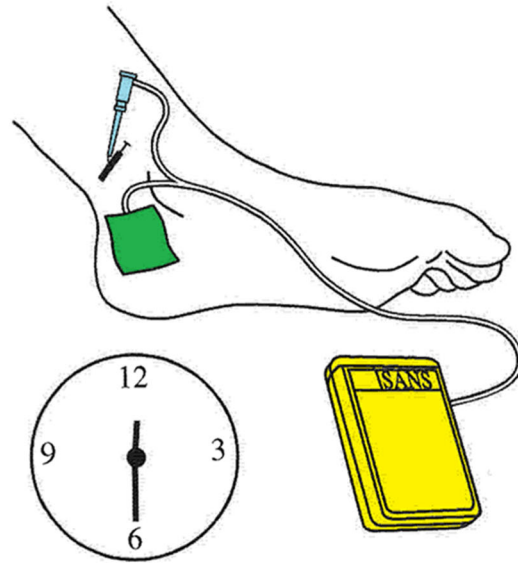


FIG. 27

'338 Patent – Figure 27



Govier – Figure 3

Based on the above, it is my opinion that if the '338 patent discloses this limitation, then so does Govier.

f. **“the percutaneous electrode having an end for inserting in proximity to a tibial nerve of the patient”**

87. Claim 1 next recites “the percutaneous electrode having an end for inserting in proximity to a tibial nerve of the patient.” Govier discloses this limitation.

88. Govier discloses placing the percutaneous needle electrode “near the tibial nerve 3 finger breadths above the ankle.” Ex. 1005 (Govier) at 1193. Govier further explains that this “point was about 1 finger breadth posterior from the edge of the tibia.” *Id.* at 1194. Govier continues that the needle was “advanced through the skin with the aid of an overlying plastic cylinder that was 3 mm shorter than the needle.” *Id.* “Once the skin was pierced the cylinder was removed, and the

needle was advanced approximately 3 to 4 cm posterior to the tibia and, if advanced further, would traverse anterior to the fibula.” *Id.* Therefore, Govier discloses a percutaneous electrode having an end for inserting in proximity to a tibial nerve of the patient.

89. Moreover, 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.

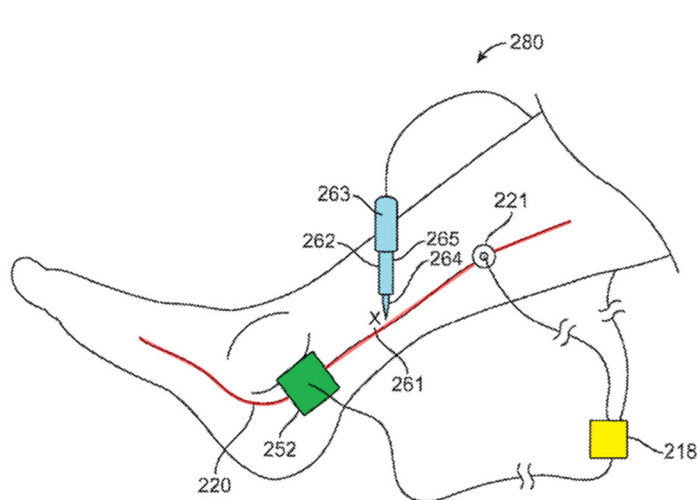


FIG. 27

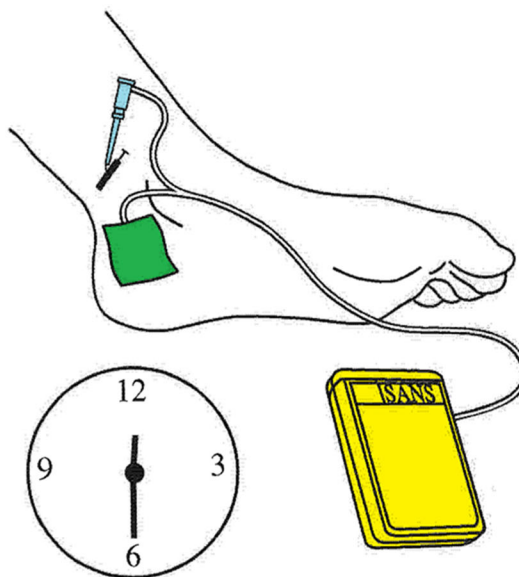


FIG. 3. Attach electrode and lead wire by placing electrode on same leg as needle near arch of foot. Connect grabber plug to needle on handle portion just above insertion point. Patient will control stimulation at comfortable level for 30 minutes.

'338 Patent – Figure 27

Govier – Figure 3

Ex. 1001 ('338 patent) at 26:66-27:16, Fig. 27; Ex. 1005 (Govier) at 1195 (Fig. 3).

Thus, it is my opinion that if the '338 patent discloses this limitation, Govier does too.

g. **“inserting the end of the percutaneous electrode into the skin in proximity to the tibial nerve of the patient”**

90. Claim 1 next recites “inserting the end of the percutaneous electrode into the skin in proximity to the tibial nerve of the patient.” Govier discloses this limitation.

91. As discussed in the section above, Govier discloses placing a percutaneous needle electrode “near the tibial nerve 3 finger breadths above the ankle.” Ex. 1005 (Govier) at 1193. Govier further discloses: “A 34 gauge, solid stainless steel needle was advanced through the skin with the aid of an overlying plastic cylinder that was 3 mm shorter than the needle. Once the skin was pierced the cylinder was removed, and the needle was advanced approximately 3 to 4 cm posterior to the tibia.” *Id.* at 1194. Therefore, Govier discloses inserting the end of the percutaneous electrode into the skin in proximity to the tibial nerve of the patient.

92. Moreover, as shown in the previous section, a side-by-side comparison of the embodiments in the ’338 patent (above left) and Govier (above right) illustrates that the percutaneous electrodes [blue] in both references are inserted at approximately the same location near the tibial nerve. Ex. 1001 (’338 patent) at 26:66-27:16, Fig. 27; Ex. 1005 (Govier) at 1195 (Fig. 3). Thus, it is my opinion that if the ’338 patent discloses this limitation, Govier does too.

h. “activating the pulse generator such that current pulses flow along the tibial nerve by passing between the electrode patch and the percutaneous electrode”

93. Claim 1 next recites “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. However, if Govier does not disclose this limitation, then Govier in combination with Williams renders this limitation obvious.

i. Govier Anticipates

94. 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 (Govier) at 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.* at 1194. Govier further discloses that the patient would control the current pulses using the stimulator for 30 minutes. *Id.*

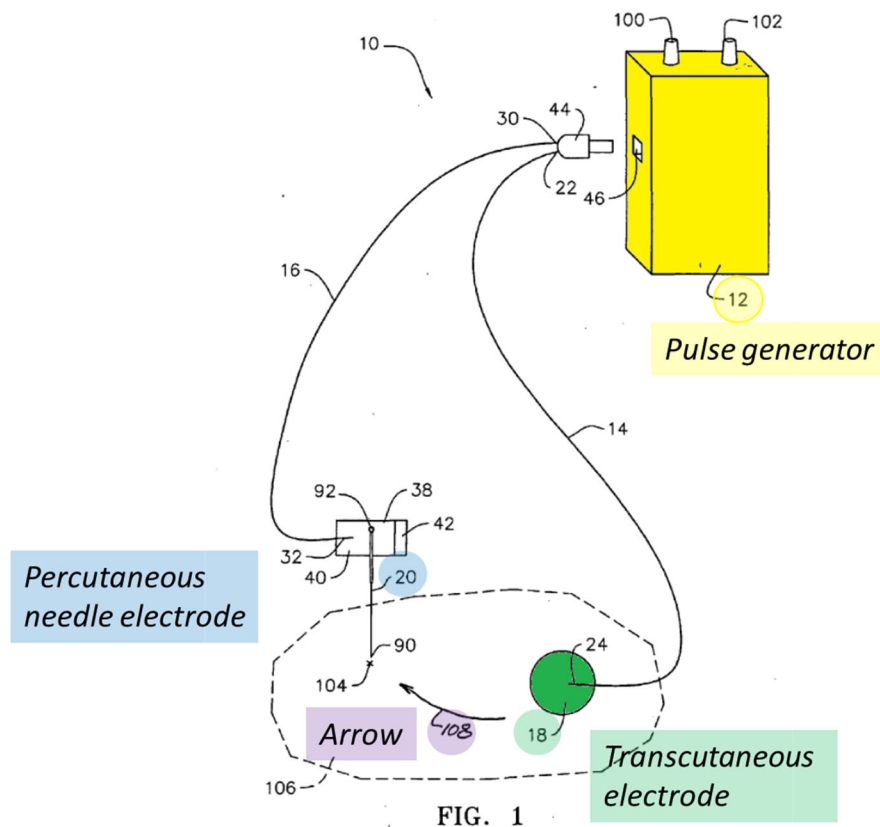
95. Govier also discloses that “[p]roper needle placement was confirmed with great toe flexion and/or fanning or plantar toe flexion of ipsilateral digits 2 through 5.” Ex. 1005 (Govier) at 1194. A person of ordinary skill in the art would

have understood that these toe behaviors would have indicated to the doctor that the current pulses were passing along the tibial nerve and between the percutaneous needle and electrode patch. As shown, for example, in Klingler Figure 1, the tibial nerve and branches thereof radiate out toward the toes. Stimulation of the nerve can cause the above toe behavior. Thus, based on these disclosures, a person of ordinary skill in the art 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.

96. I do not see a requirement in claim 1 that the current pulses must flow in a specific direction. For example, claim 1 does not say that the pulses flow *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, that Govier discloses this limitation. Without current flow between both electrodes, the tibial nerve could not be stimulated and the toes would not flex or fan. Further, a person of ordinary skill in the art would have appreciated that the current could flow in either direction and that the user could switch the direction of current flow by changing which electrode is the positive electrode, and which electrode is the negative electrode.

ii. **Govier and Williams Render Obvious**

97. If the current pulses must flow from the electrode patch to the percutaneous needle, then Govier in combination with Williams renders this limitation obvious. Williams discloses that the “pulse generator 12 is activated to generate current pulses.” Ex. 1006 (Willimas) at [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 [green] to the percutaneous needle electrode 20 [blue] as indicated by the arrow 108 [purple].” *Id.* at [0032], Fig. 1.



Williams – Figure 1

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

98. A person of ordinary skill in the art 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 in the above sections for the claim limitations (1) “applying an electrode patch to the skin such that the electrode patch is disposed on an outer surface of the skin” and (2) “the controller unit including a pulse generator.” 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 (Govier) at Fig. 3. Similarly, Williams discloses, “The transcutaneous electrode is adhered to the patient’s skin distal to the percutaneous electrode needle.” Ex. 1006 (Williams) at [0037]. For this additional reason, a person of ordinary skill in the art would have expected success in using Williams’s stimulation method in Govier.

99. Additionally, a person of ordinary skill in the art 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. A person of ordinary skill in the art would have found it obvious to use either finite option. A person of ordinary skill

in the art 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. This switch could have been accomplished by something as simple as switching the lead wires. Thus, a person of ordinary skill in the art would have expected success in transmitting current pulses in either direction. 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 ('338 patent) at 27:29-33.

i. “the current pulses configured to treat incontinence”

100. Claim 1 next recites “the current pulses configured to treat overactive bladder.” Govier discloses this limitation.

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 (Govier) at p. 1193 (Abstract). 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.* at 1193, 1198. Thus, Govier’s current pulses were configured to treat incontinence.

2. Independent Claim 2

102. Independent Claim 2 is anticipated by Govier. If Govier does not disclose each limitation of claim 2, claim 2 is also rendered obvious by Govier in combination with Williams.

a. Preamble – “A method”

103. The preamble of claim 2 simply recites “[a] method.” As explained in claim 1 above, Govier discloses a method of treating “overactive bladder” and urinary incontinence using electrical stimulation of the “tibial nerve.” Ex. 1005 (Govier) at p. 1193 (Abstract).

b. “positioning a transcutaneous electrode on skin of a patient in proximity to a tibial nerve”

104. Claim 2 next recites “positioning a transcutaneous electrode on skin of a patient in proximity to a tibial nerve.” Govier discloses this limitation. If Govier does not disclose this limitation, Govier in combination with Williams renders this limitation obvious.

105. The term “transcutaneous electrode” is not used in the specification of the ’338 patent. However, the ’338 patent does use the term “transcutaneous” near the word electrode in describing embodiments depicted in FIGS. 10 and 11,

stating: “the source of energy for nerve stimulation is electrical energy that is dispensed through a percutaneous stimulator, such as a percutaneous needle 124, or a transcutaneous stimulator, such as an electrode 126.” Ex. 1001 (’338 patent) at 16:30-34. As shown, the ’338 patent distinguishes “percutaneous” devices from “transcutaneous” devices. Further, we know from claim 1 that the percutaneous electrode is inserted “into the skin.” In contrast, claim 2 says that the transcutaneous electrode is positioned “on skin of a patient.” Based on these disclosures, it is my opinion that a person of ordinary skill in the art would have understood the term “transcutaneous electrode,” as used in claim 2, to have its ordinary and customary meaning of an electrode positioned on the patient’s skin. My understanding is confirmed by other references, like Williams, which describe a “transcutaneous electrode” as “an electrode which does not penetrate the surface of the skin.” Ex. 1006 (Williams) at [0004].

i. Govier Anticipates

106. Govier discloses applying an “electrocardiogram ground pad” [green] to the outer surface of the patient’s skin over the middle of the heel bone (i.e., calcaneus) and near the anklebone. Ex. 1005 (Govier) at p. 1194. The area around the patient’s heel and ankle bones is in proximity to the tibial nerve, a stimulation site of a patient. *See e.g.*, Ex. 1009 (Klingler) at Figure 1 (showing the tibial nerve

running along the heel and ankle). In my opinion, the “electrocardiogram ground pad” is a “transcutaneous electrode,” as required by claim 1.

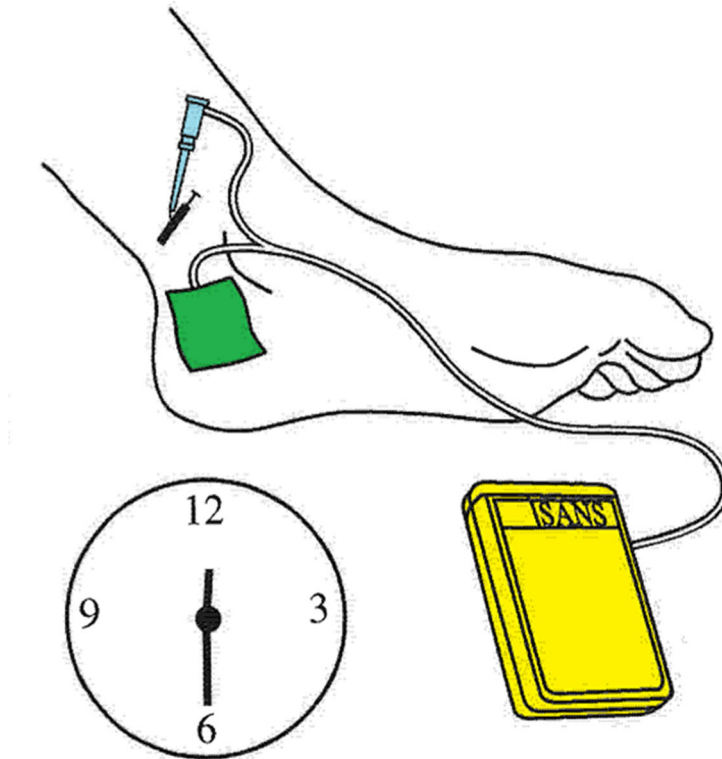


FIG. 3. Attach electrode and lead wire by placing electrode on same leg as needle near arch of foot. Connect grabber plug to needle on handle portion just above insertion point. Patient will control stimulation at comfortable level for 30 minutes.

