

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CALA HEALTH, INC.

Petitioner,

v.

EMKINETICS INC.,

Patent Owner

IPR2024-00732

U.S. Patent No. 10,786,669

**DECLARATION OF JOHN LAUGHLIN IN SUPPORT OF
PETITION FOR INTER PARTES REVIEW OF
U.S. PATENT 10,786,669**

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EXHIBIT LIST

Exhibit No.	Description
1001	U.S. Patent No. 10,786,669 to Rajguru et al. (“the ’669 patent”)
1002	Declaration of John Laughlin, M. Eng., P.E.
1003	Curriculum Vitae of John Laughlin, M. Eng., P.E.
1004	The ’669 patent prosecution history
1005	Prochazka, et al, Attenuation of Pathological Tremors by Functional Electrical Stimulation I: Method, 20 Annals of Biomedical Engineering 205 (1992)
1006	Javidan, et al, Attenuation of Pathological Tremors by Functional Electrical Stimulation II: Clinical Evaluation, 20 Annals of Biomedical Engineering 225 (1992)
1007	U.S. Patent No. 5,562,707 (“the ’707 patent”)
1008	U.S. Patent No. 6,704,603 (“Gesotti”)
1009	U.S. Patent No. 7,369,896 (“Gesotti ’896”)
1010	U.S. Patent Publication No. 2010/0168501 to Burnett et al. (“Burnett”)
1011	PCT Application No. PCT/US2011/052415 to Rajguru et al. (“the ’415 PCT Application”)
1012	U.S. Provisional Application No. 61/403,680 to Rajguru et al. (“the ’680 Provisional”)
1013	Stedman’s Medical Dictionary, 28 th Ed. 2006
1014	Prosecution History of U.S. Patent Application No. 12/508,529 (“the ’529 Application”)
1015	Provisional Application No. 60/848720 (“the ’720 provisional”)

Exhibit No.	Description
1016	U.S. Patent Publication No. 2008/0306325 (“the ’325 publication”)
1017	U.S. Patent Publication No. 2004/0102819 to Zou et al. (“Zou”)
1018	U.S. Patent Publication No. 2006/0015153 to Gliner et al. (“Gliner”)
1019	PCT Patent Publication No. WO 2006/092007 to Stephens (“Stephens”)
1020	Chang, M.D., Qwang-Yuen et al., Effect of Electroacupuncture and Transcutaneous Electrical Nerve Stimulation at Hegu (LI.4) Acupuncture Point on the Cutaneous Reflect, 27 Acupuncture & Electro-Therapeutics Res., Int. J. 191-202 (2002)

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. 10,786,669 (“the ’669 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.

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 along with my experiences within the field:

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 1-20 of the '669 patent are unpatentable for the following reasons:

Gesotti-Based Grounds

- Claims 1, 3-6, 9-10, 12-13, 16, and 18-20 are anticipated by Gesotti;
- Claims 1, 3-7, 9-13, 16, and 18-20 are rendered obvious by Gesotti;
- Claims 2, 8 and 17 are rendered obvious by Gesotti in combination with Gesotti '896; and
- Claims 14-15 are rendered obvious by Gesotti in combination with Stephens.

Burnett-Based Grounds

- Claims 1-12, 16, and 18-20 are anticipated by Burnett;
- Claims 1-12, 16, and 18-20 are rendered obvious by Burnett;
- Claim 13 is rendered obvious by Burnett in combination with Gesotti;
- Claims 14-15 are rendered obvious by Burnett in combination with Stephens; and
- Claim 17 is rendered obvious by Burnett in combination with Gesotti '896.

III. LEGAL BACKGROUND

A. Applicable Legal Standards

10. I have been asked to provide my opinion as to whether claims 1-20 of the '669 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 '669 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 appropriate 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. The references I rely on in this Declaration are from the same field as the ’669 patent, *e.g.*, devices for stimulating nerves or tissue to treat neurological disorders. The references are also pertinent to the problem the alleged inventors were addressing, *e.g.*, relieving symptoms of neurological disorders by applying electrical impulses to stimulate nerves or tissue.

17. To assess the differences between the 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 claims 1-20 of the '669 patent would have been non-obvious. To the extent EMKinetics, Inc. ("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 '669 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 September 20, 2011. However, my opinions would not materially change if Patent Owner were entitled to its earliest claimed priority date of October 2, 2006.

23. The '669 patent describes the use of well-known neuromodulation methods. Based on my review of the specification and claims of the '669 patent, it is my opinion that a person of ordinary skill in the art would be a person having an undergraduate degree in the field of biomedical engineering, or a related engineering discipline, and at least two years of experience in the design and/or analysis of biomedical devices. Additional work experience could serve as a substitute for an engineering degree and additional schooling could serve as a substitute for work experience.

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 '669 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 '669 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 method claimed in the '669 patent to be anticipated by and/or obvious in view of the prior art.

IV. THE '669 PATENT

A. Overview of the '669 Patent

1. The Specification of the '669 Patent

26. The '669 patent discloses well-known methods for magnetically and electrically stimulating various body parts. Ex. 1001 ('669 Patent) at 6:51-52 (describing “an arm applicator and a foot, knee or leg applicator”). The majority of the '669 patent describes using magnetic or electrical stimulation to treat over-active

bladder (OAB) and urinary incontinence (UI). For example, the “Background of the Invention” exclusively describes OAB and UI. *Id.* at 2:7-3:12.

27. Many of the specific examples in the '669 patent describe methods of stimulating the tibial nerve to treat OAB or UI. For example, Figure 11 illustrates methods of stimulating the tibial nerve using “electrical energy” that is dispensed through “a transcutaneous stimulator, such as an electrode 126 [red in figure below].” *Id.* at 17:4-8, Fig. 11. The electrode 126 and a sensor 130 [green in figure below] are electrically connected to an “electrical pulse controller 128” [yellow in figure below] “to provide the desired feedback and modulate the power” to the stimulator electrode. *Id.* at 17:8-15.

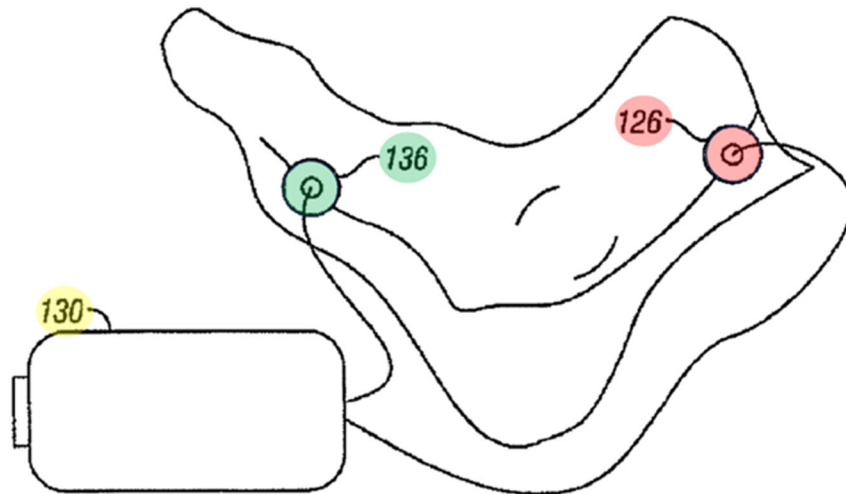


FIG. 11

28. In another embodiment, the '669 patent describes “electrodes designed for the palmar surface of the hands along with F/M wave detecting electrodes 6105.” *Id.* at 62:15-17. As shown in Figure 61A of the '669 patent below, the “contact

electrode(s) 6101 [red in figure below] are placed across the upper palm portion of the hand and second electrode 6102 [red in figure below] is place across [sic] towards, near or on the heel of the hand.” *Id.* at 62:17-20. The ’669 patent states that the “electrical stimulation of the hand will stimulate the Median or the Ulnar nerve or both.” *Id.* at 62:23-25.

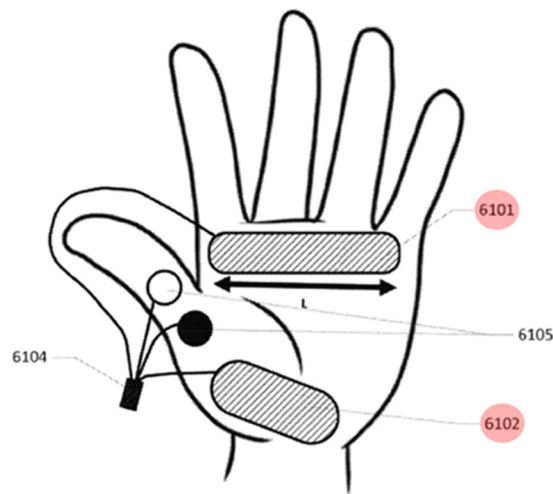


FIG. 61A

29. The ’669 patent states that the electrical stimulation of the Ulnar or Median nerves may “treat various neurological conditions, including neuropathies, migraine, pain, headaches, depression, epilepsy, post-traumatic stress disorder, overactive bladder, incontinence, subcutaneous fact, effects of stroke, memory enhancement, etc.” *Id.* at 59:15-24; *see also id.* at 59:36-47 (describing the treatment of “migraine”).)

30. I notice that the claims of the ’669 patent require the treatment of “tremor.” I have only found one mention of “tremor” in the ’669 patent

specification. The word “tremor” appears once among a list of approximately 100 other ailments that are allegedly treated by the described devices. *Id.* at 17:46-18:22. I do not see any explanation in the ’669 patent specification regarding how the disclosed devices treat or mitigate “tremor.”

2. The Claims

31. The ’669 patent has 20 claims in total. The patent includes one independent claims and 19 claims that depend, directly or indirectly, from claim 1. I offer opinions regarding claims 1-20 in this Declaration. Independent claim 1 states:

A method for providing transdermal electrical stimulation therapy to a subject for treating tremors, comprising:

positioning a stimulator electrode over a skin surface overlying a target nerve or tissue which extends through a hand of the subject;

delivering electrical stimulation via a pulse generator transdermally through the skin surface and to the target nerve or tissue to stimulate the target nerve or tissue so that tremors experienced by the subject are mitigated; and

detecting a motion from the subject via at least one sensor positioned on the subject.

B. The Prosecution History of the ’669 Patent

32. I have reviewed the prosecution history of the ’669 patent. The application that became the ’669 patent was filed on March 30, 2017 (as indicated on the front of the ’669 patent). When the application was filed, the claims described a method of providing transdermal electrical stimulation therapy “so that pain felt

by the subject is mitigated.” Ex. 1004 (’669 patent prosecution history) at 91. Almost a year later, a preliminary amendment was filed that amended the claims to replace mitigating pain with “treating tremors.” *Id.* at 230. The claims were also amended to eliminate limitations restricting the claims to “a glabrous skin surface overlying a palm.” *Id.* The amendments of claim 1 from the preliminary amendment are shown below:

1. (Currently Amended): A method for providing transdermal electrical stimulation therapy to a subject for treating tremors, comprising:
positioning a stimulator electrode over a ~~glabrous~~ skin surface overlying a target nerve or tissue which extends through a hand palm of the subject; [[and]]
delivering electrical stimulation via a pulse generator transdermally through the ~~glabrous~~ skin surface and to the [[a]] target nerve or tissue ~~within the hand~~ to stimulate the target nerve or tissue ~~within the hand~~ so that tremors experienced ~~pain felt~~ by the subject are [[is]] mitigated; and
detecting a motion from the subject via at least one sensor positioned on the subject
~~wherein the pulses generated during the electrical stimulation therapy include pulses of a first amplitude and pulses of a second amplitude, where the first amplitude is different from the second amplitude.~~

33. Next, the Examiner rejected the amended claims based on a Patent Application Publication (US 2004/0102819 A1), which I will refer to as Zou (Ex. 1017) after the first named inventor, and several other references, including an article describing “Transcutaneous Electrical Nerve Stimulation” (“Chang,” Ex. 1020) and another Patent Application Publication, which I will refer to as Gliner (Ex. Ex. 1018) after the first named inventor. Ex. 1004 (’669 patent prosecution history) at 108-

112. The Examiner found that Zou taught all the limitations in the claims except “the stimulation mitigates tremors, detecting motion using a sensor positioned on the subject, or using that sensor reading in a feedback loop to modify stimulation.” *Id.* at 110. However, the Examiner found that Chang and Gliner disclosed methods of mitigating tremor, as well as the other missing limitations, and that it would have been obvious for a person of ordinary skill in the art to use the device in Zou as taught in Chang and Gliner to mitigate tremor. *Id.* at 110-111.

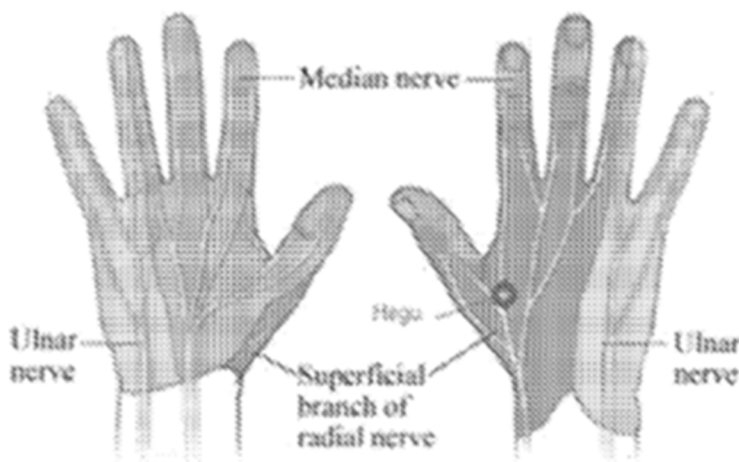
34. Next, the Patent Owner further amended the claims to reintroduce some of the limitations that were eliminated in the preliminary amendment. *Id.* at 89-92. Below is the new claim 1 presented by Patent Owner, and I have highlighted some of the terms that were reintroduced into the claim:

1. (Previously Presented): A method for providing transdermal electrical stimulation therapy to a subject for treating tremors, comprising:

- positioning a stimulator electrode over a **glabrous skin surface** overlying a target nerve or tissue which extends through a hand **palm of the subject**;
- delivering electrical stimulation via a pulse generator transdermally through the glabrous skin surface and to the target nerve or tissue within the hand to stimulate the target nerve or tissue within the hand so that tremors experienced **pain felt** by the subject are mitigated; and
- detecting a motion from the subject via at least one sensor positioned on the subject

wherein the pulses generated during the electrical stimulation therapy include pulses of a first amplitude and pulses of a second amplitude, where the first amplitude is different from the second amplitude.

35. In its arguments, Patent Owner argued that Zou did not teach all the limitations in the claims because Zou allegedly taught stimulation of the radial nerve along the back of the hand and not a “glabrous skin surface” along the “palm.” *Id.* at 94. Patent Owner specifically argued that the “radial nerve does not extend along the palmar surface of the hand and cannot be stimulated by application of electrical stimulation through the glabrous skin surface which overlies the palm of the hand.” *Id.* Patent Owner further stated, “it is the median nerve and the ulnar nerves which innervate the glabrous skin surface and are wholly distinct from the radial nerve.” *Id.* Patent Owner included a diagram to illustrate the nerves in the hand and argued that stimulating the radial nerve “cannot [be] the same as delivering stimulation to the glabrous surfaces.” *Id.*



Based on the above arguments, Patent Owner concluded that the prior art “fail[ed] to teach delivering electrical stimulation through the glabrous skin surface.” *Id.*

36. In the same response, Patent Owner also argued that the Examiner should not have relied on the Chang paper because the paper “fails to teach any mitigation of tremors.” *Id.* at 95. The patent also argued that Gliner “is a completely non-analogous reference to the teachings of either Zou or Chang” because “Gliner teaches the use and implementation of a neural stimulation device which is implanted directly within the brain of a patient...” *Id.* at 95-96. In the next Office Action, the Examiner made only a double-patenting rejection. *Id.* at 76-80. The Examiner did not make any additional prior art rejections, evidently accepting the Patent Owner’s narrowing of the claims to a “glabrous skin surface” on the “palm.” Yet, in response to the double-patenting rejection, Patent Owner again amended the claims to eliminate the limitations it relied on to overcome Zou, Chang, and Gliner, including the limitations restricting the claims to electrodes placed over a “glabrous” skin surface and a target nerve or tissue that extends through a “palm”:

1. (Currently Amended): A method for providing transdermal electrical stimulation therapy to a subject for treating tremors, comprising:
positioning a stimulator electrode over a ~~glabrous~~ skin surface overlying a target nerve or tissue which extends through a hand ~~palm~~ of the subject;
delivering electrical stimulation via a pulse generator transdermally through the ~~glabrous~~ skin surface and to the target nerve or tissue ~~within the hand~~ to stimulate the target nerve or tissue ~~within the hand~~ so that tremors experienced ~~pain-felt~~ by the subject are mitigated; and
detecting a motion from the subject via at least one sensor positioned on the subject
wherein the pulses generated during the electrical stimulation therapy include pulses of a first amplitude and pulses of a second amplitude, where the first amplitude is different from the second amplitude.

The Examiner did not revisit the prior rejections and allowed the claims. *Id.* at 19-21.

C. The Priority Date of the '669 Patent

37. For purposes of this Declaration, I have been asked to assume that the '669 patent's priority date is September 20, 2011. However, my opinions would not change if the priority date of the '669 patent were between 2006 and 2011.

D. Claim Construction of the '669 Patent

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 the earliest applicable priority date (September 2011) and in accordance with the specification and prosecution history. I have applied this standard in my analysis.

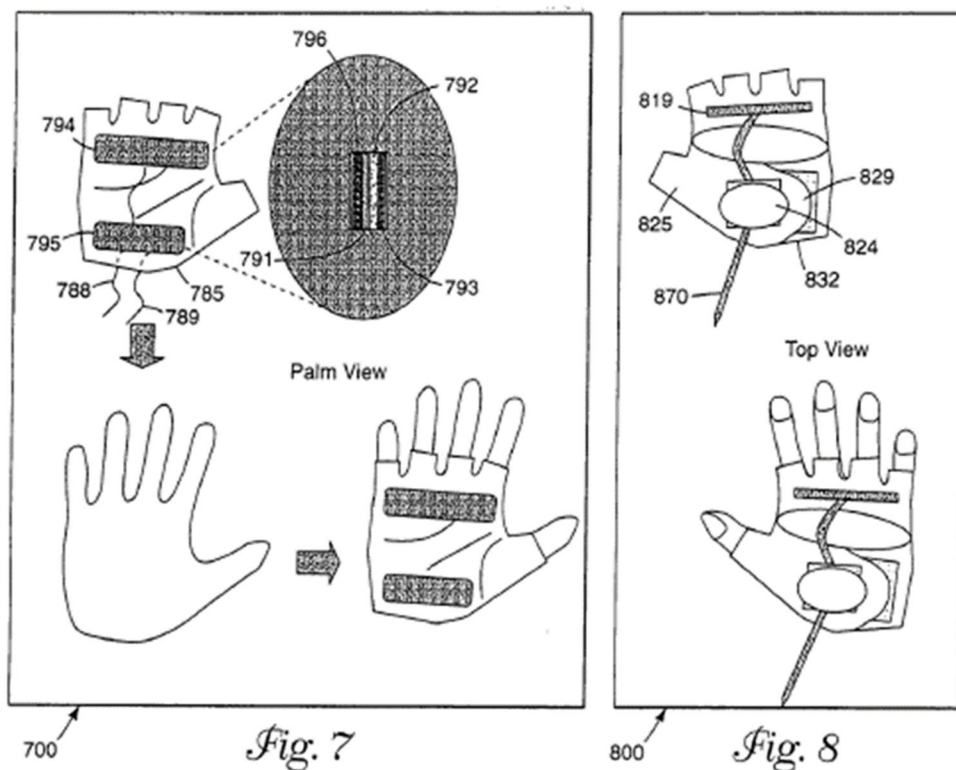
39. I am aware from reviewing the '669 patent prosecution history that the Patent Owner made arguments that the claims of the '669 patent require “electrical stimulation through the glabrous skin surface which overlies the palm of the hand.” The Gesotti patents I rely upon in this Declaration describe devices that provide electrical stimulation through the glabrous skin surface which overlies the palm of the hand. However, to the extent the claims are not so limited, I have also relied on Burnett, which discloses stimulating other skin surfaces, such as the arm, in a way that I believe satisfies the claims.

