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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CALA HEALTH, INC.,

Petitioner,

v.

EMKINETICS INC.,

Patent Owner.

IPR2024-00743

U.S. Patent 11,628,300

**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	CV 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”)

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Exhibit No.	Description
1016	U.S. Patent Publication No. 2008/0306325 (“the ’325 publication”)
1017	U.S. Patent Publication No. 2004/0102819A1 to Zou et. al. (“Zou”)
1018-1020	RESERVED
1021	U.S. Patent No. 10,786,669 to Rajguru et al. (“the ’669 patent”)

Cala Health, Inc. (“Petitioner”) requests *inter partes* review (“IPR”) of claims 1-17 of U.S. Patent No. 11,628,300 (“the ’300 Patent,” Ex. 1001), purportedly owned by EMKinetics Inc. (“Patent Owner” or “PO”).

I. SUMMARY OF THE ARGUMENT

Petitioner Cala Health challenges claims 1-17 of the ’300 patent, which claim apparatuses and methods for “treating tremor” through electrical stimulation of nerves underlying the patient’s skin. Claims 1, 7, and 12 are independent claims. Claims 2-6, 8-11, and 13-17 depend, directly or indirectly, from the independent claims.

The ’300 patent focuses on methods and apparatuses for treating overactive bladder (“OAB”) and urinary incontinence (“UI”). (*See e.g.*, Ex. 1001, 2:11-3:16 (“Background of the Invention” discusses only OAB/UI).) However, the claims diverge from this central focus of the specification and instead relate to apparatuses and methods for treating tremor. The focus of the claims on tremor is surprising because the ’300 patent mentions tremor ***only once*** amidst a list of over 100 medical ailments allegedly treated by the described device, including disparate ailments such as “skin ulcers,” “pancreatitis,” and “shingles.” (Ex. 1001, 17:51-18:27.)

Although the ’300 patent does not describe apparatuses and methods for treating tremor, the prior art extensively discloses them. As PO concedes, “[t]he use of pulsed electromagnetic stimulation (PES) ha[d] been well established as a

beneficial therapy in a variety of medical applications.” (Ex. 1001, 2:20-22.) For example, in the early 1990s, researchers published several articles describing studies using electrical stimulation to reduce tremor. (Exs. 1005-1006.) One of the researchers, Dr. Prochazka, received a patent for an electrical stimulation glove that uses electrodes and motion sensors to mitigate tremor caused by Parkinson’s disease:

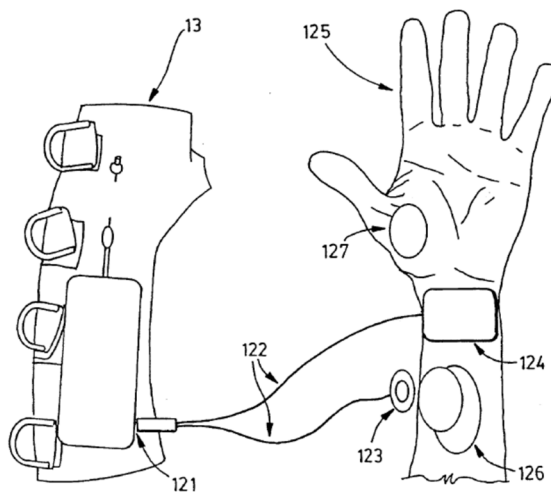


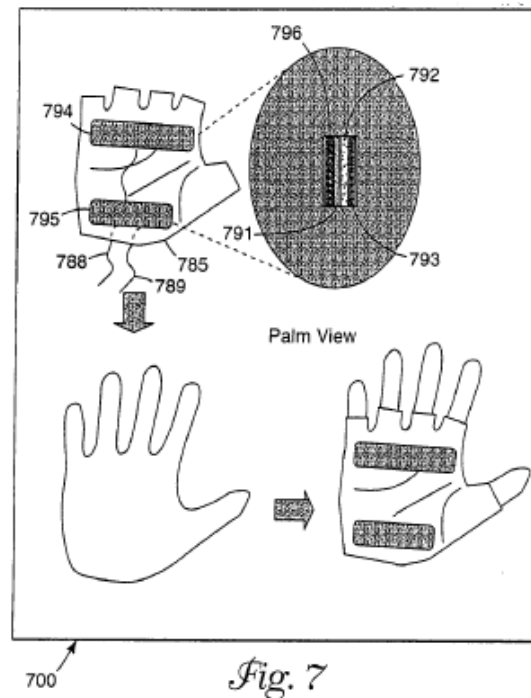
FIG. 12

(Ex. 1007 (“the ’707 patent”), Fig. 12). The glove positions electrodes (e.g., 127) at motor points on the wrist and hand to provide electrical stimulation to the underlying muscle/tissue. (*Id.*, 8:49-9:30). The glove also receives feedback from sensors positioned on the glove and uses the feedback to initiate stimulation for mitigating tremor. (*Id.*; *see also id.*, 9:20-21.)

The ’707 patent was of record during prosecution of the ’300 patent, but the Examiner did not apply the reference. In fact, the Examiner did not make any prior-

art based rejections during prosecution. The Examiner made a lone obviousness-type double patenting rejection based on the related U.S. Patent 10,786,669 (“the ’669 patent,” Ex. 1021). Petitioner has separately filed for IPR of the ’669 patent. The Examiner’s decision to allow the ’300 patent was erroneous because the prior art disclosed or rendered obvious all of the limitations of the ’300 patent claims.

For example, Petitioner relies on Gesotti (U.S. Patent No. 6,704,603), which was not of record during prosecution of the ’300 patent, and which discloses methods/apparatuses for electrically stimulating nerves underlying the hand or arm to treat tremor. (Ex. 1008.) Gesotti claims a “method of cu[r]ing an individual exhibiting one or more symptom’s [sic] of Parkinson’s disease” “wherein the one or more symptoms of Parkinson’s disease comprise *tremor*, rigidity, akinesia, bradykinesia and drooping head.” (Ex. 1008, claims 1-2 (emphasis added).) Gesotti also describes treating tremor using stimulation gloves having stimulation electrodes “in direct contact with the palm of the hand,” as illustrated in Figure 7 below:



(*Id.*, 8:20-26, Figs. 7-10.)

Petitioner also relies on Burnett to demonstrate unpatentability of the '300 patent. (Ex. 1010, U.S. Pat. Pub. 2010/0168501, "Burnett".) The '300 patent claims priority to Burnett. (*See infra* §III.C (describing priority claim).) However, PO's priority claim to Burnett is defective because there was no co-pendency between the '300 patent's predecessor, the '669 patent, and Burnett. Moreover, Burnett published over one year before the earliest possible priority date for the '300 patent and, therefore, qualifies as prior art.

Burnett contains much of the same disclosure as the '300 patent. Like the '300 patent, Burnett discloses methods of electrically stimulating nerves underlying the arm/hand using electrodes placed on skin surfaces. (Ex. 1010, [0102].) Burnett also discloses the same list of over 100 medical ailments found in the '300 patent,

including tremor. (*Id.*, [0111].) Thus, if the '300 patent adequately discloses methods/apparatuses of treating tremor, so does Burnett.

The references relied upon herein, Gesotti and Burnett, anticipate claims 1-17 of the '300 patent or render them obvious. As a result, the Board should institute this IPR and cancel challenged claims 1-17.

II. THE PARTIES

Petitioner is a bioelectronics medical company that has developed neuromodulation therapies that have transformed the standard of care for chronic disease. Petitioner's Cala Trio® and Cala kIQ™ products are currently the only non-invasive, drug free treatments that address the root cause of essential tremor with electrical stimulation. The Cala Trio has received significant praise in the industry, including being named a GOLD WINNER of the 2020 Edison Awards in the Diagnostic & Disease Treatment category. Petitioner is currently developing additional neuromodulation therapies for a host of chronic diseases in the fields of neurology, cardiology, urology, and psychiatry.

In contrast, PO does not appear to commercially practice the '300 Patent.

III. THE '300 PATENT

A. Overview

The '300 patent primarily focuses on treating OAB and UI by “providing magnetic induction therapy” to nerves in the feet and legs. (Ex. 1001, 8:26-27). A

smaller segment of the patent, however, describes methods of treating nerves (mostly in the feet/legs) by providing “electrical energy” to a target nerve. (*Id.*, 8:47-51)

In one embodiment, for example, the '300 patent describes “electrodes designed for the palmar surface of the hands along with F/M wave detecting electrodes 6105.” (*Id.*, 62:16-17.) As shown below, the “contact electrode(s) 6101 [red] are placed across the upper palm portion of the hand and second electrode 6102 [red] is place across [sic] towards, near or on the heel of the hand.” (*Id.*, 62:18-20.) The '300 patent states that the “electrical stimulation of the hand will stimulate the Median or the Ulnar nerve or both.” (*Id.*, 62:24-26.)