Govier – Figure 3

107. Figure 3 (above) confirms that the electrocardiogram ground pad is a “transcutaneous electrode” because the caption to Figure 3 refers to the ground pad as an “electrode,” and Govier confirms that the ground pad is “placed over” the patient’s skin near the “medial aspect of the calcaneus.” Ex. 1005 (Govier) at p. 1194. Govier also confirms that “electrocardiogram type electrodes,” like the transcutaneous electrode shown in Figure 3, were well known in the art as of Govier’s publication. *See id.* at p.3 1193 (describing the 1983 study that created

“electrical stimulation via a stick on electrocardiogram type electrode with foam backing”).

108. Additionally, the disclosures in the '338 patent and Govier are very similar. As can be seen in the side-by-side comparison below, the patch 252 [green] in the '338 patent and Govier's electrode pad [green] are virtually identical in appearance and are positioned in virtually identical locations on an outer surface of the skin near the tibial nerve (labeled with reference numeral 220 [red] on FIG. 27 of the '338 patent).

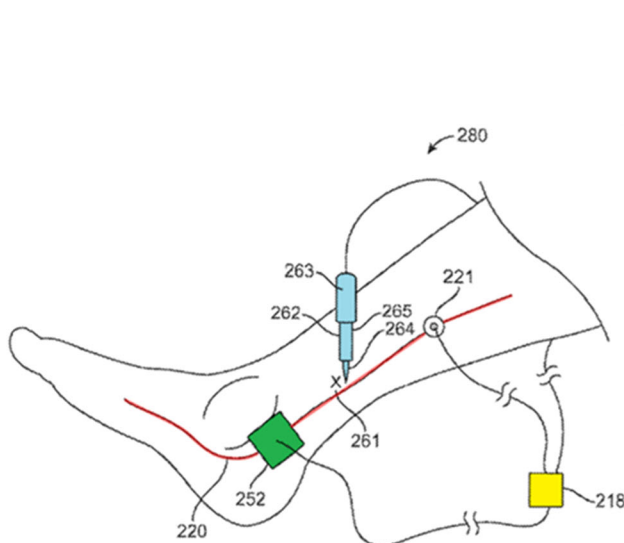
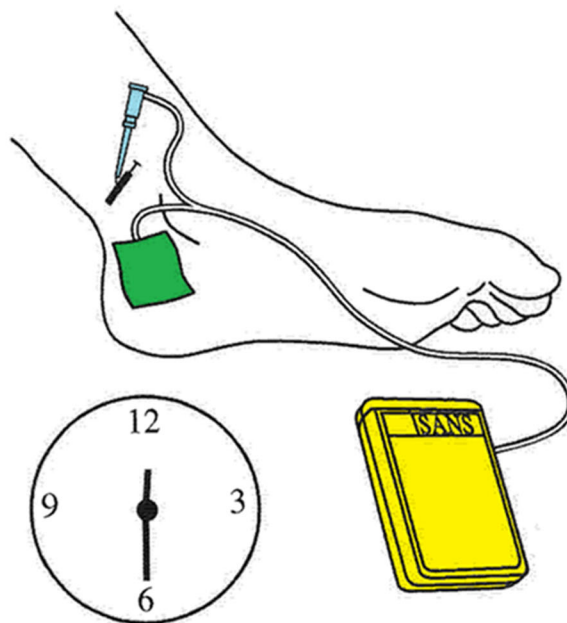


FIG. 27

'338 Patent – Figure 27

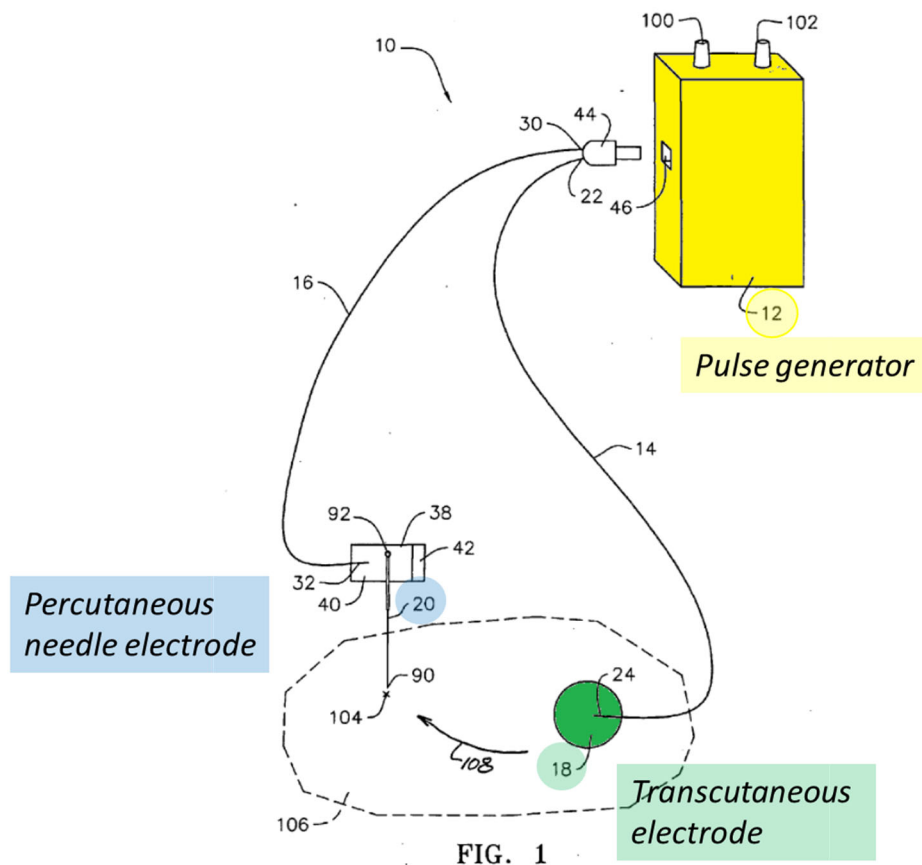


Govier – Figure 3

ii. Govier and Williams Render Obvious

109. If Govier does not disclose this limitation, it renders the limitation obvious in combination with Williams. 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 (Williams) at [0006], [0023], Fig. 1.



Williams – Figure 1

110. Williams discloses, “the transcutaneous electrode...is positioned and adhered to the patient’s skin distally proximate the stimulation site.” *Id.* at [0007]. Further, as explained above, Williams explains that a “transcutaneous electrode” is “an electrode which does not penetrate the surface of the skin.” *Id.* at [0004].

Williams explains that “[o]ne face of the transcutaneous electrode includes an electrically conductive medical grade adhesive to removably adhere the electrode to the patient’s skin near the desired stimulation site” and, as shown above, the electrode is in the form of a round patch. *Id.* at [0006], Fig. 1.

111. Williams further discloses that one specific stimulation site is in proximity to the tibial nerve. 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” and that the “transcutaneous electrode is adhered to the patient’s skin distal to the percutaneous needle electrode.” *Id.* at [0037]. Generally speaking, the medial malleolus is the bony protrusion sticking out of the inside of the foot and forms a part of the ankle, as would have been understood by a person of ordinary skill in the art. Thus, the percutaneous needle is positioned above the bony protrusion and the ground pad is placed over or just below the protrusion. Because the tibial nerve runs along the ankle (*see e.g.*, Ex. 1009 (Klingler) at Fig. 3), a person of ordinary skill in the art would have understood that Williams’ transcutaneous electrode was positioned on skin of a patient in proximity to a tibial nerve. For these reasons, Williams discloses the “transcutaneous electrode” required by claim 1.

112. A person of ordinary skill in the art would have been motivated to substitute Williams’s transcutaneous electrode for Govier’s ground pad, and

expected success in doing so, for the reasons I discussed in claim 1 for the limitation “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.” *Supra* ¶¶66-68.

c. **“inserting an end of a percutaneous needle electrode through the skin in proximity to the tibial nerve”**

113. Claim 2 next recites ““inserting an end of a percutaneous needle electrode through the skin in proximity to the tibial nerve.” Govier discloses this limitation.

114. 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 (Govier) at 1193; *see also id.*, 1194 (“A 34 gauge, solid stainless steel needle was advanced through the skin....”).) A person of ordinary skill in the art would have understood that 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 is inserted into the patient’s skin.

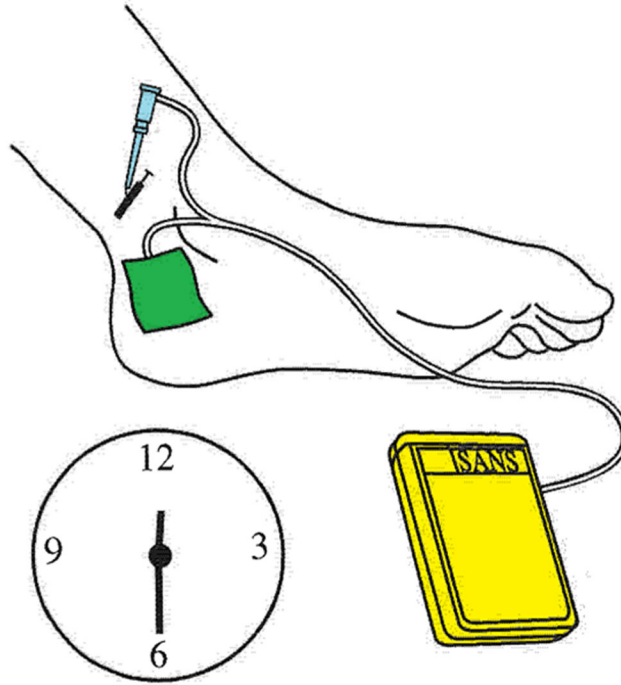
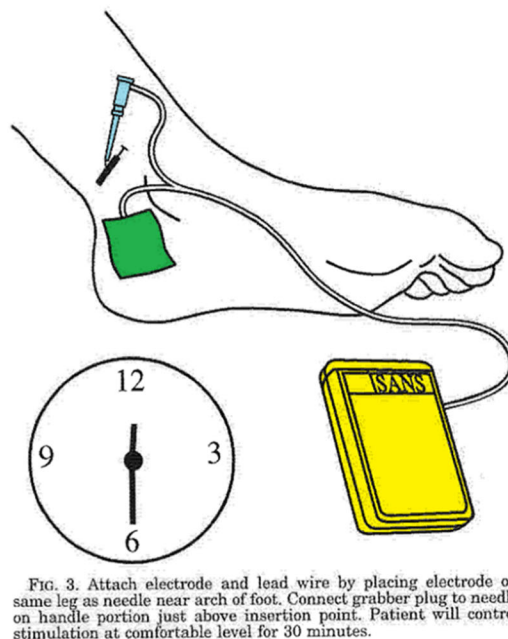
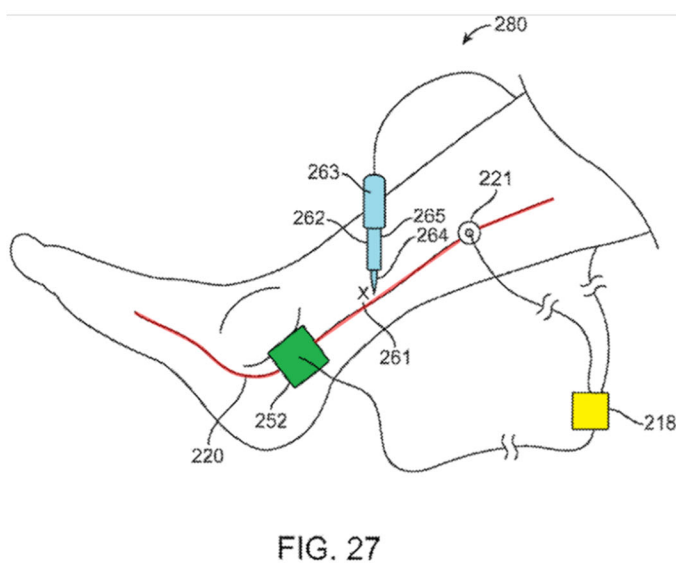


FIG. 3. Attach electrode and lead wire by placing electrode on same leg as needle near arch of foot. Connect grabber plug to needle on handle portion just above insertion point. Patient will control stimulation at comfortable level for 30 minutes.

Govier – Figure 3

115. Govier discloses placing the percutaneous needle electrode “near the tibial nerve 3 finger breadths above the ankle.” Ex. 1005 (Govier) at p. 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.* at 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.* Thus, Govier discloses inserting an end of a percutaneous needle electrode through the skin in proximity to the tibial nerve.

116. Additionally, 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.



'338 Patent – Figure 27

Govier – Figure 3

Ex. 1001 ('338 patent) at 26:66-27:16, Fig. 27; Ex. 1005 (Govier) at p. 1195 (Fig. 3). Thus, it is my opinion that if the '338 patent discloses this limitation, Govier does too.

d. “the percutaneous needle electrode including a wire disposed opposite the end”

117. Claim 2 next recites “the percutaneous needle electrode including a wire disposed opposite the end.” Govier discloses this limitation.

118. As shown in Figure 3 (below), Govier’s percutaneous needle electrode includes a wire disposed at the end opposite from the portion of the needle inserted into the patient:

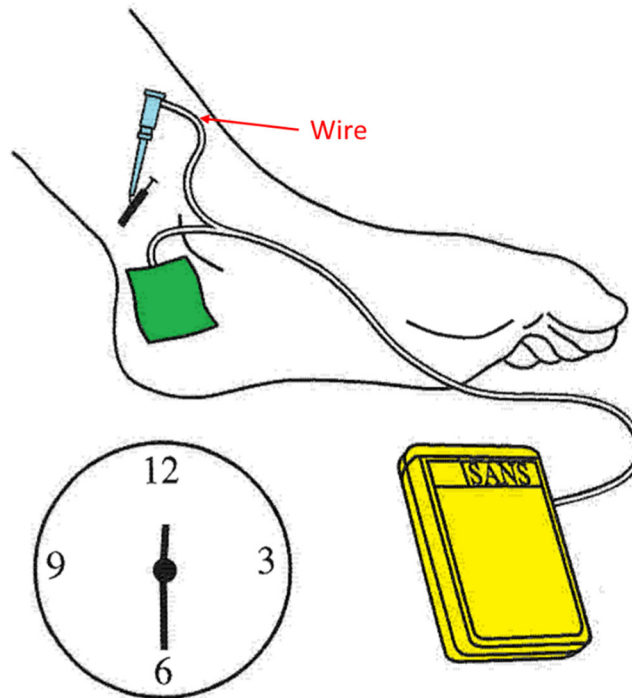


FIG. 3. Attach electrode and lead wire by placing electrode on same leg as needle near arch of foot. Connect grabber plug to needle on handle portion just above insertion point. Patient will control stimulation at comfortable level for 30 minutes.

Govier – Figure 3

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

e. **“securing a controller unit to the transcutaneous electrode such that the controller unit is electrically coupled to the transcutaneous electrode”**

119. Claim 2 next recites “securing a controller unit to the transcutaneous electrode such that the controller unit is electrically coupled to the transcutaneous electrode.” Govier discloses this limitation.

