

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CALA HEALTH, INC.

Petitioner,

v.

EMKINETICS INC.,

Patent Owner

IPR2024-00743

U.S. Patent No. 11,628,300

**DECLARATION OF JOHN LAUGHLIN IN SUPPORT OF
PETITION FOR INTER PARTES REVIEW OF
U.S. PATENT 11,628,300**

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EXHIBIT LIST

Exhibit No.	Description
1001	U.S. Patent No. 11,628,300 to Rajguru et al. (“the ’300 patent”)
1002	Declaration of John Laughlin, M. Eng., P.E.
1003	Curriculum Vitae of John Laughlin, M. Eng., P.E.
1004	The ’300 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 to Prochazka et al. (“the ’707 patent”)
1008	U.S. Patent No. 6,704,603 to Gesotti (“Gesotti”)
1009	U.S. Patent No. 7,369,896 to Gesotti (“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”)
1018-1020	RESERVED
1021	U.S. Patent No. 10,786,669 to Rajguru et al. (“the ’669 patent”)

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. 11,628,300 (“the ’300 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 1-17 of the '300 patent are unpatentable for the following reasons:

- Claims 1-17 are anticipated by Gesotti;
- Claims 1-17 are rendered obvious by Gesotti;
- Claims 1-17 are rendered obvious by Burnett; and
- Claims 1-17 are rendered obvious by Burnett in combination with Gesotti.

III. LEGAL BACKGROUND

A. Applicable Legal Standards

10. I have been asked to provide my opinion as to whether claims 1-17 of the '300 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 '300 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 '300 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 1-17 of the ’300 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 ’300 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 '300 patent describes the use of well-known neuromodulation methods. Based on my review of the specification and claims of the '300 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 '300 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 '300 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 '300 patent to be anticipated by and/or obvious in view of the prior art.

IV. THE '300 PATENT

A. Overview of the '300 Patent

1. The Specification of the '300 Patent

26. The '300 patent discloses well-known methods for magnetically and electrically stimulating various body parts. Ex. 1001 ('300 Patent) at 6:53-54 (describing “an arm applicator and a foot, knee or leg applicator”). The majority of the '300 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 2:11-3:16.

27. Many of the specific examples in the '300 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 17:9-13, 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 17:14-17.

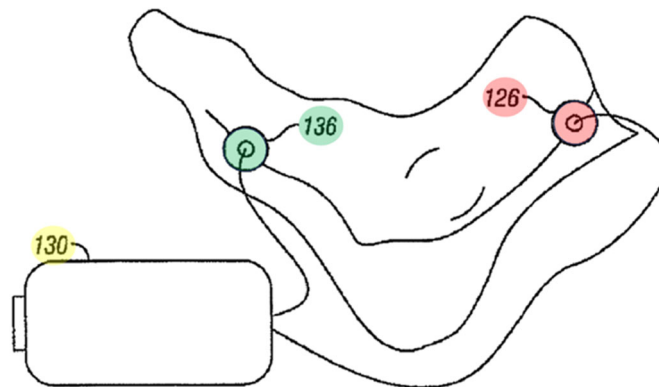


FIG. 11

28. In another embodiment, the '300 patent describes “electrodes designed for the palmar surface of the hands along with F/M wave detecting electrodes 6105.” *Id.* at 62:16-18. As shown in Figure 61A of the '300 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 '300 patent states that the “electrical stimulation of the hand will stimulate the Median or the Ulnar nerve or both.” *Id.* at 62:24-26.

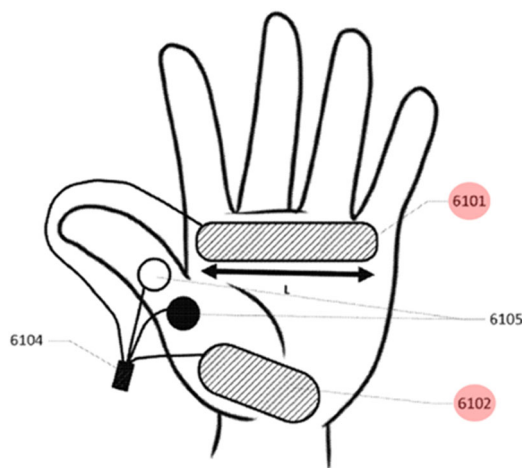


FIG. 61A

29. The '300 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 '300 patent require the treatment of “tremor.” I have only found one mention of “tremor” in the '300 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 17:51-18:34. I do not see any explanation in the '300 patent specification regarding how the disclosed devices treat or mitigate “tremor.”

2. The Claims

31. The '300 patent has 17 claims in total. The patent includes three independent claims (claims 1, 7, and 12) and claims 2-6, 8-11, 13-17 depend, directly or indirectly, from the independent claims. I offer opinions regarding claims 1-17 in this Declaration. Independent claim 1 states:

An apparatus for treating tremor in a subject, comprising:
an applicator configured for application to a hand or arm of the subject;
an electrode located along the applicator so as to contact a skin surface of the subject when the applicator is worn by the subject;

an electrical pulse generator in communication with the electrode; and

a sensor positionable on the subject and in communication with the electrical pulse generator,

wherein the electrical pulse generator provides an electrical stimulation through the electrode and into a target nerve underlying the skin surface such that the sensor detects a motion of the subject and provides a feedback signal to the electrical pulse generator so as to mitigate the tremor by adjusting or optimizing the electrical stimulation.

B. The Prosecution History of the '300 Patent

32. I have reviewed the prosecution history of the '300 patent. Patent Owner filed the application that became the '300 patent on June 11, 2021 (as shown on the front of the '300 patent). The Examiner rejected the claims for obviousness-type double patenting based on the '669 patent. Ex. 1004 at 72-76. Patent Owner submitted a terminal disclaimer, and the Examiner allowed the claims without further examination. *Id.* at 6-7, 64-65.

C. The Priority Date of the '300 Patent

33. For purposes of this Declaration, I have been asked to assume that the '300 patent's priority date is September 20, 2011. However, my opinions would not change if the priority date of the '300 patent were between 2006 and 2011.

D. Claim Construction of the '300 Patent

34. 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

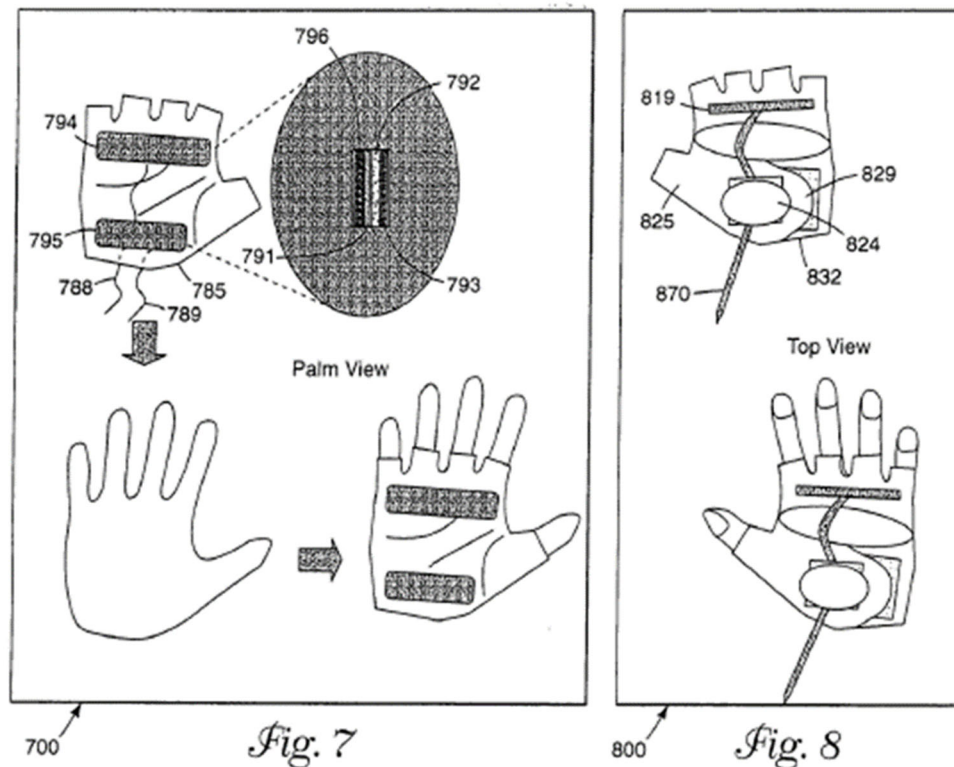
of the earliest applicable priority date (September 2011) and in accordance with the specification and prosecution history. I have applied this standard in my analysis.

V. TECHNOLOGY BACKGROUND

A. Gesotti and Gesotti '896

35. 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.

36. 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.



37. 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.

38. 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

39. 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].

40. 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 1-17 OF THE ’300 PATENT ARE UNPATENTABLE

A. Claims 1-17 Are Anticipated Or Rendered Obvious by Gesotti

1. Independent Claim 1

41. 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.

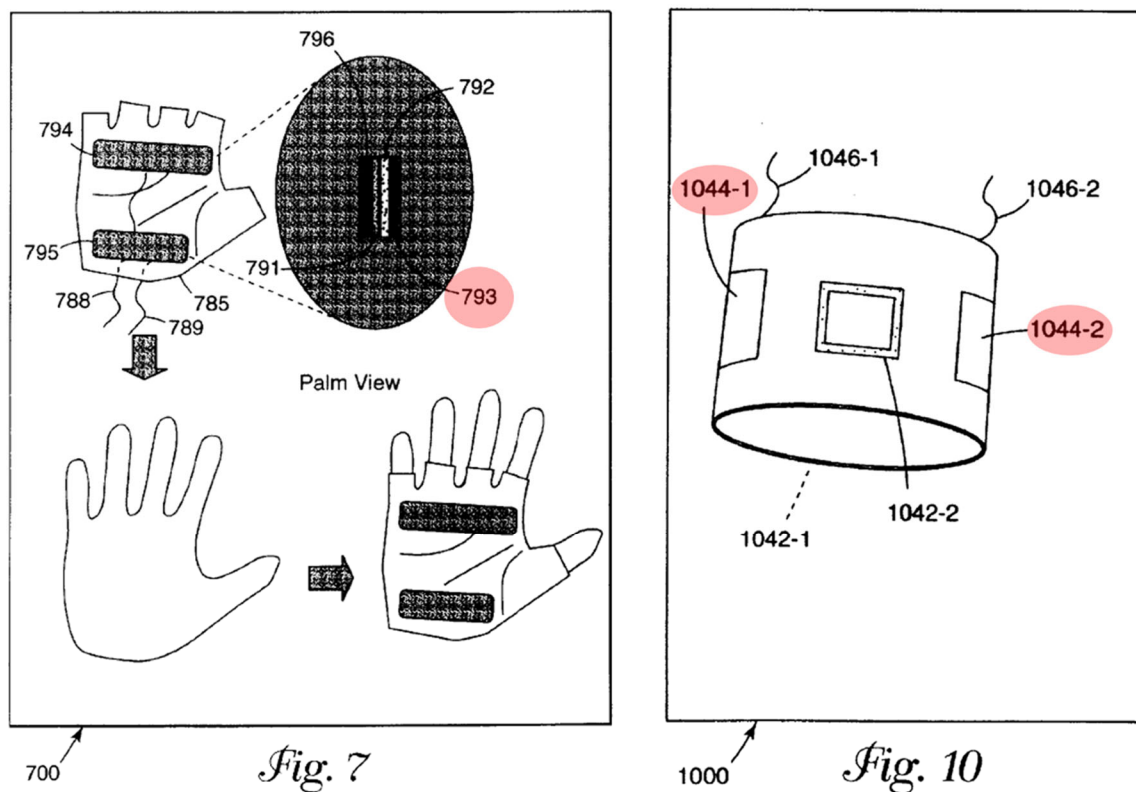
a. Preamble: “An apparatus for treating tremor in a subject, comprising”

42. The preamble of claim 1 recites “An apparatus for treating tremor in a subject, comprising.”

43. If the preamble is limiting, Gesotti discloses this apparatus. Gesotti discloses systems for 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* 1:58-66 (describing tremor). Gesotti claims, “An adaptive stimulator for curing an individual exhibiting one or more symptoms of Parkinson's disease” “wherein the impaired voluntary movement comprises one or more of *tremor*, rigidity, akinesia, bradykinesia and drooping head.” *Id.* at claims 11, 14 (emphasis added).

44. 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 also 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.

45. Gesotti discloses several configurations of stimulation electrodes, including “stimulation electrode[s] 793” [red] embedded in a “tactile sensor and stimulation glove” that fits over the patient’s hand (below left) and “first and second stimulation electrodes 1044-1 and 1044-2” [red] located on a wristband (below right):

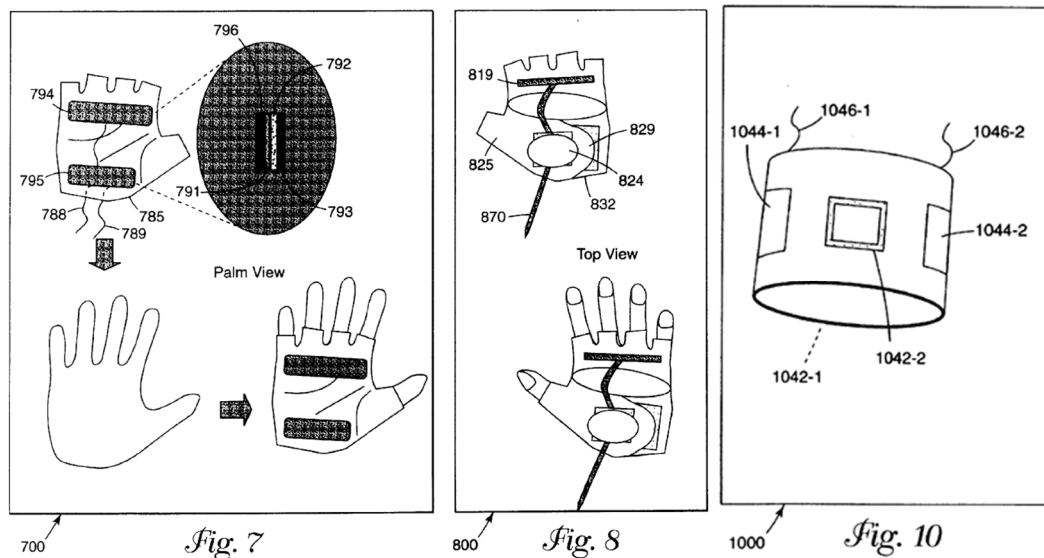


Id. at 8:16-35, 9:29-54, Figs. 7-10.

b. **Limitation [A]: “an applicator configured for application to a hand or arm of the subject”**

46. Claim 1 next recites: “an applicator configured for application to a hand or arm of the subject.” Gesotti discloses this limitation.

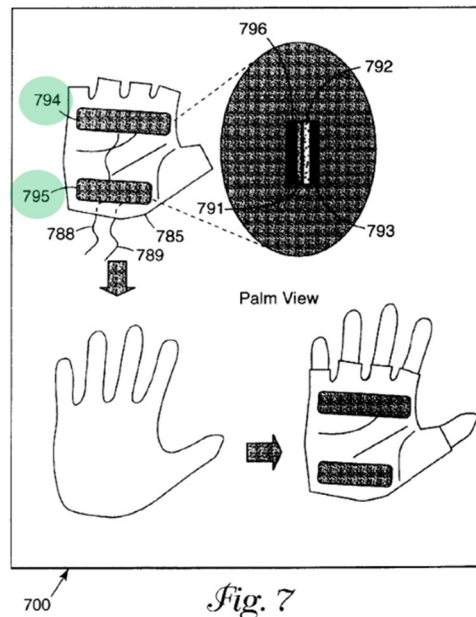
47. Gesotti discloses a “stimulation and sensing wristband,” (Ex. 1008, 9:29-30, Fig. 10,) and a “stimulation glove,” (*Id.*, 8:17, Figs. 7-9) which can be applied to a subject’s arm or hand, respectively. *See also id.* at 5:38-6:17, Fig. 2 (describing a “cylindrical stimulation electrode” for the “fingers, thumbs, wrist, ankle and other cylindrically shaped regions of the body”). The glove and wristband are “applicators.”