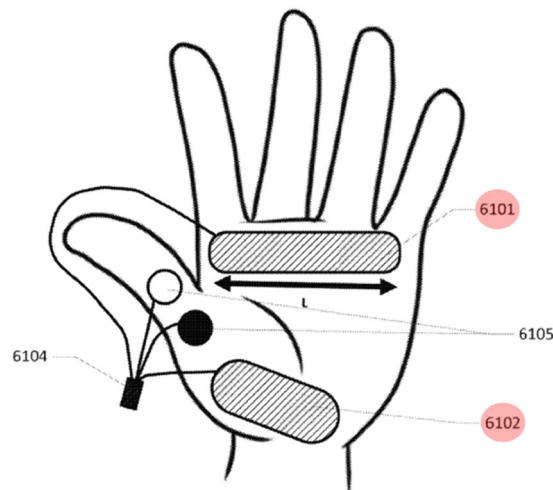


FIG. 61A

(*Id.*, Fig. 61A.) The '300 patent alleges that the electrical stimulation of the Ulnar or Medial nerves may “treat various neurological conditions, including neuropathies, migraine, pain, headaches, depression, epilepsy, post-traumatic stress disorder,

overactive bladder, incontinence, subcutaneous fat, effects of stroke, memory enhancement, etc.” (*Id.*, 59:15-24; *see also id.*, 59:36-47 (treating “migraine”).)

Notably, the list of conditions does not include tremor.

In fact, despite requiring the treatment of tremor in every claim, the ’300 patent specification mentions tremor only *once* near the bottom of a generic list of over 100 ailments that the described device allegedly treats. (*Id.*, 17:46-18:22.) The ’300 patent never explains how the disclosed device treats most of the listed medical conditions, including tremor.

B. The Prosecution History

PO filed the application that became the ’300 patent on June 11, 2021. The Examiner rejected the claims for obviousness-type double patenting based on the ’669 patent. (Ex. 1004, 72-76.) PO submitted a terminal disclaimer, and the Examiner allowed the claims without further examination. (*Id.*, 6-7, 64-65.)

C. Applicable Priority Date

The ’300 patent’s priority claim is convoluted and includes three branches. Due to several defects in the priority claim, PO is not entitled to the earliest claimed priority date of October 2, 2006. Instead, the earliest possible priority date for the ’300 Patent is **September 20, 2011**.

The ’300 patent claims priority as a continuation from Application No. 16/732,706 (“the ’706 Application”), filed on January 2, 2020. (Ex. 1001, 1:8-30.)

The '706 Application is a continuation of Application No. 15/474,875 (“the '875 Application”), filed on March 30, 2017. (*Id.*) The '875 Application became the '669 patent. The '669 patent claims priority through two different sets of continuation and continuation-in-part applications and separately to one provisional application. (Ex. 1001, 1:8-30; Ex. 1021, 1:7-25.) The one provisional application (62/350,610) was not filed until 2016 and is largely irrelevant to the present analysis. Defects exist in the other two priority branches.

First, the '669 patent claims priority as a continuation-in-part from Application No. 15/084,356 (“the '356 Application”) filed on March 29, 2016. (*Id.*) The '356 Application is allegedly a continuation of Application No. 13/840,936 (“the '936 Application”) filed on March 15, 2013. (*Id.*) The '936 Application is allegedly a continuation-in-part of PCT Application No. PCT/US2011/052415 (“the '415 PCT Application, Ex. 1011) filed on September 20, 2011. (*Id.*) Finally, the '415 PCT Application allegedly claims the benefit of Provisional Application 61/403,680 (“the '680 Provisional,” Ex. 1012) filed on September 20, 2010. (*Id.*)

However, the '669 and '300 patents are not entitled to the September 20, 2010 filing date of the '680 Provisional because that provisional application does not disclose treating or mitigating tremor, an element of all issued claims of the '669 and '300 patents. (*See e.g.*, Ex. 1012, [0017] (list of uses does not include tremor).) The first application to mention tremor is the '415 PCT Application filed on September

20, 2011. (Ex. 1011, [0119].) Thus, at best, the '300 patent is entitled to a priority date of September 20, 2011 based on this first branch.

Second, the '669 patent separately claims priority as a continuation-in-part to U.S. Application No. 12/508,529 (“the '529 Application”), and then to additional prior applications. (Ex. 1001, 1:20-26.) The '529 Application published as Burnett on July 1, 2010. (Ex. 1010.) However, PO abandoned Burnett by February 10, 2016. (Ex. 1014 (Prosecution History of '529 Application).) Because PO did not file the application that eventually led to the '669 patent (the '875 Application) until March 30, 2017, there was no co-pendency between the '875 Application and Burnett. *See* 35 U.S.C. §120. Thus, PO’s priority claim to Burnett is ineffective. Additionally, because Burnett published more than one year before the earliest possible priority date for the '300 patent (September 20, 2011), Burnett constitutes prior art under pre-AIA 35 U.S.C. §102(b).

D. Level of Ordinary Skill in the Art

A person of ordinary skill in the art (“POSITA”) at the time of the claimed invention would have had an undergraduate degree in the field of biomedical engineering or a related discipline and at least two years of experience in the design and/or analysis of biomedical devices. Additional work experience could serve as a substitute for a formal degree and vice versa. (Ex. 1002, ¶23.)

IV. CLAIM CONSTRUCTION

A claim subject to *inter partes* review “shall be construed using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. §282(b), including construing the claim in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent.” 37 C.F.R. §42.100(b); *see Phillips v. AWH Corp.*, 415 F.3d 1303, 1309 (Fed. Cir. 2005).

Petitioner does not believe any terms require construction to resolve the patentability issues herein. *See Consolidated Patent Trial Practice Guide* at 44 (November 2019); *see also Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (“we need only construe terms ‘that are in controversy, and only to the extent necessary to resolve the controversy’”) (internal citations omitted). However, if PO construes any terms in response, Petitioner intends to request authorization to address them. Additionally, for this proceeding only, Petitioner assumes the claims are not invalid under 35 U.S.C. §112 but reserves the right to contest validity in other proceedings.

V. STATEMENT OF PRECISE RELIEF REQUESTED

A. IPR Grounds

Petitioner requests cancellation of claims 1-17 based on the following grounds of unpatentability:

Ground	Claims Challenged	Pre-AIA 35 U.S.C.§	References
1	1-17	102	Gesotti
2	1-17	103	Gesotti
3	1-17	103	Burnett
4	1-17	103	Burnett and Gesotti

B. The Asserted References Are Prior Art

The earliest possible priority date for the '300 patent is September 20, 2011. (*See supra* §III.C.) The relied-upon references are prior art under pre-AIA 35 U.S.C. §102(b) because they each published more than one year before September 20, 2011. Additionally, Gesotti published more than one year before the '300 patent's *earliest* claimed priority date of October 2, 2006, and, therefore, qualifies as prior art under pre-AIA 35 U.S.C. §102(b) regardless of the priority date.

C. The Asserted References are Analogous Art

The asserted references are analogous art that is usable in an obviousness combination. *Unwired Planet, LLC v. Google Inc.*, 841 F.3d 995, 1000 (Fed. Cir. 2016). The references are from the same field as the '300 patent, *e.g.*, devices for stimulating nerves or tissue to treat neurological disorders. (Ex. 1002, ¶16.) 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. (*Id.*) Therefore, a POSITA is presumed to have been aware of the references. *In re Nilssen*, 851 F.2d 1401, 1403 (Fed. Cir. 1988).