120. Govier states: “A stimulator was then connected to...the ipsilateral ground pad (fig. 3).” Ex. 1005 (Govier) at p. 1194. Govier’s stimulator [yellow] is the “controller unit” required by claim 2 for the reasons I provided in claim 1. *Supra* ¶¶70-73.

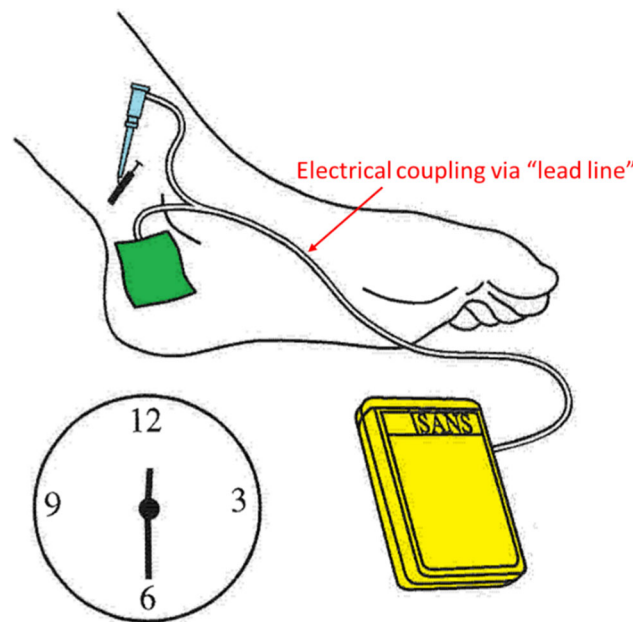


FIG. 3. Attach electrode and lead wire by placing electrode on same leg as needle near arch of foot. Connect grabber plug to needle on handle portion just above insertion point. Patient will control stimulation at comfortable level for 30 minutes.

Govier – Figure 3

121. 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 (Govier) at pp. 1194-1195. Govier further discloses that the patients also used the stimulator unit to control “the power setting for 30 minutes.” *Id.* at p. 1194; *see also id.* at p. 1195 (“Patient will control stimulation at a comfortable level for 30 minutes.”).)

122. As explained in 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. Ex. 1001 (’338 patent) at abstract, 5:45-51, 6:6-8, 23:52-57, 24:2-8. As discussed above, this is the function of Govier’s stimulator. Thus, Govier satisfies this limitation.

f. “the controller unit including a pulse generator”

123. Claim 2 next recites “the controller unit including a pulse generator.” This limitation also appeared in claim 1. *Supra* ¶¶74-81. Govier discloses this limitation, or renders the limitation obvious in view of Williams, for the reasons I previously described.

g. **“connecting the wire of the percutaneous needle electrode to the controller unit for electrically coupling the percutaneous needle electrode to the controller”**

124. Claim 2 next recites “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.

125. 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 (Govier) at p. 1193; *see also id.*, 1194 (“A 34 gauge, solid stainless steel needle was advanced through the skin....”).) A person of ordinary skill in the art would have understood that 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 is inserted into the patient’s skin.

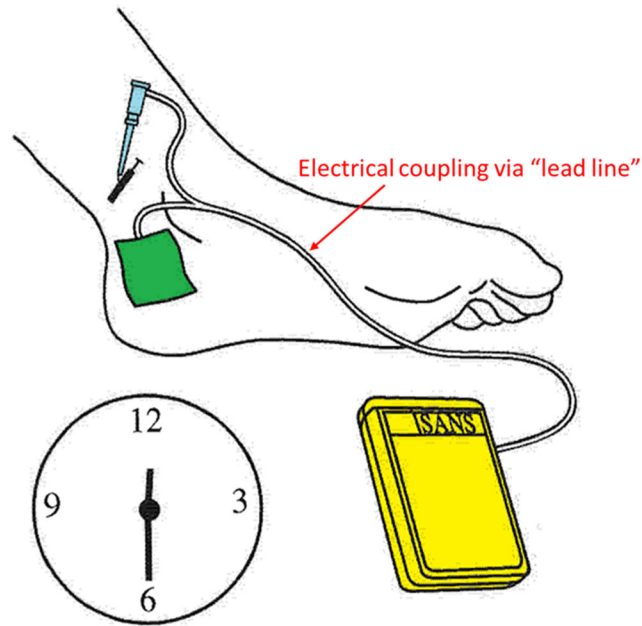


FIG. 3. Attach electrode and lead wire by placing electrode on same leg as needle near arch of foot. Connect grabber plug to needle on handle portion just above insertion point. Patient will control stimulation at comfortable level for 30 minutes.

Govier – Figure 3

126. Govier explains that the stimulator is “connected to the needle” and, as shown in Figure 3 (above), a lead wire extends from the needle to the stimulator. *Id.* at p. 1194-95; *see also id.* at p. 1195 (“Connect grabber plug to needle on handle portion just above insertion point.”). A person of ordinary skill in the art would have understood that the purpose of the wire was to electrically couple the stimulator to the needle. 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.* at p. 1194. Based on these descriptions, a person of ordinary skill in the art would have understood that the needle electrode is “electrically coupled” to the stimulator (i.e., controller unit).

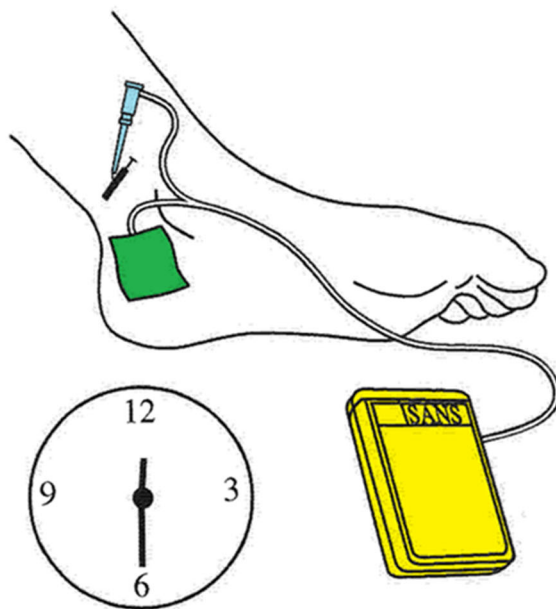
127. Also, Govier’s needle is a “percutaneous” needle electrode. Govier discloses that the needle is “advanced through the skin” and that “[o]nce the skin was pierced...the needle was advanced approximately 3 to 4 cm posterior to the tibia and, if advanced further, would traverse anterior to the fibula.” Ex. 1005 (Govier) at p. 1194. As I have explained elsewhere in this declaration, the ’338 patent uses “percutaneous” consistent with its ordinary and customary meaning to mean through the skin.

128. Again, FIG. 27 of the ’338 patent and Figure 3 of Govier have been reproduced side-by-side below to show the similarity between the configurations and placement of the percutaneous electrodes [blue] and controller units [yellow].



FIG. 27

'338 Patent – Figure 27



Govier – Figure 3

The similarity between these figures would also lead a person of ordinary skill in the art to understand that Govier discloses this limitation.

h. “activating the pulse generator such that current pulses flow along the tibial nerve by passing between the transcutaneous electrode and the percutaneous needle electrode”

129. Claim 2 next recites “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. If Govier does not disclose this limitation, Govier in combination with Williams renders this limitation obvious.

i. Govier Anticipates

130. 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 (Govier) at p. 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 tritrated from 0 to 10mA with fixed pulse 200 microseconds at frequency 20 Hz.” *Id.* at p. 1194. Govier further discloses that the patient would control the current pulses using the stimulator for 30 minutes. *Id.*

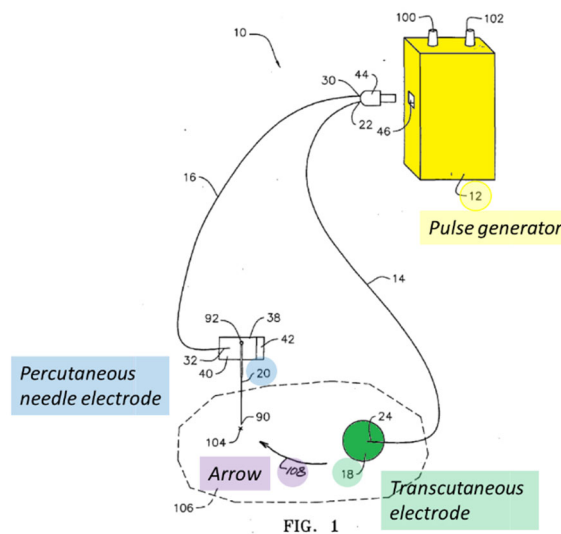
131. Govier also discloses that “[p]roper needle placement was confirmed with great toe flexion and/or fanning or plantar toe flexion of ipsilateral digits 2 through 5.” Ex. 1005 (Govier) at p. 1194. As I discussed in claim 1, these toe

behaviors would have indicated to the doctor that the current pulses were passing along the tibial nerve and between the percutaneous needle electrode and transcutaneous electrode. *Supra* ¶95. Thus, based on these disclosures, a person of ordinary skill in the art 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.

132. As in claim 1, claim 2 does not require the current pulses to flow in a specific direction (for example, *from* ground pad to percutaneous electrode). *Supra* ¶96. Rather, the claim merely requires the current pulses to pass “*between* the transcutaneous electrode and percutaneous needle electrode” and, thus, Govier discloses this limitation, as discussed in claim 1.

ii. Govier and Williams Render Obvious

133. If the current pulses must flow from the transcutaneous electrode to the percutaneous needle electrode, then Govier, in combination with Williams, renders the limitation obvious. As explained in claim 1, Williams discloses, “The current pulses from the pulse generator 12 traverse the internal stimulation site 104 by passing from the transcutaneous electrode 18 [electrode patch, green] to the percutaneous needle electrode 20 [percutaneous electrode, blue] as indicated by the arrow 108 [purple].” Ex. 1006 (Williams) at [0032], Fig. 1; *supra* ¶97.



Williams – Figure 1

Williams discloses that one of the stimulation sites is the tibial nerve. *Id.* at [0037].

134. A person of ordinary skill in the art would have been motivated to use Williams’s method in Govier’s system, and expected success in doing so, for the reasons I identified in claim 1. *Supra* ¶¶98-99.

i. “the current pulses configured to treat incontinence”

135. Claim 2 finally recites that “the current pulses configured to treat incontinence.” This limitation also appears in claim 1. *Supra* ¶¶100-101. Govier discloses this limitation for the reasons I previously identified in claim 1.

3. Dependent Claim 3 - “wherein the electrode patch is placed on an ankle of the patient”

136. 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. If Govier does not disclose this limitation, then Govier in combination with Williams discloses this limitation.

137. 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, at least partially, on the ankle [red]. Ex. 1005 (Govier) at 1194.

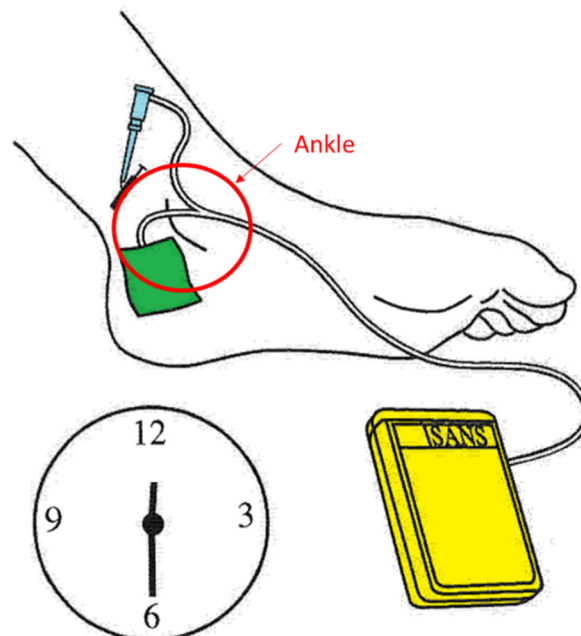


FIG. 3. Attach electrode and lead wire by placing electrode on same leg as needle near arch of foot. Connect grabber plug to needle on handle portion just above insertion point. Patient will control stimulation at comfortable level for 30 minutes.

Govier – Figure 3

It is my opinion that a person of ordinary skill in the art would have understood the ground pad (or electrode) pictured in Figure 3 to be placed on an ankle of the patient. The “electrocardiogram ground pad” is the “electrode patch” required by claim 1. *Supra* ¶¶60-63.

138. Williams also describes placing a transcutaneous electrode on an ankle of the patient. The transcutaneous electrode is the “electrode patch” required by claim 1. *Supra* ¶¶64-65. Williams discloses adhering the transcutaneous electrode to the patient’s skin distal to the percutaneous electrode needle. Ex. 1006 (Williams) at [0037]. Williams further discloses that 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 person of ordinary skill in the art 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 bony protrusion sticking out of the inside of the foot, and must be placed along the tibial nerve, which runs past the ankle. *See e.g.*, Ex. 1009 (Klingler) at Figure 1.

139. Further, a person of ordinary skill in the art would have understood that there are a finite number of locations to place the electrode patch to stimulate the tibial nerve. Consistent with Govier and Williams, Klingler discloses placing a “neutral surface electrode” over the patient’s ankle. Ex. 1009 (Klingler) at Fig. 1. The electrode is placed at this location because it must be placed in proximity to the tibial nerve, which runs past the ankle. *Id.* Thus, if Govier and Williams do not disclose placing an electrode patch “on an ankle of the patient,” a person of ordinary skill would have found it obvious to place the patch at this location.

4. **Dependent Claim 6 - “wherein the transcutaneous electrode is placed on an ankle of the patient”**

140. 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. If Govier does not disclose this limitation, then Govier in combination with Williams discloses this limitation.

141. As discussed in the previous section relating to claim 3, Govier’s Figure 3 discloses applying an “electrocardiogram ground pad” [green] to the outer surface of the patient’s skin near the heel bone (i.e., calcaneus) and, at least partially, on the ankle [red]. Ex. 1005 (Govier) at 1194; *supra* ¶137.

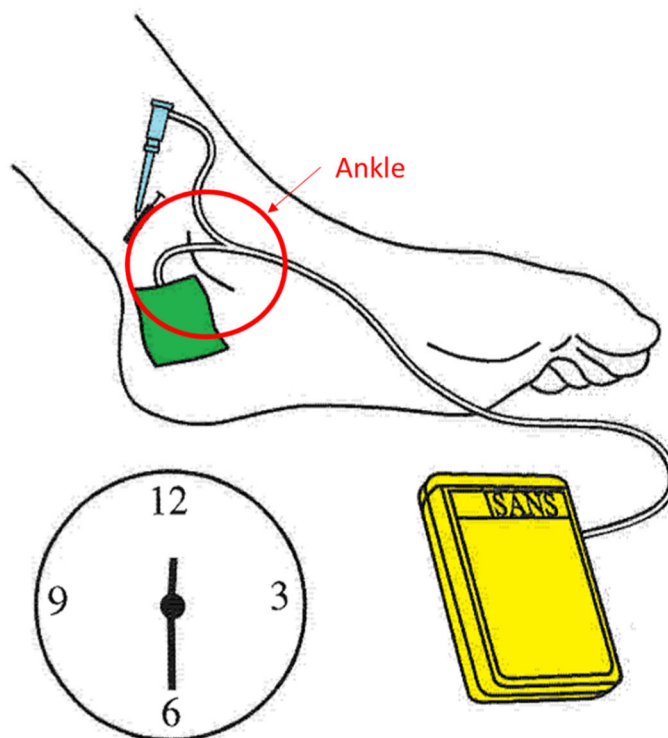


FIG. 3. Attach electrode and lead wire by placing electrode on same leg as needle near arch of foot. Connect grabber plug to needle on handle portion just above insertion point. Patient will control stimulation at comfortable level for 30 minutes.