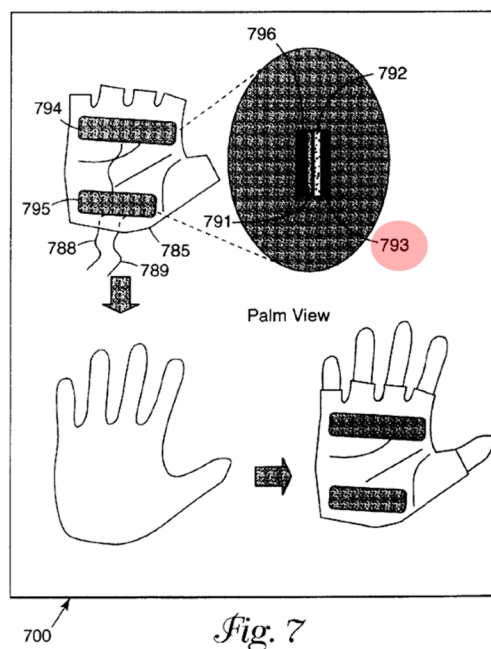
c. **Limitation [B]: “an electrode located along the applicator so as to contact the skin surface of the subject when the applicator is worn by the subject”**

48. Claim 1 next recites: “an electrode located along the applicator so as to contact the skin surface of the subject when the applicator is worn by the subject.” Gesotti’s glove (Figures 7-9) and wristband (Figure 10) embodiments satisfy this limitation or render the limitation obvious.

49. Gesotti’s “glove 785 includes a first and second tactile sensor assembly 794 and 795 [green] respectively”:

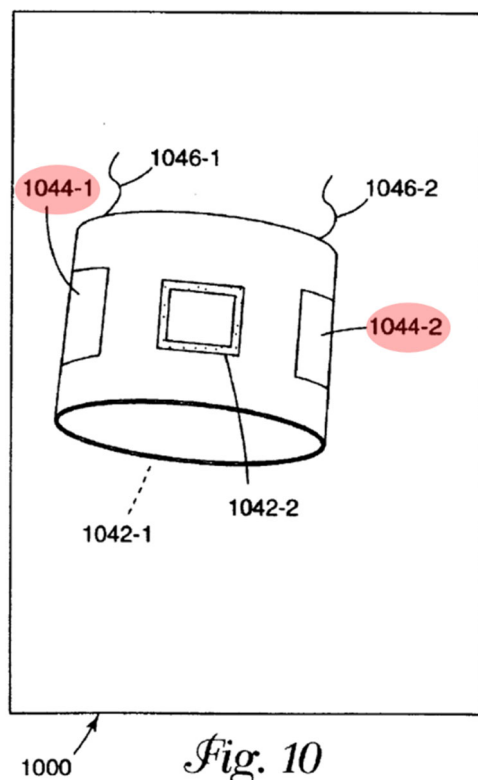


Ex. 1008 at 8:16-20, Fig. 7. “In one embodiment, each tactile sensor assembly includes *a stimulation electrode 793 [red], which is in direct contact with the palm* of the hand....” *Id.* at 8:20-26 (emphasis added).



Id. at Fig. 7. Thus, the electrode contacts the skin surface of the subject when the glove is worn by the subject.

50. Gesotti also discloses “a stimulation and sensing wristband, shown generally at 1000, constructed according to the teachings of the present invention.” *Id.* at 9:29-32. “Wristband 1000 includes first and second stimulation electrodes 1044-1 [red] and 1044-2 [red] located on the left and right sides of the wrist.” *Id.* at 9:32-34.



51. While Gesotti does not expressly state that electrodes 1044-1 and 1044-2 “contact a skin surface,” Gesotti discloses that the electrodes are in contact with the skin in other, similar stimulation and sensing bands, such as the headband illustrated in Figure 14. *See id.* at 11:4-5, Fig. 14 (“Electrical stimulation electrodes

1472-1 and 1472-2 are in direct contact with the skin.); *see also id.* at 8:49-51 (“Common return electrode 832 is in direct contact with the skin....”). Similarly, Gesotti generally discloses “cylindrical stimulation electrode[s]” for placement around the “fingers, thumbs, wrist, ankle and other cylindrically shaped regions of the body.” *Id.* at 5:38-44, Fig. 2. The electrodes provide “electrical pulses...for **cutaneous** stimulation of a region of the body by transmission of the electrical pulses to a conductive skin contact area 239 via conductor 235.” *Id.* at 5:47-52, Fig. 2 (emphasis added); *see also id.* at 6:23-26 (“electrical pulses are utilized for cutaneous stimulation of a region of the body”). Based on these descriptions, a person of ordinary skill in the art would have understood that the wristband electrodes also contact a skin surface when a subject wears the wristband.

52. If Patent Owner argues that the wristband’s electrodes do not “contact a skin surface,” Gesotti renders the limitation obvious. A person of ordinary skill in the art would have found it obvious to position the electrodes on the inside of the wristband to “contact the skin surface” based on Gesotti, which describes placing electrodes directly against the skin. 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. The sandwiching of wristband material between the electrode and skin surface could disrupt or weaken the transmission of the electrical pulses to the patient. A person

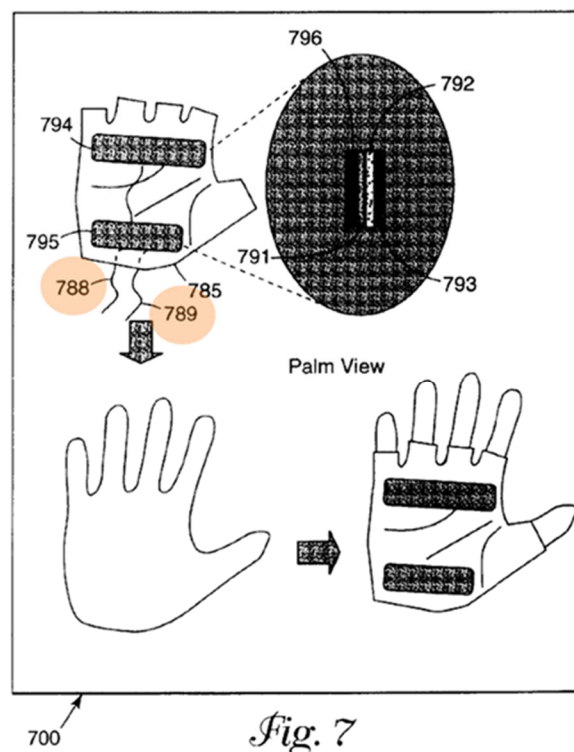
of ordinary skill in the art would have expected success in positioning the electrodes against the skin because Gesotti, among other prior art references, recommends this application and does not identify any drawbacks. Additionally, Gesotti never warns against contact between the electrodes and skin surface or that material should be placed between the electrode and skin.

53. Ultimately, the placement of the electrodes in contact with the skin surface would have been a predictable use of prior art elements (electrodes) to achieve their established functions (electrical stimulation). Additionally, a person of ordinary skill in the art would have had a finite number of identified, predictable ways to attach the electrodes to the wristband. The person of ordinary skill in the art could have positioned the electrodes on the inside of the wristband so the electrodes contact the skin surface (similar to the electrodes in Gesotti's glove), *or* the person of ordinary skill in the art could have positioned the electrodes within or on the outside of the wristband so that material resides between the electrode and skin surface (similar to the pressure sensor in Gesotti's glove). A person of ordinary skill in the art would have had a reasonable expectation of success using either option but, as discussed above, would have preferred direct contact with the skin to ensure a solid electrical connection.

d. **Limitation [C]: “an electrical pulse generator in communication with the electrode”**

54. Claim 1 next recites: “an electrical pulse generator in communication with the electrode.” Gesotti’s glove (Figures 7-9) and wristband (Figure 10) embodiments satisfy this limitation.

55. The glove’s “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.



Id. at Fig. 7. “Each electrical lead 788 and 789 is coupled to a control unit such as control unit 120....” *Id.* at 8:29-30.

56. Control unit 120 [below in yellow] is further described in Gesotti's Figure 1. *See e.g., id.* at 3:55-57 ("Adaptive stimulator 100 includes a control unit 120 coupled to at least one sensor.").

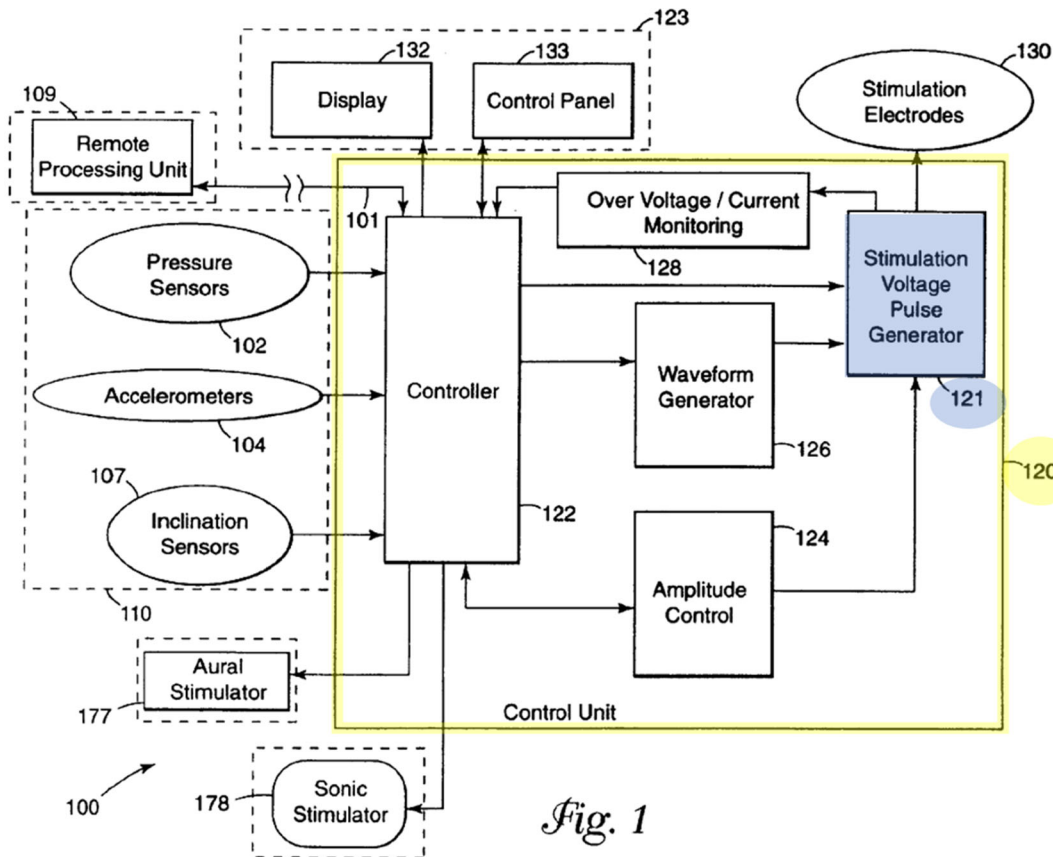
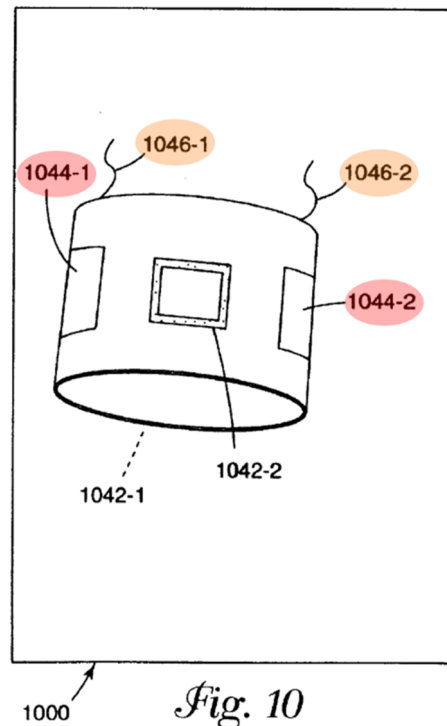


Fig. 1

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, Fig. 1. As shown above, the signal from the stimulation voltage pulse generator 121 is sent directly to the electrodes. *Id.* Thus, Gesotti discloses “an electrical pulse generator in communication with the electrode.”

57. Gesotti's wristband embodiment also “includes a first and second electrical lead 1046-1 and 1046-2 [orange] coupled to the first and second

stimulation electrodes 1044-1 and 1044-2 [red], respectively.” Ex. 1008 at 9:37-40, Fig. 10.

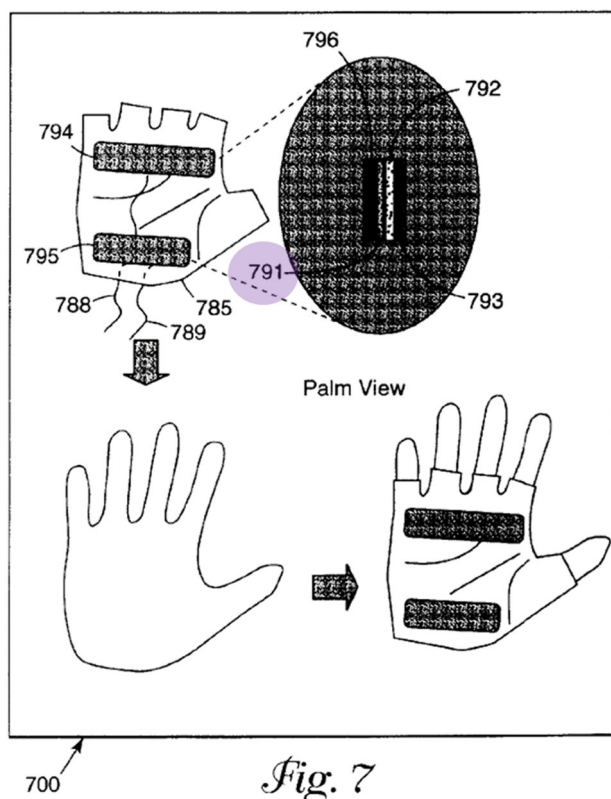


In one embodiment, “the electrical leads 1046-1 and 1046-2 are directly coupled to a control unit such as control unit 120 discussed with respect to FIG. 1.” *Id.* at 9:42-45. Control unit 120 includes the “stimulation voltage pulse generator” that provides signals directly to the electrodes, as shown above. *Id.* at 4:44-48, Fig. 1. Gesotti further confirms that “[e]lectrical stimulation signals and electrical information signals are sent and received via the electrical leads 1046-1 and 1046-2.” *Id.* at 9:45-47. Thus, Gesotti discloses a second embodiment having “an electrical pulse generator in communication with the electrode.”

e. **Limitation [D]: “a sensor positionable on the subject and in communication with the electrical pulse generator”**

58. Claim 1 next recites: “a sensor positionable on the subject and in communication with the electrical pulse generator.” Gesotti’s glove (Figures 7-9) and wristband (Figure 10) embodiments satisfy this limitation.

59. Gesotti’s glove (Figures 7-9) includes two tactile sensor assemblies (794 and 795) that include sensors 791 [purple]. Ex. 1008 at 8:16-26, Fig. 7.



As illustrated, the sensor is adjacent the stimulation electrode, which “is in direct contact with the palm of the hand.” *Id.* at 8:20-26, Fig. 7. Additionally, Gesotti discloses that the sensors are part of the glove worn by the patient. *Id.* Thus, the sensors are “positionable on the subject.”

60. Gesotti also discloses that “the first tactile sensor assembly 794 is coupled to a first electrical lead 788 and the second tactile assembly 795 is coupled to a second electrical lead 789” and that “[e]ach electrical lead 788 and 789 is coupled to a control unit such as control unit 120 [outlined in yellow].” *Id.* at 8:26-30, Fig. 1. As explained in the previous section, the control unit includes a stimulation voltage pulse generator 121 [blue]. *Supra* §VI.A.1.d.