V. TECHNOLOGY BACKGROUND

A. Gesotti and Gesotti '896

40. I plan to discuss two Gesotti patents (Gesotti (U.S. Patent No. 6,704,603) and Gesotti '896 (U.S. Patent No. 7,369,896)). Both patents relate to the same system for treating symptoms of Parkinson's disease.

41. Gesotti describes a stimulation apparatus including a glove (*see* Figures 7-8 below) having electrodes connected to a controller that stimulates the hand. Ex. 1008 at Figs. 7-9.



42. Gesotti also describes examples of electrodes that stimulate other portions of the body, including the wrist (Fig. 10), ankles/feet (Figs. 11-13), and

head/neck (Fig. 14-15). Gesotti also discusses multiple sensors that measure motion and other parameters that provide feedback signals during the stimulation. Ex. 1008 at 2:18-50, Figs. 1, 16, 17. A control unit that includes a pulse generator and a controller uses the feedback signals from the sensors to optimize the stimulation by, for example, modifying the voltage, amplitude, frequency and other parameters of the stimulation signal. *Id.* at 2:18-50, 12:38-44.

43. Gesotti '896 also describes a method for relieving symptoms of Parkinson's disease, including tremors. Ex. 1009 at 1:20-44, 4:16-17, 5:1-12, 5:44-49, 16:46-60; *see also, id.* Tables 11 and 12. Gesotti '896 incorporates by reference the patent application that issued as Gesotti. *Id.* at 1:5-17. Gesotti '896 expands upon the treatment methods disclosed in Gesotti. For example, Gesotti '896 discloses stimulation parameters and particular stimulation cycles suitable to treat symptoms of Parkinson's disease. *Id.* at 17:1-25. The stimulation parameters and electrode locations particularly suited for treating tremor are shown in Tables 11 and 12 and described in the accompanying text. *Id.*

B. Burnett

44. Burnett is a July 1, 2010 patent publication entitled "Method and Apparatus for Magnetic Induction Therapy." Ex. 1010. Burnett discloses an electrical stimulation device intended for the nerves of the foot to treat overactive bladder and incontinence. *Id.* at [0002]. However, the publication alleges that

similar sensor arrangements can be applied to other body parts to treat additional ailments. *Id.* at [0102, 0111]. “Tremor” is listed as one of the ailments. *Id.* Like the claims of the ’669 patent, Burnett discloses using electrodes to stimulate the target nerve and sensors to monitor the efficacy of the stimulation that the controller uses to adjust the stimulation parameters. *Id.* at [0032, 0036, 0088, 0109].

45. Burnett ’501 also states that it is based on a 2006 provisional application, No. 60/848720 (“the ’720 provisional”) which is incorporated by reference into Burnett ’501 in its entirety. *See* Ex. 1010 (Burnett ’501) at [0001]; *see also* Ex. 1015 (’720 provisional).

VI. CLAIMS 1-20 OF THE ’669 PATENT ARE UNPATENTABLE

A. Claims 1, 3-7, 9-13, 16, 18-20 Are Anticipated Or Rendered Obvious by Gesotti

1. Independent Claim 1

46. Independent Claim 1 is anticipated by Gesotti. To the extent Gesotti does not disclose each limitation of claim 1, claim 1 is also rendered obvious by Gesotti.

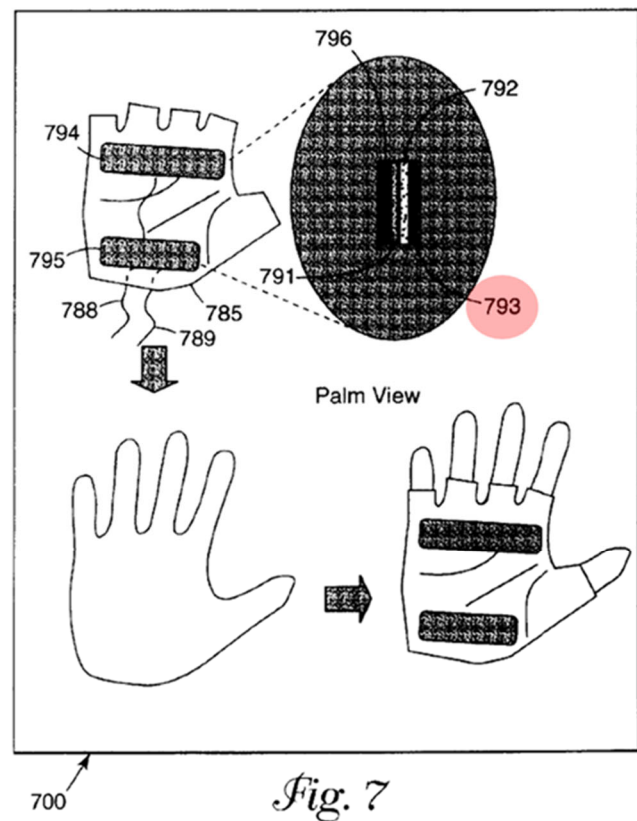
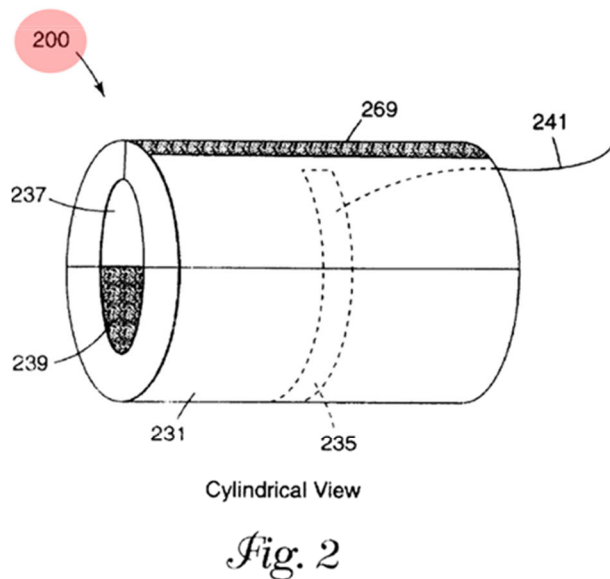
a. Preamble: “A method for providing transdermal electrical stimulation therapy to a subject for treating tremors, comprising”

47. The preamble of claim 1 recites “A method for providing transdermal electrical stimulation therapy to a subject for treating tremors, comprising.”

48. If the preamble is limiting, Gesotti discloses this method. Gesotti discloses methods of treating “Parkinson’s disease symptoms using electrical stimulation.” Ex. 1008 at 1:14-16, 2:13-17. Gesotti states, “[t]he cardinal symptoms of Parkinson’s disease are paucity of spontaneous movements, slowness of movement, rigidity of muscle tone, and *the characteristic tremor at rest.*” *Id.* at 1:32-35 (emphasis added); *see also id.* at 1:58-66 (describing tremor). Claims 1 and 2 of Gesotti specifically claim, “A method of curing an individual exhibiting one or more symptom’s [sic] of Parkinson’s disease” “wherein one or more symptoms of Parkinson’s disease comprise *tremor*, rigidity, akinesia, bradykinesia and drooping head.” *Id.* at claims 1-2 (emphasis added).

49. Gesotti treats tremor by applying transdermal electrical stimulation therapy through stimulation electrodes placed over the patient’s skin. *Id.* at 2:39-50, 3:55-4:20, 8:36-9:28. The therapeutic system includes sensors that relay information “based on human body functions such as...movement” to a control unit, which then “uses the information to determine when electrical stimulation is required at the location of each stimulation electrode.” *Id.* at 4:4-11. The control unit “adjusts stimulation voltage, frequency, pulse width, waveform shape, amplitude, modulation type and the like of each electrical stimulation signal based on sensor information.” *Id.* at 4:11-20.

50. Gesotti discloses several configurations of stimulation electrodes, including “cylindrical stimulation electrode[s]” 200 [red] to fit around “fingers, thumbs, wrist, ankle, and other cylindrically shaped regions of the body” (below left) and “stimulation electrode[s] 793” [red] embedded in a “tactile sensor and stimulation glove” that fits over the patient’s hand (below right):

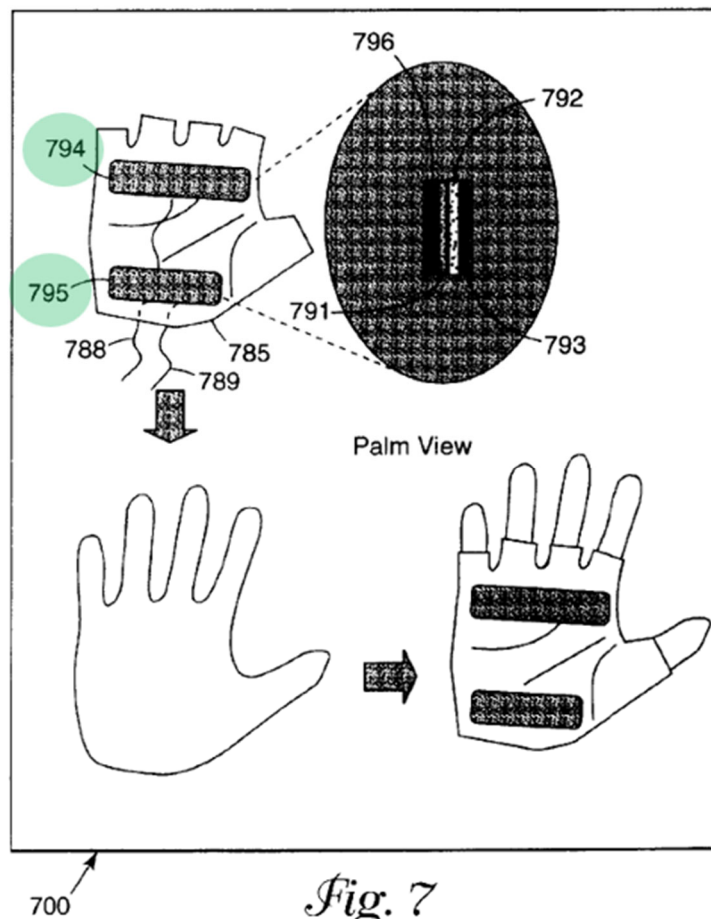


Id. at 5:38-52, 8:16-35, Figs. 2, 7-9.

b. **Limitation [A]: “positioning a stimulator electrode over a skin surface overlying a target nerve or tissue which extends through a hand of the subject”**

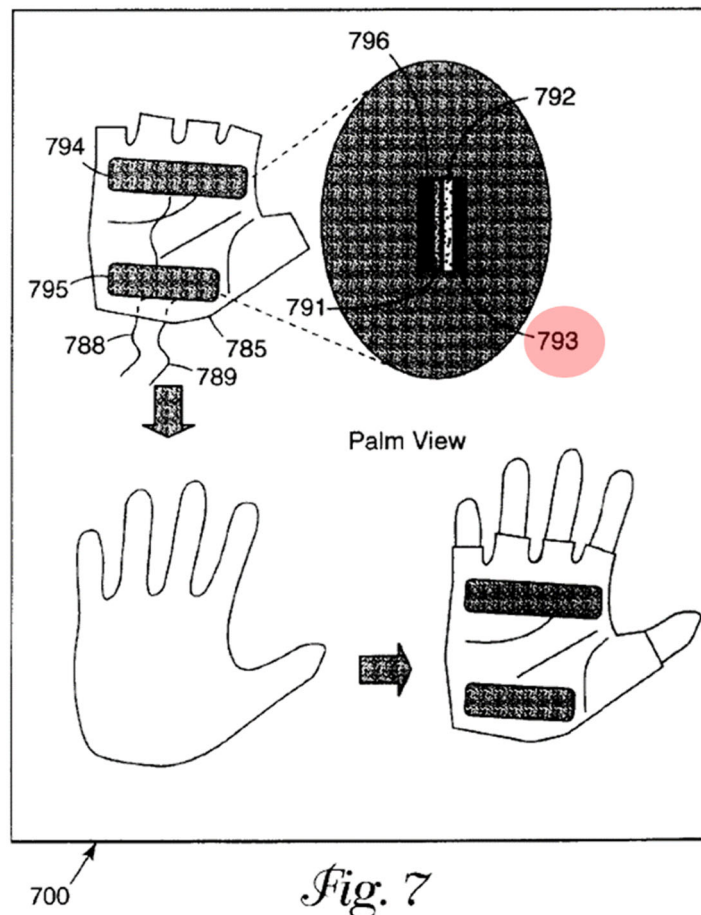
51. Claim 1 next recites “positioning a stimulator electrode over a skin surface overlying a target nerve or tissue which extends through a hand of the subject.” Gesotti describes such a method of positioning a stimulator electrode.

52. Gesotti illustrates an embodiment in Figure 7 that includes a “tactile sensor and stimulation glove.” Ex. 1008 at 8:16-19, Fig. 7. The glove positions stimulation electrodes over a patient’s palm (i.e., skin surface) overlying target nerves and tissue which extend through the patient’s hand. Gesotti discloses, “glove 785 includes a first and second tactile sensor assembly 794 and 795 [green] respectively”:



Id. at 8:19-20, Fig. 7.

53. “In one embodiment, each tactile sensor assembly includes *a stimulation electrode 793 [red], which is in direct contact with the palm* of the hand, glove material 792 sandwiched between the electrode 793 and a pressure sensor 791, and a gripping material 796, such as rubber, neoprene, or the like, on top of the pressure sensor 791.” *Id.* at 8:20-26 (emphasis added).



The stimulation electrodes 793 are positioned over, and in contact with, the tissue of the patient's palm and, therefore, satisfy the limitation "positioning a stimulator electrode over a skin surface overlying a target...*tissue* which extends through a hand of the subject."

54. The stimulation electrodes 793 in glove 785 are also positioned "over a skin surface overlying a target nerve...which extends through a hand of the subject." The ulnar and median nerves extend beneath the palm from the wrist to the fingers and pass beneath the stimulation electrodes 793 in Gesotti's stimulation glove 785. Ex. 1001 at Figs. 51-55 (identifying ulnar and median nerves). Additionally, the

median and ulnar nerves also extend up into the arm and as illustrated by the medical diagram in Figure 56A of the '669 patent.

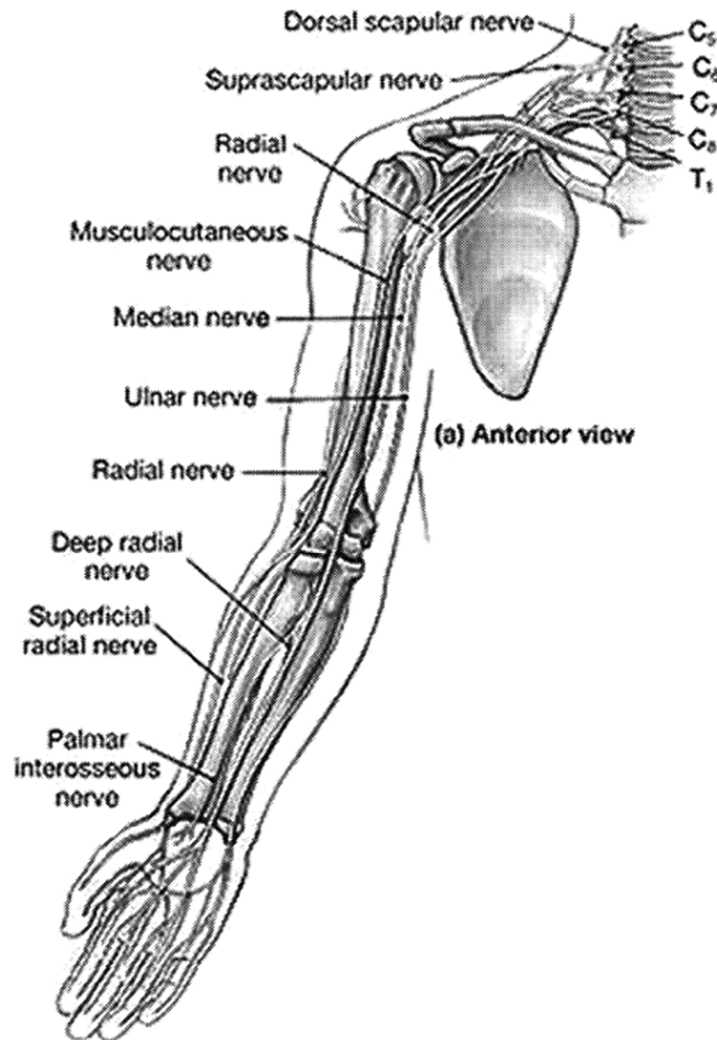
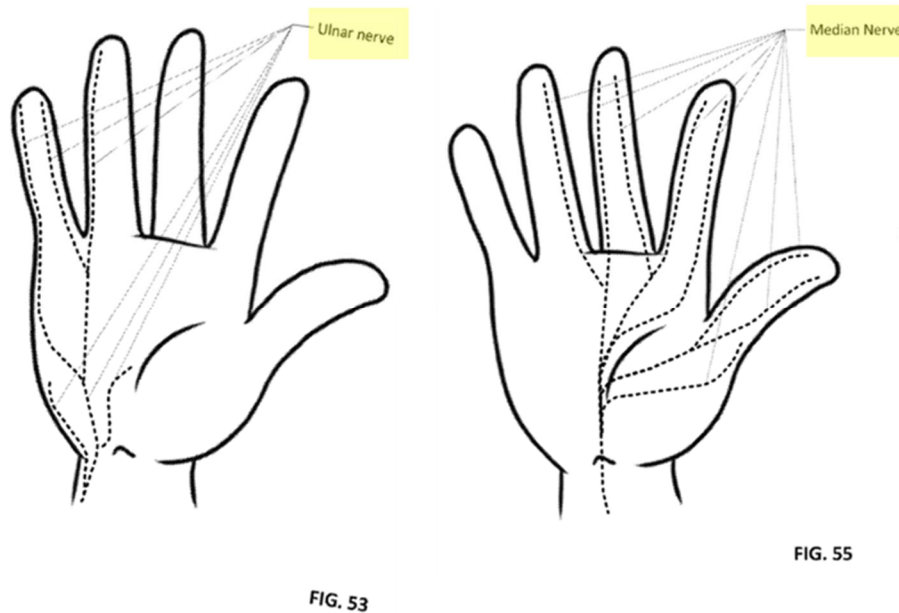


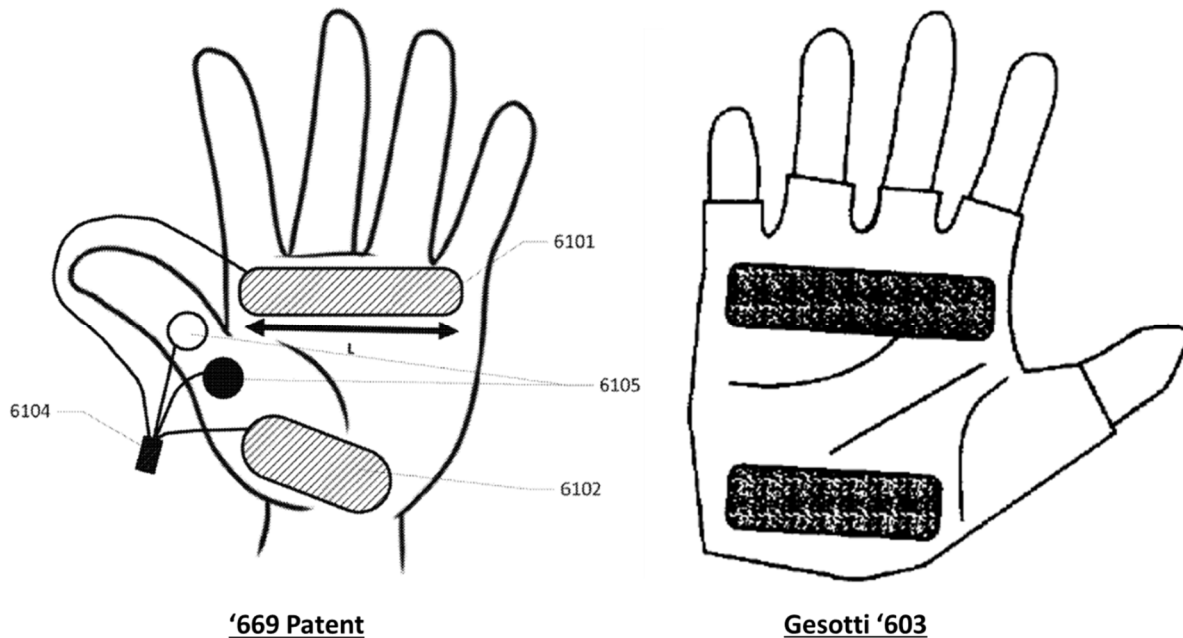
FIG. 56A

55. The '669 patent confirms that Gesotti's electrodes overlay the ulnar and median nerves. Figures 53 and 55 of the '669 patent illustrate the ulnar and median nerves [yellow] below the palm:



Ex. 1001 at Figs. 53, 55; *see also id.* at 7:46-47, 7:54-56 (describing Figures 53, 55). Gesotti's stimulation electrodes 793 overlay both nerves because the electrodes extend across the upper and lower portions of the palm. Ex. 1008 at Fig. 7.