Govier – Figure 3

The “electrocardiogram ground pad” is the “transcutaneous electrode” required by claim 2. *Supra* ¶¶106-108.

142. Williams also describes placing a transcutaneous electrode on an ankle of the patient. Williams discloses adhering the transcutaneous electrode to the patient’s skin distal to the percutaneous electrode needle. Ex. 1006 (Williams) at [0037]. Williams further discloses that 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 person of ordinary skill in the art 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 bony protrusion sticking out of the inside of the foot, and must be placed along the tibial nerve, which runs past the ankle. *See e.g.*, Ex. 1009 (Klingler) at Figure 1.

143. Further, a person of ordinary skill in the art would have understood that there are a finite number of locations to place the transcutaneous electrode to stimulate the tibial nerve. Consistent with Govier and Williams, Klingler discloses placing a “neutral surface electrode” over the patient’s ankles. Ex. 1009 (Klingler) at Fig. 1. The electrode is placed at this location because it must be placed in proximity to the tibial nerve, which runs past the ankle. *Id.* Thus, if Govier and Williams do not disclose placing a transcutaneous electrode “on an ankle of the

patient,” a person of ordinary skill would have found it obvious to place the patch at this location.

B. Claims 1-3 and 6 Are Anticipated By Williams Or Rendered Obvious By Williams Combined With Govier

1. Independent Claim 1

144. Independent Claim 1 is anticipated by Williams. To the extent Williams does not disclose each limitation of claim 1, claim 1 is also rendered obvious by Williams in combination with Govier.

a. Preamble – “A method”

145. The preamble of claim 1 recites “[a] method.” Williams discloses a method.

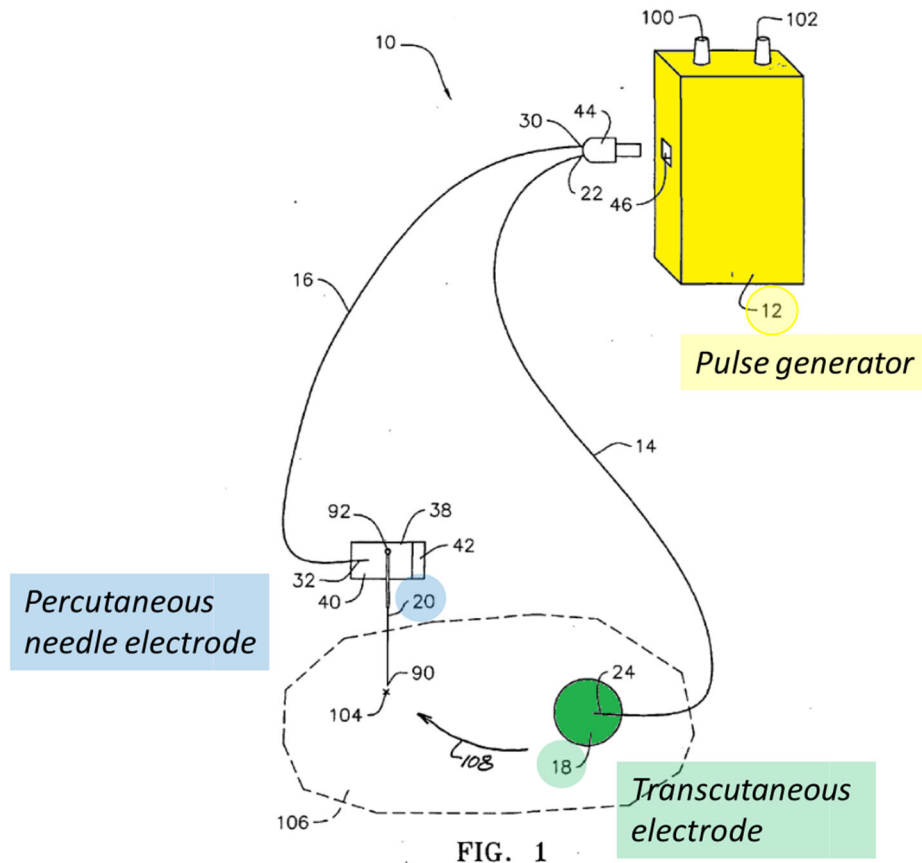
146. Williams discloses methods of using “electro-nerve stimulation systems utilizing transcutaneous and percutaneous electrodes” to treat “urinary urge incontinence.” Ex. 1006 (Williams) at [0002], [0037].

b. “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”

147. Claim 1 next recites “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.

148. 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 (Williams) at [0006], [0023], Fig. 1 (emphasis added).

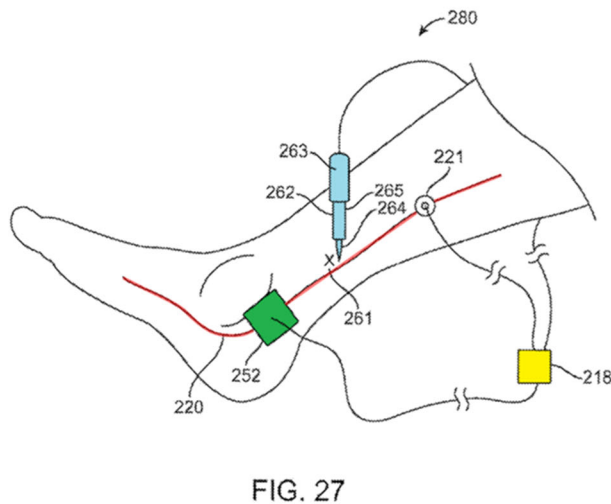


Williams – Figure 1

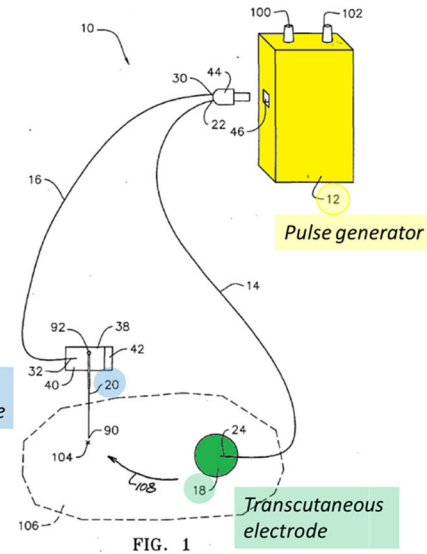
149. Williams’s “transcutaneous electrode” is the “electrode patch” required by claim 1. Williams explains that a “transcutaneous electrode” is “an electrode which does not penetrate the surface of the skin.” Ex. 1006 (Williams) at [0004]. Consistent with this description, Williams states, “the transcutaneous electrode...is positioned and adhered to the patient’s skin distally proximate the

stimulation site.” *Id.* at [0007]. 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 and described, the transcutaneous electrode is a round patch.

150. Moreover, it is my opinion that a person of ordinary skill in the art would have understood that the term “transcutaneous electrode” to be synonymous or interchangeable with the term “electrode patch,” as claimed in the ’338 patent. I do not see any disclosure in Williams or the ’338 patent that would lead a person of ordinary skill in the art to conclude that the terms refer to different structures. Rather, as can be seen in the side-by-side comparison of the disclosures below, the patch 252 [green] in the ’338 patent (which a person of ordinary skill in the art would understand to be an “electrode patch” as claimed) and Williams’s transcutaneous electrode [green] are similar in appearance and described to be positioned in similar positions on the skin.



'338 Patent – Figure 27



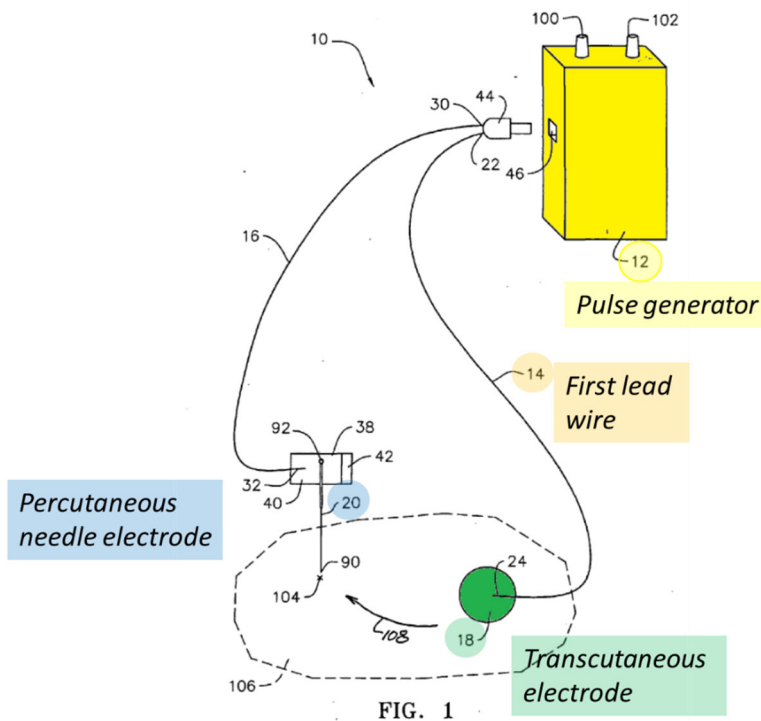
Williams – Figure 1

151. In addition, the '338 patent repeatedly refers to microneedle patches instead of electrode patches as used in Claim 1, including in connection with the examples describing current passing from a patch to an internal percutaneous electrode needle. The '338 patent states that “microneedles may be attached, deposited, or arrayed on an electrode surface or patch in a variety of configurations and arrangements, depending on where the particular microneedle patch will be utilized and the treatment to be delivered.” Ex. 1001 ('338 Patent) at 20:26-30. A person of ordinary skill in the art would have understood that a microneedle patch is a type of electrode patch and that electrode patches with or without microneedles were both well-known and could be used interchangeably as of October 2006.

c. “the electrode patch is electrically coupled with a controller unit”

152. Claim 1 next recites “the electrode patch is electrically coupled with a controller unit.” Williams discloses this limitation.

153. Williams discloses that a “pulse generator” is “electrically coupled...to an electrically conductive transcutaneous electrode.” Ex. 1006 (Williams) at [0006]; *see also id.* at [0024] (describing electrical coupling of elements). As I described in the previous section, the “transcutaneous electrode” is the “electrode patch” required by claim 1. Williams specifically describes a “first lead wire 14” [orange] that “electrically couples” the pulse generator 12 to the transcutaneous electrode 18. *Id.* at [0024].



Williams – Figure 1

154. 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.* at [0031]. Williams teaches that “[t]he pulse generator 12 is activated to generate current pulses.” *Id.* at [0032]. 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.

d. “the controller unit including a pulse generator”

155. Claim 1 next recites “the controller unit including a pulse generator.” Williams discloses this limitation.

156. As shown in Figure 1 above, Williams discloses “an electro-nerve stimulation system comprising a *pulse generator*.” Ex. 1006 (Williams) at [0006] (emphasis added). Williams discloses that the “pulse generator 12 is activated to generate current pulses.” *Id.* at [0032], Fig. 1.

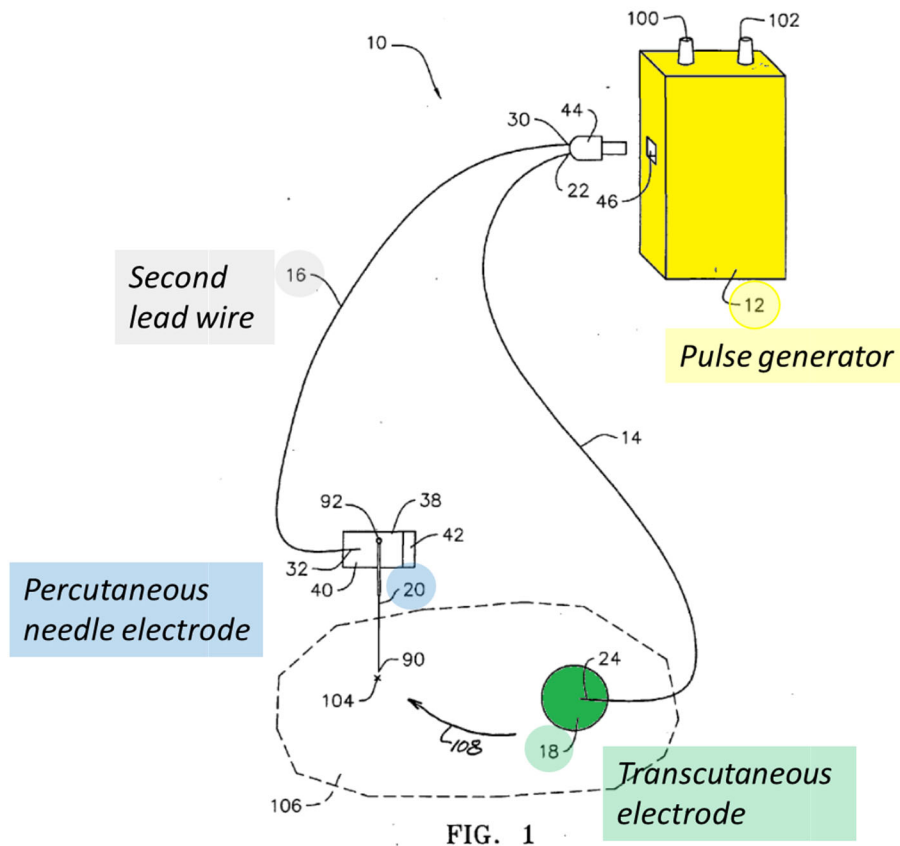
e. “electrically coupling a percutaneous electrode to the controller unit”

157. Claim 1 next recites “electrically coupling a percutaneous electrode to the controller unit.” Williams discloses this limitation.

158. Williams discloses “electro-nerve stimulation systems utilizing transcutaneous and *percutaneous electrodes*.” Ex. 1006 (Williams) at [0002] (emphasis added). In the preferred embodiment, Williams discloses that the

“percutaneous electrode” is “an electrically conductive percutaneous needle electrode 20.” *Id.* at [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.* at [0037]. Williams also discloses that a “percutaneous needle electrode 20 (FIG. 1) . . . includes a first end 90 for insertion into the patient’s body in proximity to the preselected internal stimulation site (discussed later).” *Id.* at [0030].

159. Williams also discloses that the “pulse generator” is “electrically coupled...to...an electrically conductive percutaneous needle electrode.” Ex. 1006 (Williams) at [0006]. Williams describes a “second lead wire 16” [gray] that “electrically couples” the pulse generator 12 to the percutaneous needle electrode 20. *Id.* at [0025]; *see also id.* at [0029] (describing connection between tape member 38 and electrode 20), [0032] (describing electrical coupling of pulse generator to electrode 20). A person of ordinary skill in the art would have understood that the purpose of the lead wires is to electrically couple the electrodes to the controller unit/pulse generator.