VI. PROPOSED GROUNDS FOR REJECTION

A. Grounds 1-2: Claims 1-17 Are Anticipated Or Rendered Obvious by Gesotti

1. Independent Claim 1

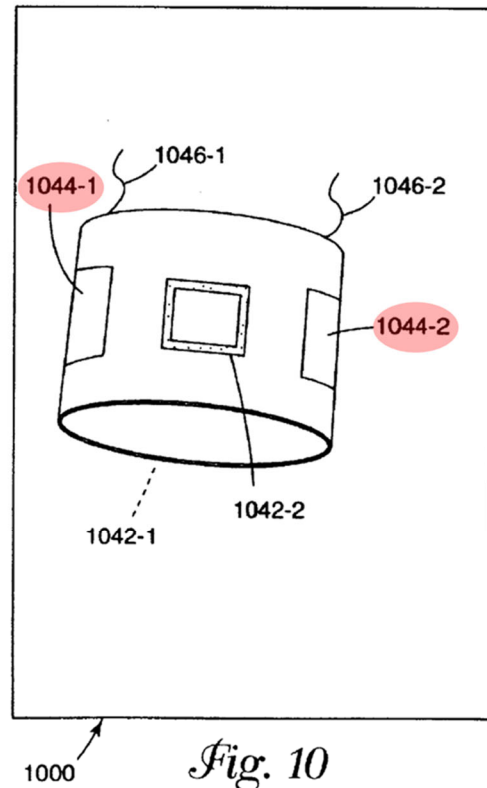
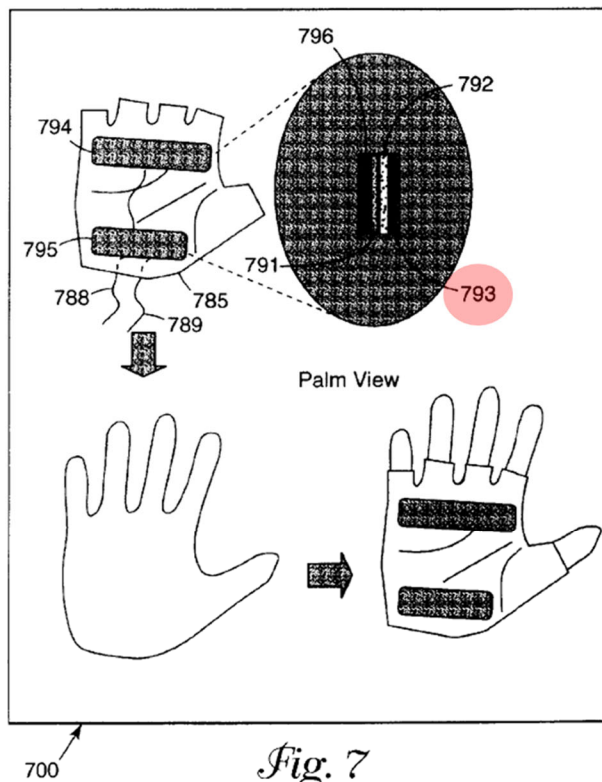
Claim 1 is anticipated or rendered obvious by Gesotti. (Ex. 1002, ¶¶41-75.)

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

If the preamble is limiting, Gesotti discloses this limitation. (Ex. 1002, ¶¶42-45.) Gesotti discloses systems for treating “Parkinson’s disease symptoms using electrical stimulation.” (Ex. 1008, 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.*, 1:32-35 (emphasis added); *see also* 1:58-66 (describing tremor).) Gesotti claims, “An adaptive stimulator for cu[r]ing 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.*, claims 11, 14 (emphasis added).)

Gesotti treats tremor by applying transdermal electrical stimulation therapy through stimulation electrodes placed over the patient's skin. (*Id.*, 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.*, 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.*, 4:11-20.)

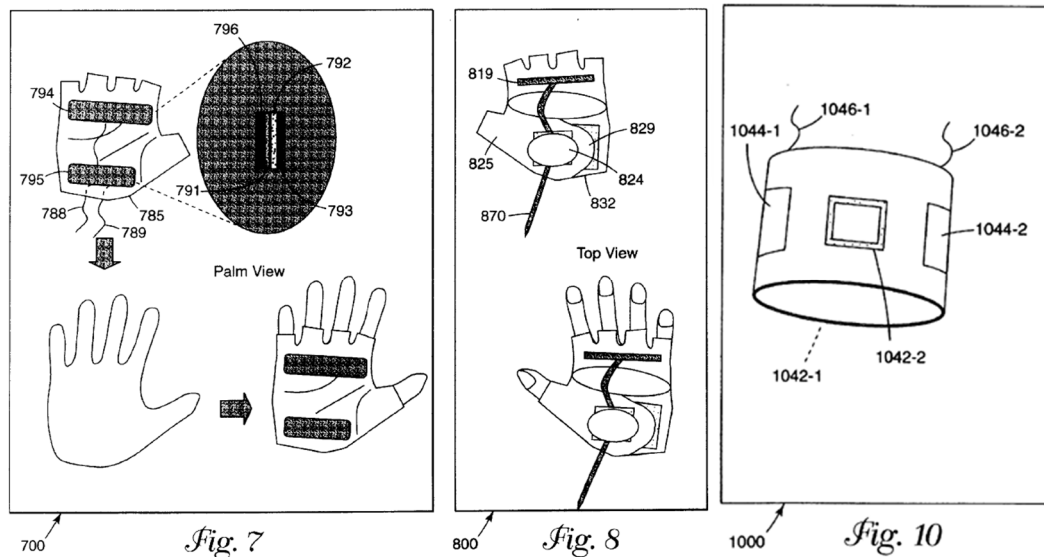
Gesotti discloses several configurations of stimulation electrodes, including “stimulation electrode[s] 793” [red] embedded in a “tactile sensor and stimulation glove” that fits over the patient's hand (below left) and “first and second stimulation electrodes 1044-1 and 1044-2” [red] located on a wristband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



(*Id.*, 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”

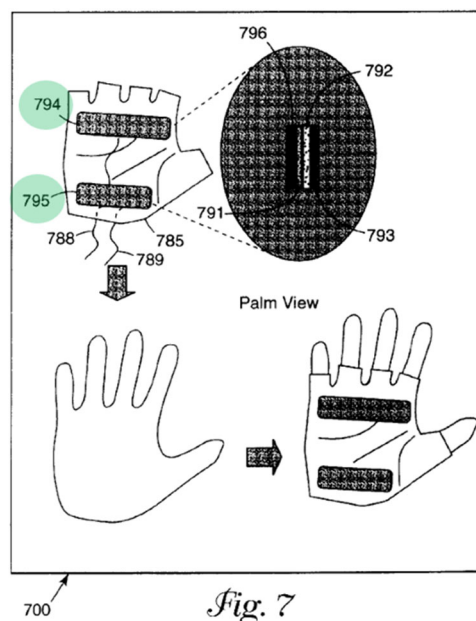
Gesotti discloses this limitation. (Ex. 1002, ¶¶46-47.) Gesotti discloses a “stimulation and sensing wristband,” (Ex. 1008, 9:29-30, Fig. 10,) and a “stimulation glove,” (*Id.*, 8:17, Figs. 7-9) which can be applied to a subject’s arm or hand, respectively. (*See also id.*, 5:38-6:17, Fig. 2 (describing a “cylindrical stimulation electrode” for the “fingers, thumbs, wrist, ankle and other cylindrically shaped regions of the body”).) The glove and wristband are “applicators.” (Ex. 1002, ¶47.)



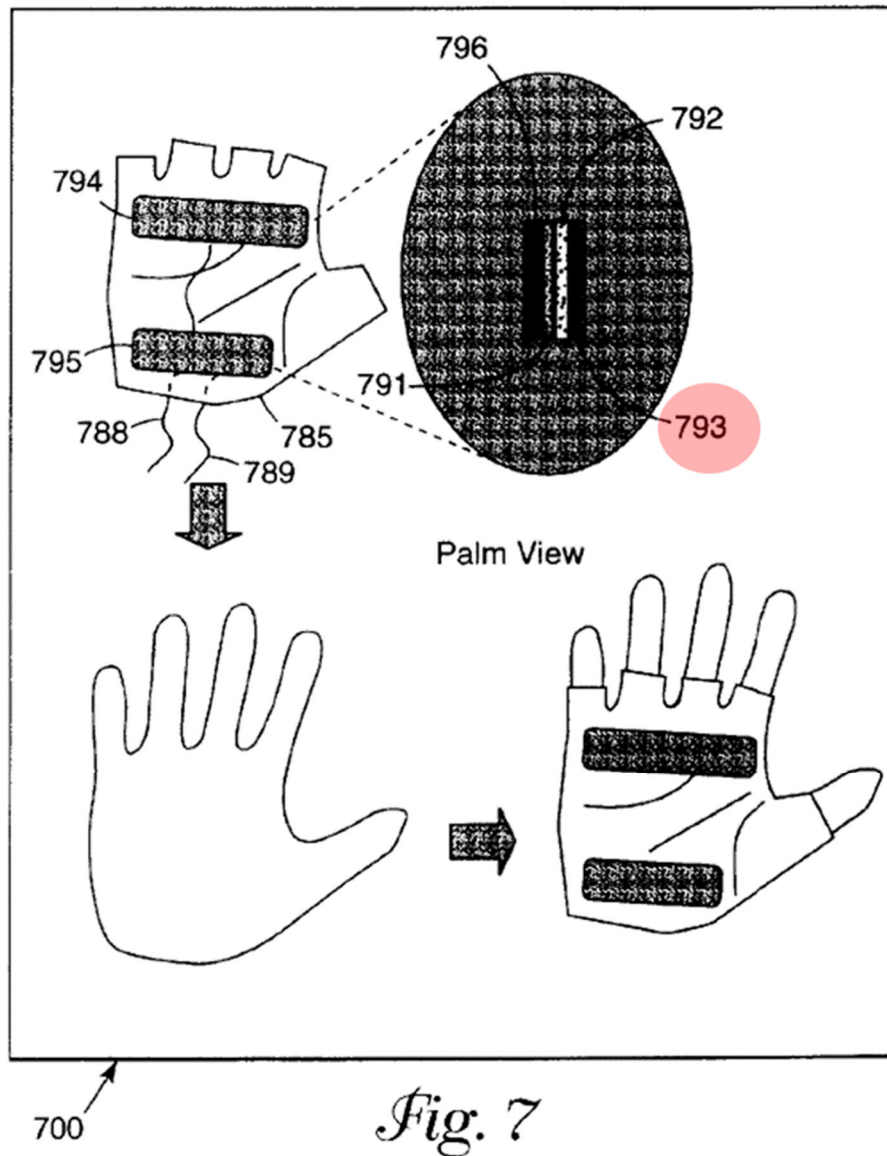
c. **Limitation [B]: “an electrode located along the applicator so as to contact the skin surface of the subject when the applicator is worn by the subject”**