56. The '669 patent's Figure 61D further confirms that Gesotti's electrodes overlay the ulnar and median nerves. Ex. 1001 at 62:37-41, Fig. 61D. The '669 patent states that the electrode patches illustrated in Figure 61D (below left) "can be used to alternatively stimulation [sic] the Ulnar and Median nerve if that is the desired stimulation therapy." *Id.* The electrode patches in the '669 patent's Figure 61D (below left) are in the same position as the electrodes in Gesotti's Figure 7 (below right):



Ex. 1001 at Fig. 61A (excerpted); Ex. 1008 at Fig. 7 (excerpted).

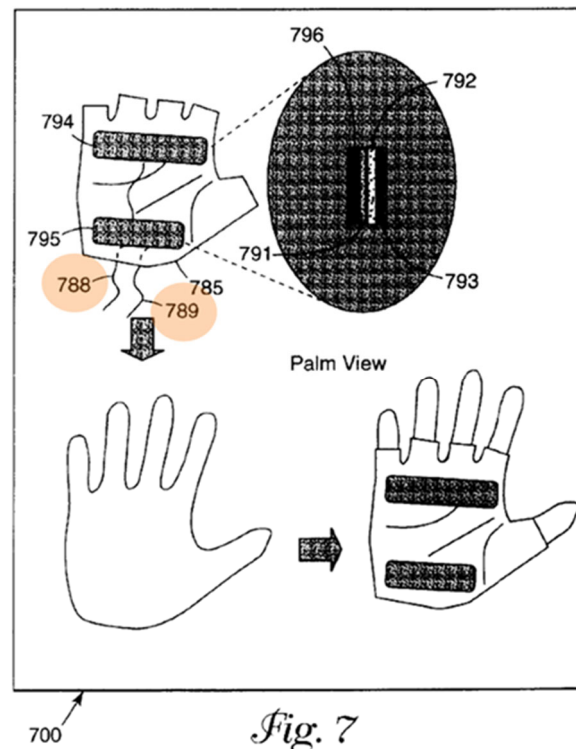
57. Thus, I conclude that Gesotti describes “positioning a stimulator electrode over a skin surface overlying a target nerve or tissue which extends through a hand of the subject.”

- c. **Limitation [B]: “delivering electrical stimulation via a pulse generator transdermally through the skin surface and to the target nerve or tissue to stimulate the target nerve or tissue so that tremors experienced by the subject are mitigated”**

58. Claim 1 next recites “delivering electrical stimulation via a pulse generator transdermally through the skin surface and to the target nerve or tissue to stimulate the target nerve or tissue so that tremors experienced by the subject are mitigated.” Gesotti describes such a method of delivering electrical stimulation.

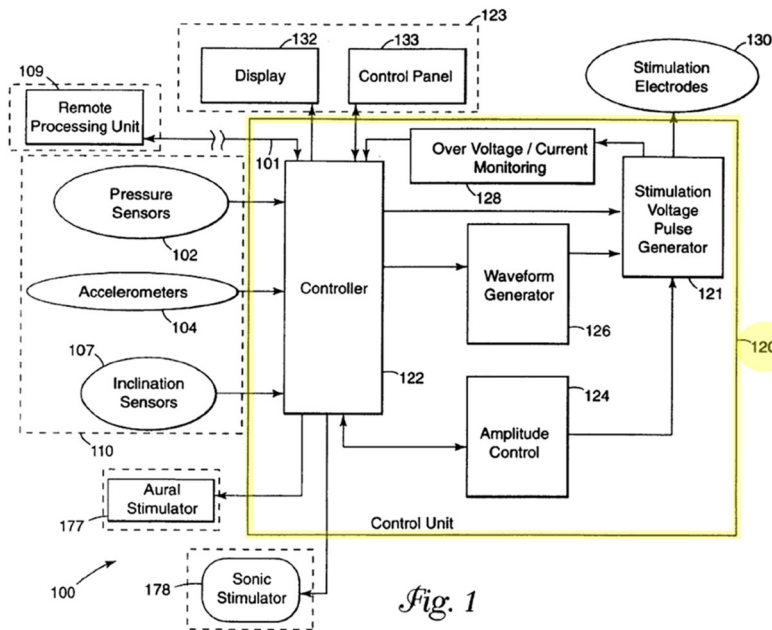
59. Gesotti describes a stimulation glove in Figure 7. The glove has first and second tactile sensor assemblies 794, 795. The “first tactile sensor assembly

794 is coupled to a first electrical lead 788 [orange] and the second tactile sensor assembly 795 is coupled to a second electrical lead 789 [orange].” Ex. 1008 at 8:26-29, Fig. 7.

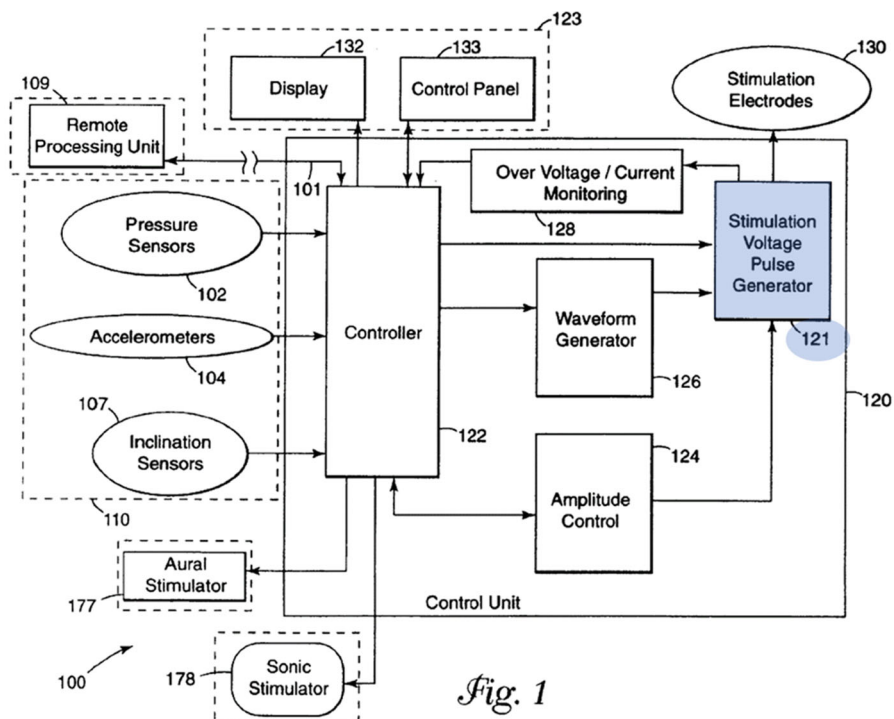


Gesotti further states that “[e]ach electrical lead 788 and 789 is coupled to a control unit such as control unit 120...” *Id.* at 8:29-30.

60. Control unit 120 [outlined in yellow below] is further described in Gesotti’s Figure 1. Gesotti states that “FIG. 1 is a block diagram of one embodiment of an adaptive stimulator...constructed according to the teachings of the present invention. Adaptive stimulator 100 includes a control unit 120 coupled to at least one sensor.” *Id.* at 3:55-57.



61. The control unit 120 includes a stimulation voltage **pulse generator** 121 [blue] that “produces individual stimulation signals for each stimulation electrode 130.” *Id.* at 4:44-48. Figure 1 also illustrates that the pulses generated by the pulse generator are applied directly to the stimulation electrodes.



62. As I explained in the previous section, the stimulation electrodes 793 attached to Gesotti's glove 785 are positioned over target nerves and tissue in the patient's palm. Gesotti's glove delivers electrical stimulation via the stimulation voltage pulse generator 121 transdermally through the palm (i.e., skin surface) and to the target nerve or tissue to stimulate the target nerve or tissue. For example, Gesotti states, "The at least one stimulation electrode is adapted to provide stimulation to an area of the body of a living subject...The adaptive stimulator is adapted to selectively provide stimulation in response to the control unit." Ex. 1008 at 2:18-38. Gesotti also states, "Control unit 120 receives the information and uses the information to determine when electrical stimulation is required at the location of each stimulation electrode 130." *Id.* at 4:8-11.

63. Gesotti discloses that the described inventions, including the stimulation glove in Figure 7, deliver electrical stimulation to mitigate the symptoms of Parkinson's disease, including tremor. Ex. 1008, claims 1-2, 1:14-16, 1:58-2:17, 2:39-50, 3:34-38, 11:46-65, 15:1-3. Gesotti provides a specific example of how the described inventions treat tremor in Figure 16. "FIG. 16 is a flow diagram of one embodiment of a method of adaptive stimulation for the treatment of the symptoms of Parkinson's disease according to the teachings of the present invention." *Id.* at 11:46-49, Fig. 16.

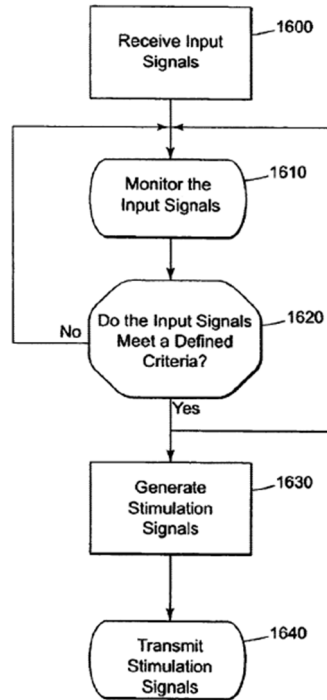


Fig. 16

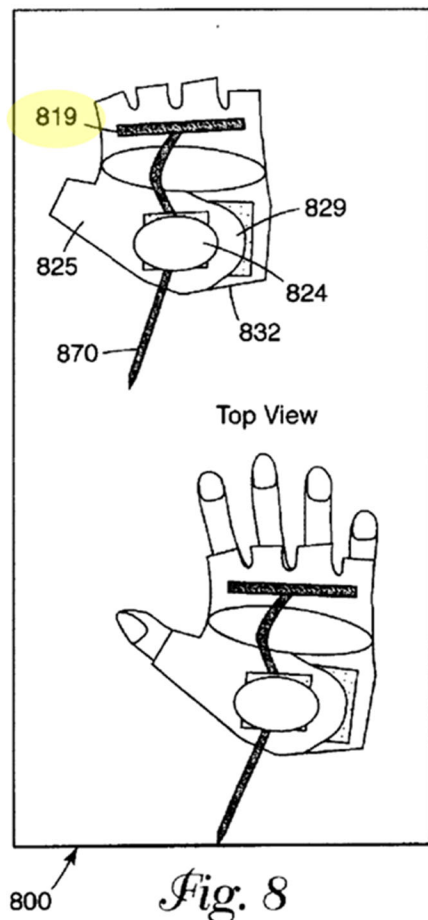
64. According to Figure 16 and the related disclosure, the treatment device, such as the stimulation glove, “receives one or more input signals from at least one sensor such as a pressure, inclination, acceleration or the like, wherein the input signals are based on physical stimulus.” *Id.* at 11:49-52. In the case of tremor, an acceleration sensor on the glove detects movement of the hand caused by the tremor. Gesotti explains that if the input signal received from the sensor meets defined criterion, the glove “generates one or more stimulation signals,” which are transmitted to the stimulators (i.e., electrodes). *Id.* at 11:53-64. The system can then adjust “stimulation voltage, frequency, pulse width, waveform shape, amplitude, modulation type and the like of each electrical signal based on sensor information.” *Id.* at 4:11-14.

65. Thus, I conclude that Gesotti describes “delivering electrical stimulation via a pulse generator transdermally through the skin surface and to the target nerve or tissue to stimulate the target nerve or tissue so that tremors experienced by the subject are mitigated.”

d. **Limitation [C]: “detecting a motion from the subject via at least one sensor positioned on the subject”**

66. Claim 1 next recites “detecting a motion from the subject via at least one sensor positioned on the subject.” Gesotti describes such a method of detecting motion.

67. Gesotti discloses a version of the stimulation glove that combines the features of the stimulation glove in Figures 7 and 8 (referred to herein the “integrated tactile sensor and stimulation glove”). Ex. 1008 at 8:65-9:2, Figs. 7-9. The stimulation glove 825 in Figure 8 includes “a wire connector 819 [yellow] for connection to additional sensors such as...acceleration or pressure sensors attached to the wrist, forearm, upper arm or the like.” *Id.* at 8:39-43, Fig. 8.



Of course, if these sensors are attached to the wrist, forearm, upper arm or the like, then the sensors are “positioned on the subject.”

68. The purpose of an acceleration sensor is to detect motion of the subject. Gesotti confirms this understanding. For example, Gesotti confirms that that acceleration sensor detects movement. *Id.* at 4:4-6 (“Each sensor 110 is strategically located to receive information based on human body functions such as tactility (pressure), **movement** (acceleration), placement (inclination) and the like.”) (emphasis added); *see also id.* at 12:28-30 (“in one embodiment, the control unit receives inputs that indicate little or no motion (acceleration) at the wrist.”). Gesotti

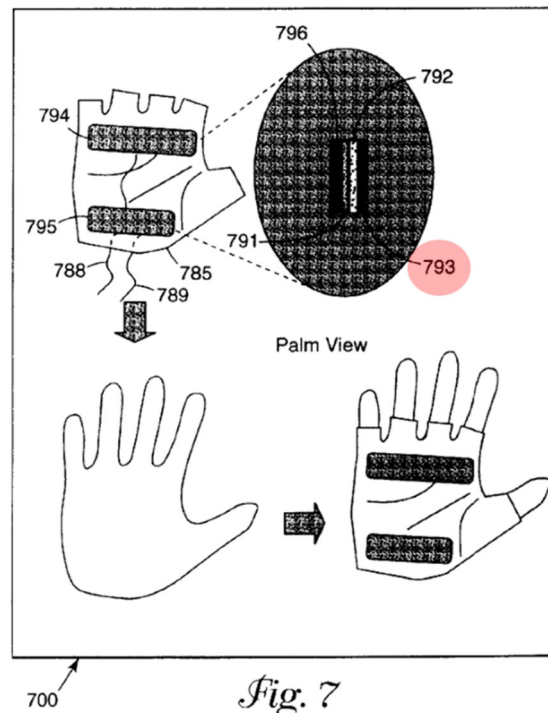
discloses the method for treating Parkinson’s disease involves receiving “one or more input signals from at least one sensor such as pressure, inclination, ***acceleration*** or the like, wherein the input signals are based on physical stimulus.” Thus, one of the purposes of Gesotti’s devices is to detect motion. Ex. 1008 at 11:46-52, 12:9-21, Fig. 16. Gesotti further explains that the “control unit receives the input signals and determines a response based on the input signals” including providing “electrical stimulation.” *Id.* at 12:9-21.

69. Thus, I conclude that Gesotti describes “detecting a motion from the subject via at least one sensor positioned on the subject.”

2. Claim 3

70. Claim 3 depends from claim 1 and recites: “wherein the stimulator electrode is a surface electrode.” Gesotti discloses this claim.

71. Gesotti’s stimulation glove 785 includes “a first and second tactile sensor assembly 794 and 795 respectively.” Ex. 1008 at 8:16-20. “[E]ach tactile sensor assembly includes a stimulation electrode 793, which is in direct contact with the palm of the hand....” *Id.* at 8:20-26. As shown in Figure 7, the electrode is positioned on the surface of the patient’s palm:



(*Id.*, Fig. 7.) Thus, because the electrode lies on the surface of the palm, the electrode is a “surface electrode.”

3. Claim 4

72. Claim 4 depends from claim 1 and recites: “wherein the electrical stimulation is delivered intermittently or on a chronic basis.” Gesotti discloses this claim or renders the claim obvious.

73. Gesotti discloses adaptive stimulators that “provide patients affected with Parkinson’s disease relief from the symptoms.” Ex. 1008 at 2:5-10. The stimulators are “adapted to selectively provide stimulation in response to” signals received from sensors. *Id.* at 14:3-9. The adaptive stimulator’s control unit 120 “selectively adjusts stimulation voltage, frequency, pulse width, waveform shape,

amplitude, modulation type and the like of each electrical stimulation signal based on sensor information.” *Id.* at 4:11-14. The “[m]odulation type allows selection of one of a collection of dynamic waveform changes that vary amplitude, frequency or pulse width in some predetermined manner.” *Id.* at 4:15-20. Gesotti explains that in “some applications, the body adapts to static waveforms decreasing sensitivity and this modulation feature prolongs stimulation effectiveness.” *Id.* Additionally, Gesotti explains that the duration of stimulation can be modified in response to feedback from the sensors. *Id.* at 13:7-19, 12:9-21. Since the duration of the stimulation is a parameter that can be programmed or controlled via feedback, Gesotti’s stimulator can provide intermittent stimulation.

74. Additionally, Figure 16 illustrates “one embodiment of a method of adaptive stimulation for the treatment of the symptoms of Parkinson’s disease according to the teachings of the present invention.” Ex. 1008 at 11:46-49.

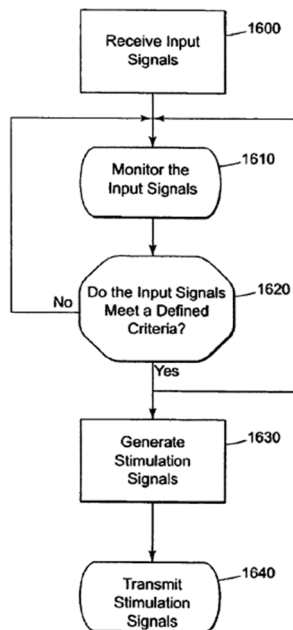


Fig. 16

The adaptive stimulator receives input signals from one or more sensors based on physical stimulus. *Id.* at 11:49-64. The stimulator then determines if the signal meets defined criteria. If the signal does not meet the defined criteria, the stimulator continues to monitor the signals. *Id.* If the signal meets defined criteria, the stimulator generates a stimulation signal **and** “continues to monitor the input signals while the method proceeds.” *Id.* at 11:59-64. Thus, the stimulator intermittently delivers electrical stimulation based on whether the criteria is met.

75. Figure 16 describes methods of treating symptoms of Parkinson’s disease “according to the teachings of the present invention,” and Figure 7-9 also discloses an embodiment “of the present invention.” Ex. 1008 at 8:16-19, 11: 46-49. Accordingly, a person of ordinary skill in the art would have understood Gesotti to disclose that the method in Figure 16 is applicable to the glove in Figure 7-9.