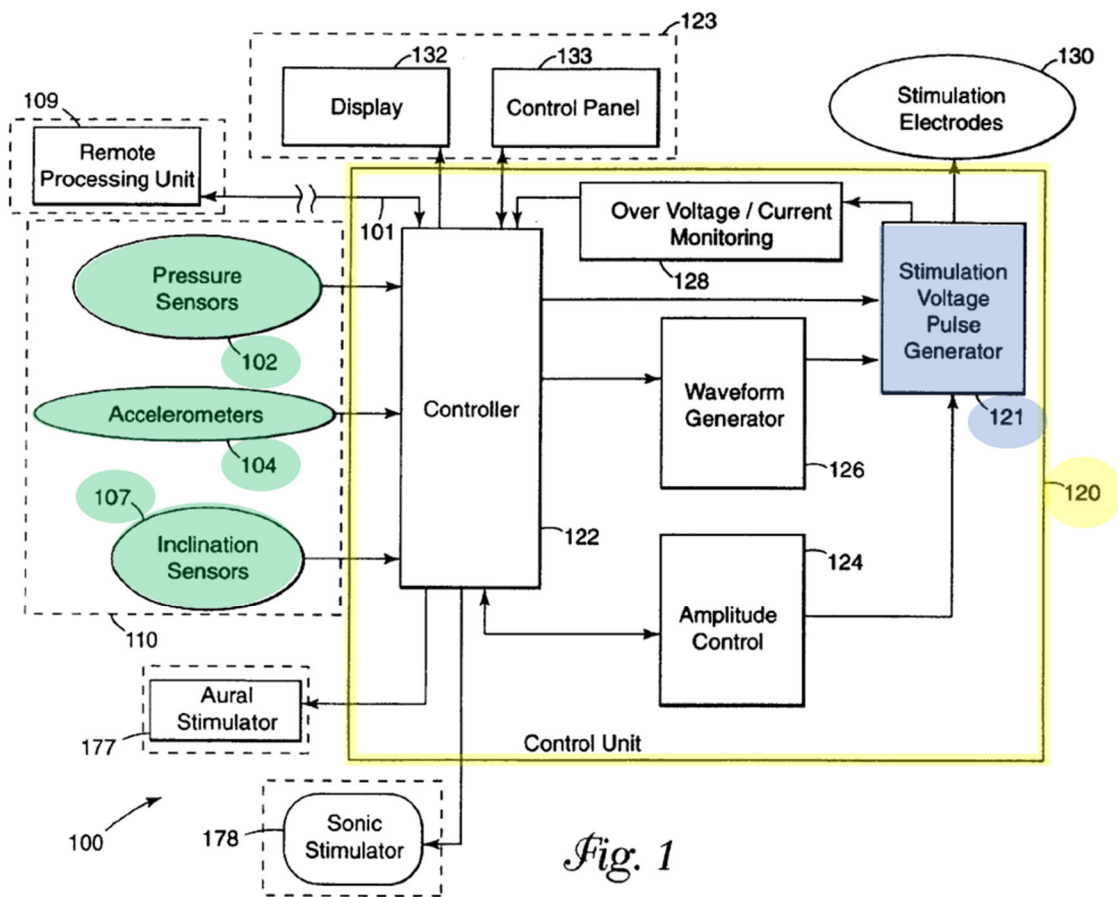
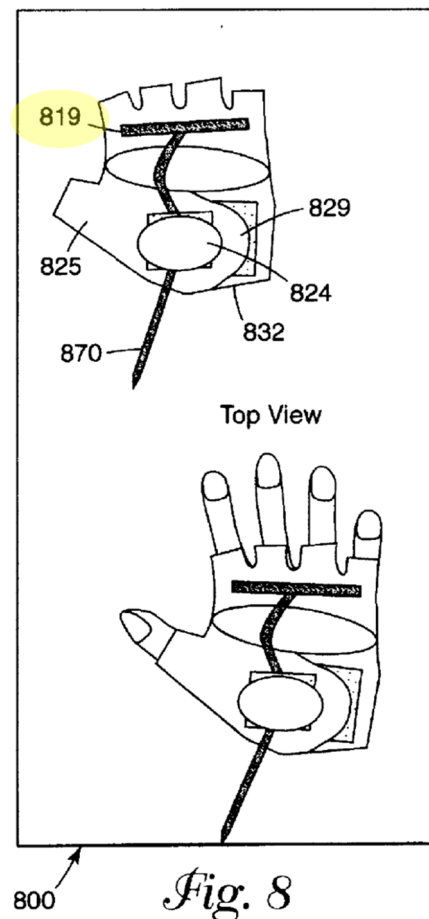


Fig. 1

Gesotti discloses that “the electrical leads provide pressure information to a control unit for a determination of the need for stimulation.” *Id.* at 8:31-33; *see also id.* at 3:57-59 (“Adaptive stimulator 100 includes a control unit 120 coupled to at least one

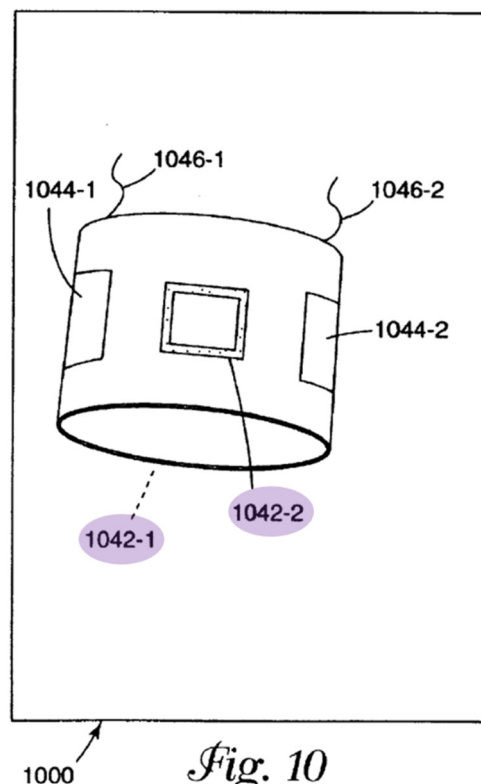
sensor 110.”). Therefore, the sensors on the glove are “in communication with” the pulse generator through the circuitry of the control unit 120.

61. Gesotti discloses another stimulation glove embodiment that combines the features of Figure 7 with Figure 8 (referred to as 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” (i.e., positionable on the subject). *Id.* at 8:39-43, Fig. 8.



The “[w]ire connector 819 includes connection cable 870 for coupling to a control unit, such as control unit 120, of FIG. 1.” Ex. 1008 at 8:43-45, Figs. 1, 8. The control unit includes the stimulation voltage pulse generator 121. *Id.* Gesotti also discloses that “connection cable 870 comprises all of the wiring to and from the control unit for stimulation and *transmission of sensor information.*” *Id.* at 8:45-47 (emphasis added). Thus, the acceleration sensor on the integrated tactile sensor and stimulation glove is “in communication with” the pulse generator through the circuitry of the control unit 120.

62. Gesotti’s wristband embodiment (Figure 10) also “includes a first and a second acceleration sensor (accelerometers) 1042-1 and 1042-2 [purple] located on the top and bottom sides of the wrist.” Ex. 1008 at 9:34-37.



The wristband also includes electrical leads 1046-1 and 1046-2, which are “directly coupled to a control unit such as control unit 120 discussed with respect to FIG. 1,” and that send “electrical information signals” from the sensors to the control unit. *Id.* at 9:42-47. As illustrated in Figure 1, the acceleration sensors transmit information to the control unit and stimulation voltage pulse generator. *Id.* at Fig. 1. Therefore, the acceleration sensors on the wristband are “in communication with” the pulse generator through the circuitry of the control unit 120.

f. **Limitation [E1]: “wherein the electrical pulse generator provides an electrical stimulation through the electrode and into a target nerve underlying the skin surface”**

63. Claim 1 next recites: “wherein the electrical pulse generator provides an electrical stimulation through the electrode and into a target nerve underlying the skin surface.” Gesotti discloses this limitation.

64. The stimulation voltage pulse generator 121 within the control unit 120 “produces individual stimulation signals for each stimulation electrode 130.” Ex. 1008 at 4:44-48, Fig. 1; *see also id.* at 2:18-38, 4:8-11 (“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.”). This disclosure applies to the electrodes in the glove and wristband embodiments. *Id.* at 8:26-33, 9:42-47. Thus, Gesotti discloses that the “electrical pulse generator provides an electrical stimulation through the electrode.”

65. The stimulation electrodes in the glove and wristband are also positioned over a target nerve underlying the skin surface so that the electrical stimulation is delivered to the nerves. At least the ulnar and median nerves lie beneath the palm and wrist and are stimulated by the electrodes on the glove and wristband. *See* Ex. 1001, Figs. 51-55 (identifying ulnar and medial nerves).

66. The '300 patent confirms that Gesotti's electrodes overlay the ulnar and median nerves. Figures 53 and 55 of the '300 patent illustrate the ulnar and median nerves [yellow] below the palm and wrist:

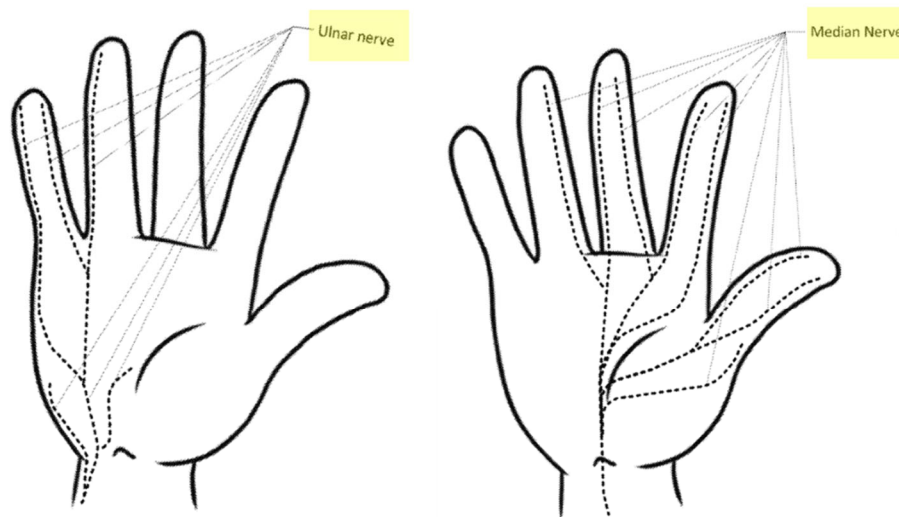


FIG. 53

FIG. 55

Ex. 1001 at Figs. 53, 55; *see also id.* at 7:46-47, 7:54-56 (describing Figures 53, 55), Figs. 52, 56A (illustrating ulnar and median nerves extend through the arm). The stimulation electrodes in Gesotti's gloves overlay both nerves because the electrodes extend across the upper and lower portions of the palm (red circles below indicating electrode positions). Ex. 1008 at Fig. 7.

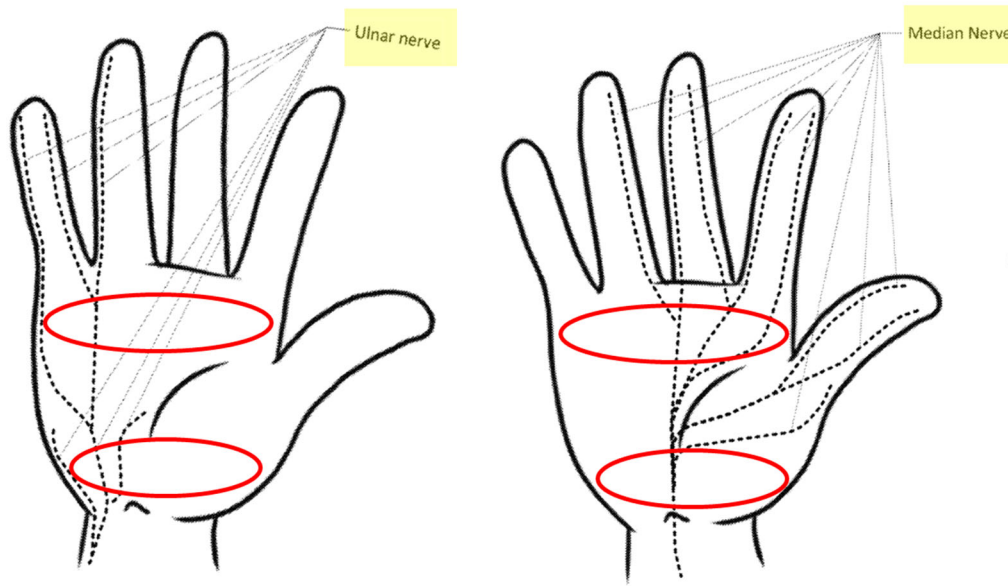


FIG. 53

FIG. 55

Likewise, the stimulation electrodes in Gesotti's wristband overlay at least the ulnar nerve because Gesotti discloses that the electrodes are positioned "on the left and right sides of the wrist" (red circles below indicating electrode positions). Ex. 1008 at 9:29-34, Fig. 10.

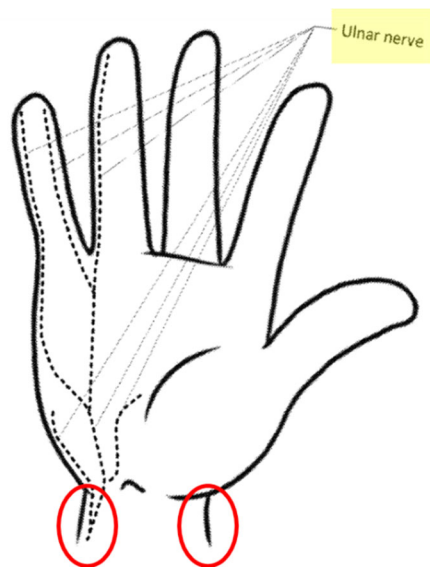
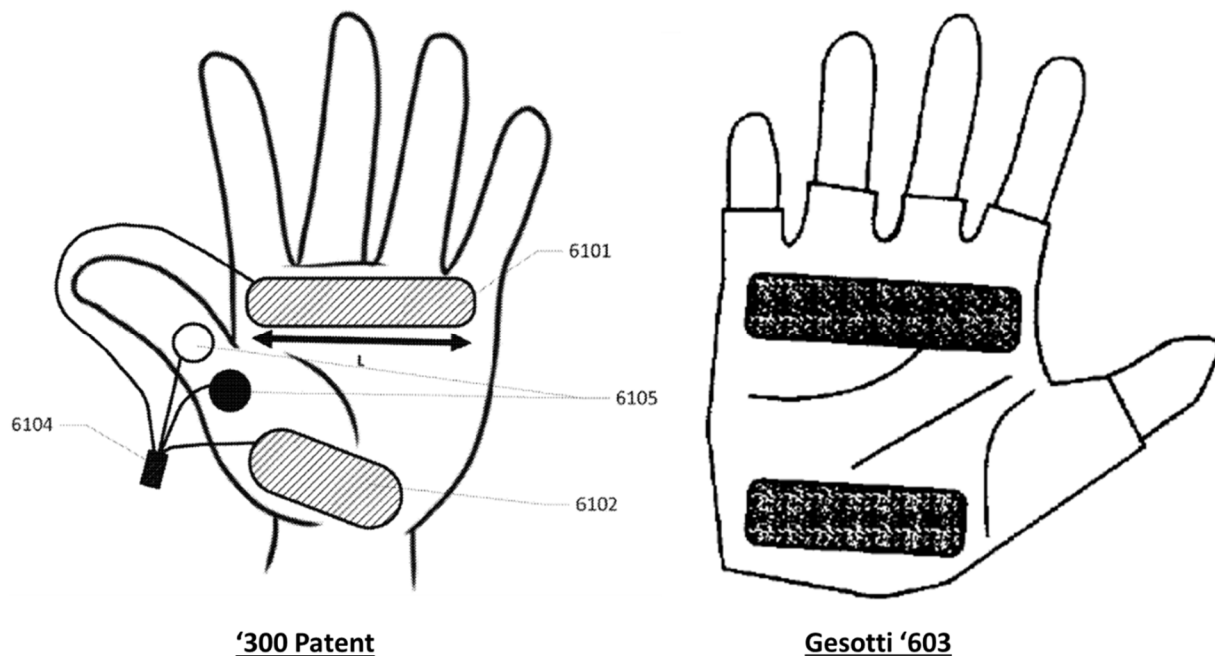


FIG. 53

67. The '300 patent's Figure 61A further confirms that Gesotti's glove electrodes overlay the ulnar and median nerves. Ex. 1001 at 62:37-42, Fig. 61A. The '300 patent states that the electrode patches illustrated in Figure 61A (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 '300 patent's Figure 61A (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). Thus, the stimulation electrodes described in Gesotti's glove and wristband embodiments satisfy this limitation.

g. **Limitation [E2]: “such that the sensor detects a motion of the subject and provides a feedback signal to the electrical pulse generator”**

68. Claim 1 next recites: “such that the sensor detects a motion of the subject and provides a feedback signal to the electrical pulse generator.” Gesotti discloses this limitation.