Gesotti’s glove (Figures 7-9) and wristband (Figure 10) embodiments satisfy this limitation or render the limitation obvious. (Ex. 1002, ¶¶48-53.)

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



(Ex. 1008, 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.*, 8:20-26 (emphasis added).)



(*Id.*, Fig. 7.) Thus, the electrode contacts the skin surface of the subject when the glove is worn by the subject. (Ex. 1002, ¶49.)

Gesotti also discloses “a stimulation and sensing wristband, shown generally at 1000, constructed according to the teachings of the present invention.” (Ex. 1008, 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.*, 9:32-34.)

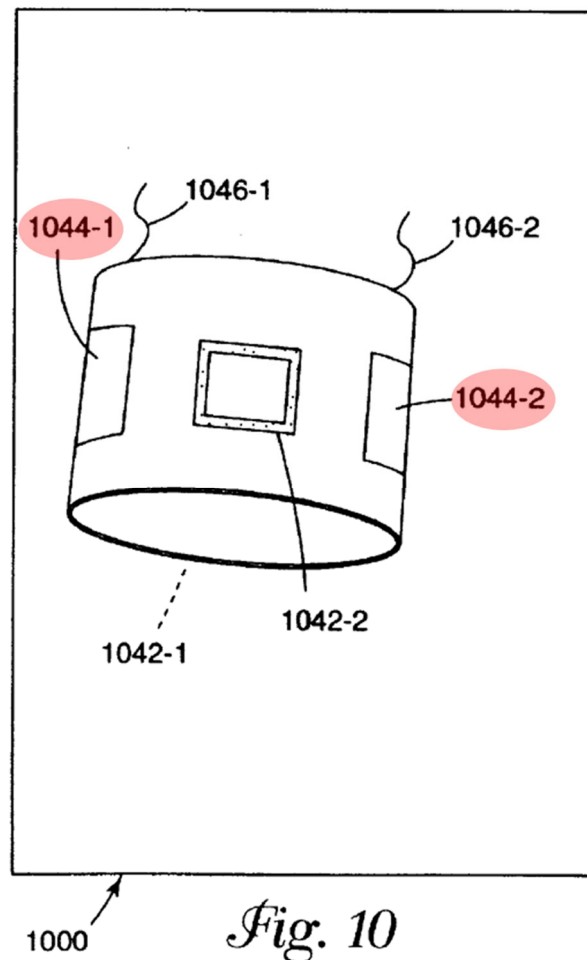


Fig. 10

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.*, 11:4-5, Fig. 14 (“Electrical stimulation electrodes 1472-1 and 1472-2 are in direct contact with the skin.”); *see also id.*, 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.*, 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.*, 5:47-52, Fig. 2 (emphasis added); *see also id.*, 6:23-26 (“electrical pulses are utilized for cutaneous stimulation of a region of the body”).) Based on these descriptions, a POSITA would have understood that the wristband electrodes also contact a skin surface when a subject wears the wristband. (Ex. 1002, ¶51.)

If PO argues that the wristband’s electrodes do not “contact a skin surface,” Gesotti renders the limitation obvious. *See Game and Tech. Co. v. Activision Blizzard Inc.*, 926 F.3d 1370, 1381 (Fed. Cir. 2019) (“A patent can be obvious in light of a single prior art reference if it would have been obvious to modify that reference to arrive at the patented invention.”) (quoting *Arendi S.A.R.L. v. Apple Inc.*, 832 F.3d 1355, 1361 (Fed. Cir. 2016)). A POSITA 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. (Ex. 1002, ¶52.)

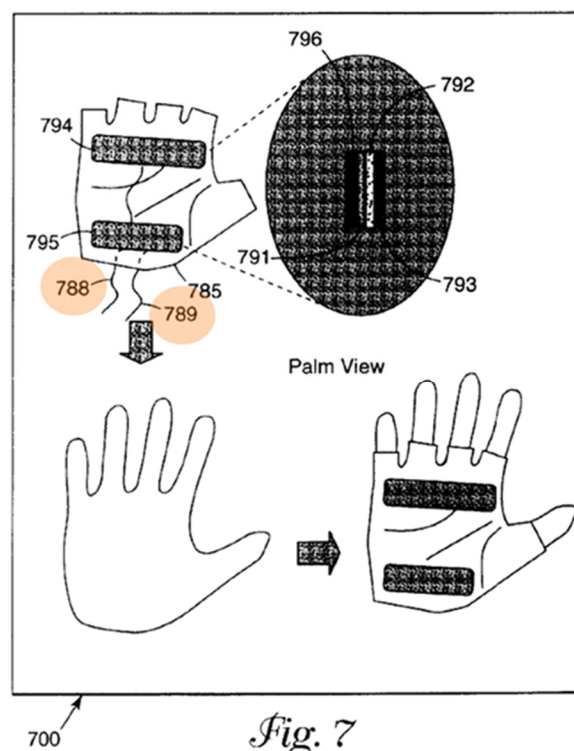
Moreover, a POSITA would have been motivated to place the electrodes in contact with the skin to ensure a better electrical connection between the patient and the electrode. (*Id.*) The sandwiching of wristband material between the electrode and skin surface could disrupt or weaken the transmission of the electrical pulses to the patient. (*Id.*) A POSITA 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. (*Id.*) Additionally, Gesotti never warns against contact between the electrodes and skin surface or that material should be placed between the electrode and skin. (*Id.*)

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). *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007); (Ex. 1002, ¶53). Additionally, a POSITA would have had a finite number of identified, predictable ways to attach the electrodes to the wristband. (*Id.* at 421; Ex. 1002, ¶53.) The POSITA 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 POSITA 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). (*Id.*, ¶53.) A POSITA 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. (*Id.*)

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

Gesotti’s glove (Figures 7-9) and wristband (Figure 10) embodiments satisfy this limitation. (Ex. 1002, ¶¶54-57.) 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, 8:26-29, Fig. 7.)