76. Moreover, Gesotti explain that the “control unit is programmable for each patient to respond based on a set of criteria.” Ex. 1008 at 12:39-40. “In one embodiment, a control unit is programmed to provide electrical stimulation and if the electrical stimulation does not produce the desired result the control unit will adapt to change the voltage, frequency, pulse width, amplitude, waveform and/or the like of the electrical stimulation signals.” *Id.* at 12:40-45. “In a further embodiment, the control unit changes the sequence or the cadence of the stimulation.” *Id.* at 12:49-50. As mentioned above, Gesotti recognizes that habituation and decreasing sensitivity to static waveforms occurs. Ex. 1008 at 4:13-20. The electrical stimulation will not produce the desired result if habituation occurs so the system must operate intermittently, such as by adapting the frequency. Thus, this disclosure further confirms that the stimulation may be delivered intermittently.

77. If the Patent Owner argues that Gesotti does not disclose the delivery of electrical stimulation intermittently or on a chronic basis, a person of ordinary skill in the art would have found it obvious to do so based on Gesotti. Gesotti discloses “there is no cure for Parkinson’s disease, only treatment to relieve the symptoms.” Ex. 1008 at 1:30-32. Additionally, Gesotti recognizes that the patient’s behavior and conditions may change over time requiring different types of treatment. *See e.g., id.*, 11:46-64 (describing treatments responsive to physical stimulus). Thus, a person of ordinary skill in the art would have been motivated to deliver the

electrical stimulation designed to “aid in the relief of symptoms of Parkinson’s disease” intermittently so that it remains effective and avoids habituation. *Id.* at 2:39-40.

78. A person of ordinary skill in the art would have reasonably expected success in delivering electrical stimulation intermittently because Gesotti provides methods to ensure that the electrical stimulation is delivered safely and effectively. As discussed above, Gesotti describes methods of modifying the electrical stimulation if the initial stimulation is ineffective. Ex. 1008 at 4:11-20, 12:39-50. Gesotti also discloses “monitoring stimulation electrode voltage and current to prevent exposure of the patient to uncomfortable stimulation levels.” *Id.* at 11:65-67; *see also id.* at 4:58-61 (“monitoring circuit 128 [that] monitors stimulation electrode voltage and current and provides information to controller 122 to prevent exposure of the patient to uncomfortable stimulation levels”).) Ultimately, the application of the electrical stimulation intermittently and on a chronic basis is a predictable use of prior art elements (adaptive stimulator) according to their established functions (delivering stimulation to treat tremor).

4. Claim 5

79. Claim 5 depends from claim 1 and recites: “adjusting or optimizing the electrical stimulation in response to a feedback signal received from the sensor

indicative of the detected motion and efficacy of the applied electrical stimulation therapy.” Gesotti discloses this claim.

80. Gesotti discloses using sensors, including accelerometers, for detecting motion of the subject. *See e.g.*, Ex. 1008, 4:4-7 (“Each sensor 110 is strategically located to receive information based on human body functions such as tactility (pressure), movement (acceleration), placement (inclination) and the like.”); Fig. 1 (identifying accelerometer). “Each sensor [green] provides information to control unit 120” [yellow]:

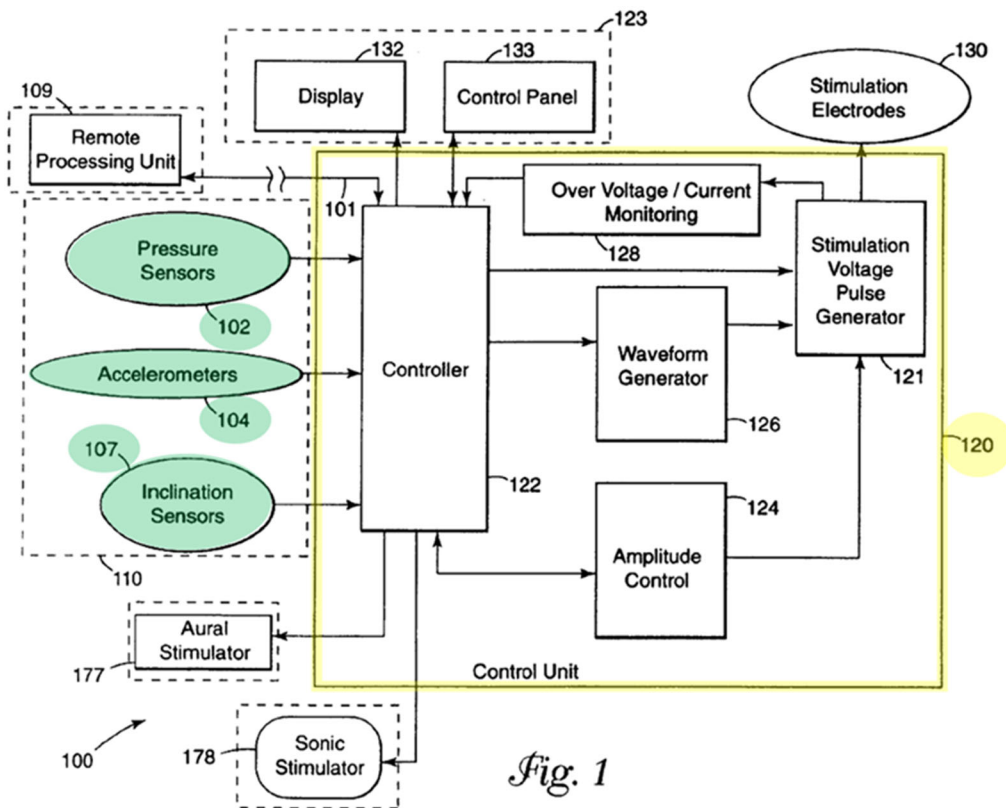


Fig. 1

Id. at 4:7-8, Fig. 1. The “[c]ontrol unit 120 receives the information and uses the information to determine when electrical stimulation is required at the location of

each stimulation electrode 103.” *Id.* at 4:8-11. For example, “[c]ontrol unit 120 selectively adjusts stimulation voltage, frequency, pulse width, waveform shape, amplitude, modulation type and the like of each electrical stimulation signal based on sensor information.” *Id.* at 4:11-14.

81. In a specific embodiment, Gesotti discloses providing stimulation based on the detection of “little or no motion (acceleration)” by the sensor. *Id.* at 12:28-33. In this embodiment, the “control unit is programmable for each patient to respond based on a set of criteria.” *Id.* at 12:39-40. “In one embodiment, a control unit is programmed to provide electrical stimulation and if the electrical stimulation does not produce the desired result the control unit will adapt to change the voltage, frequency, pulse width, amplitude, waveform and/or the like of the electrical stimulation signals.” *Id.* at 12:40-45. “In a further embodiment, the control unit changes the sequence or the cadence of the stimulation.” *Id.* at 12:49-50.

82. The stimulation glove 485 (Figure 7) “is coupled to a control unit such as control unit 120” and, therefore, the above disclosures apply to the sensors included with the stimulation glove. *Id.* at 8:29-30. In fact, Gesotti discloses using signals received from sensors in the stimulation glove to adjust the stimulation level. *See e.g., id.* at 8:31-33 (“In one embodiment, the electrical leads provide pressure information to a control unit for a determination of the need for stimulation.”). Thus, Gesotti discloses adjusting or optimizing the electrical stimulation in response to a

feedback signal received from the sensor indicative of the detected motion and efficacy of the applied electrical stimulation therapy, as required by claim 5.

5. Claim 6

83. Claim 6 depends from claim 5 and recites: “wherein the feedback is queried such that the electrical stimulation therapy is adjusted to ensure that a minimum amount of energy is being applied to stimulate the target nerve while reducing the risk of burns or intolerance.” Gesotti discloses this claim.

84. Gesotti discloses “monitoring stimulation electrode voltage and current to prevent exposure of the patient to uncomfortable stimulation levels.” Ex 1008 at 11:65-67. In one embodiment, the control unit 120 includes “an over voltage/current monitoring circuit 128 [purple] coupled between stimulation voltage pulse generator 121 and controller 128.” *Id.* at 4:55-58. The “[m]onitoring circuit 128 monitors stimulation electrode voltage and current and provides information to controller 122 to prevent exposure of the patient to uncomfortable stimulation levels.” *Id.* at 4:58-61.

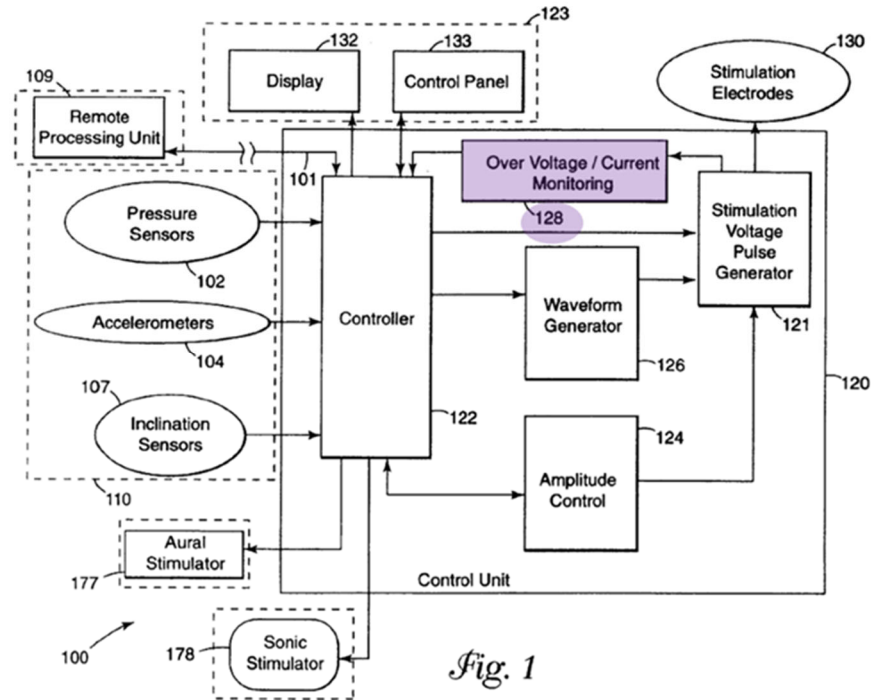


Fig. 1

Id. at Fig. 1. A person of ordinary skill in the art would have understood Gesotti's reference to "uncomfortable stimulation levels" to mean patient intolerance of the stimulation.

85. Gesotti discloses that the stimulation glove (Figure 7) "is coupled to a control unit such as control unit 120" and, therefore, the above disclosures apply to the sensors included with the stimulation glove. Ex. 1008 at 8:29-30. Thus, Gesotti discloses that the feedback is queried such that the electrical stimulation therapy is adjusted to ensure that a minimum amount of energy is being applied to stimulate the target nerve while reducing the risk of burns or intolerance.

6. Claim 7

86. Claim 7 depends from claim 5 and recites: “wherein the feedback is queried such that the positioning of the stimulator electrode is adjusted to optimize the electrical stimulation therapy.” Gesotti renders this limitation obvious.

87. Gesotti discloses several methods of querying the sensor feedback to optimize the electrical stimulation therapy, including selectively adjusting the “stimulation voltage, frequency, pulse width, waveform shape, amplitude, modulation type and the like of each electrical stimulation signal based on sensor information.” Ex. 1008 at 4:11-14. Gesotti also recognizes that the sensors must be “strategically positioned” across the patient’s body, including the hand, fingers, head, wrist, and ankle. *Id.* at 12:1-15. Based on these disclosures, a person of ordinary skill in the art would have found it obvious to adjust the position of the stimulation electrode based on the sensor feedback if the other methods for optimizing the electrical stimulation were ineffective. A person of ordinary skill in the art would have understood that there were a finite number of predictable adjustments that could be made to the stimulation electrode to improve its function. The predictable options would have included the electrical adjustments (*e.g.*, stimulation voltage, frequency, etc.) and moving the stimulation electrode to a more effective location.

88. A person of ordinary skill in the art would have reasonably expected success in adjusting the position of the stimulator electrode because Gesotti discloses placing stimulator electrodes at various positions on the human body. *See* Ex. 1008 at 6:49-53 (“cylindrical electrode 300 adjusts to fit a variety of different sized body parts for example one size that fits a variety of upper arms, forearms, wrists, torsos, ankles, knees, calves, thighs, or the like”).

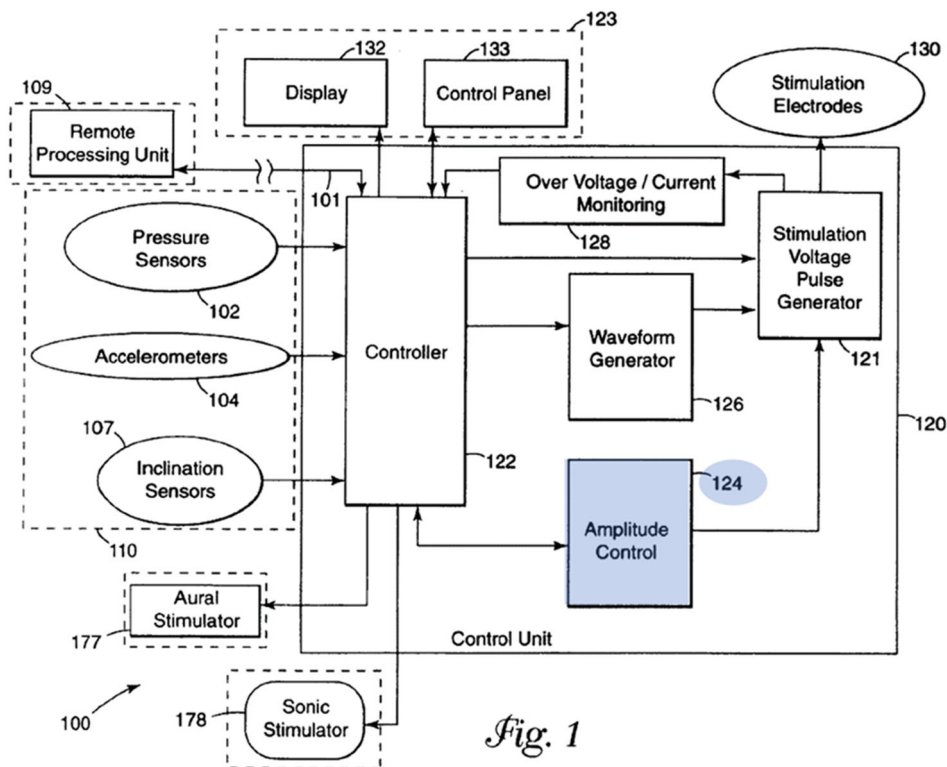
89. With respect to the patient’s hand, Gesotti discloses methods of effectively treating the patient by positioning stimulation electrodes at various locations on the hand, including the top and bottom of the palm and along the fingers. *Id.* at 8:16-9:9, Figs. 7-8. If a stimulation electrode was ineffective at the bottom of the palm, a person of ordinary skill in the art would have reasonably expected success in moving the stimulation electrode to the top of the palm or to the fingers based on the teachings in Gesotti.

7. Claim 9

90. Claim 9 depends from claim 1 and recites: “wherein the pulses generated during the electrical stimulation therapy include pulses of a first amplitude and pulses of a second amplitude, where the first amplitude is different from the second amplitude.” Gesotti discloses this claim

91. Gesotti’s “[c]ontrol unit 120 selectively adjusts stimulation voltage, frequency, pulse width, waveform shape, *amplitude*, modulation type and the like

of each electrical stimulation signal based on sensor information.” Ex. 1008 at 4:11-14 (emphasis added); *see also id.* at 4:15-17 (“Modulation type allows selection of one of a collection of dynamic waveform changes that vary amplitude, frequency or pulse width in some predetermined manner.”). The control unit 120 includes an “amplitude control device 124” to adjust the amplitude. *Id.* at 4:61-64, Fig. 1.



Id. at Fig. 1; *see also id.* at 13:29-38, Fig. 17 (describing “amplitude control potentiometer P3”. By selectively adjusting the pulse amplitude, the control unit creates pulses having a first amplitude (original amplitude) and a second amplitude (amplitude after change) where the amplitudes are different. The alternative pulse amplitudes described in Claim 9 are a subset of the possible amplitude modulations disclosed by Gesotti. Thus, Gesotti discloses this limitation.

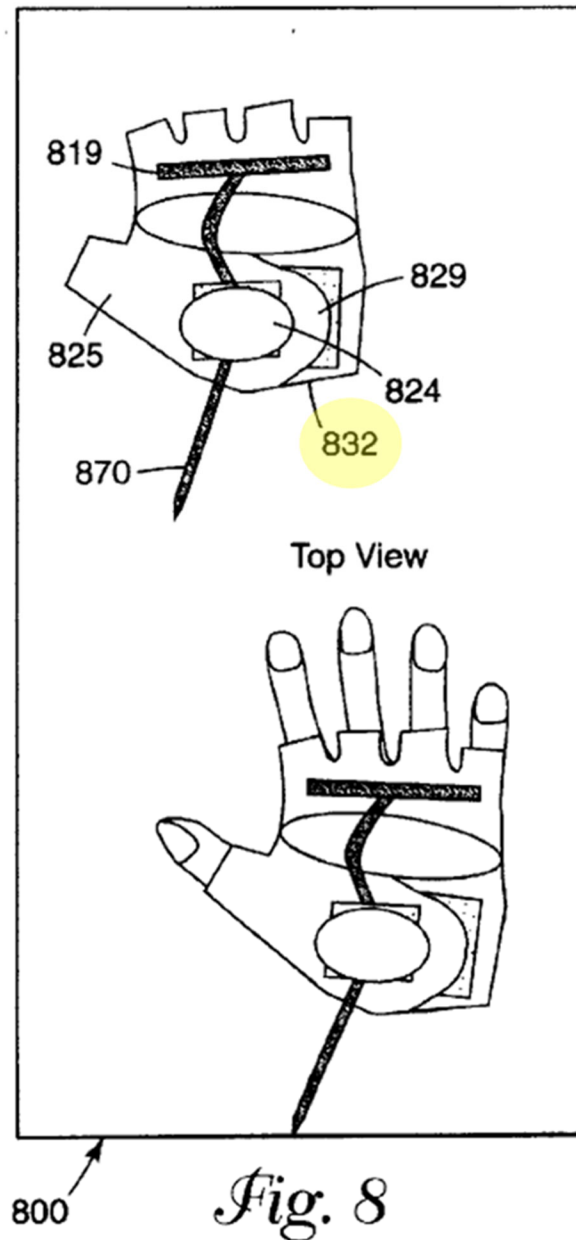
8. Claim 10

92. Claim 10 depends from claim 1 and recites: “positioning a return electrode on the subject to facilitate penetration of an electrical current through the surface to stimulate the target nerve.” Gesotti discloses this claim.

93. Gesotti discloses that “each stimulation electrode 130” connected to the control unit 120 “include[s] a common return electrode.” Ex. 1008 at 3:63-64, Fig. 1. “The common return electrode is in direct contact with the skin and provides the return path for each of the electrical stimulation electrodes.” *Id.* at 3:65-67. Gesotti further discloses that the common return electrode has “a large surface area and as a result a lower impedance than each of the stimulation electrodes” and, therefore, aids “in keeping the current at the contact location at a comfortable level for the patient.” *Id.* at 3:67-4:4. Thus, Gesotti’s return electrodes are on the subject and facilitate penetration of an electrical current through the surface to stimulate the target nerve.

94. The description of the return electrode with respect to Figure 1 also applies to the electrodes on the stimulation glove in Figure 7. As discussed previously, the stimulation electrodes on the glove are connected to control unit 120 and, therefore, the “stimulation electrodes” 130 in the block diagram of Figure 1 encompass the stimulation electrodes in the stimulation glove of Figure 7. Ex. 1008 at 8:29-30.