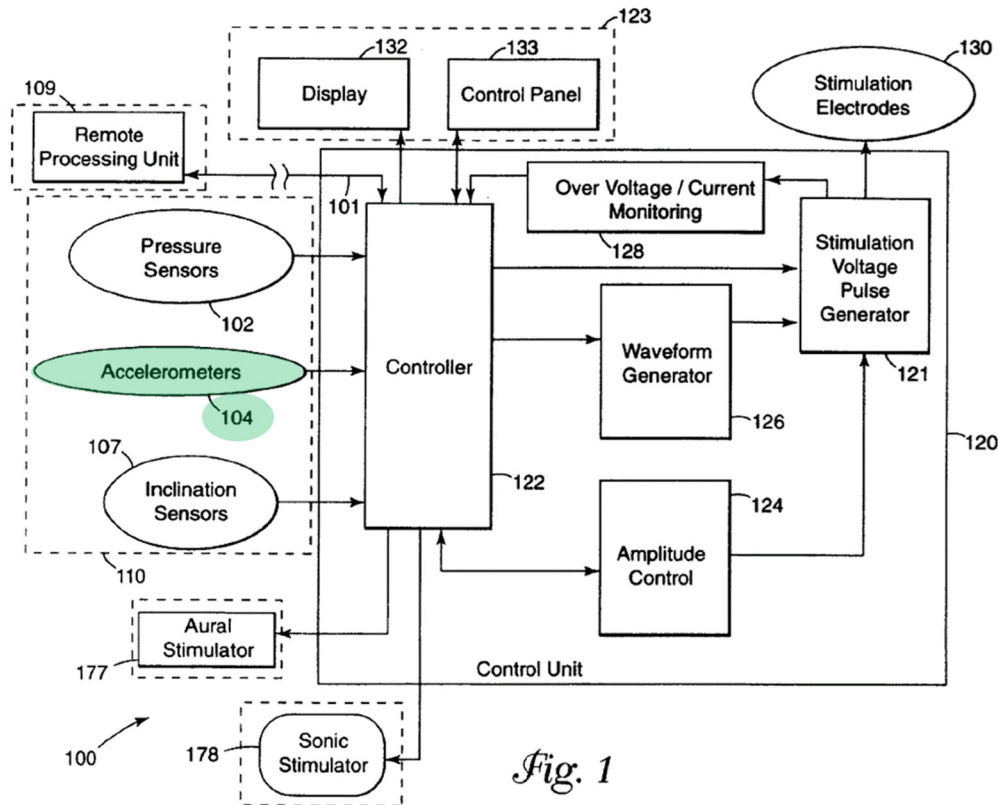
69. Gesotti’s wristband (Figure 10) includes “a first and second acceleration sensor (accelerometers) 1042-1 and 1042-2 located on the top and bottom sides of the wrist.” Ex. 1008 at 9:34-37, Fig. 10. The acceleration sensors detect motion of the subject. *See e.g., id.* at 4:4-6 (“Each sensor 110 is strategically located to receive information based on human body functions such as tactility (pressure), **movement** (acceleration), placement (inclination) and the like.”) (emphasis added); 12:28-30 (“in one embodiment, the control unit receives inputs that indicate little or no motion (acceleration) at the wrist.”).

70. Moreover, the accelerometer provides a feedback signal to the electrical pulse generator in the control unit. Gesotti discloses that the accelerometers are coupled to the control unit through “a first and a second electrical lead 1046-1 and 1046-2” and the “[e]lectrical stimulation signals and electrical information signals are sent and received via the electrical leads...” Ex. 1008 at 9:37-47, Fig. 1. The “electrical information signals” that are communicated to the control unit come from the sensors. For example, 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.” Ex. 1008 at 11:46-52, 12:9-21, Fig. 16. “A control unit receives the input signals and determines a response based on the input signals” including providing “electrical stimulation.” *Id.* at 12:9-21.

71. Gesotti’s integrated tactile sensor and stimulation glove also satisfies this limitation. As explained above, the stimulation glove 825 includes “a wire connector 819 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 (emphasis added); *supra* §VI.A.1.e. The acceleration sensors detect motion of the subject. *See e.g., id.* at 4:4-6, 12:28-30. Gesotti further discloses that a feedback signal from the sensors (including the acceleration sensors) is provided to the control unit 120 and stimulation voltage pulse generator 121. *See* Ex. 1008 at 8:43-47 (“connection cable 870 comprises all of the wiring to and from the control unit for simulation and transmission of sensor information”), Fig. 1.

72. Figure 1 illustrates that the acceleration sensors (i.e., “accelerometers 104” [green]) are in communication with the control unit 120 and stimulation voltage pulse generator 121:



Id. at 4:4-7, Fig. 1. Gesotti discloses that information from the acceleration sensors is communicated to the control unit 120, which “uses the information to determine when electrical stimulation is required at the location of each stimulation electrode.” *Id.* at 4:8-11. Thus, the acceleration sensors in the wristband and glove provide a feedback signal to the electrical pulse generator.

h. Limitation [E3]: “so as to mitigate the tremor by adjusting or optimizing the electrical stimulation.”

73. Claim 1 next recites: “so as to mitigate the tremor by adjusting or optimizing the electrical stimulation.” Gesotti discloses this limitation.

74. Gesotti’s inventions, including the integrated tactile sensor and stimulation glove (Figures 7-9) and wristband (Figure 10), deliver electrical

stimulation to mitigate the symptoms of Parkinson’s disease, including tremor. *See e.g.*, Ex. 1008 at claims 1-2 (claiming method of treating symptoms of Parkinson’s disease including “tremor”); *see also id.* at 1:14-16, 1:58-2:17, 2:39-50, 3:34-38, 11:46-65, 15:1-3.

75. For example, Figure 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. The treatment device, such as the glove or wristband, “receives 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.” *Id.* at 11:49-52. In the case of tremor, the sensors detect movement of the patient. If the input signal received from the sensor meets defined criterion, the control unit “generates one or more stimulation signals,” which are transmitted to the stimulators (i.e., electrodes). *Id.* at 11:53-64. The system can also 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; *see also id.* at 12:9-21 (similar). Thus, Gesotti describes devices “to mitigate the tremor by adjusting or optimizing the electrical stimulation” based on feedback received from sensors.

2. Claim 2

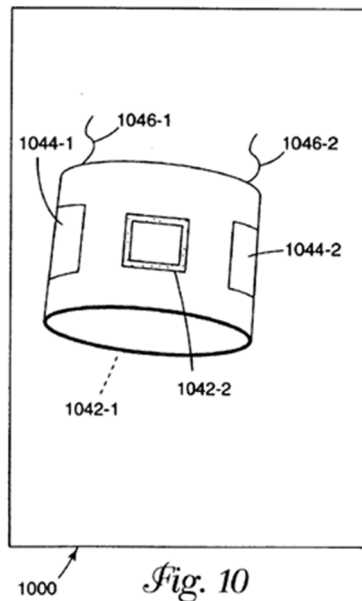
76. Claim 2 depends from Claim 1 and recites: “wherein the electrode is located along the applicator in proximity to the target nerve which extends through a hand of the subject.” Gesotti discloses this claim.

77. As explained above, the stimulation electrodes in the glove (Figures 7-9) and wristband (Figure 10) are “located along the applicator” (*supra* §VI.A.1.c) and positioned “in proximity to a target nerve (e.g., median and ulnar nerves), which extends through the hand” (*supra* §VI.A.1.f). The ulnar and median nerves extend beneath the palm and wrist and pass beneath the stimulation electrodes in Gesotti’s glove and wristband. *Id.*; *see also* Ex. 1001 at Figs. 51-56A (identifying ulnar and medial nerves beneath arm, wrist, and palm).

3. Claim 3

78. Claim 3 depends from Claim 1 and recites: “wherein the applicator comprises a strap or band.” Gesotti discloses this claim.

79. As discussed above, Gesotti discloses a “stimulation and sensing wristband” that meets the limitations of Claim 1. Ex. 1008 at 9:29-30, Fig. 10.



As I explained above, the wristband is an applicator and a band. *Supra* §VI.A.1.b.

4. Claim 4

80. Claim 4 depends from Claim 3 and recites: “wherein the electrode is attached to the strap or band so as to contact the skin surface of the subject.” Gesotti’s wristband (Figure 10) satisfies this claim, or renders it obvious, for the reasons I provided in Claim 1. *Supra* §VI.A.1.c.

5. Claim 5

81. Claim 5 depends from claim 1 and recites: “comprising an additional electrode separate from the electrode.” Gesotti discloses this claim.

82. Gesotti’s stimulation glove (Figures 7-9) and wristband (Figure 10) each have two separate electrodes. Ex. 1008 at 8:19-22, Fig. 7 (“glove 785 includes a first and a second tactile sensor assembly 794 and 795...*each tactile assembly includes a stimulation electrode 793*”), 9:32-34, Fig. 10 (“*first and second*

stimulation electrodes 1044-1 and 1044-2 located on the left and right sides of the wrist”) (emphasis added).

6. Claim 6

83. Claim 6 depends from Claim 1 and further recites: “wherein a parameter of the electrical stimulation comprises a frequency which is adjustable.” Gesotti discloses this claim.

84. Gesotti discloses that “[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, Fig. 1 (emphasis added); *see also id.* at 4:35-43. As I discussed above, the stimulation glove (Figures 7-9) and wristband (Figure 10) are coupled to control unit 120. *Supra* §VI.A.1.d.

7. Independent Claim 7

85. Claim 7 is anticipated or rendered obvious by Gesotti.

a. Preamble: “An apparatus for treating tremor in a subject, comprising:”

86. The preamble is the same as the preamble in Claim 1. If the preamble is limiting, Gesotti discloses this limitation for the reasons I provided in Claim 1. *Supra* §VI.A.1.a.

b. **Limitation [A]: “an applicator configured for application to a region of the subject”**

87. This limitation is also in Claim 1. Gesotti discloses this limitation for the reasons I provided in Claim 1. *Supra* §VI.A.1.b.

c. **Limitation [B]: “an electrode located along the applicator so as to contact a skin surface of the subject when the applicator is worn by the subject”**

88. This limitation is also in Claim 1. Gesotti discloses this limitation or renders it obvious for the reasons provided in Claim 1. *Supra* §VI.A.1.c.

d. **Limitation [C]: “a controller in communication with the electrode”**

89. Gesotti discloses this limitation. The stimulation glove’s “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.

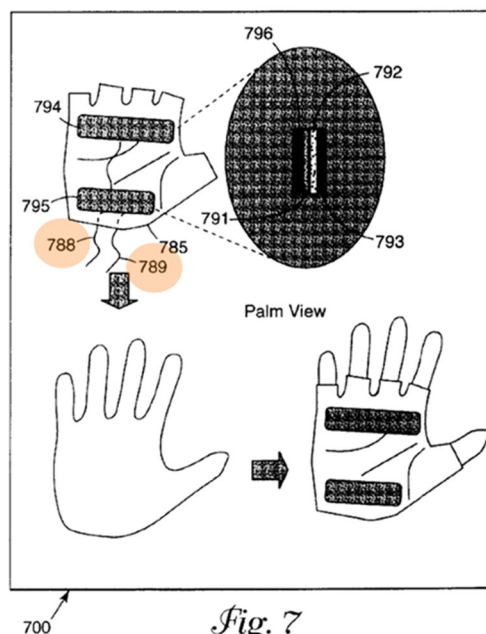


Fig. 7

Id. at Fig. 7. “Each electrical lead 788 and 789 is coupled to a control unit such as control unit 120....” *Id.* at 8:29-30.

90. Control unit 120 [below in yellow] includes a ***controller 122*** [brown].
Id. at 4:44-46.

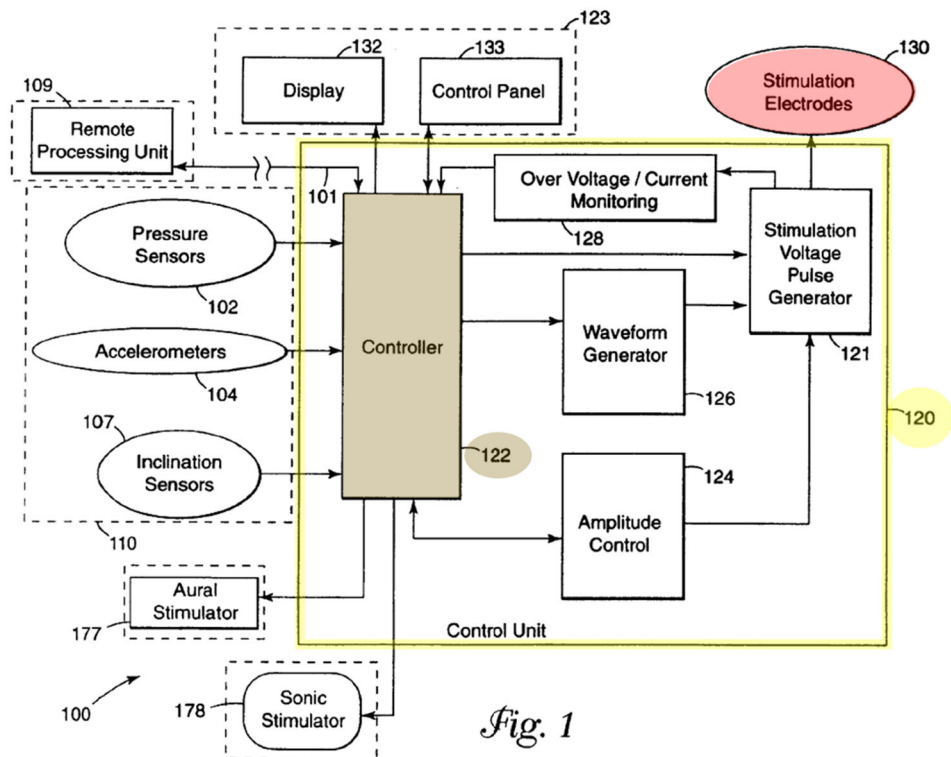


Fig. 1

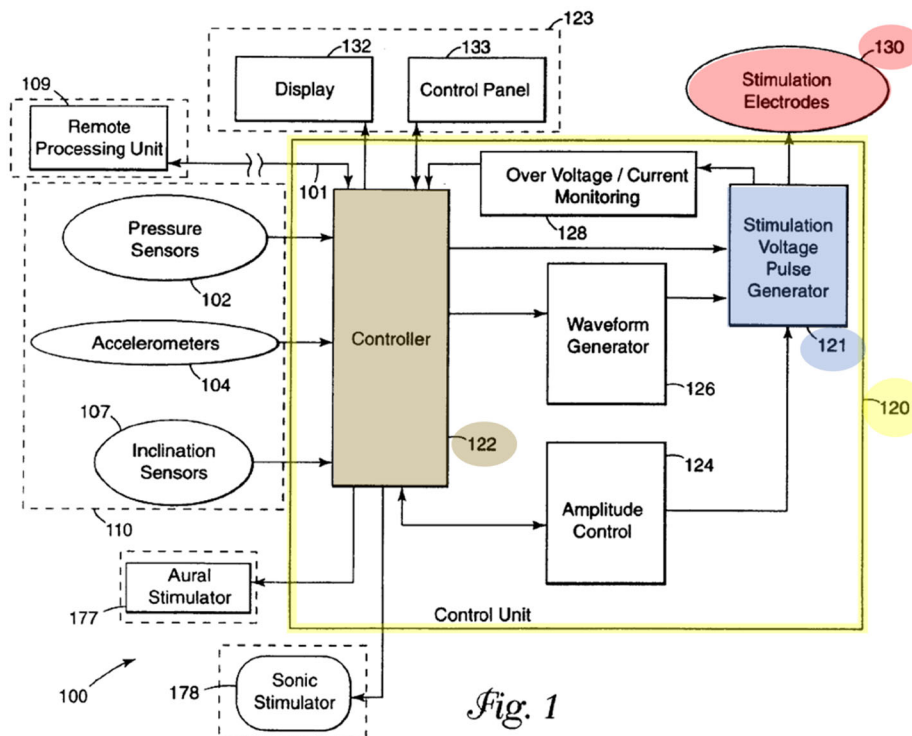
Gesotti discloses, “[w]aveform generator 126 receives input from controller 122 and generates waveforms for input to stimulation voltage pulse generator 121,” which in turn “produces individual stimulation signals for each stimulation electrode 130 [red].” *Id.* at 4:44-64, Fig. 1. Thus, the controller 122 is “in communication with” the electrodes.

e. **Limitation [D1]: “a sensor positionable on the subject and in communication with the controller,”**

91. Gesotti discloses this limitation. As I explained in connection with Claim 1, the glove (Figures 7-9) and wristband (Figure 10) include a sensor “positionable on the subject.” *Supra* §VI.A.1.e. As I also explained in connection with Claim 1, Gesotti discloses that “control unit 120 includes a controller 122 that receives information from sensors 110.” Ex. 1008 at 4:35-36, Fig. 1; *see also supra* §VI.A.1.c. Thus, the sensors are “in communication with” the controller.

f. **Limitation [D2]: “the controller transmits via the electrode an electrical stimulation having an adjustable frequency through the skin surface and into a target nerve underlying the skin surface”**

92. Gesotti discloses this limitation. Gesotti discloses that “[w]aveform generator 126 receives input from controller 122 [brown] and generates waveforms for input to stimulation voltage pulse generator 121 [blue],” which in turn “produces individual stimulation signals for each stimulation electrode 130 [red].” Ex. 1008 at 4:44-64, Fig. 1.