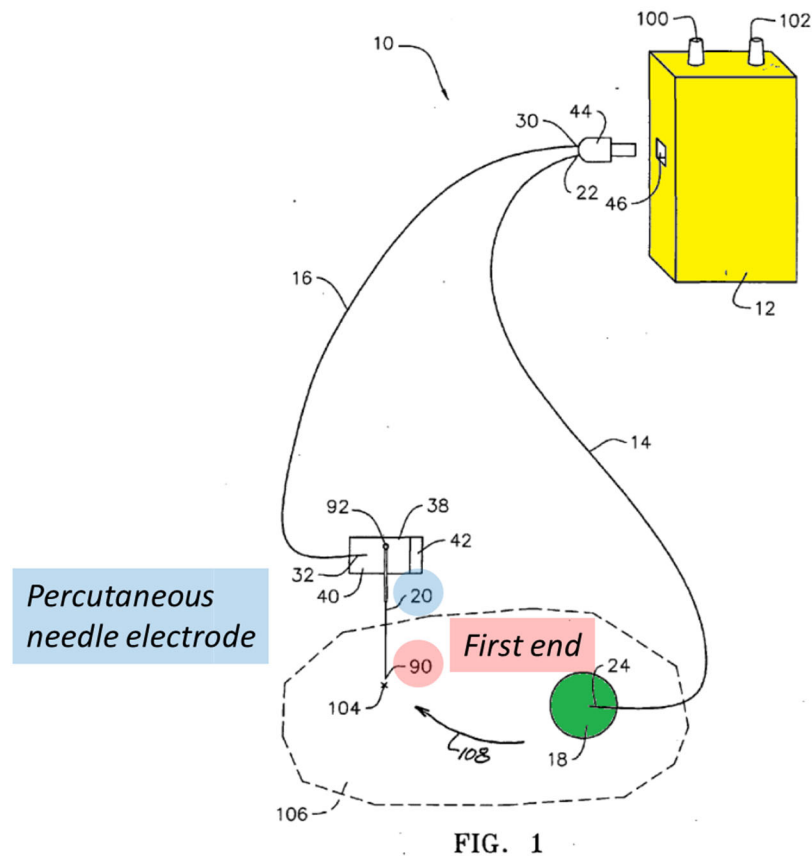


Williams – Figure 1

f. **“the percutaneous electrode having an end for inserting in proximity to a tibial nerve of the patient”**

160. Claim 1 next recites “the percutaneous electrode having an end for inserting in proximity to a tibial nerve of the patient.” Williams discloses this limitation.

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 (Williams) at [0030], Fig. 1.



Williams – Figure 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.* at [0037] (emphasis added).

g. “inserting the end of the percutaneous electrode into the skin in proximity to the tibial nerve of the patient”

162. Claim 1 next recites “inserting the end of the percutaneous electrode into the skin in proximity to the tibial nerve of the patient.” Williams discloses this limitation. 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 (Williams) at [0037] (emphasis added).

h. “activating the pulse generator such that current pulses flow along the tibial nerve by passing between the electrode patch and the percutaneous electrode”

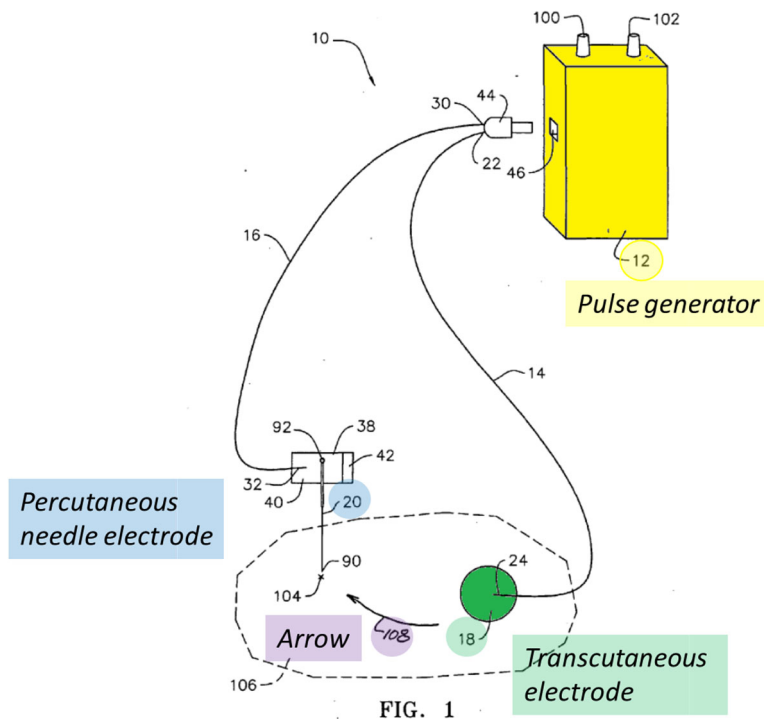
163. Claim 1 next recites “inserting the end of the percutaneous electrode into the skin in proximity to the tibial nerve of the patient.” Williams discloses this limitation. Additionally, Williams in combination with Govier renders this limitation obvious.

i. Williams Anticipates

164. 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 (Williams) at [0032].



Williams – Figure 1

165. As discussed in the prior section, Williams discloses that one “internal stimulation site” is the tibial nerve. *Id.* at [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.* Thus, Williams discloses inserting the end of the percutaneous electrode into the skin in proximity to the tibial nerve of the patient.

166. 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. This is the same arrangement of

components depicted in Figure 27 and described in the '338 patent. Ex. 1001 ('338 patent) at 26:66-27:16, Fig. 27. For example, the '338 patent states that the electrode patch is positioned “downstream or distal to a selected stimulation site 261” and that the electrode needle 262 is inserted “at a location and to a depth that brings the tip in close proximity to the target nerve to be stimulated.” *Id.*

167. As can be seen in the side-by-side comparison of Fig. 27 of the '338 patent and Fig. 1 of Williams, the two electro-nerve stimulation systems have a similar connection setup, with the pulse generator [yellow] electrically coupled to both the electrode patch (transcutaneous electrode) [green] and the percutaneous needle electrode [blue].

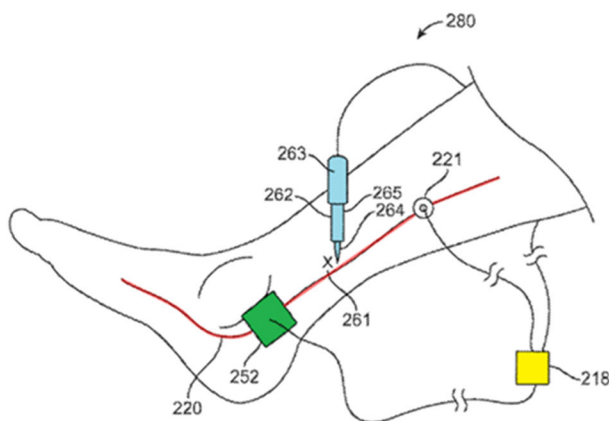


FIG. 27

'338 Patent - Figure 27

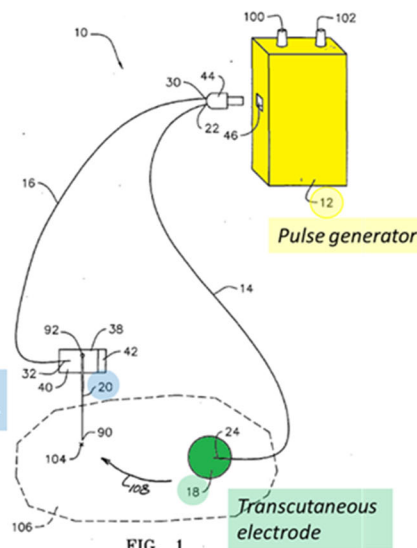


FIG. 1

Williams - Figure 1

Thus, it is my opinion that if the '338 patent discloses this limitation, so does Williams.

ii. Williams and Govier Render Obvious

168. Govier also discloses this limitation. *Supra* ¶¶94-96. 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 (Govier) at p. 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* ¶¶60-63, 82-86. A person of ordinary skill in the art would have been motivated to use Williams’s system to produce current pulses flow along the tibial nerve as described in Govier, and reasonably expected success in doing so, due to the similarities between the systems I have described previously. *Supra* ¶¶98-99.

i. “the current pulses configured to treat incontinence”

169. Claim 1 next recites “the current pulses configured to treat incontinence.” Williams discloses this limitation.

170. Williams discloses that the described system is “particularly suited for the treatment of urinary urge incontinence.” Ex. 1006 (Williams) at [0037].

2. Independent Claim 2

171. Claim 2 is anticipated by Williams or rendered obvious by Williams in combination with Govier.

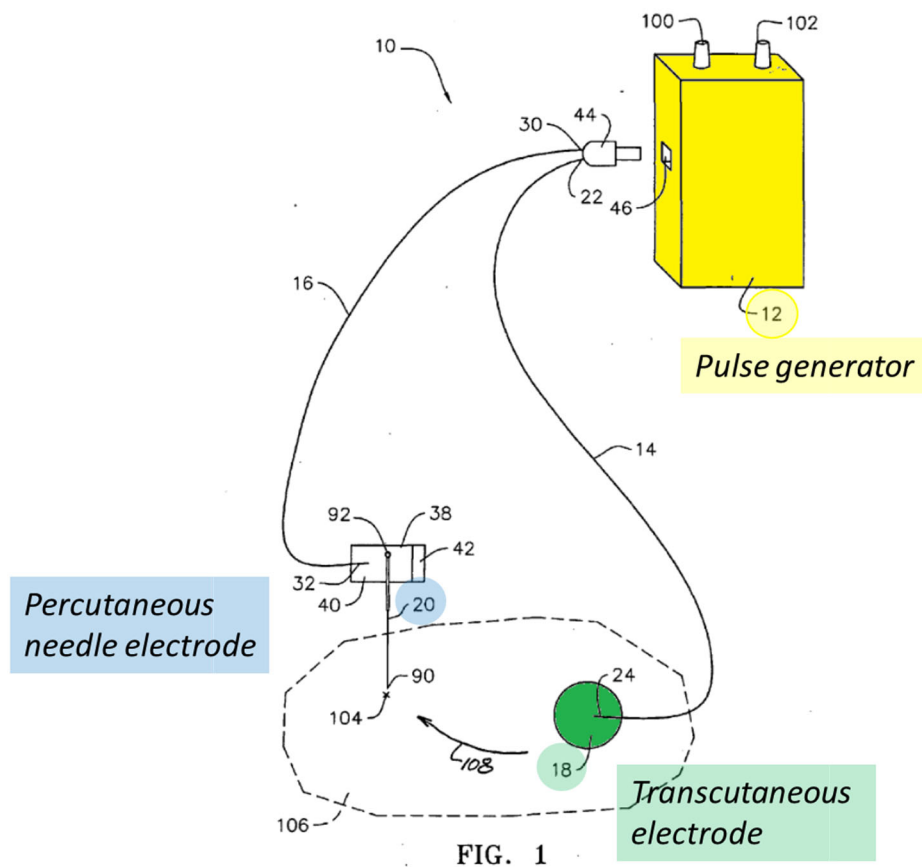
a. **Preamble – “A method”**

172. The preamble of claim 2 recites “[a] method.” Williams discloses this limitation. Williams discloses methods of using “electro-nerve stimulation systems utilizing transcutaneous and percutaneous electrodes” to treat “urinary urge incontinence.” Ex. 1006 (Williams) at [0002], [0037].

b. **“positioning a transcutaneous electrode on skin of a patient in proximity to a tibial nerve”**

173. Claim 2 next recites “positioning a transcutaneous electrode on skin of a patient in proximity to a tibial nerve.” Williams discloses this limitation.

174. 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 (Williams) at [0006], [0023], Fig. 1 (emphasis added).

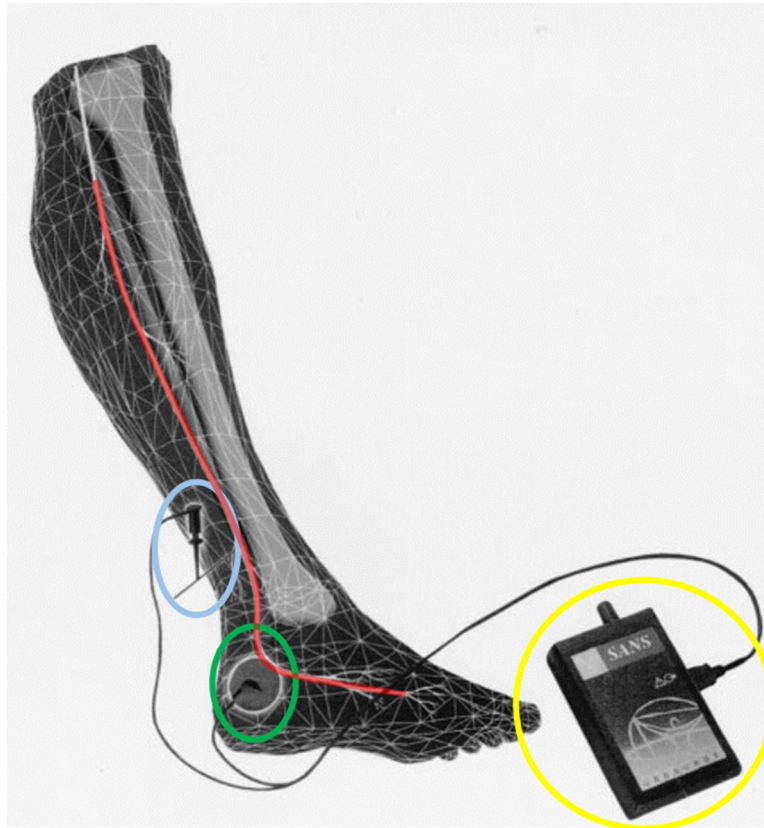


Williams – Figure 1

175. Williams’s “transcutaneous electrode” satisfies this claim limitation. Williams describes the “transcutaneous electrode” as “an electrode which does not penetrate the surface of the skin.” Ex. 1006 (Williams) at [0004]. As explained previously, this description is consistent with the ordinary and customary meaning of the term “transcutaneous.” *Supra* ¶110. Williams also states, “the transcutaneous electrode...is positioned and adhered to the patient’s skin distally proximate the stimulation site.” *Id.* at [0007]. 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.* at [0006], Fig. 1. As shown in Figure 1 above, the transcutaneous electrode is a round patch.

176. Williams also discloses positioning the transcutaneous electrode in proximity to the tibial nerve. Williams discloses that the “transcutaneous electrode is adhered to the patient's skin distal to the percutaneous needle electrode.” Ex. 1006 (Williams) at [0037]. The “percutaneous needle electrode 20 is inserted into the patient's skin in proximity to the tibial nerve cephalic to the medial malleolus.” *Id.* The medial malleolus is the bony protrusion sticking out of the inside of the foot and forms a part of the ankle, as would have been understood by a person of ordinary skill in the art. Thus, a person of ordinary skill in the art would have understood that the transcutaneous electrode must be positioned in proximity to a tibial nerve, or a branch thereof, because the tibial nerve runs distally down the foot, which is where the transcutaneous electrode is located. The path of the tibial nerve is shown in, for example, Klingler Figure 1.