95. Gesotti also describes an embodiment where “the features of stimulation glove 785 of FIG. 7 and the features of stimulation glove 825 are combined to create an integrated tactile sensor and stimulation glove which is coupled to a control unit such as control unit 120 of FIG. 1.” Ex. 1008 at 8:65-9:2. “[S]timulation glove 825 includes a common return electrode 832 [yellow].” *Id.* at 8:48-49.



Id. at Fig. 8.

96. As with the other return electrodes, the “[c]ommon return electrode 832 is in direct contact with the skin and provides the return path for each of the electrical stimulation electrodes attached to the body.” *Id.* at 8:49-51. Further, the return electrode 832 “provides a large surface and as a result a lower impedance than each

of the stimulation electrodes, this is adapted to aid in keeping the current at the contact location at a comfortable level for the patient.” *Id.* at 8:52-55. Thus, for the stimulation electrodes positioned on the palm of the glove in this embodiment, the common return electrode facilitates penetration of an electrical current through the surface to stimulate the target nerve.

9. Claim 11

97. Claim 11 depends from claim 1 and recites: “wherein the stimulator electrode is attached to the skin surface with an adhesive.” Gesotti renders this claim obvious.

98. Gesotti discloses embodiments where the stimulator electrodes are attached to the patient’s skin with a “conductive adhesive gel.” *See e.g.*, Ex. 1008 at 6:30-41 (“In one embodiment, conductive skin contact area 339 comprises a conductive adhesive gel for electrically coupling stimulation electrode 300 to the skin.”); *see also id.* at 5:56-65, 10:9-12, 11:5-8. Gesotti expressly states, “The conductive gel is adhesive in nature so that it may perform a dual function by both electrically coupling the electrode to the body and adhering the electrode to the body.” Ex. 1008 at 5:59-62.

99. Based on Gesotti’s extensive disclosure of using adhesives to attach stimulator electrodes to a patient’s skin, a person of ordinary skill in the art would have found it obvious to attach the stimulator electrode described in Figure 7 to the

patient's palm using the conductive adhesive gel. Gesotti discloses that the "conductive gel is adhesive in nature so that it may perform a dual function by both electrically coupling the electrode to the body and adhering the electrode to the body." Ex. 1008 at 5:59-62. A person of ordinary skill in the art would have been motivated to try attaching the stimulation electrode to the palm with the adhesive to achieve an enhanced connection between the electrode and skin and enhanced electrical coupling. This electrical coupling using the gel would be superior, in some circumstances, to positioning the electrode directly against the skin using only an adhesive electrode. Additionally, adhering the stimulation electrode to the skin with the adhesive can provide additional flexibility by better protecting the coupling between the skin and the electrode if the glove is removed.

100. Moreover, a person of ordinary skill in the art would have recognized there are only a finite number of predictable ways to hold the stimulator electrode in contact with the palm of the hand. A simple adhesive gel or an adhesive electrode would have been well within the skill and knowledge of a person of ordinary skill in the art.

101. A person of ordinary skill in the art would have reasonably expected success in attaching the stimulation electrode to the patient's palm with the conductive adhesive gel because Gesotti encourages using adhesive gels on various

body parts. Both adhesive electrodes and adhesive gels were well known and common methods of coupling electrodes to the skin in 2011.

10. Claim 12

102. Claim 12 depends from claim 1 and recites: “wherein the stimulator electrode is positioned over the skin surface with an ergonomic applicator.” Gesotti discloses this claim.

103. Gesotti discloses positioning a stimulator electrode over the patient’s palm with a stimulator glove. Ex. 1008 at 8:16-35, Fig. 7. Thus, Gesotti discloses the claimed ergonomic applicator.

11. Claim 13

104. Claim 13 depends from claim 12 and recites: “wherein the applicator is a glove or brace configured to be positioned against a skin surface such that the electrode delivers electrical stimulation to the target nerve or tissue.” Gesotti discloses this limitation for the reasons explained in Claims 1 and 12. *Supra* §VI.A.1.b, §VI.A.11.

12. Claim 16

105. Claim 16 depends from claim 1 and recites: “wherein once tetany is detected in a patient, indicating that a threshold frequency of the applied stimulation has been reached, the strength of the applied stimulation is automatically or manually decreased.” Gesotti anticipates this limitation or renders it obvious.

106. Tetany is the overstimulation of neuromuscular activity characterized by muscle twitches, spasms, and cramps. Ex. 1013, 1966. Gesotti does not expressly mention “tetany.” However, Gesotti discloses “monitoring stimulation electrode voltage and current to prevent exposure of the patient to uncomfortable stimulation levels.” Ex 1008 at 11:65-67. In one embodiment, the control unit 120 includes “an over voltage/current monitoring circuit 128 [purple] coupled between stimulation voltage pulse generator 121 and controller 122.” *Id.* at 4:55-58. The “[m]onitoring circuit 128 monitors stimulation electrode voltage and current and provides information to controller 122 to prevent exposure of the patient to uncomfortable stimulation levels.” *Id.* at 4:58-61.

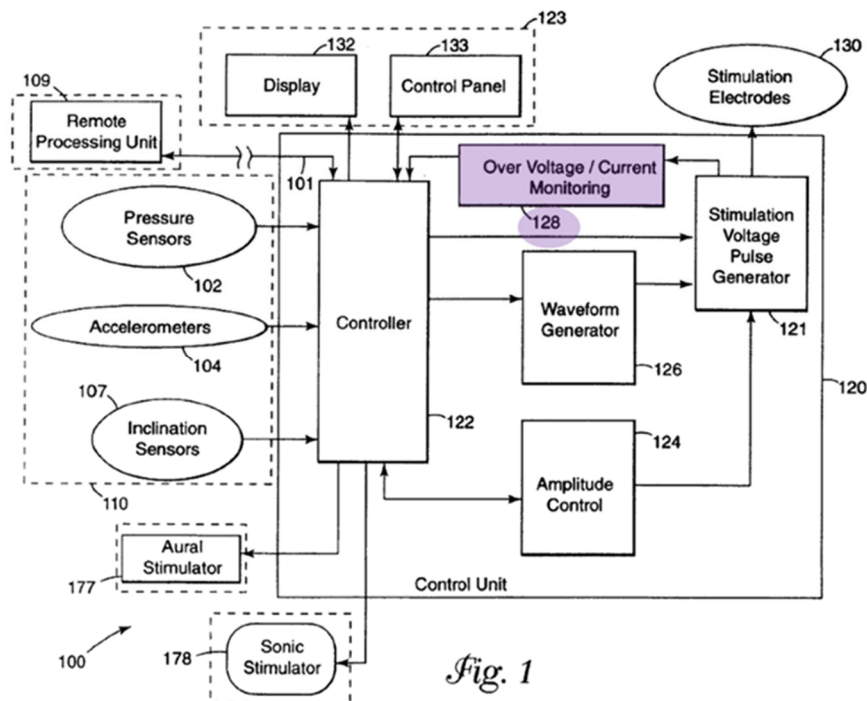


Fig. 1

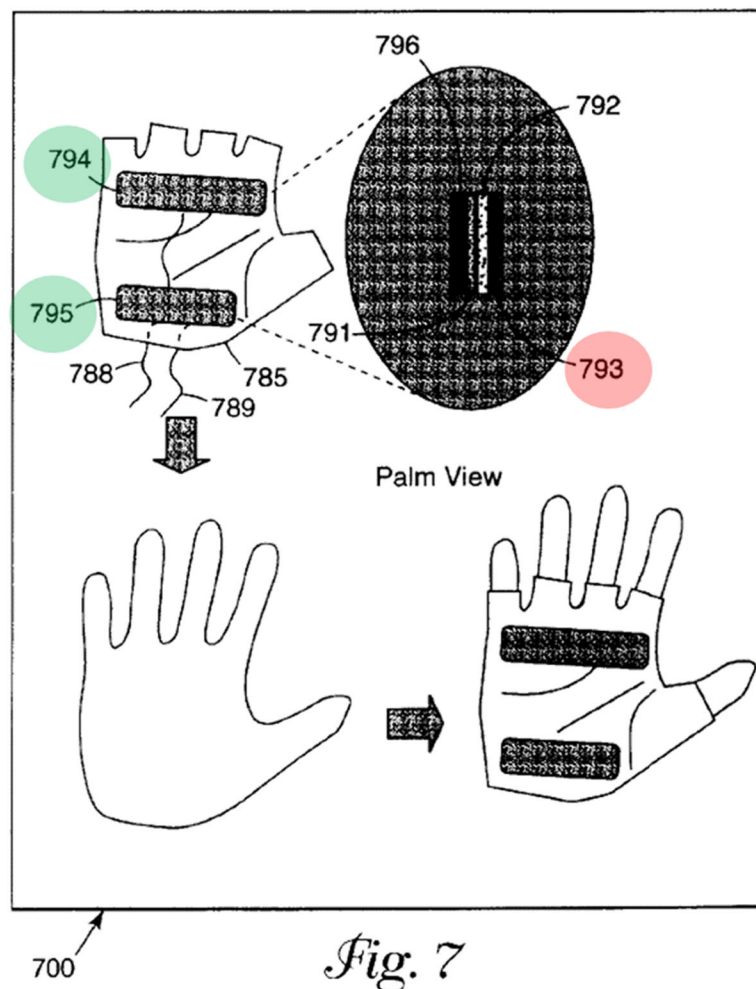
Id. at Fig. 1.

107. The symptoms of tetany (e.g., muscle twitches, spasms, and cramps) reflect uncomfortable stimulation levels, which would cause Gesotti's controller to decrease the strength of the stimulation signal. Likewise, a person of ordinary skill in the art would have found it obvious, and been motivated, to use the functionality of Gesotti's device to decrease the strength (e.g., voltage or current) of the stimulation signal when the sensors detect, or the patient experiences, tetany. Gesotti explains that "[e]ach application of an adaptive stimulator is individualized and requires criteria for each patient" and, therefore, the "control unit is programmable for each patient to respond based on a set of criteria." Ex. 1008 at 12:37-40. Gesotti explains that "a control unit is programmed to provide electrical stimulation and if the electrical stimulation does not produce the desired result the control unit will adapt to change the voltage, frequency, pulse width, amplitude, waveform and/or the like of electrical stimulation signals." *Id.* at 12:40-45. Tetany is not a "desired result." Thus, the control unit will automatically reduce the stimulation strength and, to the extent that it does not, a person of ordinary skill in the art would have been motivated to adjust the programming and reduce the stimulation strength so that the patient does not experience pain. A person of ordinary skill in the art would have expected success in reducing the stimulation strength because Gesotti suggests altering the stimulation voltage or current to prevent uncomfortable stimulation levels.

13. Claim 18

108. Claim 18 depends from claim 1 and recites: “wherein positioning a stimulator electrode comprises positioning at least two electrodes over the skin surface.” Gesotti discloses this limitation.

109. Gesotti discloses that the stimulation glove in Figures 7-9 includes two stimulation electrodes 793 in each “tactile sensor assembly” 794 and 795:



Ex. 1008 at 8:16-35, Fig. 7. Each stimulation electrode 793 “is in direct contact with the palm of the hand,” and, therefore, positioned over a skin surface. *Id.*

14. Claim 19

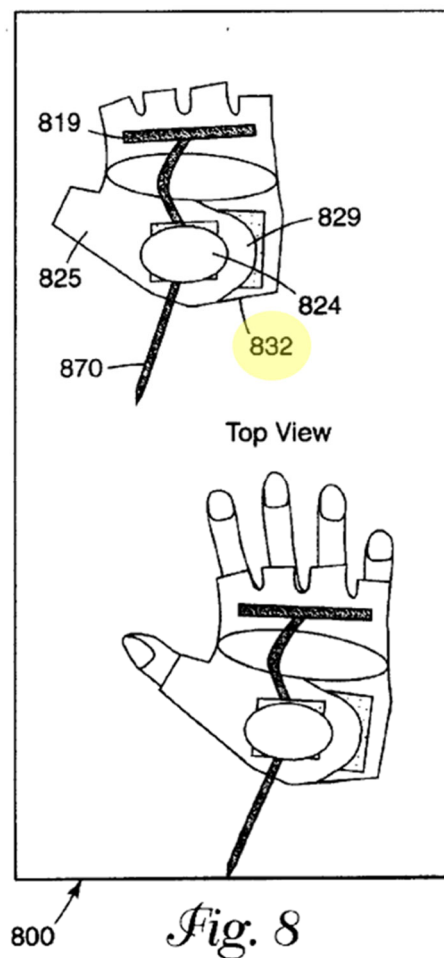
110. Claim 19 depends from claim 18 and recites: “wherein the at least two electrodes are positioned to stimulate an Ulnar or Median nerve.” Gesotti discloses this limitation for the reasons explained in Claim 1. *Supra*, §VI.A.1.b (Limitation [A]).

15. Claim 20

111. Claim 20 depends from claim 18 and recites: “wherein the at least two electrodes are positioned in opposition relative to one another.” Gesotti discloses this limitation.

112. Gesotti discloses a stimulation glove (Figure 7) having stimulation electrodes positioned on the upper and lower palm. Ex. 1008 at 8:16-35, Fig. 7. These electrodes are “in opposition relative to one another” because they are on opposite surfaces of the palm (i.e., upper and lower).

113. Gesotti also describes an additional embodiment where “the features of stimulation glove 785 of FIG. 7 and the features of stimulation glove 825 are combined to create an integrated tactile sensor and stimulation glove which is coupled to a control unit such as control unit 120 of FIG. 1.” Ex. 1008 at 8:65-9:2. “[S]timulation glove 825 includes a common return electrode 832 [yellow]” positioned on the back of the hand. *Id.* at 8:48-49.



Id. at Fig. 8. The “[c]ommon return electrode 832 is in direct contact with the skin and provides the return path for each of the electrical stimulation electrodes attached to the body.” *Id.* at 8:49-51. The return electrode 832, which is located on the back of the hand, is “positioned in opposition relative” to the stimulation electrode 793, which is located on the palm of the hand. *See* Ex. 1008 at 9:29-34, 10:31-36, Figs. 10, 13 (disclosing stimulator electrodes positioned in opposition to each other).

B. Ground 3: Claims 2, 8, 17 Are Obvious Over Gesotti and Gesotti '896

1. Motivation To Combine Gesotti and Gesotti '896

114. I understand that Gesotti '896 is related to Gesotti and incorporates Gesotti. Ex. 1009 at 1:11-17. Additionally, Gesotti '896 expressly describes using the sensors and stimulators described in Gesotti. *Id.* at 5:60-6:2. Based on these teachings, a person of ordinary skill in the art would have been motivated to combine the teachings of Gesotti '896 with Gesotti.

115. Moreover, like Gesotti, Gesotti '896 discloses methods for relieving symptoms of Parkinson's disease, including tremors. Ex. 1009 at 1:20-44, 1:55-2:10, 2:3-40, 4:16-17, 5:1-12, 5:44-49, 12:51-59, 16:46-60; *see also, id.* Tables 11 and 12. Both Gesotti patents use similar adaptive stimulators to provide stimulation and monitor feedback from the patient. *Compare* Ex. 1008, Fig. 1 *and* Ex. 1009, Fig. 1. Thus, in addition to the express suggestion to combine the patents, a person of ordinary skill in the art would have been motivated to combine the teachings of the Gesotti patents because the patents address the same problem (*e.g.*, symptoms of Parkinson's disease, including tremor) and do so using similar devices (*e.g.*, stimulation electrodes, sensors, and control units). A person of ordinary skill in the art would have reasonably expected success in using the methods described in Gesotti '896 with Gesotti because Gesotti '896 suggests the combination and the systems are so similar.

2. Claim 2

116. Claim 2 depends from claim 1 and recites “wherein the electrical stimulation is delivered at a frequency of about 5 Hz to about 60 Hz, while remaining safe and tolerable to the subject.” Gesotti in combination with Gesotti ’896 renders this claim obvious.

117. Gesotti discloses a stimulation device having a control unit 120 that “selectively adjusts stimulation voltage, *frequency*, pulse width, waveform shape, amplitude, modulation type and the like of each electrical stimulation signal based on sensor information.” Ex. 1008 at 4:11-14 (emphasis added). However, Gesotti does not expressly disclose the frequencies used in the stimulation device.

118. Gesotti ’896 discloses frequency values for the stimulation devices described in Gesotti. Gesotti ’896 explains that the stimulation periods for the described devices (referred to as “MTS”) are “typically 12-20 milliseconds.” Ex. 1009 at 11:1-4. This stimulation period corresponds to a frequency of 50-83 Hz, which is within the range recited in Claim 2. A 12-20 millisecond pulse period equates to 50-83 Hz because the inverse of .012 seconds per pulse equals 83 pulses per second (or 83 Hz). Likewise, the inverse of .020 seconds per pulse equals 50 Hz.

119. Gesotti ’896 also discloses an embodiment for “relieving bradykinesia, akinesia and freezing in Parkinson’s Disease” that uses a pulse period of 14

milliseconds (approximately 71 Hz). Ex. 1009 at 11:37-44. However, Gesotti '896 explains that this frequency is “significantly higher than the 40 Hz frequency *normally used for neuromuscular electrical stimulation and functional electrical stimulation.*” *Id.* at 11:40-44 (emphasis added). Thus, Gesotti '896 discloses that 40 Hz is the “normal frequency” used for neuromuscular stimulation, well within the range recited in Claim 2.

120. A person of ordinary skill in the art would have been motivated, and reasonably expected success, in using the frequency ranges described in Gesotti '896 with the stimulation device in Gesotti. First, Gesotti '896 incorporates the adaptive stimulator (MTS) in 'Gesotti and specifically suggests using the frequency ranges (e.g., 12-20 milliseconds) with the described MTS. Ex. 1009 at 5:60-6:2, 11:1-4. Second, a person of ordinary skill in the art would have been motivated to try the “normal” frequency for neurostimulation described in Gesotti '896 because the frequency had been commonly used and proven effective in the past.

3. Claim 8

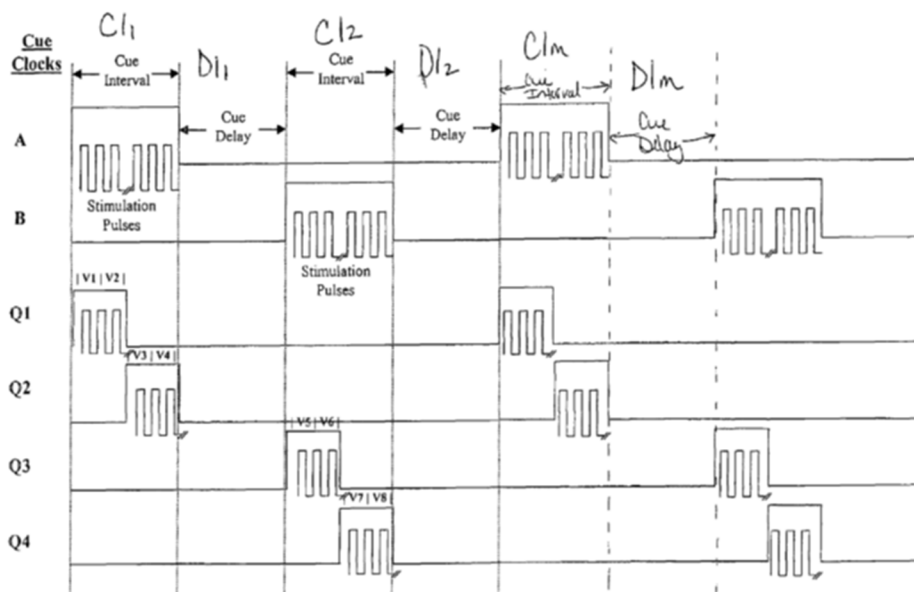
121. Claim 8 depends from claim 5 and recites: “wherein the sensor is a surface electrode.” Gesotti and Gesotti '896 render this claim obvious. Gesotti '896 discloses using electromyography in conjunction with motion sensors to detect patient motion. (See e.g., Ex. 1009, 6:3-22, 6:38-56, Fig. 1.) The electromyography includes surface electrodes. A person of ordinary skill in the art would have been

motivated to combine the electromyography with the gloves disclosed in Gesotti, and expected success in doing so, for the reasons provided above. (Supra §VI.B.1.)