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

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

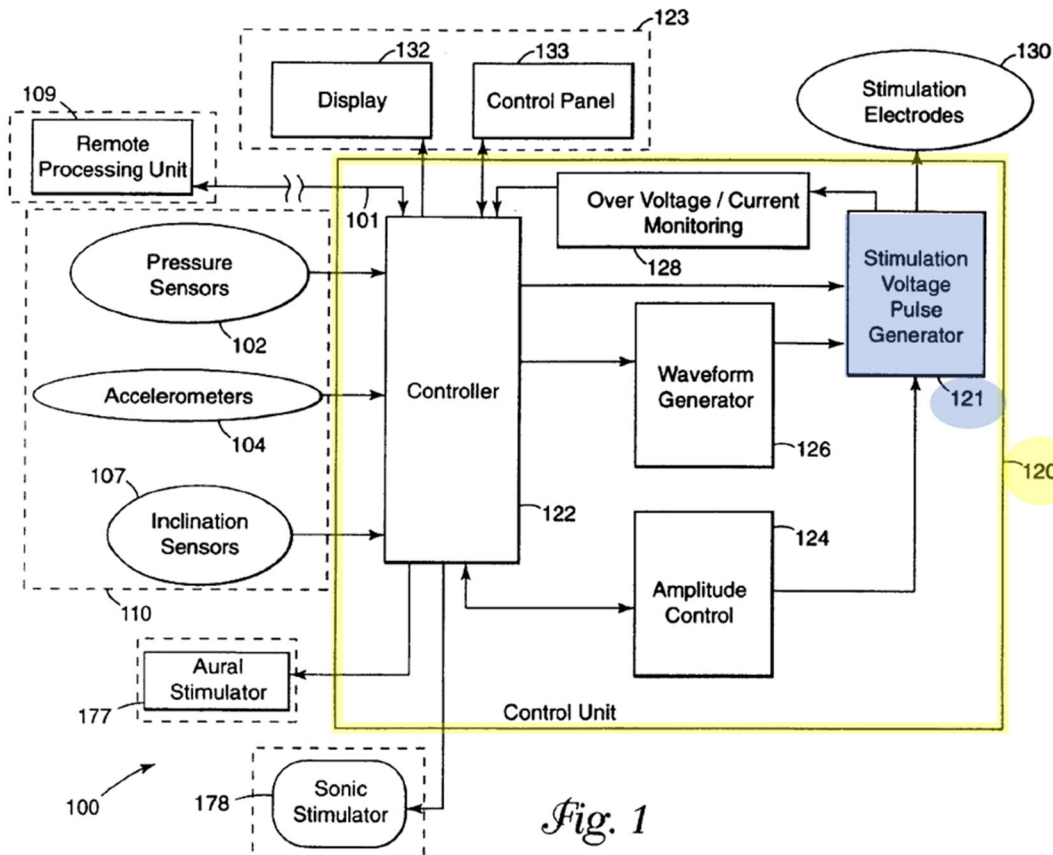
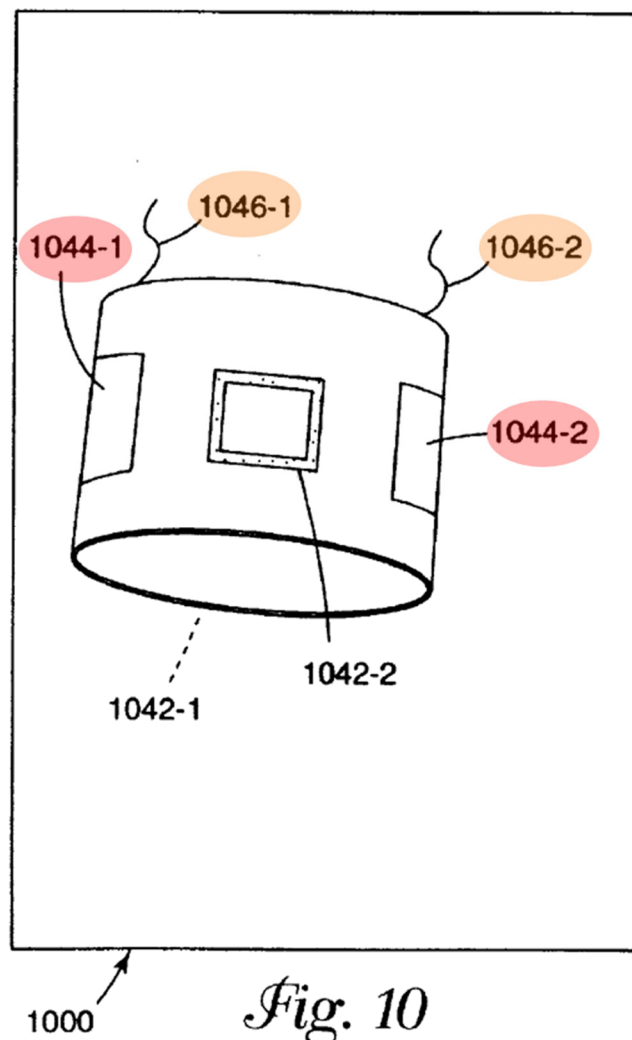


Fig. 1

The control unit 120 includes a stimulation voltage **pulse generator** 121 [blue] that “produces individual stimulation signals for each stimulation electrode 130.” (*Id.*, 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.” (Ex. 1002, ¶56.)

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, 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.*, 9:42-45.) Control unit 120 includes the "stimulation voltage pulse generator" that provides signals directly to the electrodes, as shown above. (*Id.*, 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.*, 9:45-47.) Thus, Gesotti discloses a second embodiment having “an electrical pulse generator in communication with the electrode.” (Ex. 1002, ¶57.)

e. **Limitation [D]: “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. (Ex. 1002, ¶¶58-62.) Gesotti’s glove (Figures 7-9) includes two tactile sensor assemblies (794 and 795) that include sensors 791 [purple]. (Ex. 1008, 8:16-26, Fig. 7.)

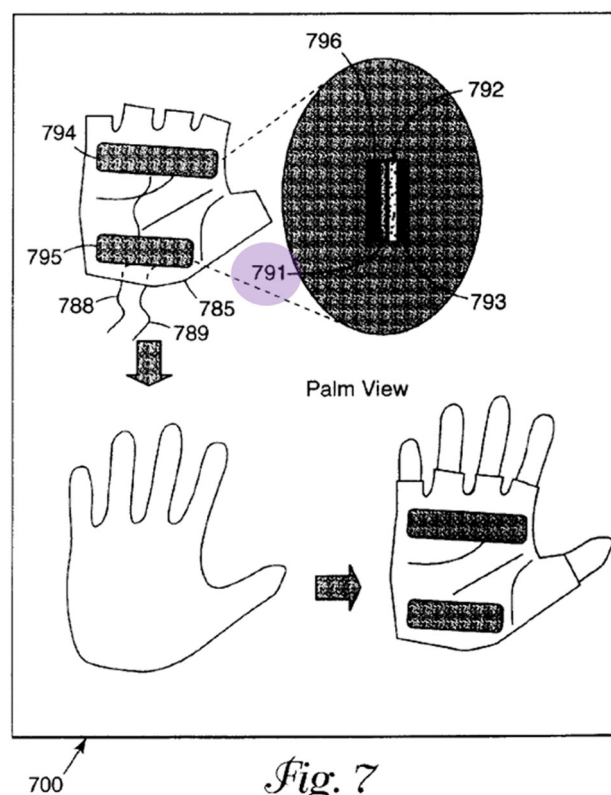


Fig. 7

As illustrated, the sensor is adjacent the stimulation electrode, which “is in direct contact with the palm of the hand....” (*Id.*, 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.” (Ex. 1002, ¶59.)

Gesotti also discloses that “[t]he 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].” (Ex. 1008, 8:26-30, Fig. 1.) The control unit includes a stimulation voltage pulse generator 121 [blue]. (*Supra* §VI.A.1.d.)

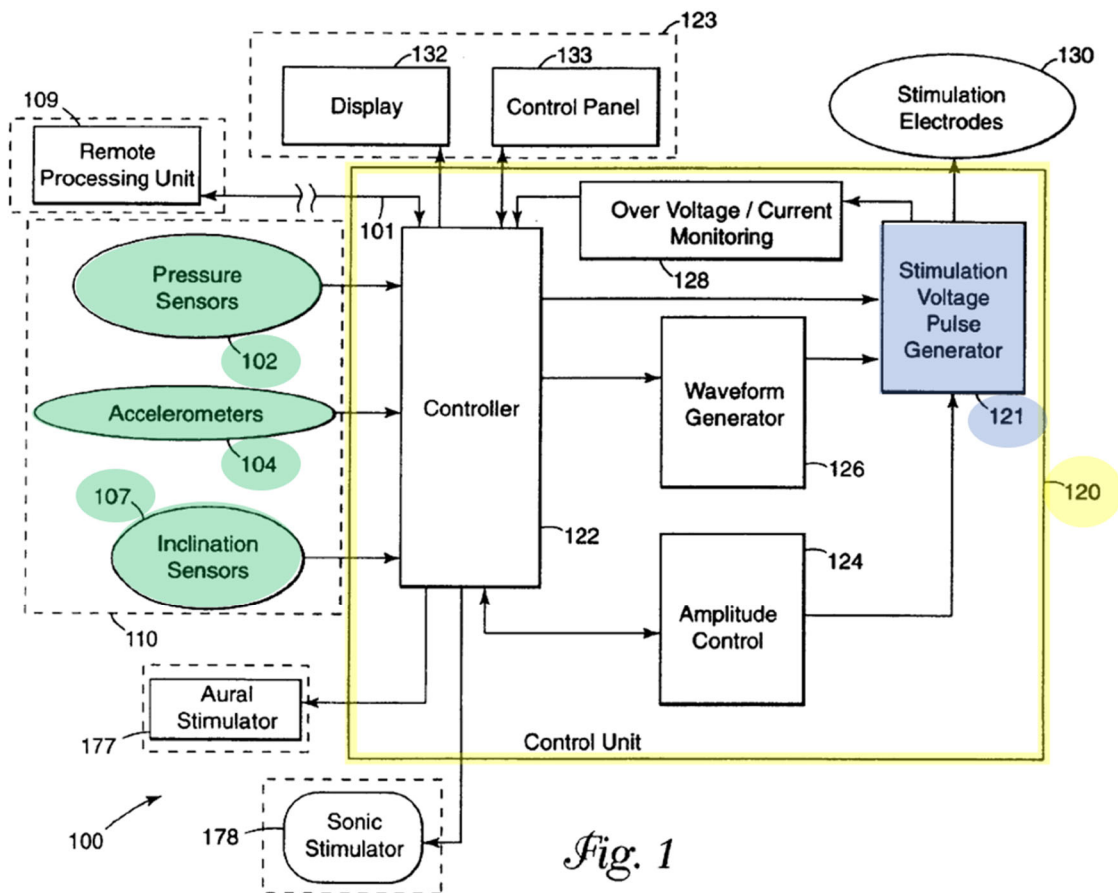
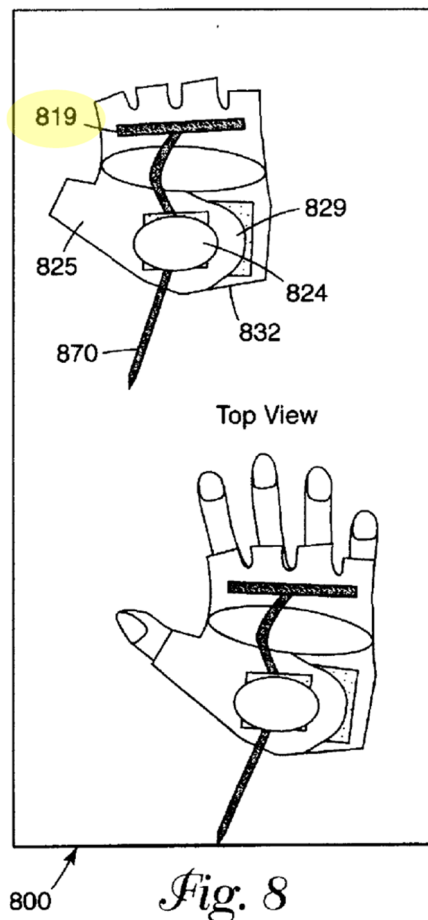