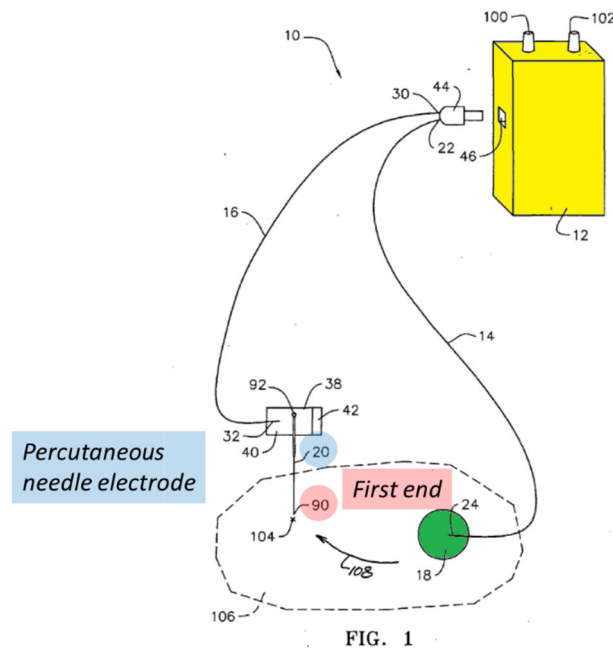
Klingler – Figure 1

Klingler generally shows a transcutaneous electrode [green] in the position described by Williams. Moreover, a person of ordinary skill in the art would have recognized that the transcutaneous electrode must be located in proximity to the tibial nerve in order for the system to stimulate the tibial nerve.

c. **“inserting an end of a percutaneous needle electrode through the skin in proximity to the tibial nerve”**

177. Claim 2 next recites “inserting an end of a percutaneous needle electrode through the skin in proximity to the tibial nerve.” Williams discloses this limitation.

178. Williams discloses “electro-nerve stimulation systems utilizing transcutaneous and *percutaneous electrodes*.” Ex. 1006 (Williams) at [0002]. In the preferred embodiment, Williams discloses that the “percutaneous electrode” is “an electrically conductive percutaneous needle electrode 20.” *Id.* at [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.* at [0030], Fig. 1.



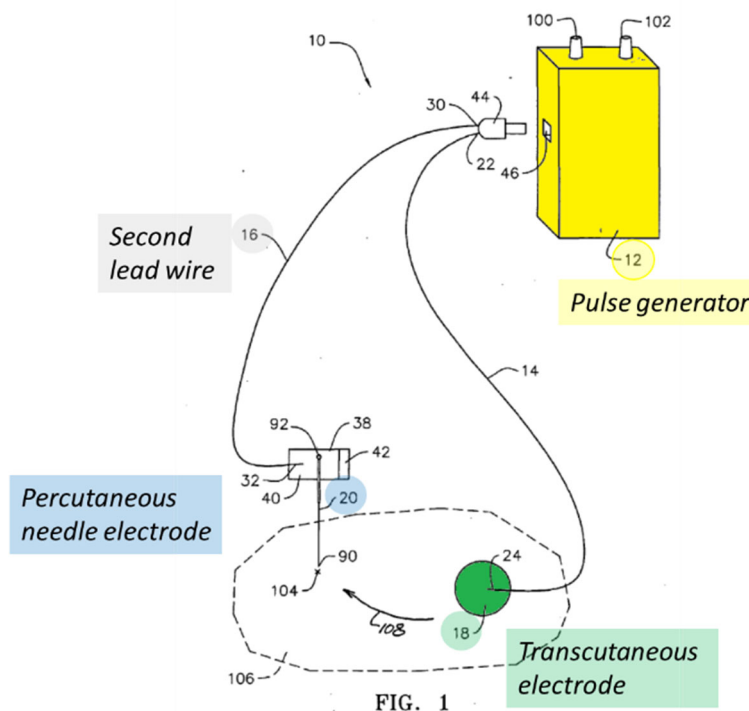
Williams – Figure 1

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.* at [0037] (emphasis added).

d. **“the percutaneous needle electrode including a wire disposed opposite the end”**

179. Claim 2 next recites “the percutaneous needle electrode including a wire disposed opposite the end.” Williams discloses this limitation.

180. Williams discloses that the percutaneous needle electrode 20 includes an adaptor or clip (38 or 130) and a “second lead wire 16” [gray] at an end that is opposite end 90. Ex. 1006 (Williams) at [0025]. The second lead wire 16 “electrically couples” the percutaneous needle electrode 20 to the pulse generator 12. *Id.*; see also *id.* at [0029] (describing connection between tape member 38 and electrode 20), [0032] (describing electrical coupling of pulse generator to electrode 20), claims 1, 24.

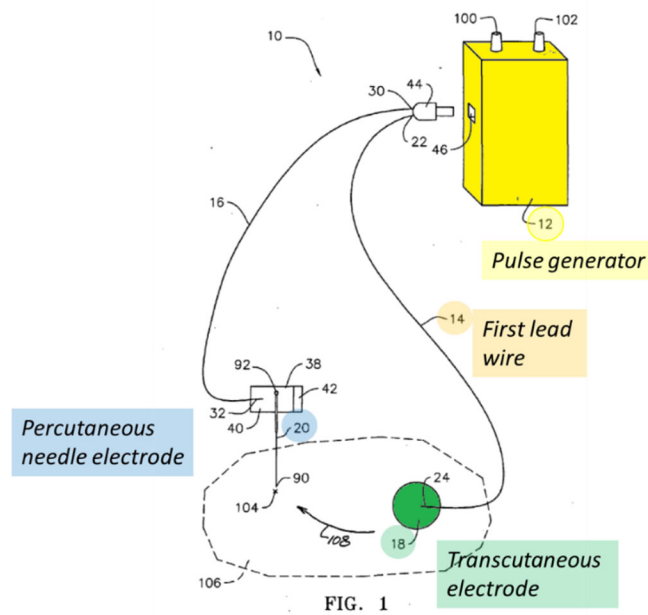


Williams – Figure 1

e. **“securing a controller unit to the transcutaneous electrode such that the controller unit is electrically coupled to the transcutaneous electrode”**

181. Claim 2 next requires “securing a controller unit to the transcutaneous electrode such that the controller unit is electrically coupled to the transcutaneous electrode.” Williams discloses this limitation.

182. Williams discloses that a “pulse generator” is “electrically coupled ... to an electrically conductive transcutaneous electrode.” Ex. 1006 (Williams) at [0006]; *see also id.* at [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. *Id.* at [0024]. A person of ordinary skill in the art would have understood that the lead wires are present to electrically couple the components.



Williams – Figure 1

183. 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.* at [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. *Supra* ¶73 (describing use of “controller unit” in ’338 patent).

f. “the controller unit including a pulse generator”

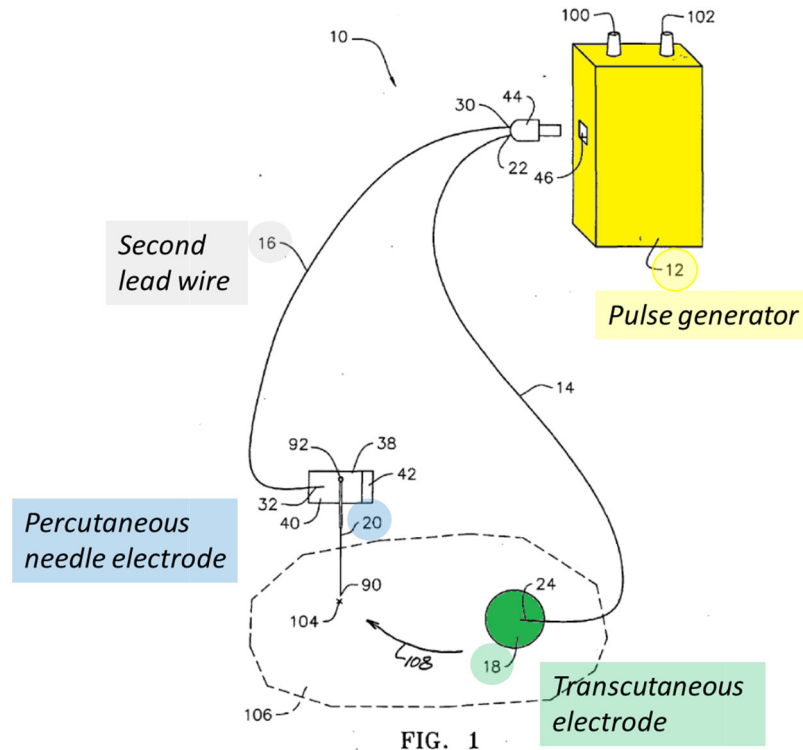
184. Claim 2 next recites “the controller unit including a pulse generator.” This limitation also appears in claim 1. *Supra* ¶¶155-156. Williams discloses this limitation for the reasons I previously provided.

g. “connecting the wire of the percutaneous needle electrode to the controller unit for electrically coupling the percutaneous needle electrode to the controller”

185. Claim 2 next recites “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.

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

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



Williams – Figure 1

- h. **“activating the pulse generator such that current pulses flow along the tibial nerve by passing between the transcutaneous electrode and the percutaneous needle electrode”**

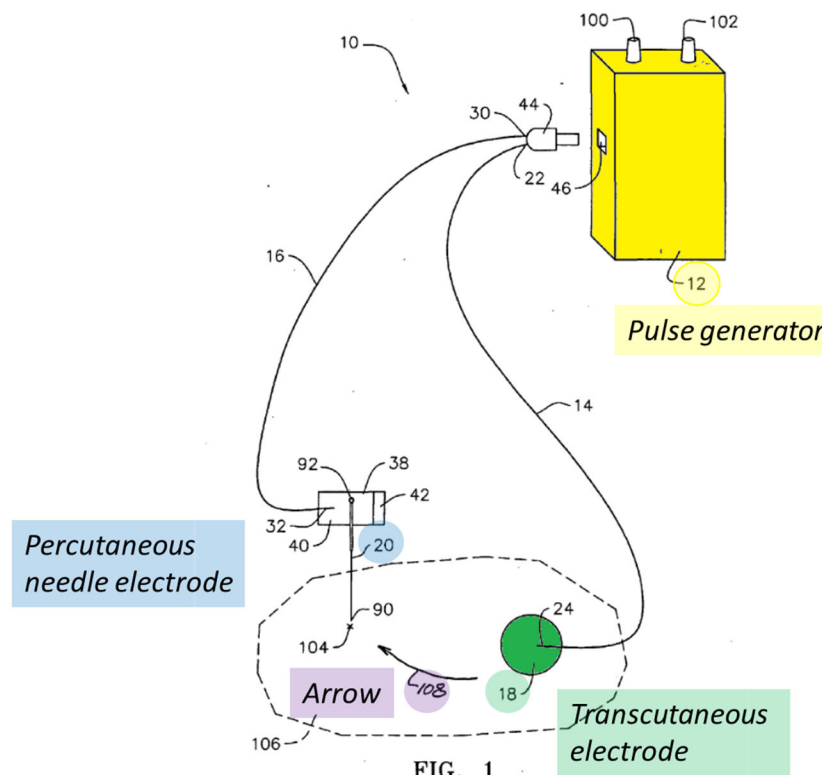
187. Claim 2 next recites “activating the pulse generator such that current pulses flow along the tibial nerve by passing between the transcutaneous electrode and the percutaneous needle electrode.” Williams discloses this limitation.

188. 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 (Williams) at [0032].



Williams – Figure 1

189. As discussed above, Williams discloses that one “internal stimulation site” is the tibial nerve. *Id.* at [0037]. In that 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.* Thus, Williams discloses activating the pulse generator such that current pulses flow along the tibial nerve, or a branch thereof, by passing between the transcutaneous electrode and the percutaneous needle electrode.

190. 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. 1001 (’338 patent) at 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.

i. “the current pulses configured to treat incontinence”

191. Claim 2 finally recites “the current pulses configured to treat incontinence.” This limitation also appears in claim 1. *Supra* ¶¶169-170. Williams discloses this limitation for the reasons I previously described in claim 1.

3. Dependent Claim 3 - “wherein the electrode patch is placed on an ankle of the patient”

192. Claim 3 depends from claim 1 and recites “wherein the electrode patch is placed on an ankle of the patient.” Williams discloses this limitation.

193. As I explained in claim 1, Williams’s “transcutaneous electrode” is the “electrode patch” required by claim 1. *Supra* ¶¶147-151. Williams states, “the transcutaneous electrode...is positioned and adhered to the patient’s skin distally proximate the stimulation site.” Ex. 1006 (Williams) at [0007]; *see also id.* at [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.* at [0037]. Based on this description, a person of ordinary skill in the art would have understood that the needle electrode was inserted near the top of the bony protrusion sticking out of the inside of the foot (medial malleolus) and the transcutaneous electrode was placed over the lower portion of the ankle (i.e., distal the needle electrode). The transcutaneous electrode would need to be placed on the ankle because the tibial nerve runs along the ankle. *See e.g.*, Ex. 1009 (Klingler) at Figure 1.

4. Dependent Claim 6 - “wherein the transcutaneous electrode is placed on an ankle of the patient”

194. Claim 6 depends from claim 2 and recites: “wherein the transcutaneous electrode is placed on an ankle of the patient.” Williams discloses this limitation.

195. As discussed in the prior section on claim 3, Williams states, “the transcutaneous electrode...is positioned and adhered to the patient’s skin distally proximate the stimulation site.” Ex. 1006 (Williams) at [0007]; *see also id.* at [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.* at [0037]. Based on this description, a person of ordinary skill in the art would have understood that the needle electrode was inserted near the top of the bony protrusion sticking out of the inside of the foot (medial malleolus) and the transcutaneous electrode was placed over the lower portion of the ankle (i.e., distal the needle electrode). The transcutaneous electrode would need to be placed on the ankle because the tibial nerve runs along the ankle. *See e.g.*, Ex. 1009 (Klingler) at Figure 3.

C. Claims 4-5 and 7-8 are Obvious over Govier in Combination With Mumford or Govier in Combination With Williams and Mumford

1. Introduction to Claims 4-5 and 7-8

196. 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 requires a wire extending from the controller unit to the electrodes to carry the electrical signal. For example, claim 2 specifically states “connecting the *wire* of the percutaneous needle electrode to the controller unit *for electrically coupling* the percutaneous needle electrode to the controller.” Claim 2 is consistent with the specification, which describes Figure 10 as illustrating an

“electrical pulse controller 128” that is “electrically connected to percutaneous needle 124” through a wire. Ex. 1001 (’338 patent) at 16:34-38, Fig. 10. Similarly, the specification differentiates between wired and wireless communications. *See e.g., id.* at 15:43-49. Thus, I understand claims 4-5 and 7-8 to require a wired connection between the controller unit and electrodes (i.e., an electrical coupling) and wireless communication between the controller unit and electrodes.

197. I understand this to be the case for an additional reason. Claims 1 and 2 state that the controller unit includes a pulse generator. The only way the controller unit could send the current pulses generated by the pulse generator to the electrodes (and thereby stimulate the nerve) would be through an electrical wire. Wireless communication alone would be insufficient to transmit the current pulses from the controller unit to the electrodes. I note that the ’338 patent says very little about the wireless communication between the controller unit and electrodes. The patent uses the term “wireless” or “wirelessly” only 6 times. Ex. 1001 (’338 patent) at 15:43-49, 18:29-34, 18:52-57, 20:2-6, 34:62-35:1, 35:1-7. In each case, the patent generally refers to a wireless signal, wireless connection, or wireless communication but does not provide any information regarding the hardware used to transmit the wireless signal and certainly does not disclose a method of transmitting current pulses wirelessly. Further, I note that the specification refers to “wireless” communications with sensors “that may detect voltage or current.”