4. Claim 17

122. Claim 17 depends from claim 1 and recites: “wherein electrical stimulation is provided by delivering a cycle comprising a preset number of pulses followed by a pause in stimulation, followed by a preset number of pulses, and repeating the cycle as necessary.” Gesotti in combination with Gesotti ’896 renders this claim obvious.

123. Gesotti ’896 discloses providing electrical stimulation through a preset number of pulses, followed by a cue delay (i.e., pause in stimulation), followed by another preset number of pulses:



Ex. 1009 at Fig. 4.

124. Gesotti '896 further explains that the preset number of pulses shown in Figure 4 is a “burst” that has a preset pulse count. Ex. 1009 at 8:35-55, Fig. 2. The preset number of pulses (burst count) can be customized for each channel. *Id.* at 8:41-43. Likewise, the cue delay between each burst can be preset for each channel or random. *Id.* at 8:52-56. Gesotti '896 discloses that the burst and cue settings can be adjusted depending on the treatment plan. For example, exemplary cue intervals and cue delays to reduce tremor are shown in Table 11. *Id.* at 17:15-25. A person of ordinary skill in the art would have been motivated to combine the treatment protocols of Gesotti '896 with Gesotti, and expected success in doing so, for the reasons previously provided. *Supra* §VI.B.1.

C. Ground 4: Claims 14-15 Are Obvious Over Gesotti and Stephens

1. Claim 14

125. Claim 14 depends from claim 1 and recites: “wherein the electrical stimulation is automatically paused for a preset amount of time every 10 minutes to overcome habituation.” Gesotti in combination with Stephens renders this limitation obvious.

126. Gesotti recognizes that habituation and decreasing sensitivity to static waveforms can occur. Ex. 1008 at 4:13-20 (“In some applications, the body adapts to static waveforms decreasing sensitivity....”). Thus, Gesotti discloses different modulation features to prolong “stimulation effectiveness.” *Id.* The modulation

feature permits the control unit to select “one of a collection of dynamic waveform changes that vary amplitude, frequency or pulse width in some predetermined manner.” *Id.* Gesotti also discloses that the control unit can make additional modifications to the stimulation based on information received from the sensors, including modifying “the type of stimulation, duration, frequency, amplitude and the like in order to produce the desired results.” *Id.* at 13:7-16. While Gesotti recognizes the problem caused by habituation and describes making adjustments to the stimulation, Gesotti does not expressly disclose the timing of the adjustments.

127. Stephens discloses methods of electrically stimulating nerves to treat urinary incontinence. Ex. 1019 at abstract, 1:9-13. “In an embodiment, rather than constant stimulation of the one or more nerves, stimulation may be by way of a duty cycle, the nerve stimulation being on for a period and off for a period.” *Id.* at 6:1-4, 9:19-22. Like Gesotti, Stephens explains that the “[d]uty cycle and other signal characteristics may be adjusted to provide the most effective stimulation.” *Id.* at 21:28-30. Stephens specifically claims generating a stimulation signal in accordance with the duty cycle “wherein the on period is 10 minutes or more and the off period is 20 minutes or more.” *Id.* at 42:6:8; *see also id.* at 42:9-14 (claiming on periods of “8 minutes or more” and “5 minutes or more”). Stephens also discloses that the on and off periods may be the same. *See e.g., id.* at 20:7-9 (“The signal may be long duty cycle stimulation (e.g. five minutes on, five minutes off.”). Thus, Stephens

discloses automatically pausing stimulation for a preset amount of time every 10 minutes (e.g., 10 minutes on/10 minute off or 10 minutes on/20 minutes off).

128. A person of ordinary skill in the art would have been motivated to vary the duration of the pulse signal, as taught in Gesotti, according to the timings disclosed in Stephens to address the known problem of habituation. Both references disclose methods of using electrical stimulation to treat neurological disorders. While Stephens focuses on a treating urinary incontinence using implantable electrodes, persons of ordinary skill in the art using electrical stimulation for one application regularly consulted the use of electrical stimulation in other applications. In fact, the '669 patent assumes that methods of electrical stimulation for treating urinary incontinence are applicable to treating tremor. While the '669 patent extensively discusses using electrical stimulation to treat urinary incontinence, it mentions “tremor” only once and still claims that the disclosed devices may treat “tremor.” Ultimately, the use of Stephens stimulation durations with Gesotti is merely the application of a known technique (Stephens’ timing) to a known device (Gesotti’s stimulator) ready for improvement to yield predictable results.

129. A person of ordinary skill in the art would have expected success in adjusting the duration of Gesotti’s system using the timing set forth in Stephens. Gesotti already discloses that adjustments to the stimulation may be necessary to avoid habituation. Ex. 1008 at 4:11-19. Moreover, Gesotti discloses that the

stimulation may be turned on and off based on feedback from sensors and that the duration of the signal may be changed. *Id.* at 13:7-19, 12:9-21. A person of ordinary skill in the art would have recognized that 10 minutes falls within a typical range for stimulating a patient and, so long as the other aspects of the stimulation like current and voltage were appropriately set, would not have expected any negative results from that duration of treatment.

2. Claim 15

130. Claim 15 depends from claim 1 and recites: “wherein the electrical stimulation is automatically paused for a preset amount of time every 10 minutes based on feedback provided by the at least one sensor.” Gesotti in combination with Stephens renders this limitation obvious.

131. As explained above, Gesotti discloses that the stimulation may be turned on and off based on feedback from sensors and that the duration of the signal may also be changed based on the feedback. *Supra* §VI.C.1 (Claim 14). Stephens discloses automatically pausing electrical stimulation for a preset amount every 10 minutes. *Id.* A person of ordinary skill in the art would have found it obvious to combine the teachings of Gesotti and Stephens, and expected success in doing so, for the reasons provided above.

D. Grounds 5-6: Claims 1-12, 16, 18-20 Are Anticipated Or Rendered Obvious by Burnett

1. Independent Claim 1

132. Claim 1 is anticipated or rendered obvious by Burnett.

a. Preamble

133. The preamble of claim 1 recites “A method for providing transdermal electrical stimulation therapy to a subject for treating tremors, comprising.”

134. If the preamble is limiting, Burnett discloses this limitation. The ’669 patent is a continuation-in-part of Burnett (App. No. 12/508,529). Ex. 1001 at 1:15-17. Consequently, Burnett includes large portions of the ’669 patent specification. For example, Burnett includes Figures 1-30b of the ’669 patent and the accompanying description of those figures. *Compare* Ex. 1001 at 10:18-63:63, Figs. 1-30b *with* Ex. 1010 at [0070-0193], Figs. 1-31.

135. Burnett describes electrical and magnetic stimulation devices to treat overactive bladder and incontinence. Ex. 1010 at [0002, 0036, 0038, 0070]. However, Burnett includes the same list of over 100 ailments found in the ’669 patent, including “tremor.” *Id.* at [0111]. Thus, if the ’669 patent discloses a “method...for treating tremors,” then so does Burnett.

136. Burnett also describes transdermal electrical stimulation therapy. For example, Burnett discloses embodiments for nerve stimulation where electrical

energy is dispensed through “a transcutaneous stimulator, such as an electrode 126 [red].” Ex. 1010 at [0109].

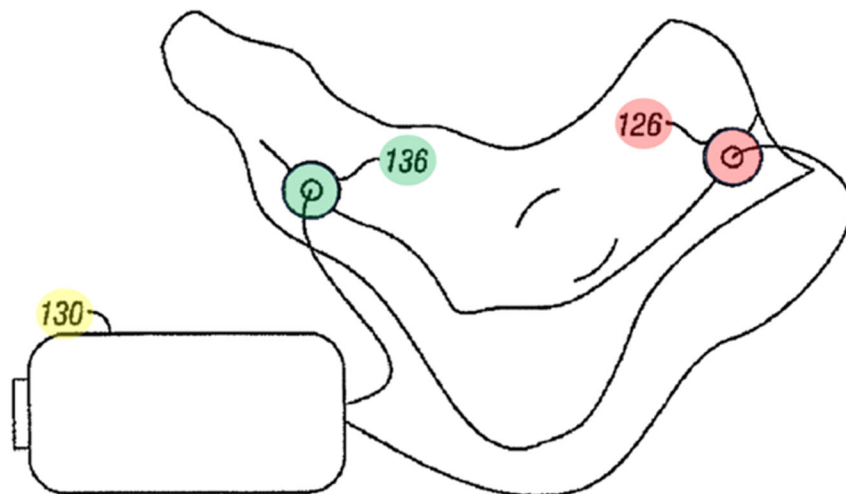


FIG. 11

Id. at Fig. 11. As shown, the transcutaneous stimulator (electrode) is a transdermal patch placed on the patient’s skin. An “electrical pulse controller 130 [yellow] is connected to both electrode 126 and to sensor 136 [green]” “to provide the desired feedback and modulate the power to” the electrode 126. Ex. 1010 at [0109]. Thus, the transcutaneous stimulator (electrode 126) provides transdermal electrical stimulation therapy. *See* Ex. 1010 at [0032, 0036, 0038, 0088, 0109] (describing other embodiments).

137. While Figure 11 illustrates the stimulation of the “posterior tibial nerve,” Burnett discloses that the stimulation devices may be used to treat “other peripheral nerves,” which would include the nerves in the arm and hand. Ex. 1010 at [0110]; *see also id.*, at [0102] (“One or more of the illustrated sensors 94 may be

employed over body regions being stimulated (for example, back, leg, arm, neck, head, torso, etc.)...”); [0126] (“The invention described herein may be applied to any body tissues, including nerve, muscle, skin, vasculature, or any other organ or tissue within the human body.”).

b. **Limitation [A]: “positioning a stimulator electrode over a skin surface overlying a target nerve or tissue which extends through a hand of the subject”**

138. Claim 1 next recites “positioning a stimulator electrode over a skin surface overlying a target nerve or tissue which extends through a hand of the subject.” If “skin surface” is not limited to a “glabrous skin surface which overlies the palm of the hand,” and instead has its plain and ordinary meaning, then Burnett discloses this limitation or renders it obvious. *See also supra* §IV (discussing claim construction).

139. Burnett discloses positioning “a transcutaneous stimulator, such as an electrode 126 [red],” over a skin surface overlying a target nerve (e.g., tibial nerve below):

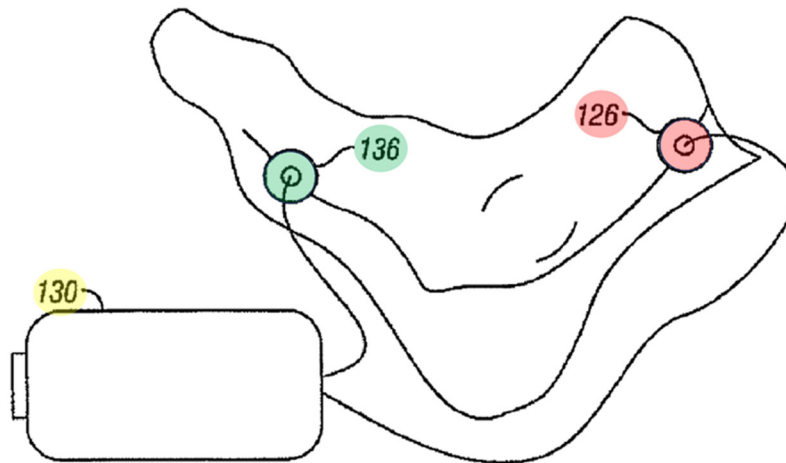


FIG. 11

Ex. 1010 at [0109], Fig. 11; *see also id.* at [0164] (describing “electrode patch” “to provide or deliver an electrical stimulus or magnetic field, e.g., to a target nerve”).

140. Burnett also discloses additional varieties of stimulator electrodes for placement over a skin surface including, for example, “a microneedle patch 252...having one or more microneedle arrays deposited on a surface of one or more electrodes.” Ex. 1010 at [0154]; *see also id.* at [0166] (“In the case of a microneedle patch, the patch may be attached to the subject’s skin.”). “The microneedle patch 252 is configured such that an electrical current generated by the controller 218 is passed through the microneedle patch 252...delivering or generating an electrical or magnetic stimulus to a target nerve, e.g., the tibial nerve 220, a muscle or other body part containing a portion of a target nerve, or any nerves branching off of a target nerve, located in proximity to microneedle patch 252.” *Id.* at [0154].

141. While many of the preferred embodiments focus on the electrical stimulation of nerves in the feet, Burnett describes those applications as exemplary. *See e.g., id.* at [0153] (“e.g., on the leg as shown); [0154] (“e.g., the tibial nerve”). Burnett states that the disclosed stimulation electrodes may be used to treat “other peripheral nerves,” which would include the nerves in the arm and hand, and a “muscle or other body part containing a portion of a target nerve.” *Id.* at [0110]. Likewise, Burnett states that the “invention described herein may be applied to any body tissues, including nerve, muscle, skin, vasculature, or any other organ or tissue within the human body.” *Id.* at [0126].

142. Burnett discloses that the body regions that may be stimulated include the “back, leg, *arm*, neck, head, torso, etc.” *Id.* at [0102] (emphasis added). Likewise, Burnett discloses incorporating the stimulation devices into a band that “may be wrapped around a body portion (for example, an *arm*)....” *Id.* at [0107] (emphasis added); *see also id.* at [0112].

143. The ’669 patent acknowledges that peripheral nerves extend along the arm and through the hand. Figure 56A, for example, illustrates that the Radial, Median, and Ulnar nerves traverse the arm before terminating in the patient’s hand:

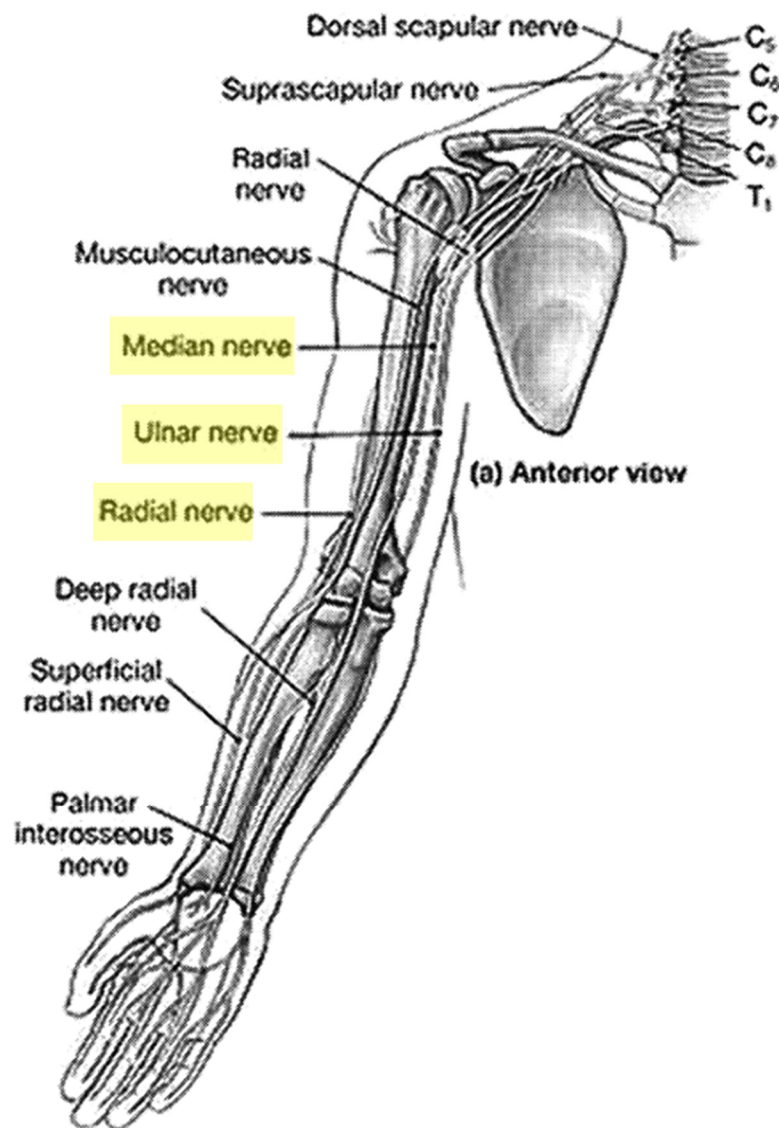


FIG. 56A

Ex. 1001 at Fig. 56A. Therefore, a band wrapped around the arm, or an electrode placed on the arm, as taught in Burnett, will overlie a target nerve (e.g., Median, Ulnar, or Radial) that extends through a hand of the subject. Thus, Burnett discloses this claim limitation.

144. If the Patent Owner argues that Burnett does not disclose this limitation, it renders the limitation obvious. Burnett discloses methods of stimulating target nerves, including peripheral nerves. Ex. 1010 at [0110]. Additionally, Burnett discloses that the stimulation devices, including the described electrodes, can be used to stimulate nerves and muscles on a patient's arm. Ex. 1010 at [0102], [0107].) A person of ordinary skill in the art would have understood that the Median, Ulnar, and Radial nerves are peripheral nerves extending through a patient's arm.

145. A person of ordinary skill in the art would have been motivated to use the stimulation devices described in Burnett to stimulate the nerves in the arms to treat tremor. Burnett discloses that the described systems treat "tremor," and, thus, a person of ordinary skill in the art would have consulted other references describing methods to treat tremor. Ex. 1010 at [0111]. Persons of ordinary skill in the art would have been familiar with many prior-art references that disclose treating tremor by stimulating nerves running through the arm. For example, the Prochazka articles disclose methods of treating tremor by stimulating the biceps and triceps. *See* Ex. 1005 at 207, Fig. 2 ("Triceps and biceps brachii are selectively stimulated with surface electrodes."). Similarly, Gesotti discloses devices for treating "Parkinson's disease symptoms," including cylindrical electrodes for "upper arms, forearms, [and] wrists." Ex. 1008 at 6:1-17; *see also id.* at 6:42-53, 9:25-28. Likewise, Gesotti '896 discloses methods of reducing "arm tremor" by placing surface

electrodes at different positions along the arm, including at the brachioradialis (forearm) and pronator teres (forearm). Ex. 1009 at 4:16-28, 5:1-2, 16:46-67, Tables 11-12. The teachings in these references, in conjunction with the teachings in Burnett, would have motivated a person of ordinary skill in the art to try using Burnett’s stimulation electrodes to stimulate nerves running through the arm and hand. The use of Burnett’s stimulation electrodes to stimulate the nerves extending through the arm would have been the predictable use of prior art elements (Burnett electrodes) according to their established functions (nerve stimulation).

146. A person of ordinary skill in the art would have expected success in stimulating the nerves running through the arm to treat tremor because the prior art references disclose that such stimulation had been successful. *See* Ex. 1005 at *abstract* (finding system “attenuated 2-5 Hz tremors substantially”); Ex. 1008 at 11:46-12:27, Fig. 16 (disclosing methods to safely provide stimulation to treat tremor). Moreover, Burnett already discloses methods of adjusting the stimulation to improve efficacy and ensure that the patient is not over-stimulated. *See e.g.*, Ex. 1010 at [0078] (“The level of stimulation may be also controlled through a combination of feedback from sensor 30 and feedback based on perceptions of the patient.”).

c. **Limitation [B]: “delivering electrical stimulation via a pulse generator transdermally through the skin surface and to the target nerve or tissue to stimulate the target nerve or tissue so that tremors experienced by the subject are mitigated”**

147. Claim 1 next recites “delivering electrical stimulation via a pulse generator transdermally through the skin surface and to the target nerve or tissue to stimulate the target nerve or tissue so that tremors experienced by the subject are mitigated.” Burnett discloses this limitation.