Thus, the controller “transmits via the electrode an electrical stimulation.”

93. Gesotti also discloses that the electrical stimulation may have an adjustable frequency. Gesotti explains that “[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).

94. Finally, as I discussed in connection with Claim 1, the stimulation electrodes in the stimulation glove (Figure 7) and wristband (Figure 10) deliver electrical stimulation through the skin surface and into a target nerve (e.g., median and ulnar nerves) underlying the skin surface. *Supra* §VI.A.1.f.

- g. **Limitation [E]: “wherein the sensor detects a motion of the subject and provides a feedback signal to the controller so as to mitigate the tremor by adjusting or optimizing the electrical stimulation.”**

95. Gesotti discloses this limitation. As I explained in connection with Claim 1, Gesotti’s integrated tactile sensor and stimulation glove (Figures 7-9) and wristband (Figure 10) include acceleration sensors that detect the motion of a subject. *Supra* §VI.A.1.g.

96. As I also explained in connection with Claims 1 and 6, the feedback signal from the acceleration sensors is used to adjust or optimize the electrical stimulation to mitigate tremor including, for example, adjusting the frequency of the stimulation. *Supra* §VI.A.1.h, §VI.6.

97. Additionally, Gesotti discloses that the sensors provide the feedback signal to the controller. Gesotti discloses that the controller 122 “receives information from sensors 110.” Ex. 1008 at 4:35-36, Fig. 1. Additionally, “[c]ontroller 122 includes software that includes algorithms for processing the information from input signals and determines the response(s) required to produce simulation and stimulation.” *Id.* at 4:36-39. “The controller 122 generates the basic timing for the stimulation waveforms and adjusts frequency, pulse width, waveform shape, and amplitude ***based on sensor information*** or sensor information and operator controls.” *Id.* at 4:40-43 (emphasis added).

8. Claim 8

98. Claim 8 depends from claim 7 and recites: “wherein the electrode is located along the applicator in proximity to the target nerve which extends through a hand of the subject.” Gesotti discloses this claim for the reasons I provided in connection with Claim 2. *Supra* §VI.A.2.

9. Claim 9

99. Claim 9 depends from claim 7 and recites: “wherein the applicator comprises a strap or band.” Gesotti discloses this claim for the reasons I provided in connection with Claim 3. *Supra* §VI.A.3.

10. Claim 10

100. Claim 10 depends from claim 9 and recites: “wherein the electrode is attached to the strap or band so as to contact the skin surface of the subject.” Gesotti discloses this claim, or renders it obvious, for the reasons I provided in connection with Claim 4. *Supra* §VI.A.4.

11. Claim 11

101. Claim 11 depends from claim 7 and recites: “an additional electrode separate from the electrode.” Gesotti discloses this claim for the reasons I provided in connection with Claim 5. *Supra* §VI.A.5.

12. Independent Claim 12

102. Claim 12 is anticipated or rendered obvious by Gesotti.

a. **Preamble: “A method of treating tremors in a subject, comprising:”**

103. 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). Gesotti claims, “A method of cu[r]ing 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).

b. **Limitation [A]: “transmitting an electrical stimulation from an electrical pulse generator through an electrode located along an applicator and contacted against a skin surface of a hand or arm of the subject such that the electrical stimulation targets a nerve underlying the skin surface”**

104. Gesotti discloses this limitation, or renders it obvious, for the reasons I provided in connection with Claim 1. *Supra* §§VI.A.1.c-d, f.

105. Gesotti discloses transmitting an electrical stimulation from an electrical pulse generator through the electrodes in the glove and wristband. As I discussed previously, the stimulation electrodes in the stimulation glove (Figures 7-9) and wristband (Figure 10) are coupled to the control unit 120. Ex. 1008 at 8:26-

33, 9:42-47. The control unit 120 includes a stimulation voltage pulse generator 121 that “produces individual stimulation signals for each stimulation electrode 130.” *Id.* at 4:44-48, Fig. 1.

106. As I discussed in connection with Claim 1, the electrodes in the stimulation glove and wristband are also along the applicator (i.e., glove or wristband) and contacted against a skin surface of the hand or arm of the subject. *Supra* §§VI.A.1.b-c; *see also id.* at 8:16-35 (describing stimulation glove), 9:29-54 (describing wristband).) The stimulation glove includes “a stimulation electrode 793, ***which is in direct contact with the palm*** of the hand....” *Id.* at 8:20-26 (emphasis added). Likewise, “[w]ristband 1000 includes first and second stimulation electrodes 1044-1 and 1044-2 located on the left and right sides of the wrist.” *Id.* at 9:32-34.

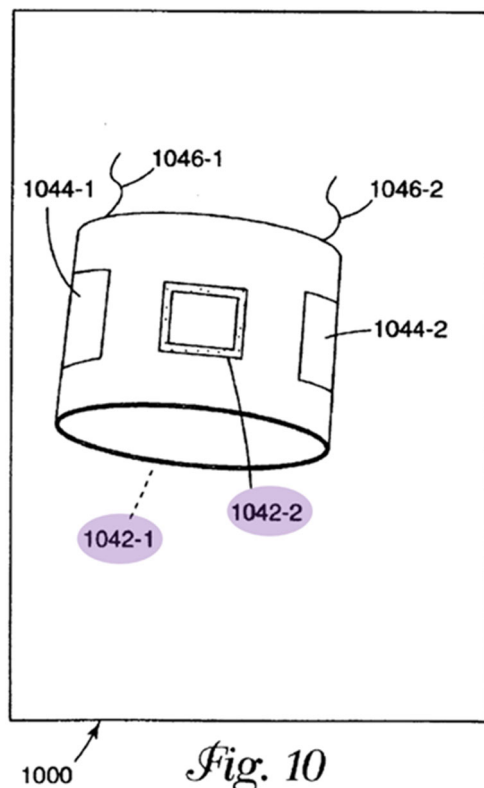
107. As I discussed in connection with Claim 1, if the electrodes on the wristband are not “contacted against a skin surface” of the arm, a person of ordinary skill in the art would have found it obvious to modify the wristband so that the electrodes contact the skin surface for the reasons provided in connection with Claim 1. *Supra* §VI.A.1.c.

108. Finally, the stimulation electrodes in the stimulation glove and wristband target a nerve (e.g., median or ulnar nerve) underlying the skin surface as described in Claim 1. *Supra* §VI.A.1.f. The stimulation electrodes in Gesotti’s

gloves overlay at least the median and ulnar nerves because the electrodes extend across the upper and lower portions of the palm. Ex. 1008, Fig. 7. Likewise, the stimulation electrodes in Gesotti's wristband overlay at least the ulnar nerve because the electrodes are positioned on the "left and right sides of the wrist." Ex. 1008 at 9:29-34; Fig. 10.

c. **Limitation [B]: "monitoring for a motion of the subject via a sensor positionable on the subject and in communication with the electrical pulse generator"**

109. Gesotti discloses this limitation. Gesotti's wristband (Figure 10) includes acceleration sensors that meet this limitation. As I explained in connection with Claim 1, "wristband 1000 includes a first and a second acceleration sensor (accelerometers) 1042-1 and 1042-2 located on the top and bottom sides of the wrist" (i.e., positionable on the subject). Ex. 1008 at 9:34-37, Fig. 10; *supra* §VI.A.1.e.



The acceleration sensors monitor for a motion of the subject. *See e.g., 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). The acceleration sensors also generate “electrical information signals [that] are sent via the electrical leads 1046-1 and 1046-2” to the control unit 120 and stimulation voltage pulse generator 121. *Id.* at 9:45-47; 3:57-59, Fig. 1; *see also supra* §VI.A.1.e (addressing similar limitation). Thus, the acceleration sensors are “in communication with” the electrical pulse generator. *Supra* §VI.A.1.g.

110. Gesotti’s “integrated tactile sensor and stimulation glove” (Figures 7-9) also includes acceleration sensors that meet this limitation. As explained in

connection with Claim 1, the stimulation glove 825 incorporates “**acceleration**...sensors attached to the wrist, forearm, upper arm or the like.” Ex. 1008 at 8:39-43, Fig. 8 (emphasis added); *supra* §VI.A.1.e. The acceleration sensors detect motion of the subject. *See e.g., id.* at 4:4-6, 12:28-30. As I also explained in connection with Claim 1, the acceleration sensors are “in communication with” the stimulation voltage pulse generator 121 through wire connection 819 and connection cable 870. *Supra* §VI.A.1.e.

d. Limitation [C]: “receiving a feedback signal via the sensor”

111. Gesotti discloses this limitation. As I discussed in connection with Claim 1, Gesotti’s “control unit” is “in communication with” the sensors, including the acceleration sensors on the wristband and integrated tactile sensor and stimulation glove. *Supra* §VI.A.1.g. The “[c]ontrol unit 120 receives the information [from the sensors] and uses the information to determine when electrical stimulation is required at the location of each stimulation electrode 103.” Ex. 1008 at 4:7-11; *see also id.* at 4:35-39 (the controller 122 includes software “for processing the information from input signals and determines the response(s) required to produce simulation and stimulation”).

e. **Limitation [D]: adjusting or optimizing the electrical stimulation from the electrical pulse stimulation in response to the feedback signal until the tremors are mitigated.**

112. Gesotti discloses this limitation. As I discussed in connection with Claim 1, Gesotti discloses that the described inventions, including the stimulation glove (Figures 7-9) and wristband (Figure 10), deliver electrical stimulation to mitigate the symptoms of Parkinson's disease, including tremor. *Supra* §VI.A.1.h; *see also*, Ex. 1008 at claims 1-2 (claiming method of treating symptoms of Parkinson's disease including "tremor"); *see also id.* at 1:14-16, 1:58-2:17, 2:39-50, 3:34-38, 11:46-65, 15:1-3.

113. Figure 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.*, 11:46-49 at Fig. 16. The treatment device, such as the stimulation glove or wristband, "receives 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." *Id.* at 11:49-52. In the case of tremor, the acceleration sensor 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 or wristband "generates one or more stimulation signals," which are transmitted to the stimulators (i.e., electrodes). Ex. 1008 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. Thus, Gesotti discloses “adjusting or optimizing the electrical stimulation from the electrical pulse stimulation in response to the feedback signal until the tremors are mitigated.”

13. Claim 13

114. Claim 13 depends from claim 12 and further recites: “wherein the electrode is located along the applicator in proximity to the target nerve which extends through a hand of the subject.” Gesotti discloses this claim for the reasons I provided in connection with Claim 2. *Supra* §VI.A.2.

14. Claim 14

115. Claim 14 depends from claim 12 and further recites: “wherein transmitting the electrical stimulation comprises transmitting through the electrode located along an applicator comprising a strap or band.” Gesotti discloses this claim for the reasons I provided in connection with Claim 3. *Supra* §VI.A.3.

15. Claim 15

116. Claim 15 depends from claim 14 and further recites: “wherein the electrode is attached to the strap or band so as to contact the skin surface of the subject.” Gesotti discloses this claim or renders it obvious for the reasons I provided in connection with Claim 4. *Supra* §VI.A.4.

16. Claim 16

117. Claim 16 depends from claim 12 and further recites: “transmitting the electrical stimulation via an additional electrode separate from the electrode.” Gesotti discloses this claim for the reasons I provided in connection with Claim 5. *Supra* §VI.A.5.

17. Claim 17

118. Claim 17 depends from claim 12 and further recites: “adjusting a frequency of the electrical stimulation in response to the feedback signal.” Gesotti discloses this claim.

119. Gesotti discloses that “[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, Fig. 1 (emphasis added); *see also id.* at 4:35-43.) As discussed in connection with Claim 1, the stimulation glove and wristband are coupled to control unit 120. *Supra* §VI.A.1.d.

B. Ground 3: Claims 1-17 Are Rendered Obvious By Burnett

1. Independent Claim 1

120. Claim 1 is rendered obvious by Burnett.

a. Preamble: “An apparatus for treating tremor in a subject.”

121. If the preamble is limiting, Burnett discloses this limitation. The ’300 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 '300 patent specification. For example, Burnett includes Figures 1-30b of the '300 patent and the accompanying description of those figures. *Compare* Ex. 1001, 10:21-63:63, Figs. 1-30b *with* Ex. 1010, [0070-0193], Figs. 1-31.

122. Burnett describes electrical and magnetic stimulation devices to treat OAB and UI. Ex. 1010 at [0002, 0036, 0038, 0070]. However, Burnett includes the same list of over 100 ailments found in the '300 patent, including “tremor.” *Id.* at [0111]. Thus, if the '300 patent discloses an “apparatus for treating tremors,” then so does Burnett.

b. Limitation [A]: “an applicator configured for application to a hand or arm of the subject”

123. Burnett discloses this limitation. Burnett discloses that the energy emitting devices may stimulate various body regions, including the “back, leg, *arm*, neck, head, torso, etc.” Ex. 1010 at [0102] (emphasis added). To facilitate this stimulation, Burnett discloses incorporating the energy emitting devices into a garment, such as a band 114 [yellow] that “may be wrapped around a body portion (for example, an *arm*) and be retained in place by a system known in the art...” *Id.* at [0107] (emphasis added), Fig. 9C.

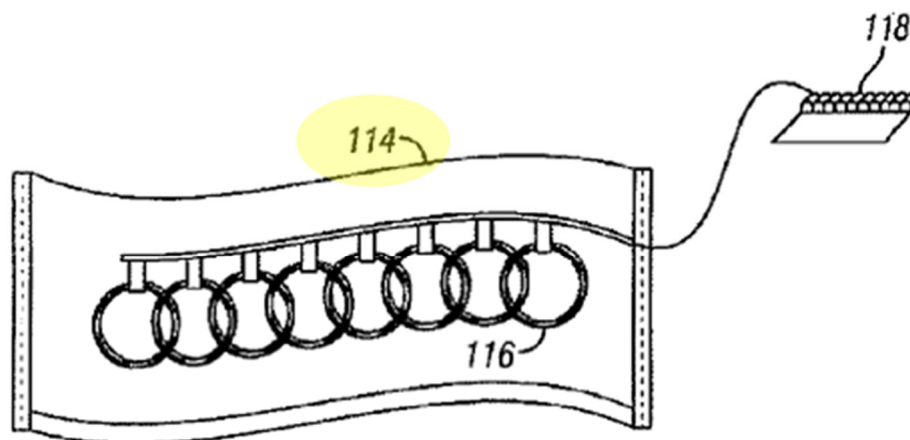


FIG. 9C

Thus, Burnett discloses an applicator configured for application to the arm.

- c. **Limitation [B]: “an electrode located along the applicator so as to contact the skin surface of the subject when the applicator is worn by the subject”**

124. Burnett renders this limitation obvious. Burnett discloses various types of electrodes that contact the skin surface of a subject. For example, Burnett discloses positioning “a transcutaneous stimulator, such as an electrode 126 [red],” over a skin surface overlying a target nerve (e.g., the tibial nerve in Figure 11 below):

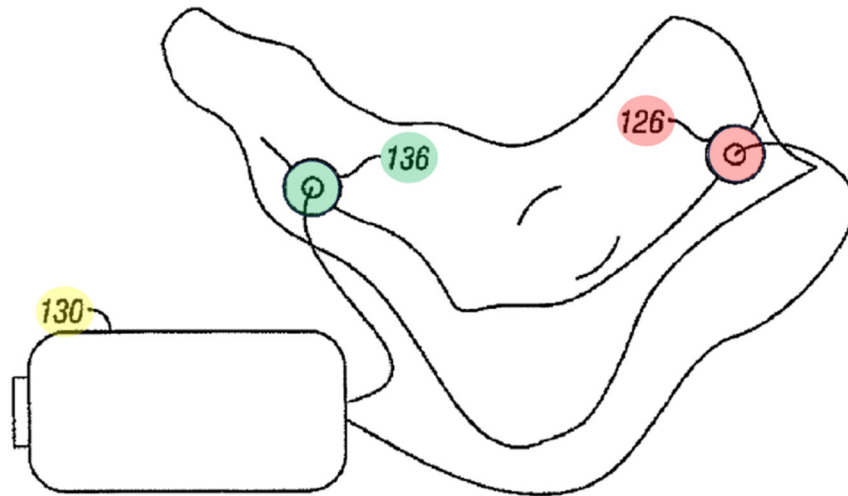


FIG. 11

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”).