Fig. 1

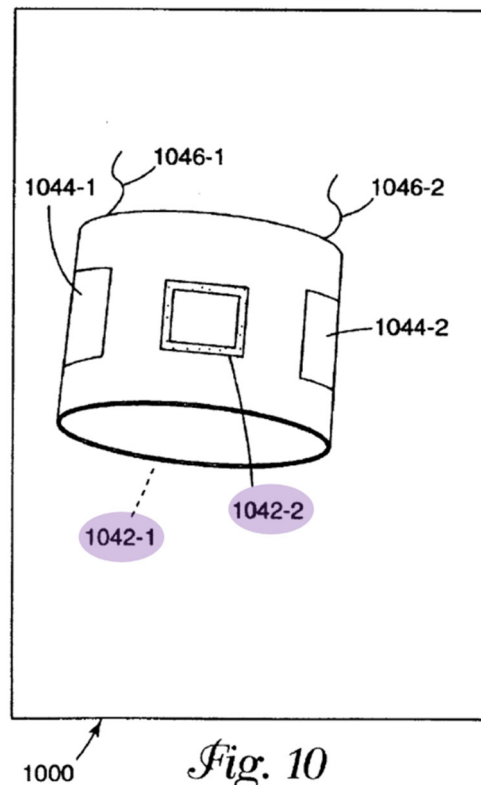
Gesotti discloses that “the electrical leads provide pressure information to a control unit for a determination of the need for stimulation.” (*Id.*, 8:31-33; *see also id.*, 3:57-59 (“Adaptive stimulator 100 includes a control unit 120 coupled to at least one sensor 110.”).) Therefore, the sensors on the glove are “in communication with” the pulse generator through the circuitry of the control unit 120. (Ex. 1002, ¶60.)

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, 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.*, 8:39-43, Fig. 8; Ex. 1002, ¶61.)



The “[w]ire connector 819 includes a connection cable 870 for coupling to a control unit, such as control unit 120, of FIG. 1.” (Ex. 1008, 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.*, 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. (Ex. 1002, ¶61.)

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, 9:34-37.)



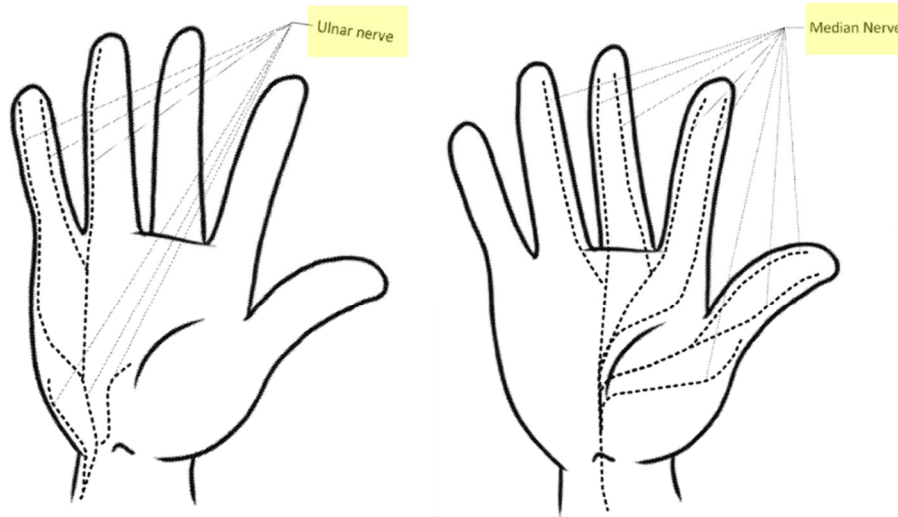
The wristband also includes electrical leads 1046-1 and 1046-2, which are “directly coupled to a control unit such as control unit 120 discussed with respect to FIG. 1,” and that send “electrical information signals” from the sensors to the control unit. (*Id.*, 9:42-47.) As illustrated in Figure 1, the acceleration sensors transmit information to the control unit and stimulation voltage pulse generator. (*Id.*, Fig. 1.) Therefore, the acceleration sensors on the wristband are “in communication with” the pulse generator through the circuitry of the control unit 120. (Ex. 1002, ¶62.)

f. **Limitation [E1]: “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. (Ex. 1002, ¶¶63-67.) The stimulation voltage pulse generator 121 within the control unit 120 “produces individual stimulation signals for each stimulation electrode 130.” (Ex. 1008, 4:44-48, Fig. 1; *see also id.*, 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.*, 8:26-33, 9:42-47.) Thus, Gesotti discloses that the “electrical pulse generator provides an electrical stimulation through the electrode.” (Ex. 1002, ¶64.)

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. (Ex. 1002, ¶65.) At least the ulnar and median nerves lie beneath the palm and wrist and are stimulated by the electrodes on the glove and wristband. (*Id.*; *see also* Ex. 1001, Figs. 51-55 (identifying ulnar and medial nerves).)

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:



(Ex. 1001, Figs. 53, 55; *see also id.*, 7:46-47, 7:54-56 (describing Figures 53, 55), Figs. 52, 56A (illustrating ulnar and median nerves extend along 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, Fig. 7; Ex. 1002, ¶66.)

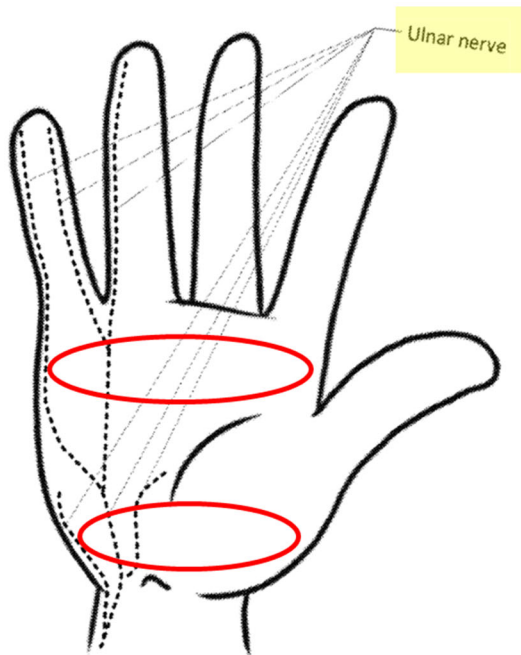


FIG. 53

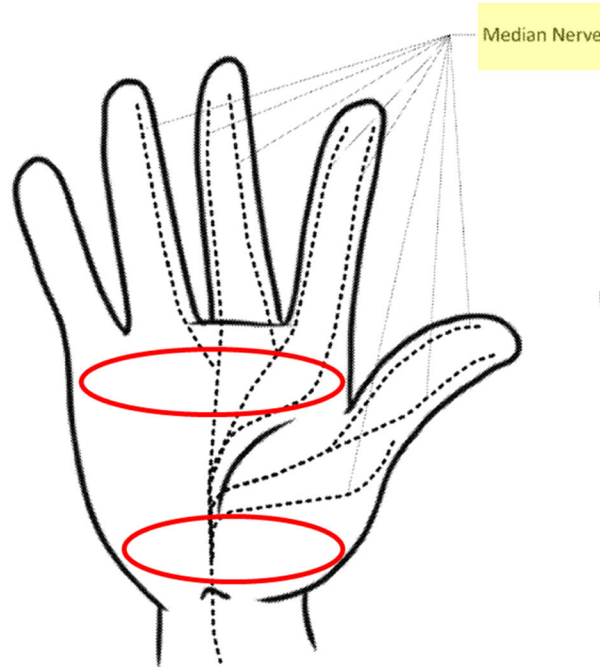


FIG. 55

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, 9:29-34, Fig. 10; Ex. 1002, ¶66.)