148. Burnett includes the same list of over 100 ailments that are allegedly treated by the disclosed stimulation devices that is found in the '669 patent. Ex. 1010 at [0111]. Further, like the '669 patent, Burnett mentions “tremor” only in this list of ailments. If the single mention of tremor in the '669 patent is sufficient to disclose mitigating tremors, then so is the mention of tremor in Burnett.

149. Burnett discloses delivering electrical stimulation transdermally through a skin surface and to the target nerve to stimulate the target nerve. *Supra* §VI.D.1.a-b. Burnett further discloses that the electrical stimulation is delivered via an “electric pulse controller 130” to “provide the desired feedback and modulate the power” to the transcutaneous stimulator, such as electrode 126 [red]. Ex. 1010 at [0109], Fig. 11. An electric pulse controller is a pulse generator.

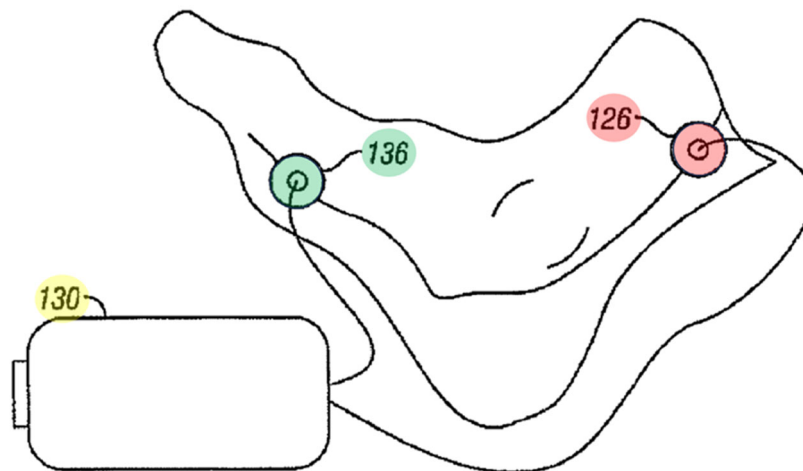


FIG. 11

150. Similarly, Figure 26 illustrates an energy emitting system 250 having a microneedle patch 252 and sensor 221. Ex. 1010 at [0155]. “Once conductive microneedle patch 252 and sensor 221 are in position, a current is passed from controller 218 through conductive microneedle patch 252, resulting in an electrical stimulus of the posterior tibial nerve 220.” *Id.* at [0156].

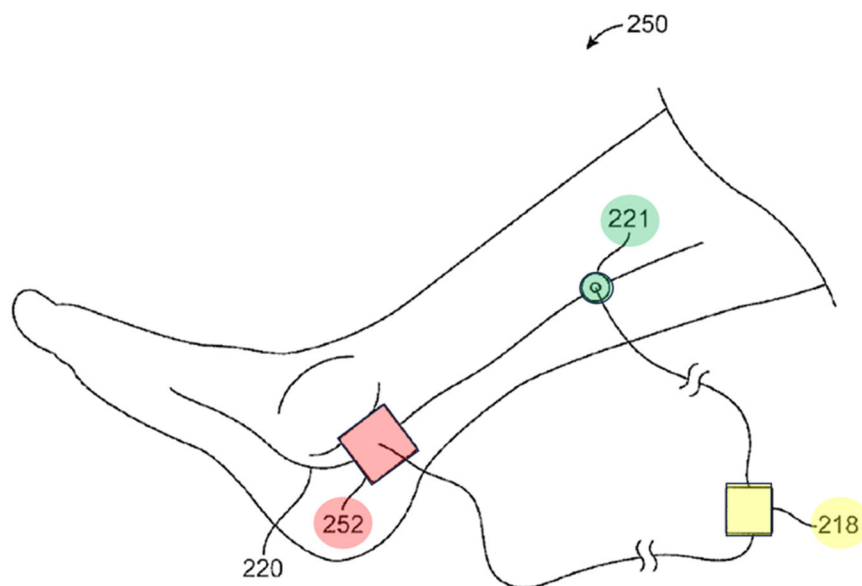


FIG. 26

Id. at Fig. 26. The controller 218 is a pulse generator. Burnett explains that the “controller can...be varied or adjusted based on the signal from sensor 221 to ensure that adequate conduction of the posterior tibial nerve 220 occurs and an adequate and accurate dosage of treatment is being received,” demonstrating that the controller generates the pulses. *Id.* at [0156].

d. **Limitation [C]: “detecting a motion from the subject via at least one sensor positioned on the subject”**

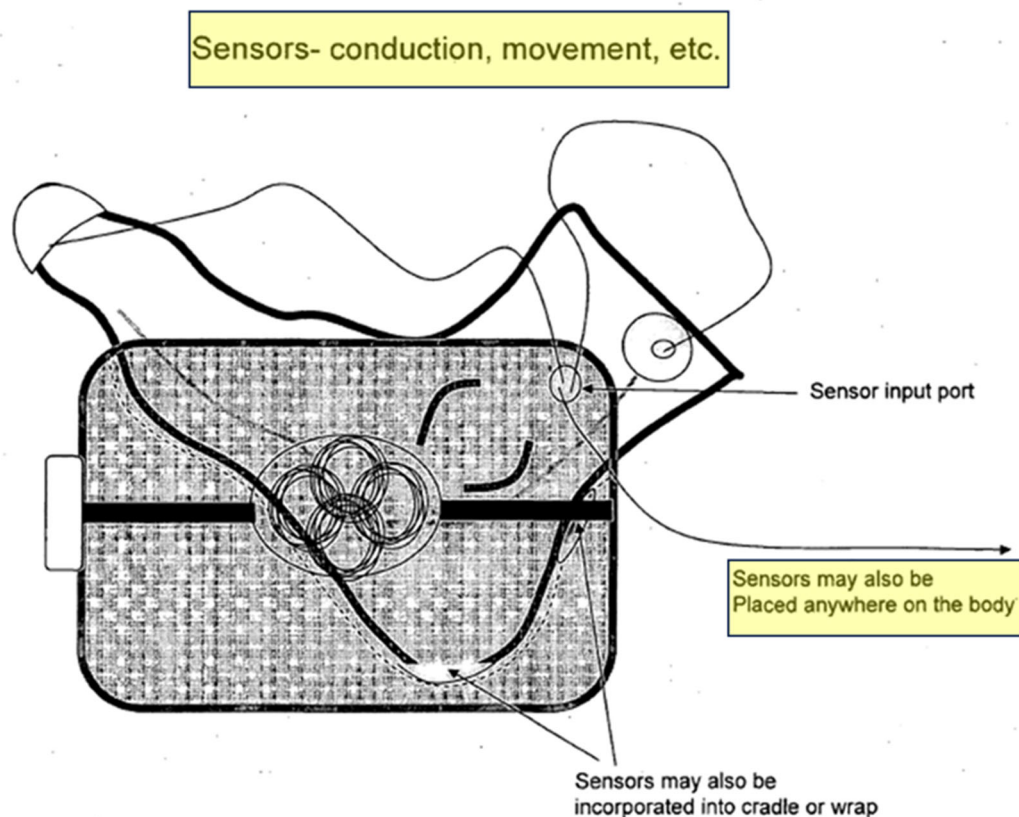
151. Claim 1 next recites “detecting a motion from the subject via at least one sensor positioned on the subject.” Burnett discloses this limitation.

152. Burnett’s sensors “may detect a variety of physiological changes, including neural impulses, ***muscular contraction, twitching***, etc. that may occur with neural or muscular stimulation.” Ex. 1010 at [0101] (emphasis added); *see also id.* at [0145] (“Microneedle patch 228 detects corresponding muscle stimulation or twitching or electrical conduction through the stimulated posterior tibial nerve.”); [0173] (similar); [0179] (same), [0184] (same).) In the case of at least twitching, the sensor detects motion of the subject.

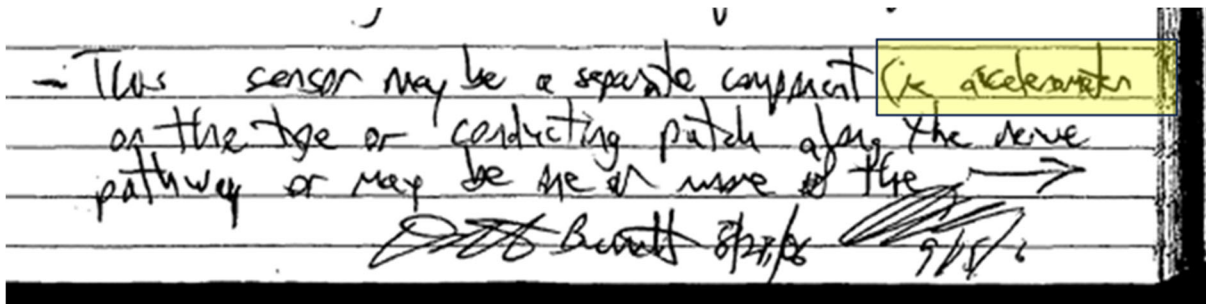
153. Burnett discloses that the sensor can take a variety of forms, including a microneedle patch or “a sensor type known in the art.” Ex. 1010 at [0128], [0147]. One type of sensor known in the art was an accelerometer, which detects motion. Gesotti and Gesotti ’896 both disclose accelerometers to detect patient motion. *See*

e.g., Ex. 1008 at Fig. 1 (identifying “accelerometer”); Ex. 1009 at Fig. 1 (identifying “motion sensors”).

154. Additionally, the ’720 provisional, which is incorporated into Burnett, discloses sensors that are responsive to a variety of physiologic changes, including movements of the patient such as muscle contractions and twitching. Ex. 1015 at [55]. Like Burnett, the ’720 provisional discloses that sensors “may also be placed anywhere on the body” to measure physiologic changes in the patient:



Ex. 1015 at Fig. 8. Moreover, the handwritten notes in the ’720 provisional expressly state that the “sensor may be a separate component (i.e. *accelerometer*).”



Thus, Burnett discloses detecting a motion from the subject via at least one sensor positioned on the subject.

2. Claim 2

155. Claim 2 depends from claim 1 and recites “wherein the electrical stimulation is delivered at a frequency of about 5 Hz to about 60 Hz, while remaining safe and tolerable to the subject.” Burnett renders this claim obvious.

156. Burnett discloses that the “optimal stimulation may be determined by a variety of manners,” including operating the stimulation device “at a frequency of 10-30 Hz at the targeted tissue depth.” Ex. 1010 at [0122]. Burnett further discloses “[e]xemplary parameters for treating various conditions...using the systems and methods described herein....” *Id.* at [0187]. The “systems and methods described herein” include the electrical stimulation embodiments in Figures 10-11 and 26-28. Among the exemplary parameters, Burnett discloses operating the stimulation devices “at about 10 to 20 hertz” or “about 5 to 100 hertz.” *Id.*

157. Burnett also discloses methods of delivering the electrical stimulation at the identified frequencies while remaining safe and tolerable. Burnett discloses

using sensors in conjunction with the electrical stimulation electrodes so that stimulation “may be tailored to provide optimal therapy and, in the case of electrode migration or other electrode malfunction, to report lack of stimulation of the bodily tissues.” Ex. 1010 at [0109]; *see also id.* at [0170]. Additionally, Burnett discloses methods of controlling the stimulation “through a combination of feedback from sensor 30 and feedback based on perceptions of the patient.” *Id.* at [0078]. For example, “the patient may activate a switch once she perceives an excessive stimulation, in particular, an excessive level of muscular stimulation.” *Id.* This patient control ensures that the treatment remains safe and tolerable. *Id.*

3. Claim 3

158. Claim 3 depends from claim 1 and recites: “wherein the stimulator electrode is a surface electrode.” Burnett discloses this claim.

159. Burnett describes a “transcutaneous stimulator, such as an electrode 126 [red]” and Figure 11 illustrates that the electrode 126 is a surface electrode applied to the patient’s foot. Ex. 1010 at [0109], Fig. 11; *see also id.* at [0164] (describing “electrode patch” placed on patient’s skin); [0126] (“The invention described herein may be applied to any body tissues, including...skin....”).

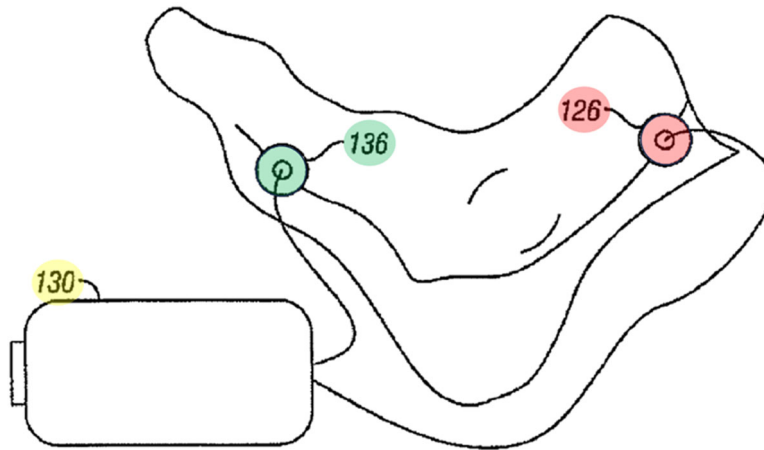


FIG. 11

160. Similarly, Burnett discloses embodiments having “a microneedle patch 252...having one or more microneedle arrays deposited on a surface of one or more electrodes.” Ex. 1010, [0154]. As shown in Figure 26, the microneedle patch is a surface electrode placed on the patient’s skin. Burnett also discloses that the microneedle patch may be “utilized to provide superior anchoring properties such that a microneedle patch may effectively adhere or attache [sic] to a subject’s skin.” Ex. 1010 at [0134]; *see also id.* at [0128] (“the sensor may be in the form of a microneedle patch 228, which can be removably attached to the skin surface of a subject”); [0166] (similar).

4. Claim 4

161. Claim 4 depends from claim 1 and recites: “wherein the electrical stimulation is delivered intermittently or on a chronic basis.” Burnett discloses this claim.

162. Burnett discloses “[e]xemplary treatment parameters for treating various conditions,” including stimulating the patient “for a duration of about 30 minutes/day or 30 minutes per week, depending on the severity of the symptoms, until symptoms subside.” Ex. 1010 at [0187]. Burnett discloses other treatment periods, including “for about 15 minutes to 2 hours per day or week” and “for 30 minutes/week or 30 minutes/month.” *Id.*; *see also id.* at [0122-0125] (describing intermittent treatments.) Burnett further discloses that “[a]ny treatment parameter may be varied or modified based on the effect on the patient or sensor or patient feedback regarding stimulation, until the desired result of treating or preventing a condition is achieved.” *Id.* at [0187]. Thus, Burnett discloses intermittent treatment.

5. Claim 5

163. Claim 5 depends from claim 1 and recites: “adjusting or optimizing the electrical stimulation in response to a feedback signal received from the sensor indicative of the detected motion and efficacy of the applied electrical stimulation therapy.” Burnett discloses this claim.

164. Burnett discloses sensors for detecting patient motion including “twitching.” *Supra* §VI.D.1.d. For example, Burnett discloses that “[m]icroneedle patch 228 detects corresponding muscle stimulation or twitching” and relays the signal to a controller. *Id.* at [0145]; *see also id.* at [0035]. “The controller can then be varied or adjusted (to adjust the current or magnetic field) based on the signal

received from the microneedle patch 228 to ensure that adequate conduction of the posterior tibial nerve 220 occurs and an adequate and accurate dosage of treatment is being received.” *Id.*; *see also id.* at [0168-0169], [0173-0174], [0179-0180], [0184-0185] (describing use of sensors to detect motion and adjust energy generator in response to sensor signal to improve efficacy).

6. Claim 6

165. Claim 6 depends from claim 5 and recites: “wherein the feedback is queried such that the electrical stimulation therapy is adjusted to ensure that a minimum amount of energy is being applied to stimulate the target nerve while reducing the risk of burns or intolerance.” Burnett discloses this claim.

166. Burnett discloses that an “electrical pulse controller 130 [yellow] is connected both to electrode 126 [red] and to sensor 136 [green]” “to provide the desired feedback and modulate the power” to the electrode 126. Ex. 1010 at [0109].

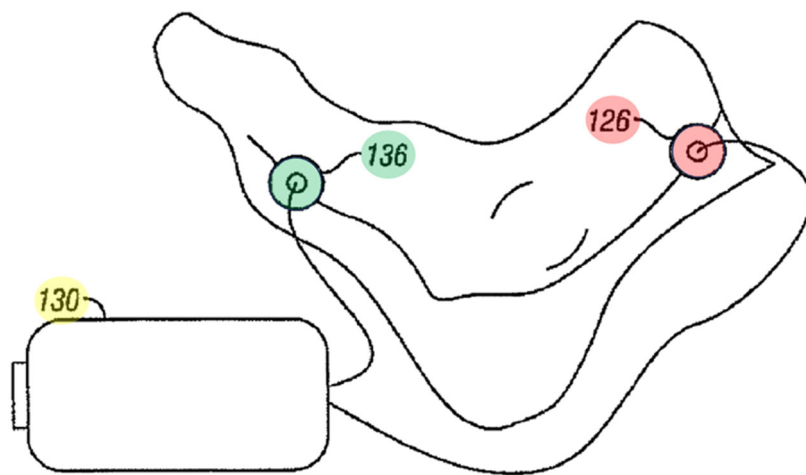


FIG. 11

In this configuration, “direct electrical stimulation of nerve and muscle may be tailored to provide optimal therapy and, in the case of electrode migration or other electrode malfunction, to report lack of stimulation of the bodily tissues.” *Id.* Moreover, “these embodiments enable a **reduction in power requirement** because control of the signal is provided by the sensor to signal generator loop.” *Id.* (emphasis added). Thus, Burnett discloses querying the sensor feedback so that the electrical stimulation therapy is adjusted to ensure that a minimum amount of energy is applied to stimulate the target nerve.

167. Additionally, Burnett discloses using sensor feedback to prevent burns and intolerance. *See supra* §VI.D.2 (describing use of signals to make device tolerable). Burnett explains that the prior art did not measure the efficacy of stimulation treatment, which could cause insufficient or excessive stimulation. Ex. 1010 at [0017]. To address this issue, Burnett incorporates sensors, such as a “transcutaneous electrical stimulation sensor,” within wraps to provide “feedback as to the quality of the electrical connection to the skin, which is directly related to the **burn risk** inherently associated with this type of therapy.” *Id.* at [0112]. Similarly, Burnett describes supplying feedback from the sensors regarding efficacy to the logic controller of the energy generator “to modulate the current.” *Id.* at [0032]; *see also id.* at [0109] (sensor feedback permits system to “modulate the power”); [0112] (same).

7. Claim 7

168. Claim 7 depends from claim 5 and recites: “wherein the feedback is queried such that the positioning of the stimulator electrode is adjusted to optimize the electrical stimulation therapy.” Burnett discloses this claim.

169. Burnett alleges the prior art made no provision to ensure “that the nerve was actually being stimulated or to adjust the device in response to commonly occurring psychological and anatomic variations in nerve locations.” Ex. 1010 at [0014]. Burnett purports to address this issue by positioning sensors on an “appropriate portion of the patient’s body[] in order to detect conductivity...in another target nerve.” *Id.*, [0091]. Conductivity may, for example, be detected by muscle movement (e.g., twitching). *Id.* at [0127] (“The sensor may be placed over a muscle to detect muscle stimulation resulting from stimulating the target nerve (as shown in FIG. 12) or over any other portion of the subject’s body suitable for detecting conduction of the target nerve.”). Burnett discloses that a healthcare provider then analyzes conductivity measurements provided by the sensor and adjusts the positioning of the stimulator until conduction in the nerve is detected. Ex. 1010 at [0092]; *see also id.* at [0047], Figs. 6A-6D.