Burnett also discloses “a microneedle patch 252...having one or more microneedle arrays deposited on a surface of one or more electrodes.” *Id.* 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].

125. As described in the previous section, Burnett also discloses incorporating the stimulation coils and sensors *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] (“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.* at Fig. 9C), a person of ordinary skill in the art would have found it obvious to substitute electrodes or microneedle patches for the coils in those embodiments.

126. 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] (similar).

127. 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.

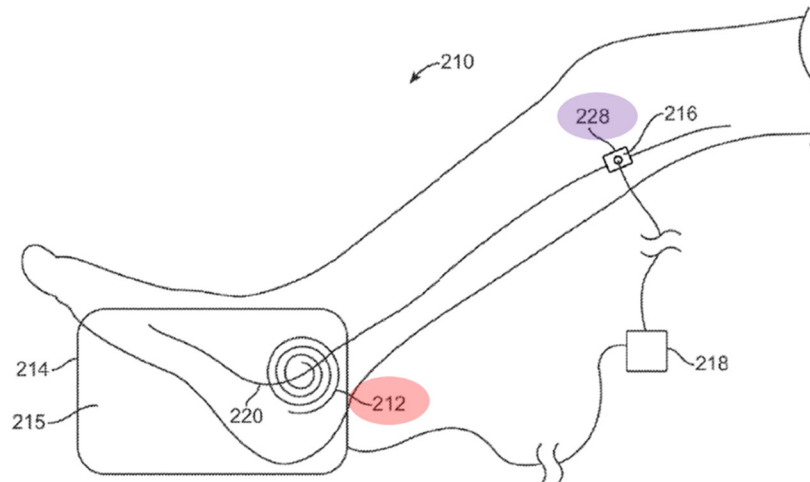


FIG. 21

128. 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.” *Id.* at [0154], Fig. 26. Burnett explains that the microneedle patch can deliver or generate “an electrical or magnetic stimulus to a target nerve.” *Id.*

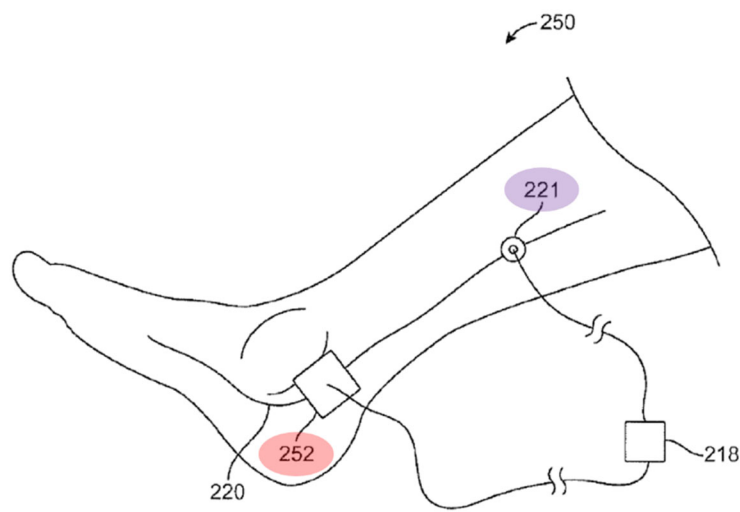


FIG. 26

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

129. 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 an 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 adequately address neurological movement disorders like tremor.

130. 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. Ex. 1010 at [0107].

131. 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 electrodes that “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.

132. 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.

133. 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 against the skin and suggests that such positioning can improve the function of the device.

134. 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.

d. **Limitation [C]: “an electrical pulse generator in communication with the electrode”**

135. Burnett discloses this limitation. As I discussed in connection with Claim 1, Burnett discloses delivering electrical stimulation transdermally through a skin surface and to the target nerve to stimulate the target nerve. *Supra* §VI.B.1.c. Burnett further discloses that the electrical stimulation is delivered via an “electric pulse controller 130” [yellow] to “provide the desired feedback and modulate the power” to the transcutaneous stimulator, such as electrode 126 [red]. Ex. 1010 at [0109]. An electric pulse controller is a pulse generator.

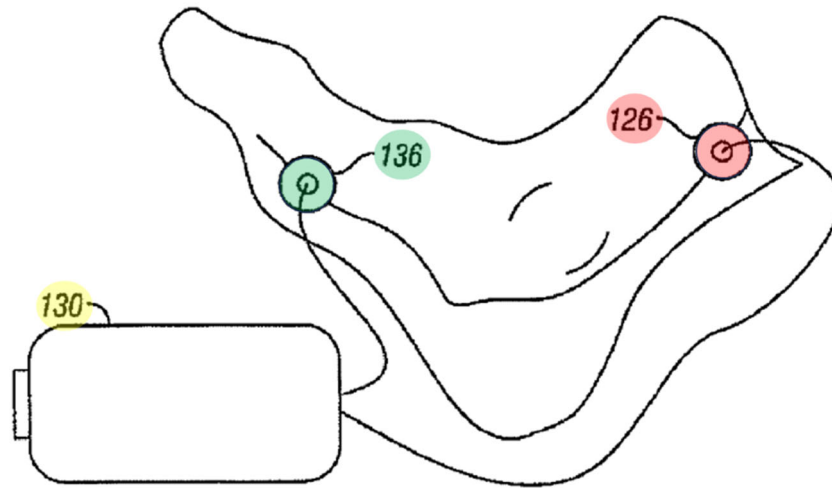


FIG. 11

Ex. 1010 at Fig. 11. As shown in Figure 11 above, for example, the electrical pulse generator 130 is “in communication with” the electrode 126 through the wires.

e. **Limitation [D]: “a sensor positionable on the subject and in communication with the electrical pulse generator”**

136. Burnett discloses this limitation. Burnett describes embodiments, such as Figure 11, having “one or more energy generators, a logic controller electrically connected to one or more energy generators, and one or more sensors for detecting electrical conduction in a target nerve, *which are connected to the logic controller.*”

Ex. 1010, [0032] (emphasis added). “The one or more energy generators produce energy focused on the target nerve upon receiving a signal from the logic controller, and the applied energy is *varied by the logic controller according to an input provided by the one or more sensors* based on electrical conduction in the target

nerve.” *Id.* (emphasis added). In these embodiments, the energy generators are the pulse generators.

137. Figure 26, for example, illustrates an energy emitting system 250 having a microneedle patch 252 and **sensor 221**. *Id.* 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].

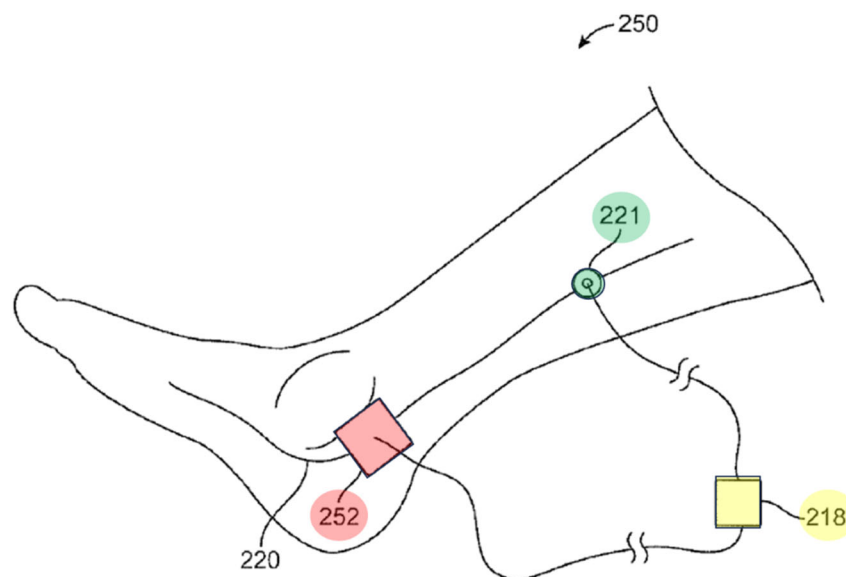


FIG. 26

Id. at Fig. 26. The controller 218 is the pulse generator. “Sensor 221 detects electrical conduction through the stimulated posterior tibial nerve 220, and then transmits the signal to controller 218.” Ex. 1010 at [0156], Fig. 26. Thus, the sensor is “positionable on the subject and in communication with the electrical pulse generator.”

f. **Limitation [E1]: “wherein the electrical pulse generator provides an electrical stimulation through the electrode and into a target nerve underlying the skin surface”**

138. Burnett discloses this limitation. As I discussed in connection with Claim 1, Burnett discloses an electrode in communication with an electrical pulse controller, which is an electrical pulse generator. *Supra* §VI.B.1.d.

139. Burnett discloses that the electrical pulse generator provides electrical stimulation through the electrode and into a target nerve underlying the skin surface. For example, Burnett 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. The electric pulse controller is a pulse generator.

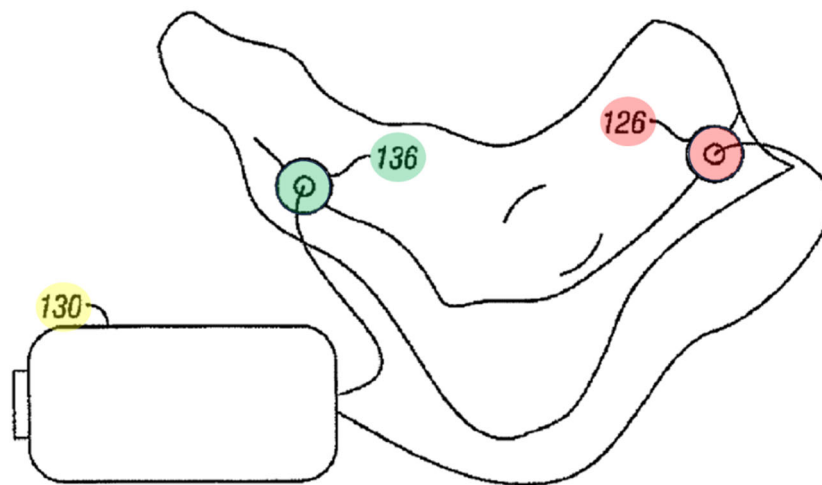


FIG. 11

140. 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].

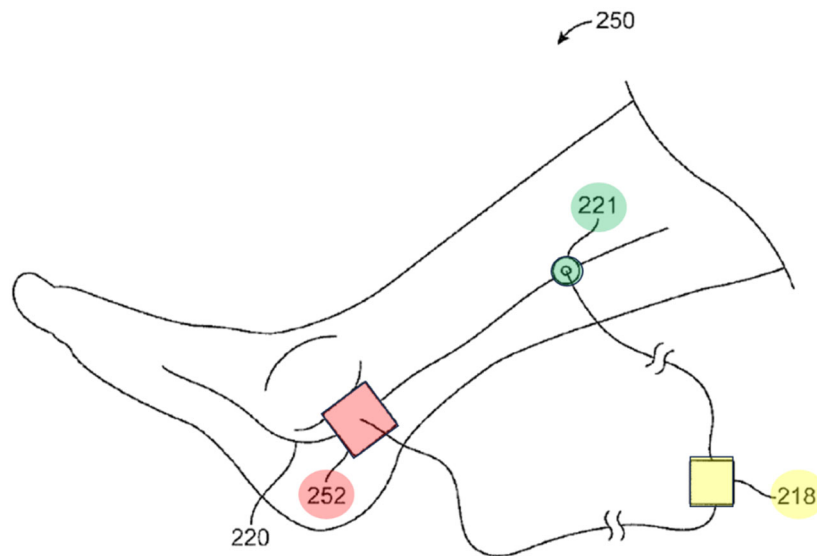


FIG. 26

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].

141. While the above figures illustrate stimulation of the “posterior tibial nerve,” Burnett discloses that the stimulation devices may 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.”).

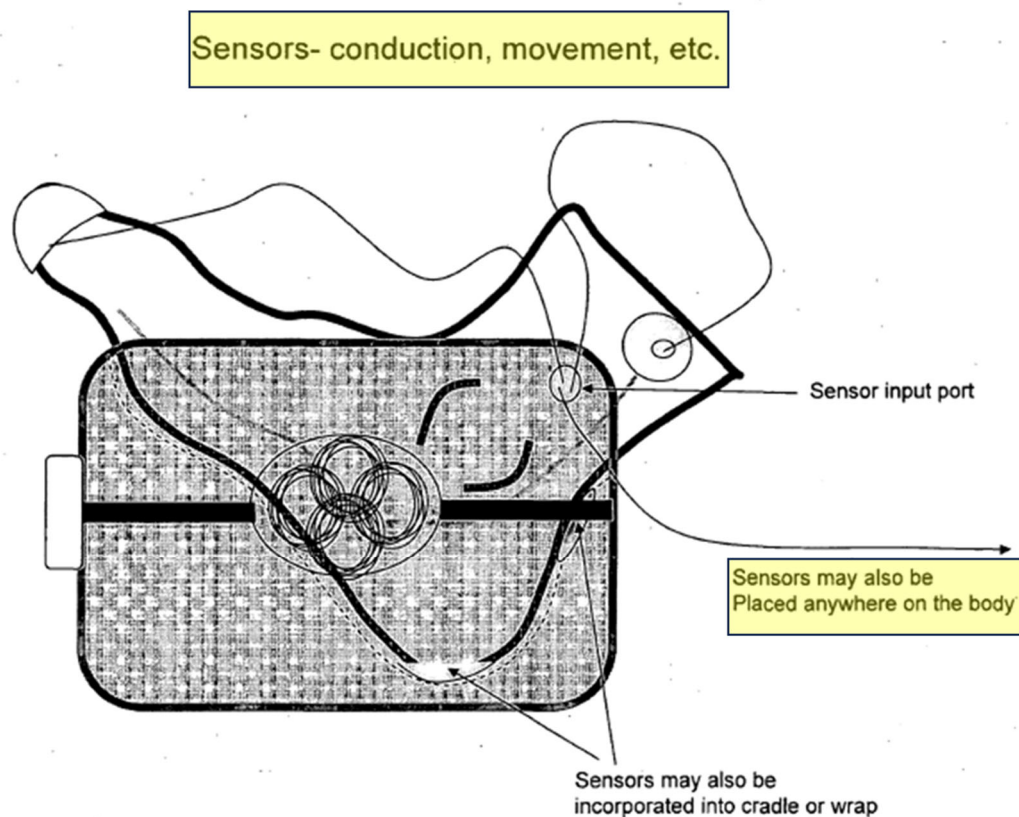
g. **Limitation [E2]: “such that the sensor detects a motion of the subject and provides a feedback signal to the electrical pulse generator”**

142. Burnett discloses this limitation. 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.*, [0145] (“Microneedle patch 228 detects corresponding muscle stimulation or ***twitching***”) (emphasis added); [0173] (“Optionally, a sensor may be positioned over a corresponding muscle to detect muscle stimulation or ***twitching*** resulting from nerve stimulation.”) (emphasis added); [0179] (same), [0184] (same). In the case of at least twitching, the sensor detects motion of the subject via the sensor.

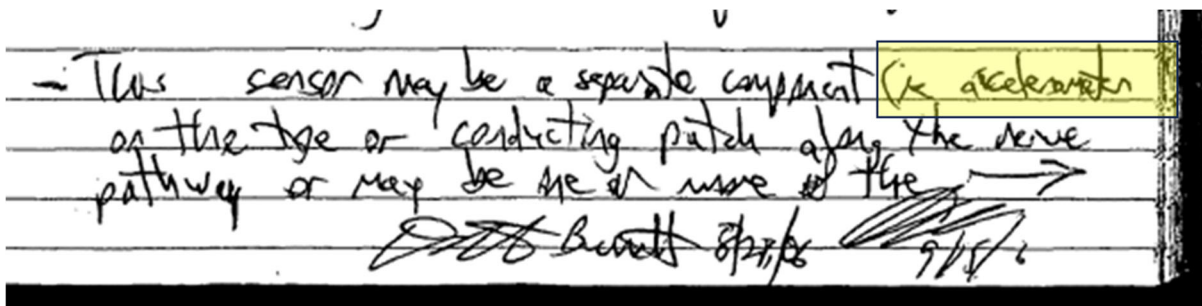
143. Burnett discloses that the sensor can take a variety of forms, including a microneedle patch or “a sensor type known in the art.” Ex. 1010 at [0128], [0147]. One sensor type known in the art was an accelerometer, which detects motion. For example, Gesotti and Gesotti ’896 disclose accelerometers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

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

144. 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 twitching. Ex. 1015 at [0055]. Like Burnett, the '720 provisional recognizes 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*).”