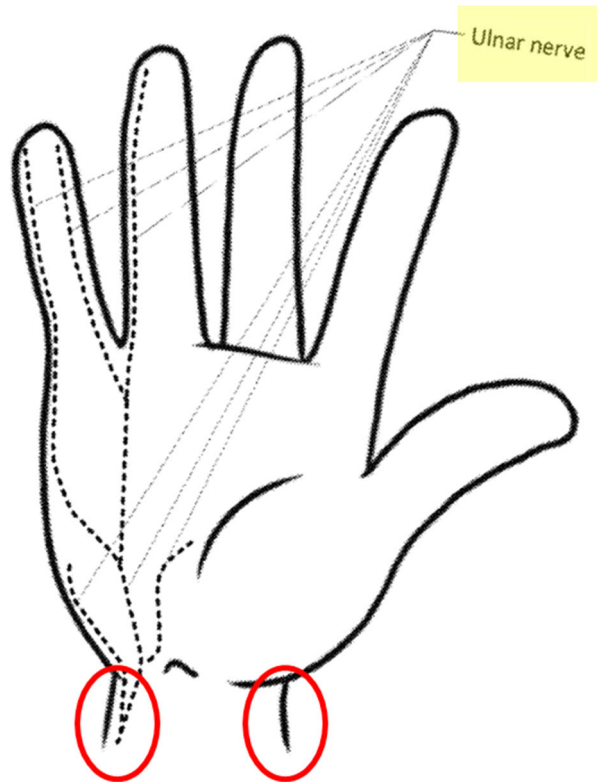
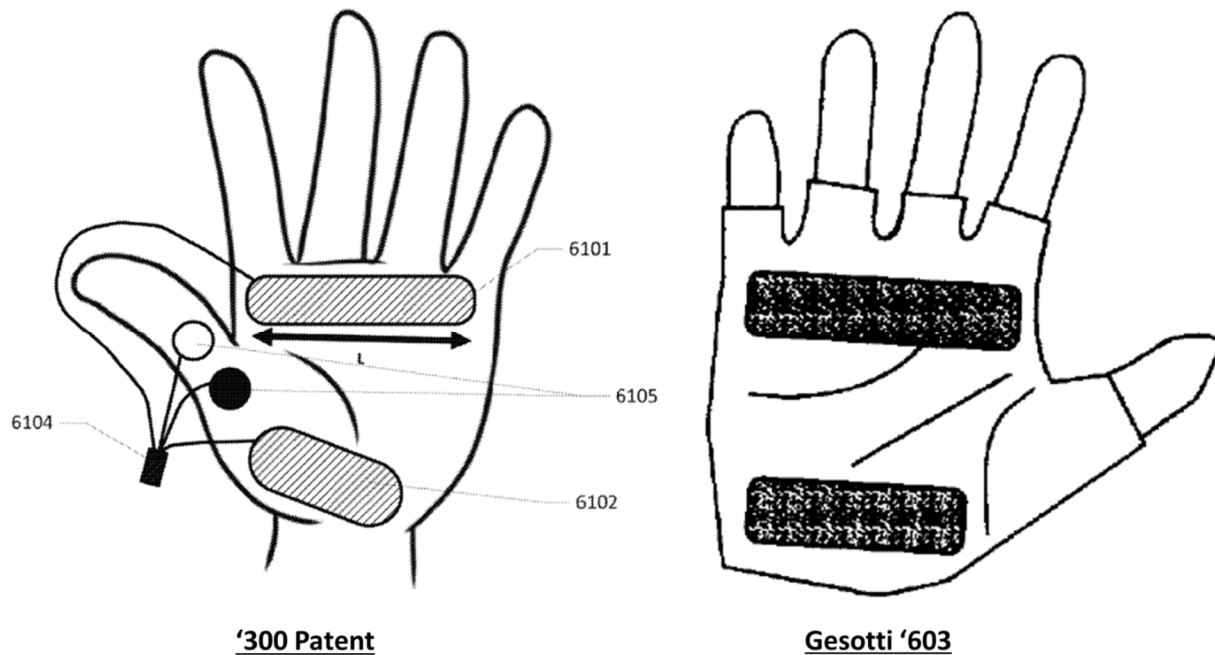


FIG. 53

The '300 patent's Figure 61A further confirms that Gesotti's glove electrodes overlay the ulnar and median nerves. (Ex. 1001, 62:37-41, 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, Fig. 61A (excerpted); Ex. 1008, Fig. 7 (excerpted).)

Thus, the stimulation electrodes described in Gesotti’s glove and wristband satisfy this limitation. (Ex. 1002, ¶67.)

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

Gesotti discloses this limitation. (Ex. 1002, ¶¶68-72.) 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, 9:34-37, Fig. 10.) The acceleration sensors detect motion of the subject. (*See e.g., id.*, 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....”); Ex. 1002, ¶69.)

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, 9:37-47, Fig. 1.)

The “electrical information signals” that are communicated to the control unit come from the sensors. (Ex. 1002, ¶70.) 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, 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.*, 12:9-21.)

Gesotti’s integrated tactile sensor and stimulation glove also satisfies this limitation. (Ex. 1002, ¶71.) 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.*, 8:39-43, Fig. 8 (emphasis added); *supra* §VI.A.1.e.) The acceleration sensors detect motion of the subject. (*See e.g., id.*, 4:4-6, 12:28-30; Ex. 1002, ¶71.) Gesotti further discloses that a feedback

signal from the sensors (including acceleration sensors) is provided to the control unit 120 and stimulation voltage pulse generator 121. (See Ex. 1008, 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.)

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:

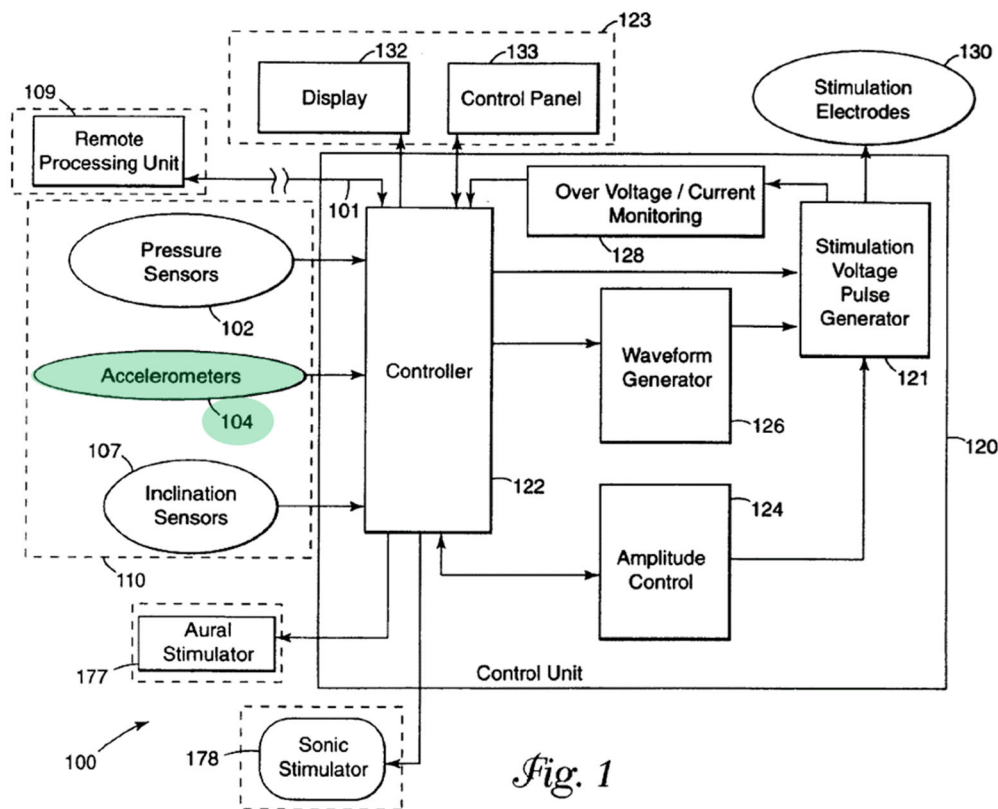


Fig. 1

(*Id.*, 4:4-7, Fig. 1.) 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.*, 4:8-11.)