Id. at 20:2-6, 34:62-35:1. This further influences my opinion that the claimed wireless communication involves the relay of information or data and not the transmission of a current pulse (which as I have described above is not possible).

198. Again, the '338 patent is silent regarding the hardware being used to wirelessly communicate with the electrodes. The '338 patent also does not disclose any benefits that result from wireless communication, any disadvantages for a wired system, or any reasons to use the claimed system having a wired connection and wireless communication. However, a person of ordinary skill in the art would have understood that the wireless connection could serve as a monitor for the current or could be used to detect action potentials when the wired connection is not stimulating.

199. To the extent a person of ordinary skill in the art wanted to wirelessly initiate current pulses using a pulse generator, the prior art discussed below discloses how to create such a system. Mumford, for example, discloses a “wireless stimulator 32” that includes, among other things, “a stimulation generation unit 36, a stimulation transceiver 38 with an antenna 40,” and a “battery 46.” Ex. 1019 (Mumford) at [0034]. In the below example, the stimulation generation unit 36 is a pulse generator. *Id.* at [0035].

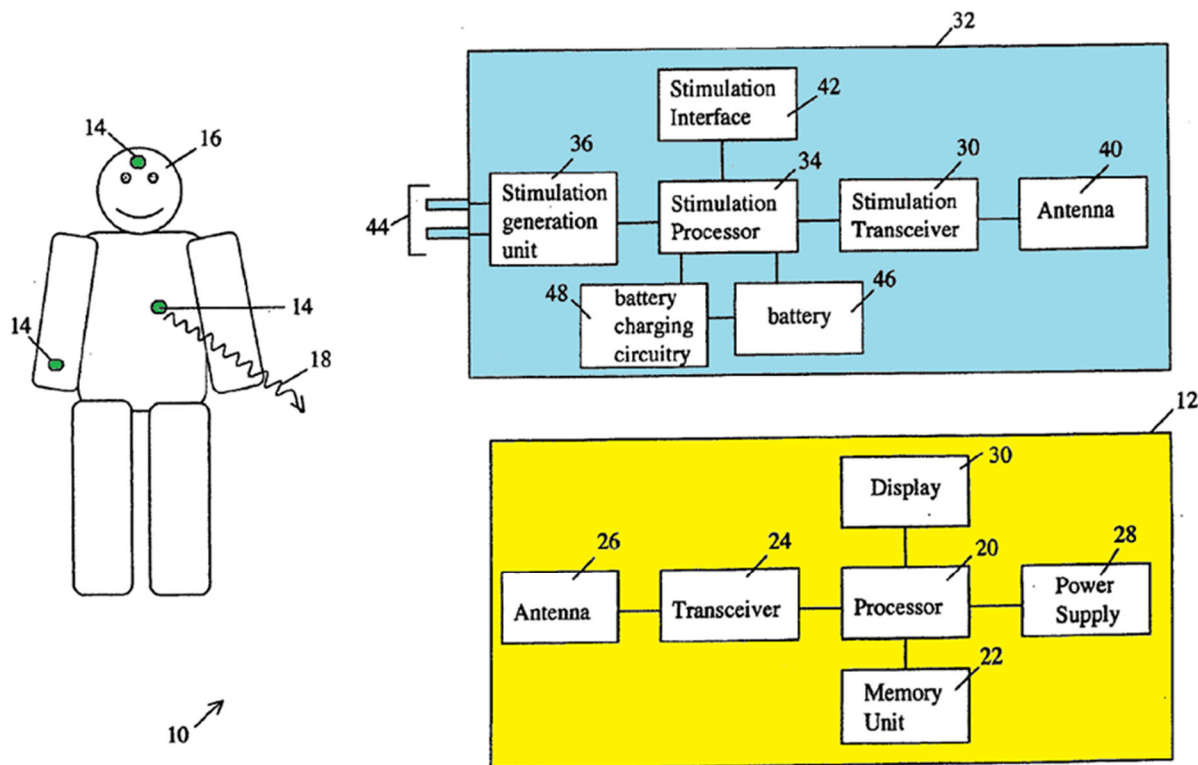


FIGURE 1

Mumford – Figure 1

The wireless stimulator 32 can “generate a stimulation current when the stimulation transceiver 38 receives an appropriate command signal form the monitoring device 12....” *Id.* at [0034]. Sarwal discloses another device in Figure 13, which can also create current pulses and can receive wireless communications. Ex. 1020 (Sarwal) at 10:66-19, Fig. 13. Both of these references provide significantly more information regarding how to wirelessly communicate with an electrode device than the ’338 patent.

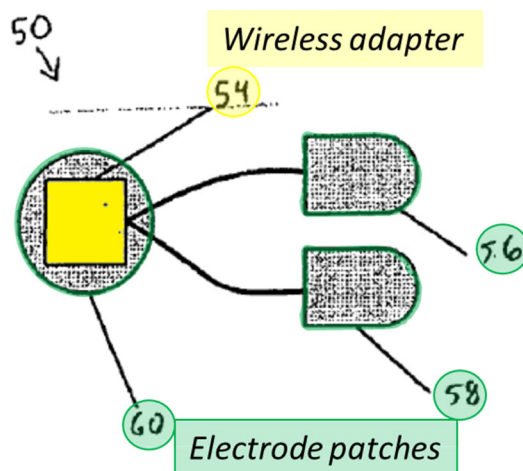
200. As discussed below, the prior art discloses methods of adapting wired electrodes for wireless communication. Moreover, the prior art discloses methods

of wirelessly communicating with an electrode having an integrated pulse generator and battery.

2. **Dependent Claim 4 - “wherein the controller unit communicates wirelessly with the electrode patch”**

201. 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.

202. Mumford discloses, “the wireless sensor [green in Figure 1 above] may be a wireless surface electrode assembly.” Ex. 1019 (Mumford) at [0007]. In a preferred embodiment, the wireless surface electrode assembly includes three conductive electrodes [green] and a wireless adapter 54 [yellow]. *Id.* at [0040].



Mumford – Figure 2a

The electrodes further include “an adhesive portion” to attach the electrodes to the patient’s skin. *Id.* at [0043]. As shown in Figure 2a above, Mumford’s electrode 60 forms a round patch. 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.* at [0050]-[0056], Fig. 4.

203. Mumford discloses that the monitoring device 12 [yellow in Figure 1 below] “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.” *Id.* at [0030]. Similarly, Mumford explains that “[d]uring operation, the wireless sensors 14 are instructed by the monitoring device 12 to start and stop data transmission so that power and bandwidth is not wasted.” *Id.* at [0059].

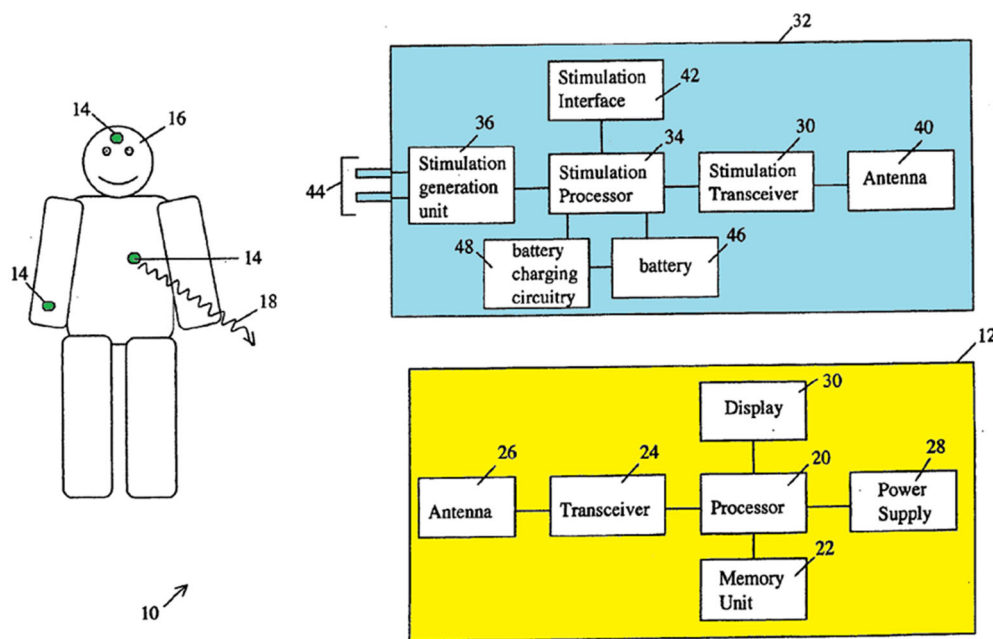


FIGURE 1

Mumford – Figure 1

Mumford’s “transceiver 24 operates according to a suitable wireless communication protocol,” such as “the Bluetooth communication protocol.” (*Id.*; *see also id.*, [0057]-[0062] (describing Bluetooth communication).) A person of ordinary skill in the art would have understood that Mumford’s monitoring device 12 is a controller unit because it controls the operation of the wireless sensors by wirelessly communicating with the wireless adapter attached to the sensors. Thus, Mumford discloses a controller unit that communicates wirelessly with one or more electrode patches.

204. Mumford also discloses a “wireless stimulator 32 [blue] for performing certain diagnostic tests on the patient 16 such as nerve conduction velocity tests.” *Id.* at [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.* at [0034]; *see also id.* at [0036] (“The stimulation interface 42 allows a medical practitioner to control the wireless stimulator.”).

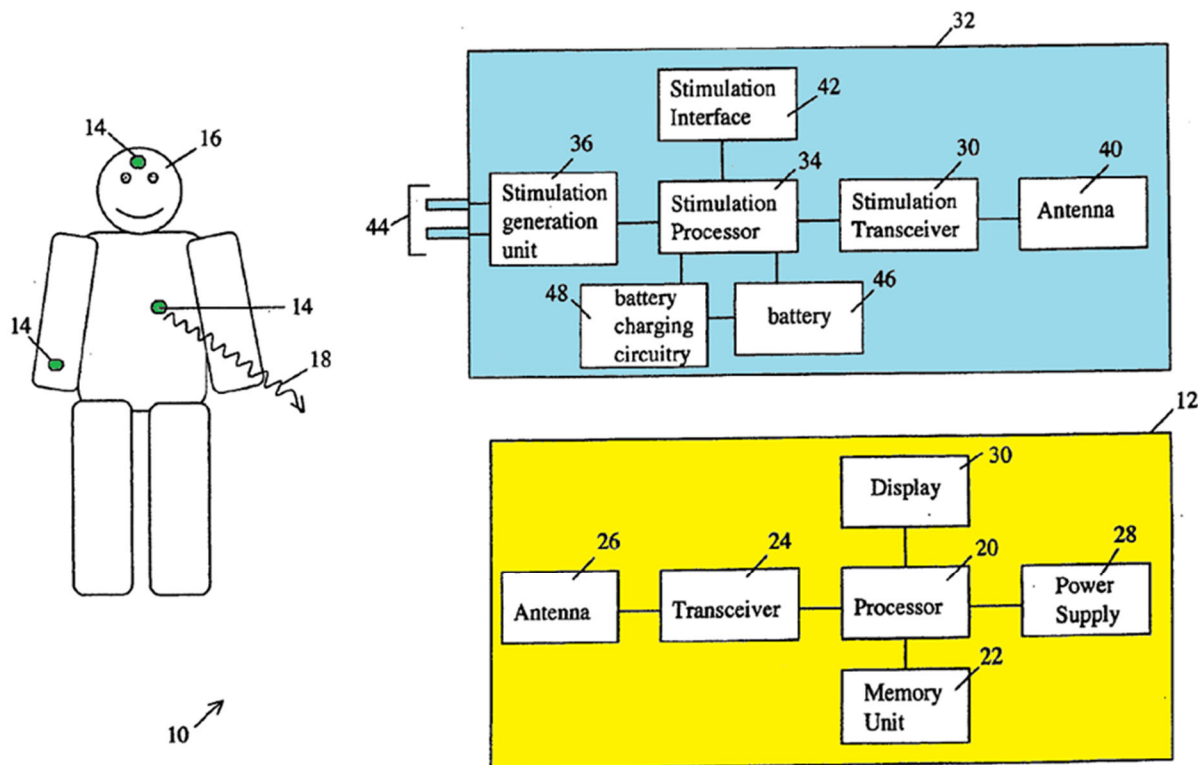


FIGURE 1

Mumford – Figure 1

205. Mumford explains, “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.* at [0037]. Each prong on the stimulator is an electrode (e.g., cathode terminal and anode terminal). *Id.* Mumford further discloses that the wireless stimulator can be equipped with adapter connections “to stimulate through smaller external electrodes or needles for cases in which the prongs 44 are not appropriate.” *Id.* at [0037]. A person of ordinary skill in the art would have understood that the prongs could also be exchanged for electrode patches. The patches would serve the same purpose as the prongs and, like the

prongs, would be applied to the patient's skin. Thus, Mumford provides a second example of a controller unit (monitoring device 12) that communicates wirelessly with an electrode.

206. A person of ordinary skill in the art would have been motivated to combine Mumford's wireless communication system (i.e., Bluetooth or another suitable wireless communication protocol and wireless adapter) with the electrodes in Govier and Williams for a number of reasons. 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 (Mumford) at [0006], [0033], [0039]; Ex. 1005 (Govier) at 1193-94; Ex. 1006 (Willaims) at [0007], [0037].

207. Additionally, Mumford describes the disadvantages of wired connections between sensors and a controller unit. Ex. 1019 (Mumford) at [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 person of ordinary skill in the art to modify Govier's and Williams's systems, which include wired connections between the

controller unit and the electrodes, to utilize the wireless communication system disclosed in Mumford. Moreover, just as the wired system could act as a backup for the wireless system, the reverse is also true.

208. Additionally, Mumford discloses that wireless communication is enabled by attaching simple wireless adapters to the electrodes and incorporating the Bluetooth protocol (or other known protocol) into a processor in the controller unit. Ex. 1019 (Mumford) at [0042]. Mumford discloses that one benefit of the wireless adapter is that the “wireless adapter 54 can be reused and the measurement module 52 [i.e., electrode] can be discarded.” *Id.* Moreover, Mumford discloses that the “battery 100 for the wireless adapter 54 is a low voltage battery” that “reduces the possibility of electrical shock to the patient” and “ensures that the battery 100 can operate for a long time before requiring replacement.” *Id.* at [0056]. A person of ordinary skill in the art would have been further motivated to use Mumford’s **reusable** wireless adapters with the electrodes disclosed in Govier or Williams because they would operate safely and efficiently, and would not significantly increase costs and may, in fact, decrease costs by eliminating several cables.

209. A person of ordinary skill in the art 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 electrodes and

protocol) for another (i.e., wired electrodes) to obtain predictable results. 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). For at least these reasons, a person of ordinary skill in the art would have been motivated to modify Govier and Williams' systems to include Mumford's wireless communication system.

210. A person of ordinary skill in the art would have had a reasonable expectation of success in combining Mumford's wireless communication system with Govier's and Williams's systems because Mumford's system uses well-known wireless communication protocols, including the Bluetooth protocol, which would have been available and well understood by persons of ordinary skill in the art in 2006. Moreover, Mumford specifically describes ways to safely use the Bluetooth protocol in combination with a controller unit and electrode patch, including using a low voltage battery, which would have given a person of ordinary skill in the art increased confidence that the system would work for its intended purpose. Ex. 1019 (Mumford) at [0056]-[0062]. For these reasons, a person of ordinary skill in the art would have found it obvious to combine a processor hosting the Bluetooth protocol (or other well-known protocol) with a controller unit and use it with the systems in Govier and Williams. 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 (’338 patent) at 35:1-7; *see also id.* at 15:43-49 (acknowledging Bluetooth protocol was known).