Id. at 35.

145. Additionally, Burnett discloses, “The one or more energy generators produce energy focused on the target nerve upon receiving a signal from the logic controller, and the applied energy is *varied by the logic controller according to an input provided by the one or more sensors* based on electrical conduction in the target nerve.” Ex. 1010 at [0032]. In this embodiment, the energy generators are the pulse generators. Thus, Burnett discloses “the sensor detects a motion of the subject and provides a feedback signal to the electrical pulse generator.”

h. Limitation [E3]: “so as to mitigate the tremor by adjusting or optimizing the electrical stimulation.”

146. Burnett discloses this limitation. Burnett includes the same list of over 100 ailments found in the ’300 patent, including “tremor.” Ex. 1010 at [0111]. If the single mention of tremor in the ’300 patent is sufficient to disclose mitigating tremors, then so is the mention of tremor in Burnett.

147. 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 “adjusts or optimiz[es] the electrical stimulation.” Ex. 1010 at [0156].

2. Claim 2

148. Claim 2 depends from claim 1 and recites: “wherein the electrode is located along the applicator in proximity to the target nerve which extends through a hand of the subject.” Burnett discloses this claim.

149. Burnett discloses positioning “a transcutaneous stimulator, such as an electrode 126 [red],” over a skin surface overlying a target nerve (e.g., the tibial nerve in Figure 11 below):

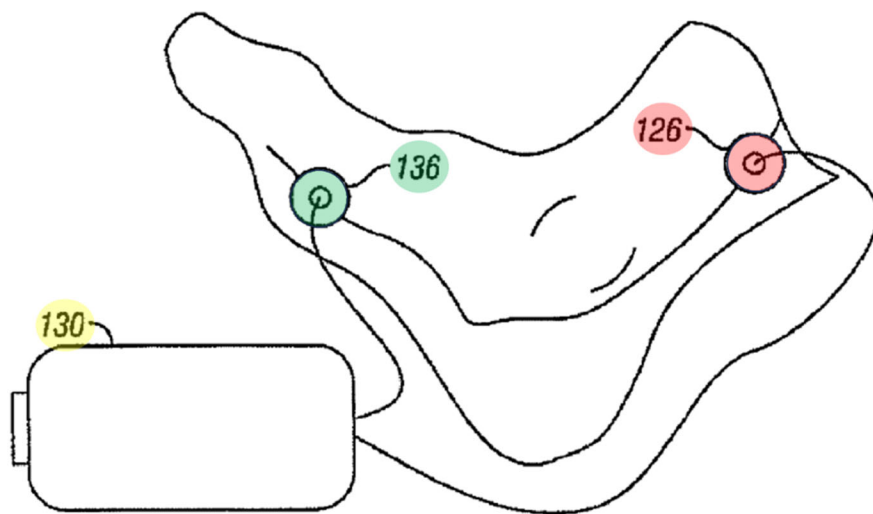


FIG. 11

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

150. 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] (“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].

151. While many of the preferred embodiments focus on the electrical stimulation of nerves in the feet or legs, 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.” Ex. 1010, [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].

152. Burnett discloses various body regions that may be stimulated using the disclosed devices, including 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] (“The transcutaneous electrical stimulation sensor may be placed in the body independently or be incorporated within the wrap....”).

153. The '300 patent acknowledges that the peripheral nerves in the arm extend 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:

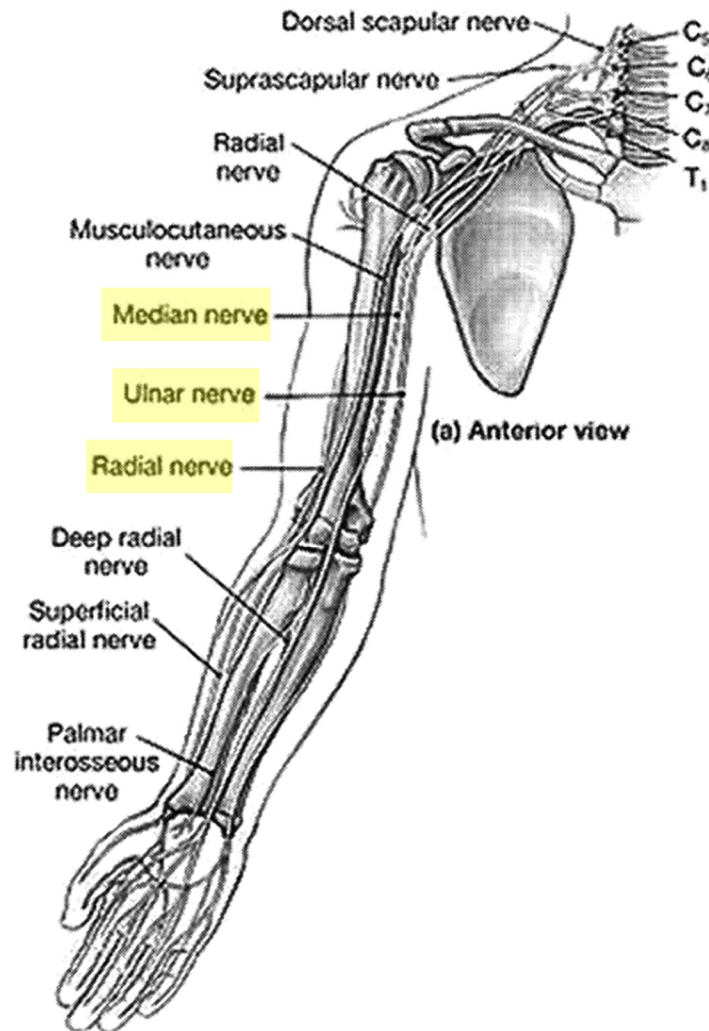


FIG. 56A

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) which extends through a hand of the subject. Thus, Burnett discloses this limitation.

3. Claim 3

154. Claim 3 depends from claim 1 and recites: “wherein the applicator comprises a strap or band.” Burnett discloses this claim. Burnett discloses incorporating the stimulation devices 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....”).

4. Claim 4

155. Claim 4 depends from claim 3 and recites: “wherein the electrode is attached to the strap or band so as to contact the skin surface of the subject.” Burnett renders this claim obvious for the reasons I provided in connection with Claim 1. *Supra* §VI.B.1.c.

5. Claim 5

156. Claim 5 depends from claim 1 and recites: “comprising an additional electrode separate from the electrode.” Burnett discloses this limitation. 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] (emphasis added); *see also id.* at [0142], Figs. 20a-2, claim 5 (describing separate positive, negative, and ground electrodes); [0144] (“Microneedle patch 228 may be composed of...one or more electrodes.”), [0154] (same).

6. Claim 6

157. Claim 6 depends from Claim 1 and recites: “wherein a parameter of the electrical stimulation comprises a frequency which is adjustable.” Burnett discloses this limitation.

158. Burnett discloses that “[a]n apparatus according to the present invention may deliver any frequency of stimulation.” Ex. 1010 at [0110]. Additionally, Burnett disclose that “[i]n certain embodiments, the amplitude, *frequency*, direction of a generated magnetic field, electrical or magnetic stimulus, or firing sequence of the coils or microneedles making up the microneedle array *may be adjusted.*” *Id.* at [0170] (emphasis added), [0175], [0181], [0186]; *see also id.* at [0188] (“Controls may also be included to affect the following:...frequency...other parameters one of skill in the art would find necessary or useful to control or monitor.”).

7. Independent Claim 7

159. Claim 1 is rendered obvious by Burnett.

a. **Preamble**

160. Claim 1 includes the same preamble. If the preamble is limiting, Burnett discloses the preamble for the reasons I provided in connection with Claim 1. *Supra* §VI.B.1.a.

b. **Limitation [A]: “an applicator configured for application to a region of the subject”**

161. Claim 1 includes this limitation. Burnett discloses this limitation for the reasons I provided in connection with Claim 1. *Supra* §VI.B.1.b.

c. **Limitation [B]: “an electrode located along the applicator so as to contact a skin surface of the subject when the applicator is worn by the subject”**

162. Claim 1 includes this limitation. Burnett renders this limitation obvious for the reasons I provided in connection with Claim 1. *Supra* §VI.B.1.c.

d. **Limitation [C]: “a controller in communication with the electrode”**

163. Burnett discloses this limitation. Burnett discloses “an energy emitting apparatus for delivering medical therapy that includes one or more energy generators [and] a logic controller electrically connected to the one or more energy generators....” Ex. 1010 at [0032]. “The one or more energy generators produce energy focused on the target nerve upon receiving a signal from the logic controller....”

164. Similarly, Figure 26 illustrates an energy emitting system 250 having a microneedle patch 252 and sensor 221. *Id.* 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].

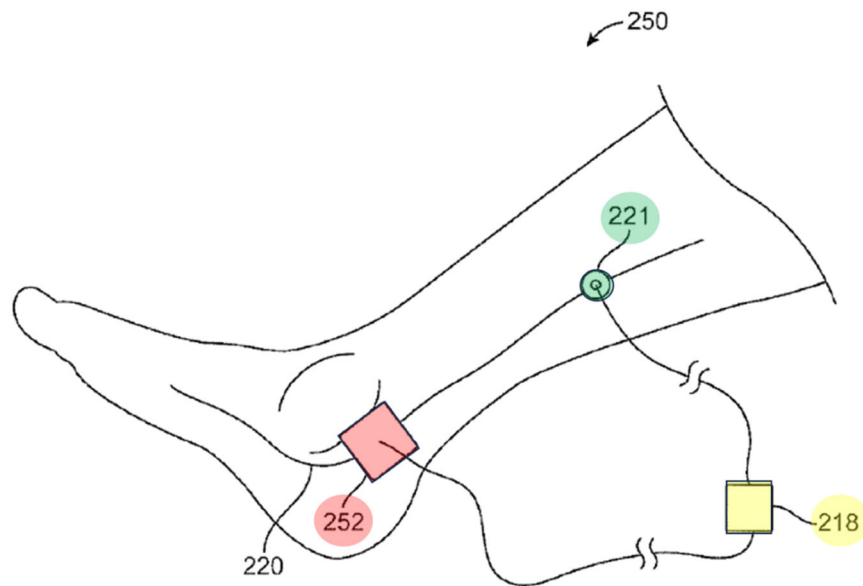


FIG. 26

Id. at Fig. 26. Thus, Burnett discloses “a controller in communication with the electrode.”

e. **Limitation [D1]: “a sensor positionable on the subject and in communication with the controller,”**

165. Burnett discloses this limitation. 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].

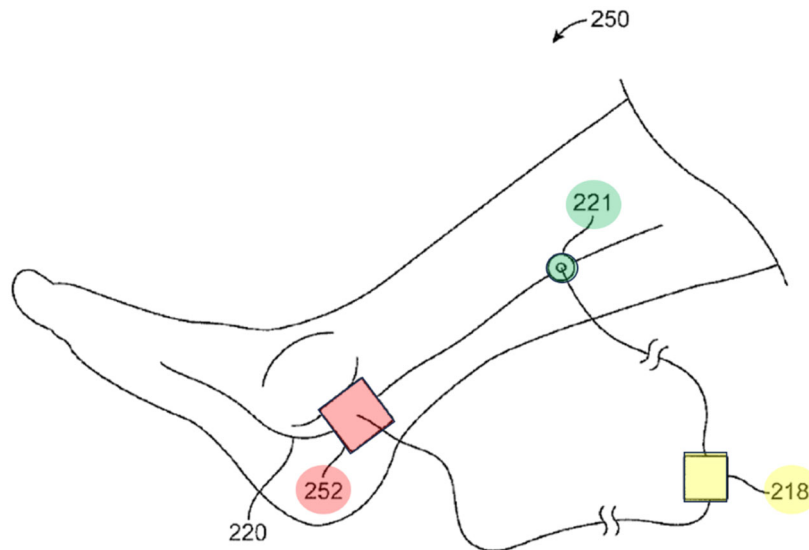


FIG. 26

Id. at Fig. 26. “Sensor 221 detects electrical conduction through the stimulated posterior tibial nerve 220, and then *transmits the signal to controller 218.*” *Id.* at [0156] (emphasis added). Thus, Burnett discloses “a sensor positionable on the subject and in communication with the controller.”

- f. **Limitation [D2]: “the controller transmits via the electrode an electrical stimulation having an adjustable frequency through the skin surface and into a target nerve underlying the skin surface”**

166. Burnett discloses this limitation. 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] (emphasis added).

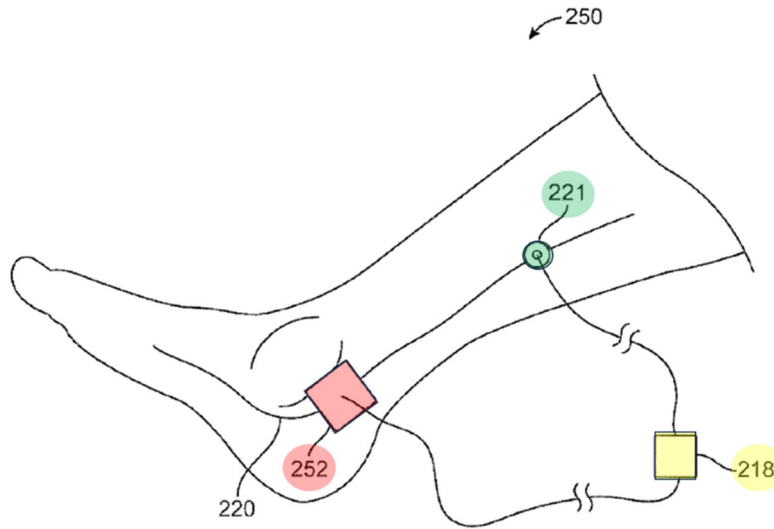


FIG. 26

Id. at Fig. 26. Additionally, the “controller can then be varied or adjusted based on the signal from the 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.” *Id.* at [0156]. As I explained in connection with Claim 6, Burnett discloses that one of the adjustments includes changing the frequency. *Supra* §VI.B.6.

- g. **Limitation [E]: “wherein the sensor detects a motion of the subject and provides a feedback signal to the controller so as to mitigate the tremor by adjusting or optimizing the electrical stimulation.”**

167. Burnett discloses this limitation. As I explained in connection with Claim 1, Burnett discloses sensors that detect motion of the subject. *Supra* §VI.B.1.g. Likewise, as I explained above, the sensor provides a feedback signal to the controller. *Supra* §VI.B.7.e. Further, the signal provided to the controller is

used to mitigate tremor by adjusting or optimizing the electrical stimulation. *Supra* §VI.B.1.h.

8. Claim 8

168. Claim 8 depends from claim 7 and recites: “wherein the electrode is located along the applicator in proximity to the target nerve which extends through a hand of the subject.” Burnett discloses this claim for the reasons I provided in connection with Claim 2. *Supra* §VI.B.2.

9. Claim 9

169. Claim 9 depends from claim 7 and recites: “wherein the applicator comprises a strap or band.” Burnett discloses this claim for the reasons I provided in connection with Claim 3. *Supra* §VI.B.3.

10. Claim 10

170. Claim 10 depends on claim 9 and recites: “wherein the electrode is attached to the strap or band so as to contact the skin surface of the subject.” Burnett renders this claim obvious for the reasons I provided in connection with Claim 4. *Supra* §VI.B.4.

11. Claim 11

171. Claim 11 depends from claim 7 and recites: “an additional electrode separate from the electrode.” Burnett discloses this claim for the reasons I provided in connection with Claim 5. *Supra* §VI.B.5.

12. Independent Claim 12

172. Claim 12 rendered obvious by Burnett.

a. Preamble: “A method for treating tremors in a subject.”

173. If the preamble is limiting, Burnett discloses this limitation. Burnett describes electrical and magnetic stimulation devices to treat OAB and UI. Ex. 1010 at [0002, 0036, 0038, 0070]. However, Burnett includes the same list of over 100 ailments found in the '300 patent, including “tremor.” *Id.* at [0111]. Thus, if the '300 patent discloses an “apparatus for treating tremors,” then so does Burnett.

b. Limitation [A1]: “transmitting an electrical stimulation from an electrical pulse generator through an electrode located along an applicator and contacted against a skin surface of a hand or arm of the subject such that the electrical stimulation targets a nerve underlying the skin surface”

174. Burnett discloses this limitation. Burnett 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]. An electric pulse controller is a pulse generator.