170. While Burnett describes adjusting the location of magnetic coils in many of the preferred embodiments, Burnett also establishes that the position of electrical stimulators, like the electrodes in Figures 11-12 and 26-27, can also be

adjusted based on sensor feedback. For example, Burnett discloses that the “positioning of the microneedle patch relative to the first portion of the subject’s body may be adjusted to re-focus the electrical or magnetic stimulus or field on the posterior tibial nerve [or other target nerve] as needed.” Ex. 1010 at [0167], [0172], [0178], [0183], claims 50-51; *see also id.* at [0170] (“In certain embodiments, the amplitude, frequency, *direction of a generated...electrical...stimulus*, or firing sequence of the...microneedles making up the microneedle array may be adjusted.”) (emphasis added).

8. Claim 8

171. Claim 8 depends from claim 5 and recites: “wherein the sensor is a surface electrode.” Burnett discloses “sensor 54 may be a sensor patch that is [] applied to the skin of the patient.” (Ex. 1010, [0088]; *see also id.*, [0128].) Thus, the sensor is a surface electrode.

9. Claim 9

172. Claim 9 depends from claim 1 and recites: “wherein the pulses generated during the electrical stimulation therapy include pulses of a first amplitude and pulses of a second amplitude, where the first amplitude is different from the second amplitude.” Burnett discloses this claim.

173. Burnett changes the stimulation amplitude based on input from the sensors. Ex. 1010 at [33, 121]. For example, Burnett discloses ramping up the

stimulation amplitude progressively “so that the magnetic field is increased in strength and/or breadth until nerve conduction is detected” *Id.* at [0078]; *see also id.* at [0121] (disclosing ramp up). Similarly, Burnett discloses that “sensor input may cause logic controller 28 to alter the strength or *pulse amplitude* of the magnetic field based on sensor input...” *Id.* at [0074] (emphasis added); *see also id.* at [0170], [0175], [0181], [0186], claim 49 (adjusting amplitude for microneedle patches). Where the pulse amplitude is adjusted, the system operates at a first amplitude (original) and a second amplitude (after adjustment) where the amplitudes are different.

10. Claim 10

174. Claim 10 depends from claim 1 and recites: “positioning a return electrode on the subject to facilitate penetration of an electrical current through the surface to stimulate the target nerve.” Burnett discloses this claim.

175. Burnett discloses “a microneedle patch or applicator” that includes “multiple electrodes on a single patch or applicator, e.g., positive, negative, and/or control or ground electrodes, where the microneedles will be grouped in multiple arrays such that they conduct to the appropriate electrode.” Ex. 1010 at [0142], Figs. 20a-2, claim 5. Alternatively, Burnett discloses that the positive and negative electrodes may be separate patches or applicators. *Id.* The negative electrode is a

return electrode and facilitates penetration of an electrical current through the surface to stimulate the target nerve.

11. Claim 11

176. Claim 11 depends from claim 1 and recites: “wherein the stimulator electrode is attached to the skin surface with an adhesive.” Burnett discloses this claim.

177. Burnett discloses that “a microneedle patch may include an *adhesive electrode pad* and may utilize a conductive gel to help hold the microneedles in place to prevent shear from breaking or bending the microneedles.” Ex. 1010 at [0141] (emphasis added); *see also id.* at [0134] (“the microneedles...may still be utilized to provide superior anchoring properties such that a microneedle patch may effectively adhere or attache [sic] to a subject’s skin”); [0164] (“The electrode may optionally be attached to various other materials or adhesive materials.”).

12. Claim 12

178. Claim 12 depends from claim 1 and recites: “wherein the stimulator electrode is positioned over the skin surface with an ergonomic applicator.” Burnett renders this claim obvious.

179. Burnett discloses incorporating stimulation coils and sensors *into a band* that “may be wrapped around a body portion (for example, an *arm*)....” Ex. 1010 at [0107] (emphasis added); *see also id.* at [0112] (“The transcutaneous

electrical stimulation sensor may be placed in the body independently or be incorporated within the wrap....”). While the preferred embodiments of the bands include stimulation coils (*see e.g., id.*, Fig. 9C), a person of ordinary skill in the art would have found it obvious to substitute the electrodes for the stimulation electrodes or microneedle patches for the coils in those embodiments.

180. Burnett repeatedly suggests that the magnetic coils (which generate magnetic energy) and electrodes (which generate electric energy) may be substituted for each other in the various embodiments. For example, Burnett states, “In certain embodiments, apparatus and methods for treating a variety of ailments by providing energy to a target nerve, for example *magnetic energy*, *electrical energy* or ultrasound energy, at a location and in an amount optimized by detecting conduction in the target nerve are provided.” Ex. 1010 at [0031]; *see also id.* at [0033] (“The applied energy may be a magnetic field, an electrical field, an ultrasound, a visible light, or an infrared or an ultraviolet energy.”).

181. Burnett discloses several examples of energy emitting systems that use coils and electrodes interchangeably. For example, Figure 21 discloses any energy emitting system 210 that includes one or more conductive coils 212 [red] disposed within housing 214 and a microneedle patch 228 [purple] to sense electrical conduction caused by the magnetic coils. Ex. 1010 at [0143], [0146], Figs. 12, 21.

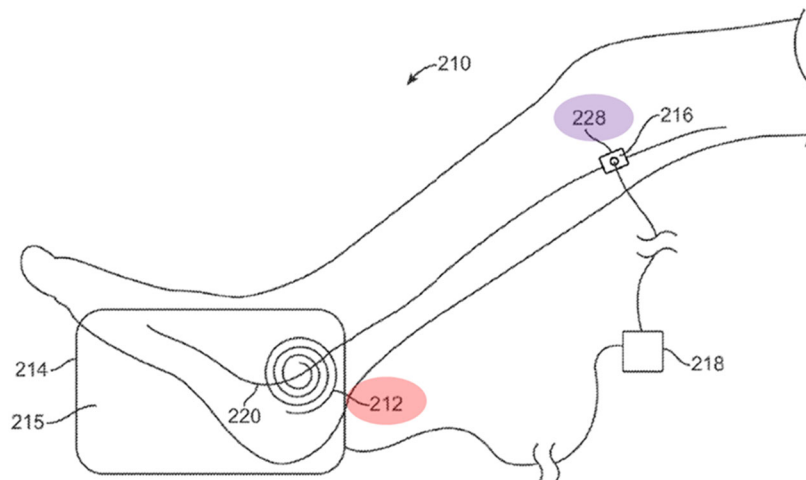


FIG. 21

182. In Figure 26, however, the magnetic coil is replaced with a “microneedle patch 252 (e.g., conductive microneedle patch) having one or more microneedle arrays deposited on a surface of one or more electrodes” and “one or more sensors 221 configured to detect muscle stimulation.” Ex. 1010 at [0154], Fig. 26. Burnett explains that the microneedle patch can deliver or generate “an electrical or magnetic stimulus to a target nerve.” *Id.*

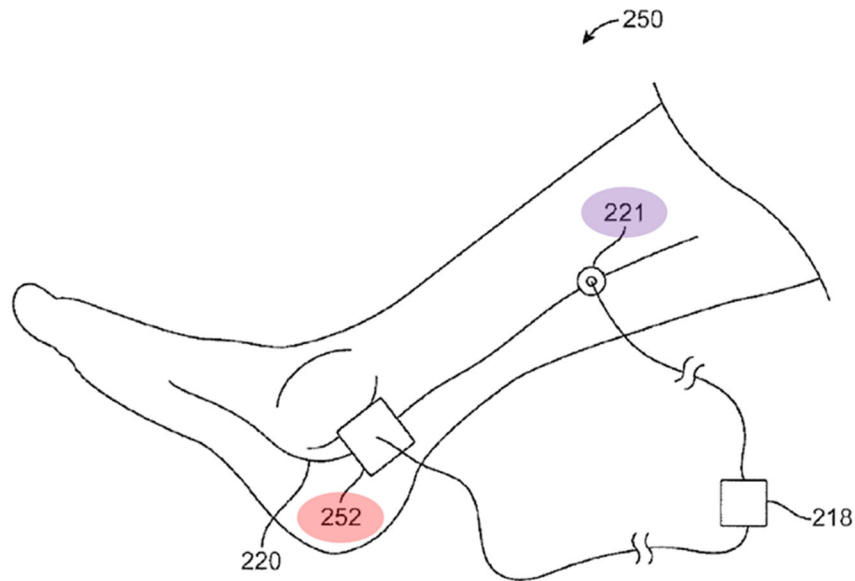


FIG. 26

See also id. at Figures 6A-6B, Figs. 10-11.

183. Moreover, many prior art references described the effectiveness of placing stimulation electrodes within ergonomic applicators. *See e.g.*, Ex 1008 at Figs. 7-15; Ex. 1007 at Figs. 1-2, 12. These teachings in combination with the suggestion in Burnett would have motivated a person of ordinary skill in the art to include the electrode within the ergonomic applicator. Moreover, a person of ordinary skill in the art would have expected success in combining the electrode with the applicator because the prior art references disclose that such a combination will aid in adhering the electrode to the skin and adequately address neurological movement disorders like tremor.

184. A person of ordinary skill in the art would have been motivated to position the electrodes within an ergonomic band, such as the band in Figure 9c, to

make it easier for a patient to use the electrodes. Rather than separately applying each electrode and sensor to the skin, the band allows the patient to apply the electrodes and sensors with one device. Burnett specifically discloses that the band may be retained in place using simple connectors such as “a hook and loop system, a strap and buckle system, or simply a hook disposed on one end of the band 114 for engaging fabric or other material in another portion of the band 114.” Ex. 1010 at [0107].

185. Additionally, a person of ordinary skill in the art would have been motivated to position the electrodes on the inside surface of the band so that the electrodes “contact the skin surface.” Burnett already discloses placing the electrodes in “contact the skin surface.” *See e.g.*, Ex. 1010 at [0166] (“In the case of a microneedle patch, the patch may be attached to a subject’s skin.”), Fig. 26.

186. Moreover, a person of ordinary skill in the art would have been motivated to place the electrodes in contact with the skin to ensure a better electrical connection between the patient and the electrode. Burnett discloses that placing an electrode, such as a microneedle patch, on the skin may “provide a superior signal as the current detected is conducted through the microneedle 235, thereby bypassing the poorly conductive stratum corneum layer 15 which generally encompasses the outer 10 to 15 microns of the skin.” Ex. 1010 at [0140], Fig. 19. A person of ordinary skill in the art would have understood that sandwiching band material

between the electrode and skin surface could disrupt or weaken the transmission of the electrical pulses to the patient.

187. A person of ordinary skill in the art would have expected success in positioning the electrodes within the band and against the skin surface for several reasons. First, several prior art references disclosed placing electrodes within an ergonomic applicator, such as a wristband, and indicated that such devices successfully treated tremor. *See e.g.*, Ex. 1008 at Figs. 7-10; Ex. 1007 at Fig. 12, Ex. 1017 at Fig. 3. These prior art references would have encouraged a person of ordinary skill in the art to try such a combination here. Additionally, Burnett already describes placing electrodes directly to the skin and suggests that such an attachment can improve the function of the device.

188. Ultimately, incorporating the electrodes into Burnett's ergonomic band would have been nothing more than the combination of prior art elements according to known methods to yield predictable results and a predictable use of prior art elements according to their established functions. Moreover, a person of ordinary skill in the art would have had a finite number of identified, predictable solutions for applying Burnett's electrode to the patient. Burnett discloses two options: (1) placing the electrodes directly on the skin surface, or (2) incorporating the electrodes into an ergonomic applicator like a band. A person of ordinary skill in

the art would have found it obvious to try either option, and would have reasonably expected success in doing so for the reasons explained above.

13. Claim 16

189. Claim 16 depends from claim 1 and recites: “wherein once tetany is detected in a patient, indicating that a threshold frequency of the applied stimulation has been reached, the strength of the applied stimulation is automatically or manually decreased.” Burnett discloses this claim.

190. Burnett discloses manually or automatically decreasing stimulation once the symptoms of tetany, such as twitching, are detected. Burnett discloses that “the patient may activate a switch once she perceives an excessive stimulation, in particular, an excessive level of muscular stimulation.” Ex. 1010 at [0078]. “In one instance, the patient may be asked to push a button or turn a knob when she feels her toe twitching or when she experiences paresthesia over the sole of her foot.” *Id.* The patient will then decrease the strength of the stimulation until the appropriate treatment level is reached. *Id.*

14. Claim 18

191. Claim 18 depends from claim 1 and recites: “wherein positioning a stimulator electrode comprises positioning at least two electrodes over the skin surface.” Burnett discloses this claim.

192. For example, Burnett discloses “one or more microneedle patches having...one or more electrodes and configured to generate or deliver an electrical or magnetic stimulus or field focused on a target nerve in proximity to the microneedle patch.” Ex. 1010 at [0038]; *see also supra* §VI.D.10 (describing separate positive, negative, and ground electrodes); [0144] (“Microneedle patch 228 may be composed of...one or more electrodes.”), [0154] (same).)

15. Claim 19

193. Claim 19 depends from claim 18 and recites: “wherein the at least two electrodes are positioned to stimulate an Ulnar or Median nerve.” Burnett renders this claim obvious for the reasons provided with respect to Claim 1. *Supra* §VI.D.1.b.

16. Claim 20

194. Claim 20 depends from claim 18 and recites: “wherein the at least two electrodes are positioned in opposition relative to one another.” Burnett renders this claim obvious.

195. Burnett explains: “When a plurality of coils is utilized, such coils may be disposed on a single side of the ankle 22, or may be disposed on more than one side, for example, *on opposing sides*, strengthening and directionalizing the flow of

the magnetic field through the tibial nerve 24 or other peripheral nerves of interest.”¹

Ex. 1010 at [0072] (emphasis added). I note that the ’669 patent contains this same statement regarding the benefits of opposing electrodes. Ex. 1001 at 10:55-60. While Burnett discusses placing coils on opposite sides of the nerve, a person of ordinary skill in the art would have recognized the same benefits could be achieved by placing electrodes in opposition to each other. For example, Burnett discloses that the described system may use a control/ground electrode that is placed on a different body part, such as “above or near bone,” while the positive or negative electrodes “may be attached above a nerve or muscle.” Ex. 1010 at [0142]. Based on this description, a person of ordinary skill in the art would have understood that a system for treating tremor could use a ground electrode placed near the elbow (i.e., a bone) with a positive or negative electrode placed on the forearm above the target nerve. *See also supra* §VI.D.1.b. A person of ordinary skill in the art would have expected success in applying the electrodes in this way based on Burnett’s teachings and the teachings in Gesotti and Gesotti ’896 that describe treating tremor by stimulating portions of the arm.

¹ The ’669 patent contains this same statement regarding the benefits of opposing electrodes. Ex. 1001 at 10:55-60.

E. Gound 7: Claim 13 Is Obvious Over Burnett And Gesotti

196. Claim 13 depends from claim 12 and recites: “wherein the applicator is a glove or brace configured to be positioned against a skin surface such that the electrode delivers electrical stimulation to the target nerve or tissue.” Burnett and Gesotti render claim 13 obvious.

197. Burnett does not expressly disclose a glove. However, the ’720 provisional discloses that “the device may be designed to target the nerve, or other nerves, via alternative ergonomic applicators including wraps, cradles, supports for the foot, leg, lower back, arm, ***hand***, neck, thorax, etc.” Ex. 1015 at 53 (emphasis added). Moreover, Gesotti discloses gloves for stimulating nerves. *See supra* §VI.A.12. A person of ordinary skill in the art would have been motivated, and expected success, in using a glove to stimulate the “hand” based on the disclosure in Gesotti because Gesotti describes in detail how gloves may be used for such a purpose. Moreover, a person of ordinary skill in the art designing an ergonomic applicator for the “hand,” as described in the ’720 provisional, would have had a finite number of predictable options. One option for such an ergonomic applicator would have been a glove. For this additional reason, a person of ordinary skill in the art would have found it obvious to try using Burnett’s electrodes with a glove.

F. Ground 8: Claims 14-15 Are Obvious Over Burnett And Stephens

1. Claim 14

198. Claim 14 depends from claim 1 and recites: “wherein the electrical stimulation is automatically paused for a preset amount of time every 10 minutes to overcome habituation.” Burnett in combination with Stephens renders this claim obvious.

199. Burnett discloses methods of using information received from sensors “to vary or adjust the controller to ensure that adequate conduction of a target nerve...or muscle stimulation occurs and an adequate and accurate dosage of treatment is being received.” Ex. 1010 at [0188]. Burnett discloses that “controls may also be included to affect the following:...start/pause and cancellation of therapy (as shown) or other parameters one of skill in the art would find necessary or useful to control or monitor.” *Id.* While Burnett does not expressly disclose pausing every 10 minutes, Stephens does. *See supra* §VI.C.1 (describing Stephens).

200. A person of ordinary skill in the art would have been motivated to vary the duration of the pulse signal, as taught in Burnett, according to the timings disclosed in Stephens to address the known problem of habituation. Both references disclose methods of using electrical stimulation to treat neurological movement disorders. While Stephens focuses on a treating urinary incontinence using implantable electrodes, persons of ordinary skill in the art using electrical

stimulation for one application regularly consulted the use of electrical stimulation in other applications. In fact, the '669 patent assumes that methods of electrical stimulation for treating urinary incontinence are applicable to treating tremor. While the '669 patent extensively discusses using electrical stimulation to treat urinary incontinence, it mentions “tremor” only once and still claims that the disclosed devices may treat “tremor.” Ultimately, the use of Stephens’ stimulation durations with Burnett is merely the application of a known technique (Stephens’ timing) to a known device (Burnett’s stimulator) ready for improvement to yield predictable results.

201. A person of ordinary skill in the art would have expected success in adjusting the duration of Burnett’s system using the timing set forth in Stephens. Burnett already discloses that the stimulation may be paused. Ex. 1010 at [0188]. A person of ordinary skill in the art would have recognized that 10 minutes falls within a typical range for stimulating a patient and, so long as the other aspects of the stimulation like current and voltage were appropriately set, would not have expected any negative results from that duration of treatment.

2. Claim 15

202. Claim 15 depends from claim 1 and recites: “wherein the electrical stimulation is automatically paused for a preset amount of time every 10 minutes

based on feedback provided by the at least one sensor.” Burnett in combination with Stephens renders this claim obvious.

203. Burnett discloses that the stimulation may be paused based on feedback from sensors and that the duration of the signal may also be changed based on the feedback. *Supra* §VI.F.1. Stephens discloses automatically pausing electrical stimulation for a preset amount every 10 minutes. *Id.* A person of ordinary skill in the art would have found it obvious to combine the teachings of Burnett and Stephens, and expected success in doing so, for the reasons provided above. *Id.*

G. Ground 9: Claim 17 Is Obvious Over Burnett And Gesotti ’896

204. Claim 17 depends from claim 1 and recites: “wherein electrical stimulation is provided by delivering a cycle comprising a preset number of pulses followed by a pause in stimulation, followed by a preset number of pulses, and repeating the cycle as necessary.” Burnett in combination with Gesotti ’896 renders this claim obvious.

205. Gesotti ’896 discloses providing electrical stimulation through a preset number of pulses. *See supra* §VI.B.3. Gesotti ’896 discloses that the burst and cue settings can be adjusted depending on the treatment plan. For example, exemplary cue intervals and cue delays to reduce tremor are shown in Table 11. Ex. 1009 at 17:15-25. A person of ordinary skill in the art would have been motivated to combine the treatment protocols of Gesotti ’896 with Burnett, and expected success

in doing so, because both references disclose methods of treating neurological disorders with electrical stimulation. Moreover, Burnett does not expressly describe the treatment protocols necessary to address tremor, so a person of ordinary skill in the art would have naturally looked to a reference like Gesotti '896 that includes those protocols.

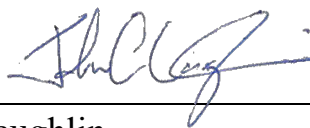
VII. CONCLUSION

206. For at least the foregoing reasons, it is my opinion that claims 1-20 of the '669 patent are anticipated or rendered obvious by the cited prior art.

207. 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.

208. 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: March 29, 2024

By: 
John Laughlin