211. Mumford also discloses a simple method for wirelessly communicating with the electrodes through a wireless adapter 54. *Id.* at [0043]. Mumford explains that the wireless adapter can be “snap-fit” or “friction-fit” with the electrode. *Id.* at [0042]. A person of ordinary skill in the art would have appreciated that a simple snap- or friction-fit device would have made the use of the device in medical setting simple and straightforward. The simple connections also would have made it simple to adapt the electrodes in Govier or Williams for wireless communication by providing them with the described wireless adapter. For these reasons, a person of ordinary skill in the art would have expected success in combining Mumford’s wireless communication system with the systems in Govier and Williams.

3. **Dependent Claim 5 - “wherein the controller unit communicates wirelessly with the percutaneous electrode”**

212. 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.

213. First, Mumford discloses that at least one of the wireless sensors 14 may also be a “wireless needle assembly 70.” Ex. 1019 (Mumford) at [0044]. The wireless needle assembly 70 also includes a snap- or friction-fit wireless adapter 54 and “a shaft with a needle tip 74 disposed at the end.” *Id.* at [0045].

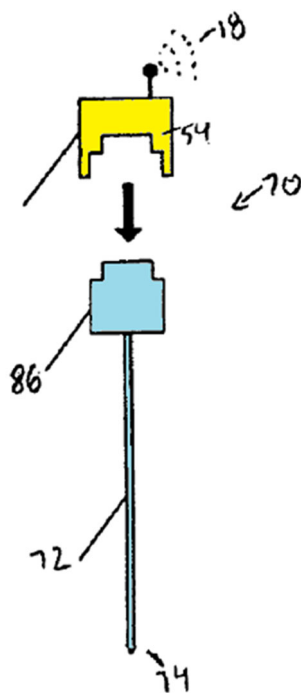


FIGURE 3a

Mumford – Figure 3a

Mumford explains that the wireless needle includes at least one electrode (referred to as a conductor). *Id.* at [0045]-[0047], [0049]; *see also* Ex. 1021 (Mumford – Needle Patent) at 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, a person of ordinary skill in the art would have understood that Mumford’s wireless needle is a percutaneous electrode or percutaneous needle electrode. Ex. 1019 (Mumford) at [0048].

214. As with the patch electrodes discussed in claim 4 above, the wireless adapter 54 on Mumford’s percutaneous 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.” *Id.* at [0030], [0047]. Thus, Mumford’s monitoring device 12 is a controller unit because it controls the operation of the wireless sensors, including the needle 70. Mumford explains that the “transceiver 24 operates according to a suitable wireless communication protocol,” such as “the Bluetooth communication protocol.” *Id.*; *see also id.* at [0057]-[0062] (describing Bluetooth communication). Thus, Mumford discloses a controller unit that communicates wirelessly with the percutaneous electrode.

215. Second, Mumford discloses a “wireless stimulator 32 [blue] for performing certain diagnostic tests on the patient 16 such as nerve conduction velocity tests.” *Id.* at [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.* at [0034]; *see also id.* at [0036] (“The stimulation interface 42 allows a medical practitioner to control the wireless stimulator.”).

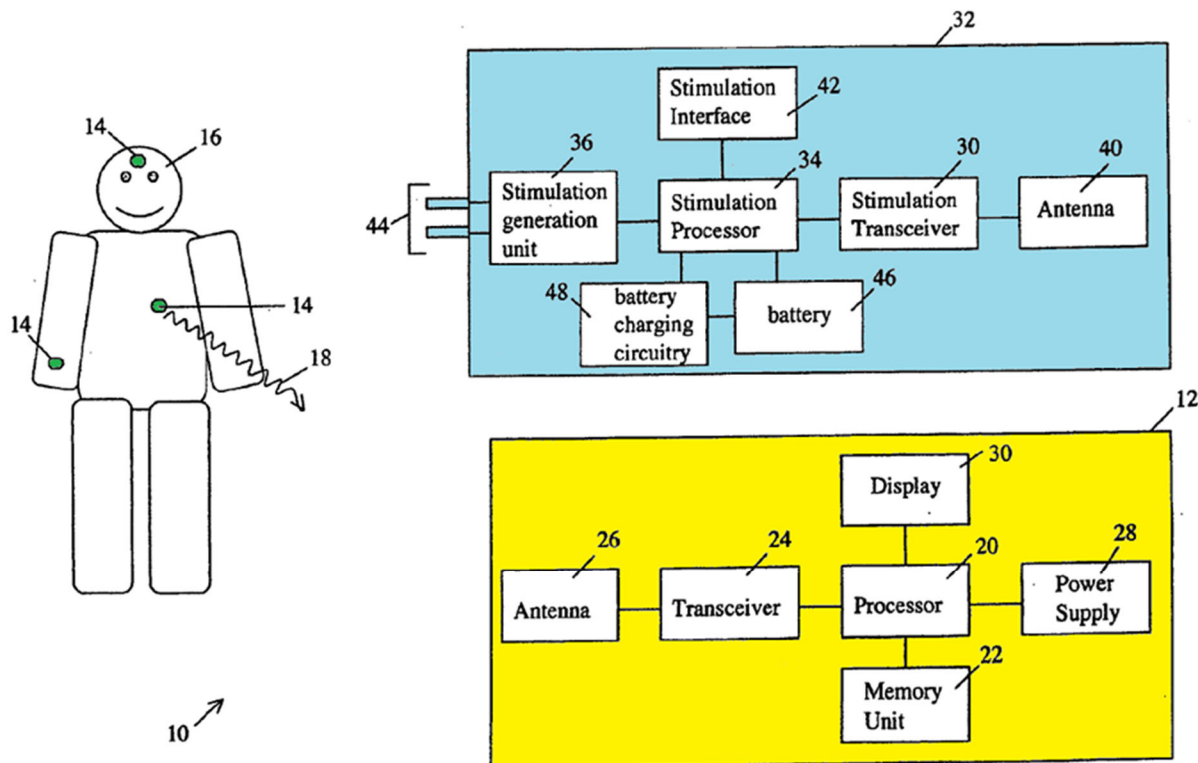


FIGURE 1

Mumford – Figure 1

216. Mumford explains, “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.* at [0037]. Each prong on the stimulator is an electrode (e.g., cathode terminal and anode terminal). *Id.* 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.” *Id.* at [0037] (emphasis added). Thus,

Mumford discloses that the stimulator may be equipped with percutaneous needle electrodes that communicate wirelessly with a controller unit.

217. A person of ordinary skill in the art 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 I provided in Claim 4. *Supra* ¶¶196-204.

4. Dependent Claim 7 - “wherein the controller unit communicates wirelessly with the transcutaneous electrode”

218. 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 I provided in claim 4 above. *Supra* ¶¶196-204.

5. Dependent Claim 8 - “wherein the controller unit communicates wirelessly with the percutaneous needle electrode”

219. 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 I provided in Claims 4-5. *Supra* ¶¶196-204, 205-210.

D. Claims 4-5 and 7-8 are Obvious over Williams in Combination With Mumford or Williams in Combination With Govier and Mumford

220. A person of ordinary skill in the art 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* ¶¶196-212.

E. Claims 4-5 and 7-8 are Obvious over Govier in Combination With Sarwal or Govier in Combination With Williams and Sarwal

1. Dependent Claim 4 - “wherein the controller unit communicates wirelessly with the electrode patch”

221. 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.

222. Sarwal’s wireless remote server 160 (i.e., controller unit – yellow below) wirelessly communicates with an external stimulator 152 [yellow circle below] having an “external (primary) coil 170” to induce a current that flows between electrodes 160, 161. Ex. 1020 (Sarwal) at 10:49-60.

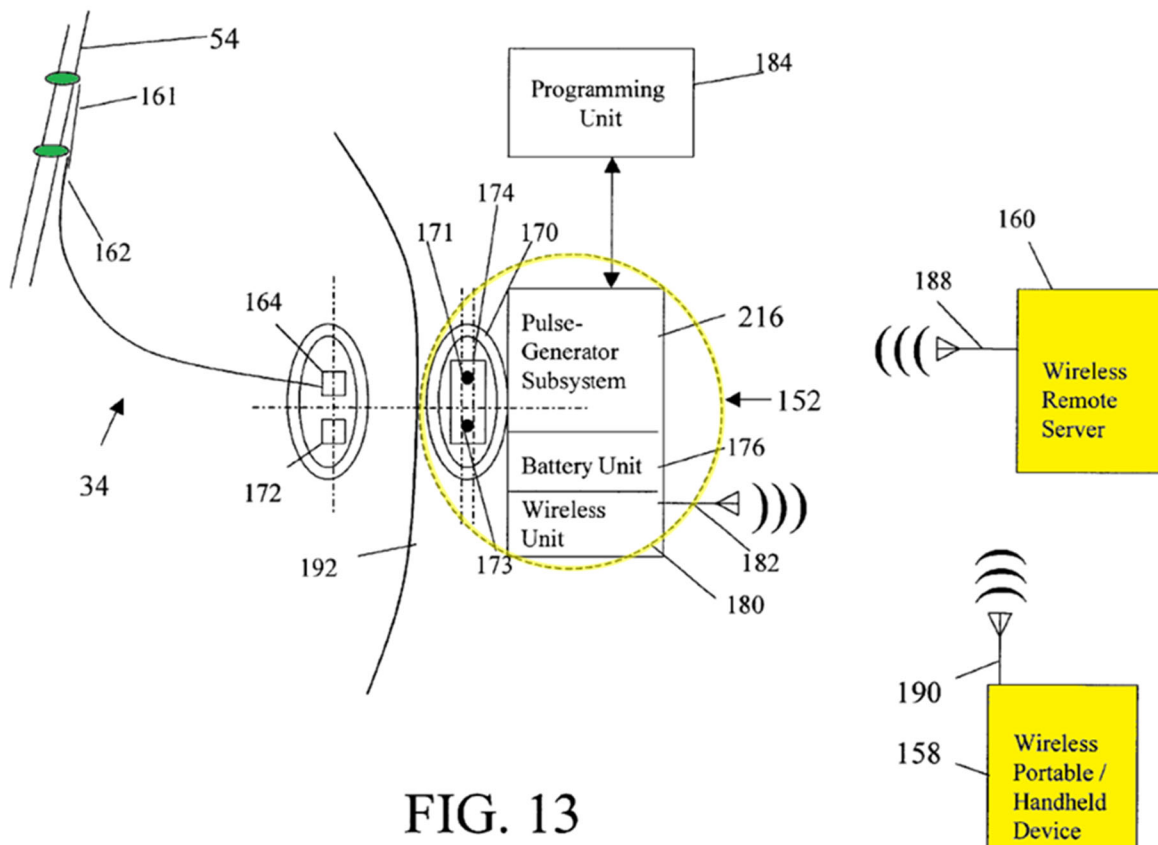


FIG. 13

Sarwal – Figure 13

The external stimulator 152 includes “a patch 175 that connects to the skin 192.” *Id.* at 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 Wireless Application Protocol (WAP).” *Id.* at 11:1-7, 14:35-15:27, Fig. 20. While Sarwal discloses that the external stimulator 152 inductively generates a current between electrodes 161-162 by activating external coil 170, a person of ordinary skill in the art would have recognized that with slight modifications the external stimulator could also be attached to electrodes (rather than a coil), such as the electrode patch or needle electrodes described in Govier

and Williams, to generate a current. More specifically, the components of the stimulator (wireless unit, battery unit, and pulse generator subsystem) could have been integrated with an electrode, such as the ground pads or percutaneous electrode needles described in Govier and Williams. A person of ordinary skill in the art would have recognized that Sarwal discloses the external stimulator in combination with an external coil because the overall system incorporates implantable features. However, a person of ordinary skill in the art reviewing Govier or Williams would have appreciated that an implantable component was not necessary to treat urinary incontinence by stimulating the tibial nerve. Govier and Williams demonstrate that the treatment was effective using one surface electrode and one percutaneous electrode. A person of ordinary skill in the art would have appreciated the benefits of wireless communication, as described in Sarwal, and would have found it obvious to combine Sarwal's wireless stimulator components with the electrodes in Govier and Williams.

223. A person of ordinary skill in the art 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. 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 (Sarwal) at 10:25-30, Fig. 10B; Ex. 1005 (Govier) at 1193-94; Ex. 1006 (Williams) at [0007], [0037].

224. Additionally, Sarwal discloses that the wireless communication system permits the physician to beneficially control the stimulation of the nerve via the wireless stimulator. Ex. 1020 (Sarwal) at 8:51-64. As an example, Sarwal cites the case of Alzheimer's patients and the benefit of permitting the physician to remotely program the stimulator to work for multiple weeks. *Id.*

225. A person of ordinary skill in the art would have also been motivated to combine Sarwal's wireless communication system with the systems in Govier and Williams to address the disadvantages of wired systems identified in Mumford. Ex. 1019 (Mumford) at [0004]-[0005]; *supra* ¶200.

226. A person of ordinary skill in the art would have found the substitution of Sarwal's wireless communication system for the wired systems in Govier and Williams a simple substitution of one known element (wireless stimulator and WAP protocol) for another (wired configuration) to obtain predictable results. 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 wirelessly communicate with electrodes). For these reasons, a person of ordinary skill in the art would have been motivated to modify Govier's and Williams' systems to include Sarwal's wireless communication system.

227. A person of ordinary skill in the art 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 persons of ordinary skill in the art in 2006. Moreover, Sarwal expressly describes one way WAP could function with a controller unit and electrode, which would have given a person of ordinary skill in the art increased confidence that the system would work for its intended purpose. Ex. 1020 (Sarwal) at 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 with electrodes for wireless communication. A person of ordinary skill in the art in 2006 would have possessed the skill and knowledge to combine a wireless unit and electrode to enable wireless communication, particularly after reviewing the disclosures in Mumford and Sarwal. Additionally, a person of ordinary skill in the art 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. 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 (’338 patent) at 35:1-7.

2. Dependent Claim 5 - “wherein the controller unit communicates wirelessly with the percutaneous electrode”

228. 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.

229. A person of ordinary skill in the art would have been motivated to, and reasonably expected success in, combining Sarwal’s wireless communication system with the systems in Govier and Williams so that the controller unit could wirelessly communicate with the percutaneous needle electrode for the reasons I provided in claim 4. *Supra* ¶¶214-220.

3. Dependent Claim 7 - “wherein the controller unit communicates wirelessly with the transcutaneous electrode”

230. 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* ¶¶214-220.

4. Dependent Claim 8 - “wherein the controller unit communicates wirelessly with the percutaneous needle electrode”

231. 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* ¶¶214-222.

F. Claims 4-5 and 7-8 are Obvious over Williams in Combination With Sarwal or Williams in Combination With Govier and Sarwal

232. A person of ordinary skill in the art 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* ¶¶214-224.

VII. CONCLUSION

233. For at least the foregoing reasons, it is my opinion that claims 1-8 of the '338 patent are anticipated or rendered obvious by the cited prior art.

234. I reserve the right to supplement my opinions in the future to respond to any arguments or positions that the Patent Owner may raise, taking account of new information as it becomes available to me.

235. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Dated: 23-November-2022

By: // *John Laughlin*
John Laughlin