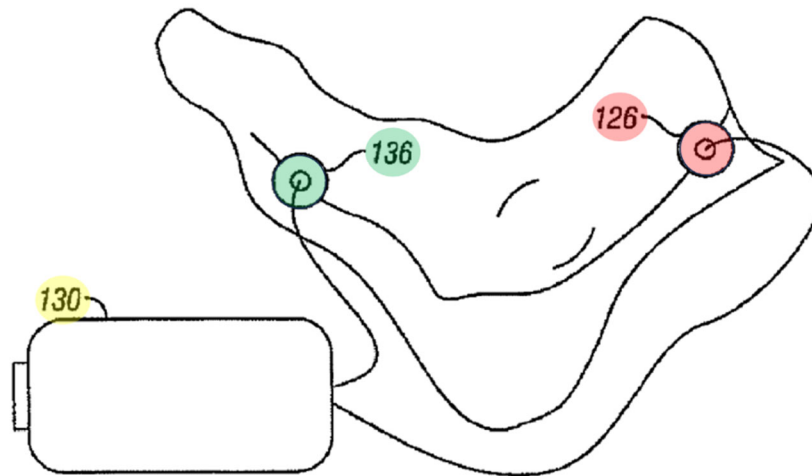


FIG. 11

Id. at Fig. 11.

175. Similarly, Burnett describes additional embodiments, like the embodiment in Figure 11, having “one or more energy generators, a logic controller electrically connected to one or more energy generators, and one or more sensors for detecting electrical conduction in a target nerve, which are connected to the logic controller.” *Id.* at [0032]. “The one or more energy generators produce energy focused on the target nerve upon receiving a signal from the logic controller, and the applied energy is varied by the logic controller according to an input provided by the one or more sensors based on electrical conduction in the target nerve.” *Id.* In these embodiments, the energy generators are the pulse generators.

176. Additionally, 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].

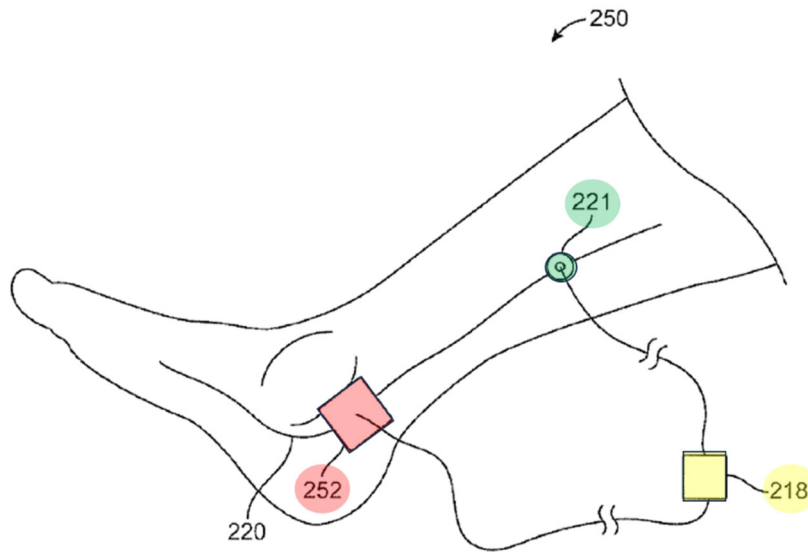


FIG. 26

Id. at Fig. 26. The controller 218 is the pulse generator in this embodiment.

177. Additionally, Burnett renders obvious an electrode located along an applicator and contacted against a skin surface of a hand or arm of the subject for the reasons I provided in connection with Claim 1. *Supra* §VI.B.1.b-c.

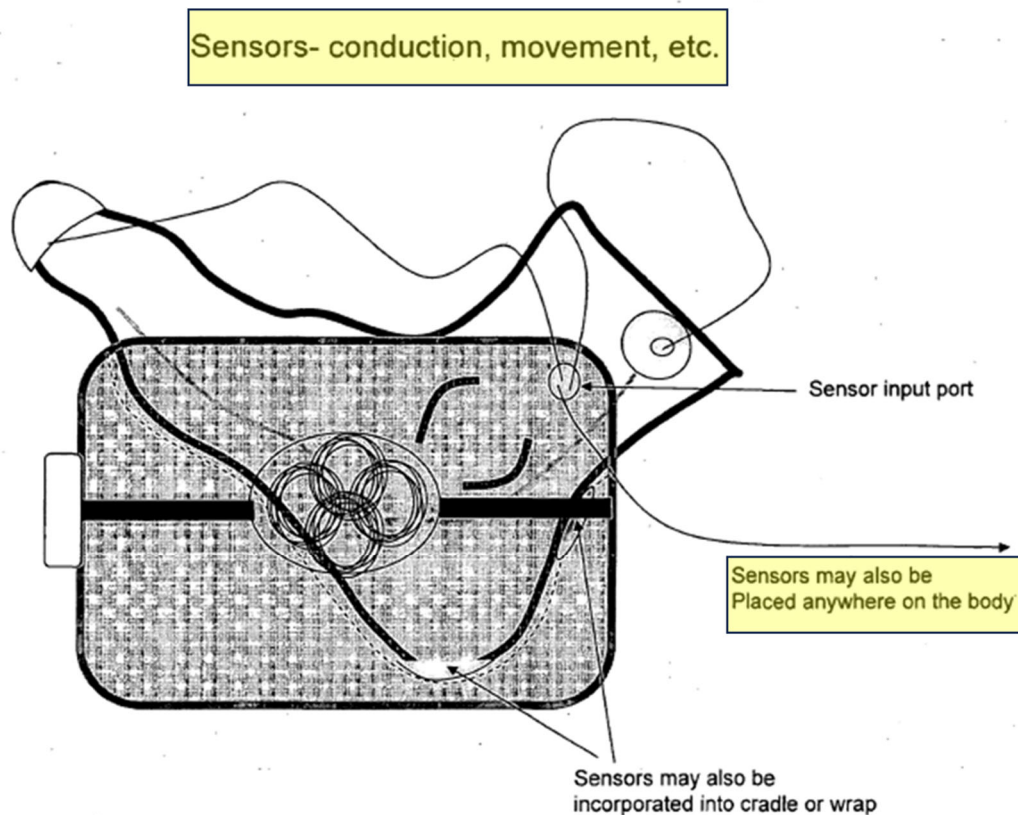
c. **Limitation [B]: “monitoring for a motion of the subject via a sensor positionable on the subject and in communication with the electrical pulse generator”**

178. Burnett discloses this limitation. Burnett discloses that the described 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*”) (emphasis added); [0173] (“a sensor may be positioned over a corresponding muscle to detect muscle stimulation or *twitching* resulting from nerve stimulation”) (emphasis added); [0179] (same), [0184] (same). In the case of at least twitching, the sensor operates by detecting motion of the subject via the sensor.

179. 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 sensor type known in the art was an accelerometer, which detects motion. For example, Gesotti and Gesotti ’896 disclose accelerometers to detect patient motion. *See e.g.*, Ex. 1008 at Fig. 1 (identifying “accelerometer”); Ex. 1009 at Fig. 1 (identifying “motion sensors”).

180. 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 twitching. Ex. 1015 at [55]. Like Burnett, the ’720 provisional recognizes that sensors “may also be placed anywhere on the body” to measure physiologic changes in the patient:



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

— This sensor may be a separate component (i.e. accelerometer) on the type of conducting patch along the nerve pathway or may be one or more of the →
Burnett 8/2/16 9/15/16

Id. at 35.

181. Additionally, Burnett discloses that “The one or more energy generators produce energy focused on the target nerve upon receiving a signal from the logic controller, and the applied energy is *varied by the logic controller*

according to an input provided by the one or more sensors based on electrical conduction in the target nerve.” Ex. 1010 at [0032]. In this embodiment, the energy generators are the pulse generators.

182. Moreover, the sensors are “positionable on the subject” and “in communication with” the electrical pulse generator for the reasons I provided in connection with Claim 1. *Supra* §VI.B.1.e.

d. Limitation [C]: “receiving a feedback signal via the sensor”

183. Burnett discloses this limitation. Burnett discloses “the one or more energy generators produce energy focused on the target nerve upon receiving a signal from the logic controller, and the applied energy is varied by the logic controller *according to an input provided by the one or more sensors* based on electrical conduction in the target nerve.” Ex. 1010 at [0032].

184. 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].

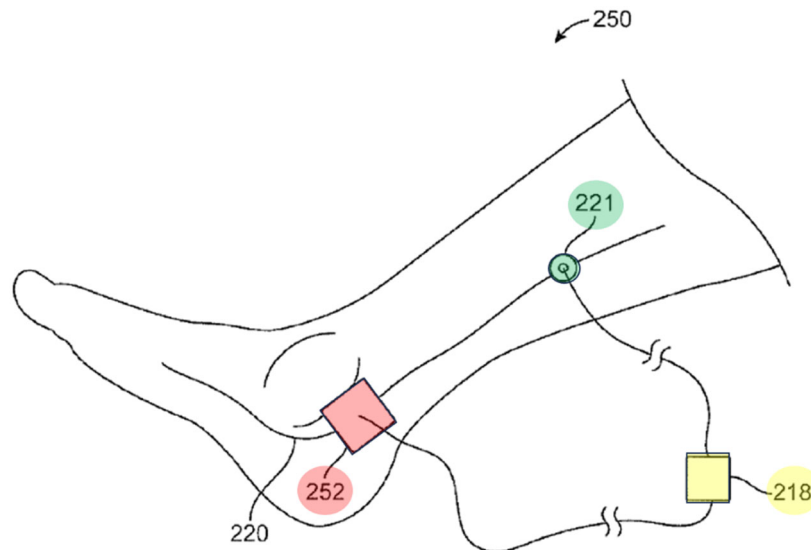


FIG. 26

Id. at Fig. 26. “Sensor 221 detects electrical conduction through the stimulated posterior tibial nerve 220, and then *transmits the signal to controller 218.*” *Id.* at [0156] (emphasis added). Thus, Burnett discloses “receiving a feedback signal via the sensor.”

- e. **Limitation [D]: “adjusting or optimizing the electrical stimulation from the electrical pulse stimulation in response to the feedback signal until the tremors are mitigated.”**

185. Burnett discloses this limitation. As I explained in connection with Claim 1, Burnett discloses sensors that detect motion of the subject. *Supra* §VI.B.1.g. Likewise, as I explained above, the sensor provides a feedback signal to the electrical pulse generator. *Supra* §VI.B.7.e. Moreover, the signal provided to the electrical pulse generator is used to mitigate tremor (to the extent disclosed) by adjusting or optimizing the electrical stimulation. *Supra* §VI.B.1.h.

13. Claim 13

186. Claim 13 depends from claim 12 and recites: “wherein the electrode is located along the applicator in proximity to the target nerve which extends through a hand of the subject.” Burnett discloses this claim for the reasons I provided in connection with Claim 2. *Supra* §VI.B.2.

14. Claim 14

187. Claim 14 depends from claim 12 and recites: “wherein transmitting the electrical stimulation comprises transmitting through the electrode located along an applicator comprising a strap or band.” Burnett discloses this claim for the reasons I provided in connection with Claim 3. *Supra* §VI.B.3.

15. Claim 15

188. Claim 15 depends from claim 14 and recites: “wherein the electrode is attached to the strap or band so as to contact the skin surface of the subject.” Burnett renders this claim obvious for the reasons I provided in connection with Claim 4. *Supra* §VI.B.4.

16. Claim 16

189. Claim 16 depends from claim 12 and recites: “transmitting the electrical stimulation via an additional electrode separate from the electrode.” Burnett discloses this claim for the reasons I provided in connection with Claim 5. *Supra* §VI.B.5.

17. Claim 17

190. Claim 17 depends from claim 12 and further recites: “adjusting a frequency of the electrical stimulation in response to the feedback signal.” Burnett discloses this claim.

191. 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].

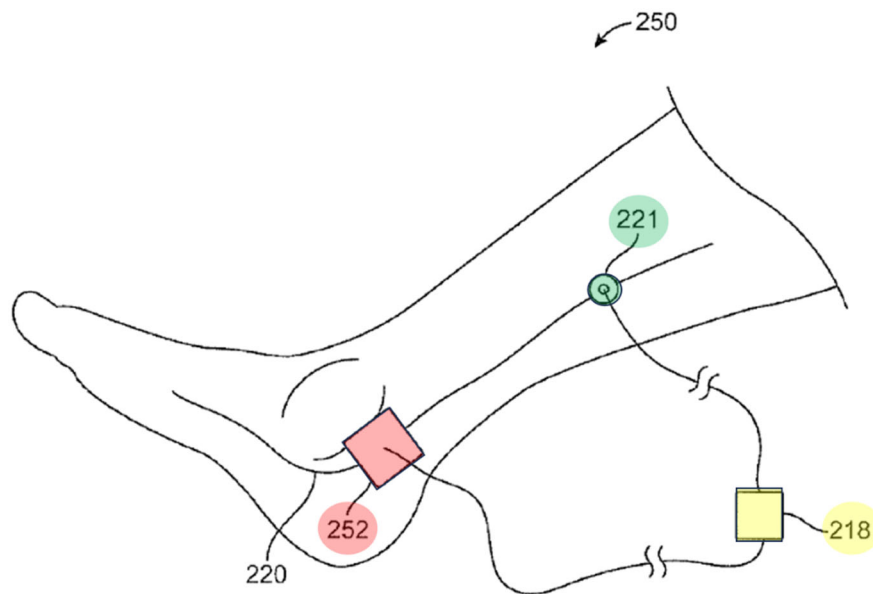


FIG. 26

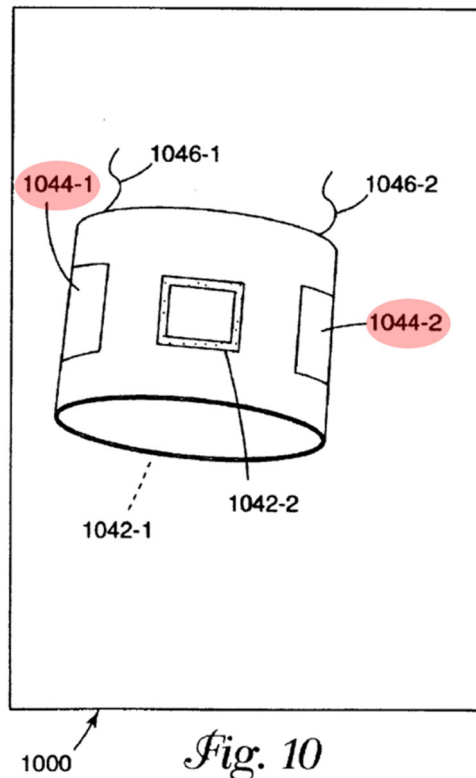
Id. at Fig. 26. Additionally, the “controller can then be varied or adjusted based on the signal from the sensor 221 to ensure that adequate conduction of the posterior tibial nerve 220 occurs and an adequate and accurate dosage of treatment is being

received.” *Id.* at [0156]. As I explained in connection with Claim 6, Burnett discloses that one of the adjustments includes changing the frequency. *Supra* §VI.B.6.

C. Ground 4: Claims 1-17 Are Rendered Obvious By Burnett And Gesotti

192. As I explained in connection with Claim 1, a person of ordinary skill in the art would have found it obvious to include electrodes in the ergonomic applicators, such as the bands, based on Burnett alone. *Supra* §VI.B.1.c. A person of ordinary skill in the art would have also found it obvious to include the electrodes in Burnett’s ergonomic applicators based on Gesotti.

193. Gesotti discloses “a stimulation and sensing wristband, shown generally at 1000, constructed according to the teachings of the present invention.” *Id.* at 9:29-32. “Wristband 1000 includes first and second stimulation electrodes 1044-1 [red] and 1044-2 [red] located on the left and right sides of the wrist.” *Id.* at 9:32-34.



The wristband in Gesotti is like the ergonomic bands for use on a patient's arm described in Burnett. Ex. 1010 at [0107], Fig. 9C. Gesotti would have motivated a person of ordinary skill in the art implementing Burnett's devices to place the electrodes within the band, and led to a reasonable expectation of success, because Gesotti discloses such bands are effective for treating tremor.

194. Alternatively, a person of ordinary skill in the art would have been motivated to use the wristband in Gesotti with Burnett's stimulation systems. Gesotti's wristband includes electrical leads that can couple the device to a controller or pulse generator, as taught in Burnett. Thus, no significant modifications would be necessary to adapt the wristband for use with Burnett's stimulation systems.

VII. CONCLUSION

195. For at least the foregoing reasons, it is my opinion that claims 1-17 of the '300 patent are anticipated or rendered obvious by the cited prior art.

196. 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.

197. 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