Thus, the acceleration sensors in the wristband and glove provide a feedback signal to the electrical pulse generator. (Ex. 1002, ¶72.)

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

Gesotti discloses this limitation. (Ex. 1002, ¶¶73-75.) Gesotti’s 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. (*See e.g.*, Ex. 1008, claims 1-2 (claiming method of treating “tremor”); *see also id.*, 1:14-16, 1:58-2:17, 2:39-50, 3:34-38, 11:46-65, 15:1-3.)

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.*, 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.*, 11:49-52.) In the case of tremor, the sensors detect movement of the patient. (Ex. 1002, ¶75.) 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). (Ex. 1008, 11:53-64.) The system can also adjust “stimulation voltage, frequency, pulse width, waveform shape, amplitude, modulation type and the like of each electrical stimulation signal based on sensor information.” (*Id.*, 4:11-14; *see*

also id., 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. (Ex. 1002, ¶75.)

2. Claim 2

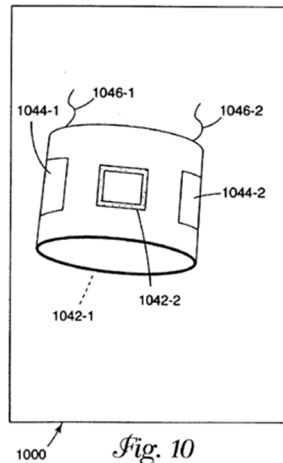
Claim 2 depends from Claim 1 and recites: “wherein the electrode is located along the applicator in proximity to the target nerve which extends through a hand of the subject.” Gesotti discloses this claim. (Ex. 1002, ¶¶76-77.)

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). (Ex. 1002, ¶77.) 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, Figs. 51-56A (identifying ulnar and median nerves beneath arm, wrist, and palm).)

3. Claim 3

Claim 3 depends from Claim 1 and recites: “wherein the applicator comprises a strap or band.” Gesotti discloses this claim. (Ex. 1002, ¶¶78-79.)

Gesotti discloses a “stimulation and sensing wristband” that meets the limitations of Claim 1. (Ex. 1008, 9:29-30, Fig. 10.)



The wristband is an applicator and a band. (*Supra* §VI.A.1.b; Ex. 1002, ¶79.)

4. Claim 4

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 provided in Claim 1. (*Supra* §VI.A.1.c.)

5. Claim 5

Claim 5 depends from claim 1 and recites: “comprising an additional electrode separate from the electrode.” Gesotti discloses this claim. (Ex. 1002, ¶¶81-82.)

Gesotti’s stimulation glove (Figures 7-9) and wristband (Figure 10) each have two separate electrodes. (Ex. 1008, 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

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. (Ex. 1002, ¶¶83-84.)

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, 4:11-14, Fig. 1 (emphasis added); *see also id.*, 4:35-43.) As 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

Claim 7 is anticipated or rendered obvious by Gesotti. (Ex. 1002, ¶¶85-97.)

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

If the preamble is limiting, Gesotti discloses this limitation for the reasons provided in Claim 1. (*Supra* §VI.A.1.a.)

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

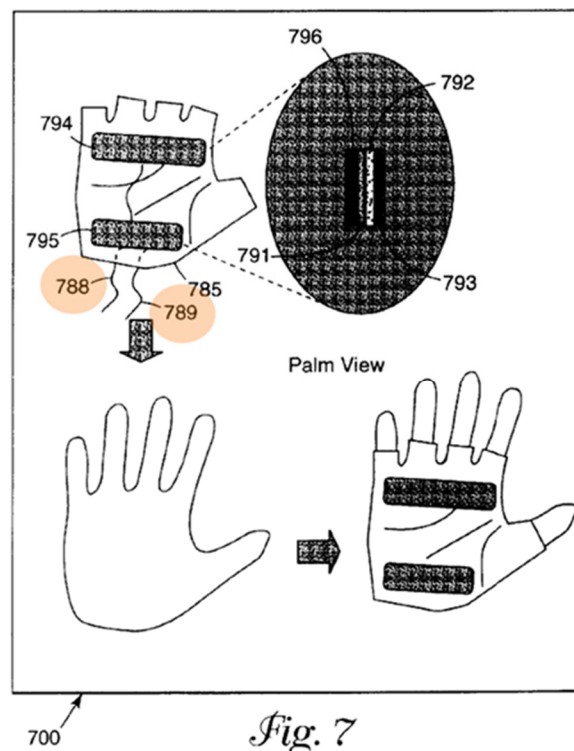
Gesotti discloses this limitation for the reasons provided in Claim 1. (*Supra* §VI.A.1.b.)

- 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”**

Gesotti discloses this limitation or renders it obvious for the reasons provided in Claim 1. (*Supra* §VI.A.1.c.)

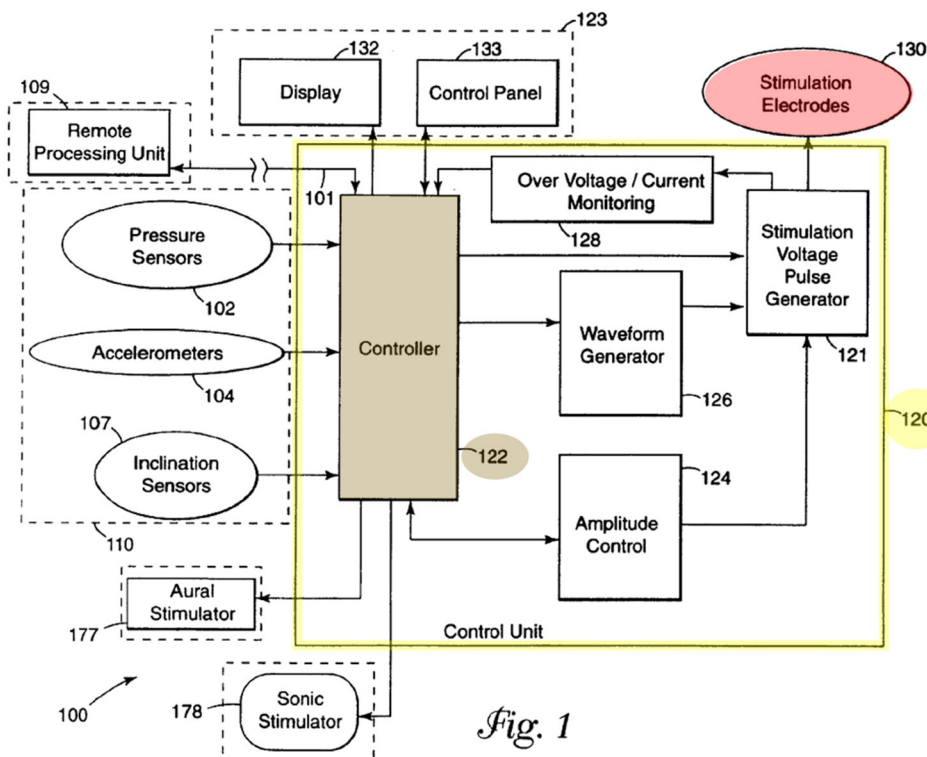
- d. **Limitation [C]: “a controller in communication with the electrode”**

Gesotti discloses this limitation. (Ex. 1002, ¶¶89-90.) 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, 8:26-29, Fig. 7.)



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

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



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.*, 4:44-64, Fig. 1.) Thus, the controller 122 is “in communication with” the electrodes. (Ex. 1002, ¶90.)

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

Gesotti discloses this limitation. (Ex. 1002, ¶¶91.) As explained in Claim 1, the glove (Figures 7-9) and wristband (Figure 10) include a sensor “positionable on the subject.” (*Supra* §VI.A.1.e.) Gesotti further discloses that “control unit 120 includes

a controller 122 that receives information from sensors 110.” (Ex. 1008, 4:35-36, Fig. 1; *see also supra* §VI.A.1.c.) Thus, the sensors are “in communication with” the controller. (Ex. 1002, ¶¶91.)

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”**

Gesotti discloses this limitation. (Ex. 1002, ¶¶92-94.) 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, 4:44-64, Fig. 1.)

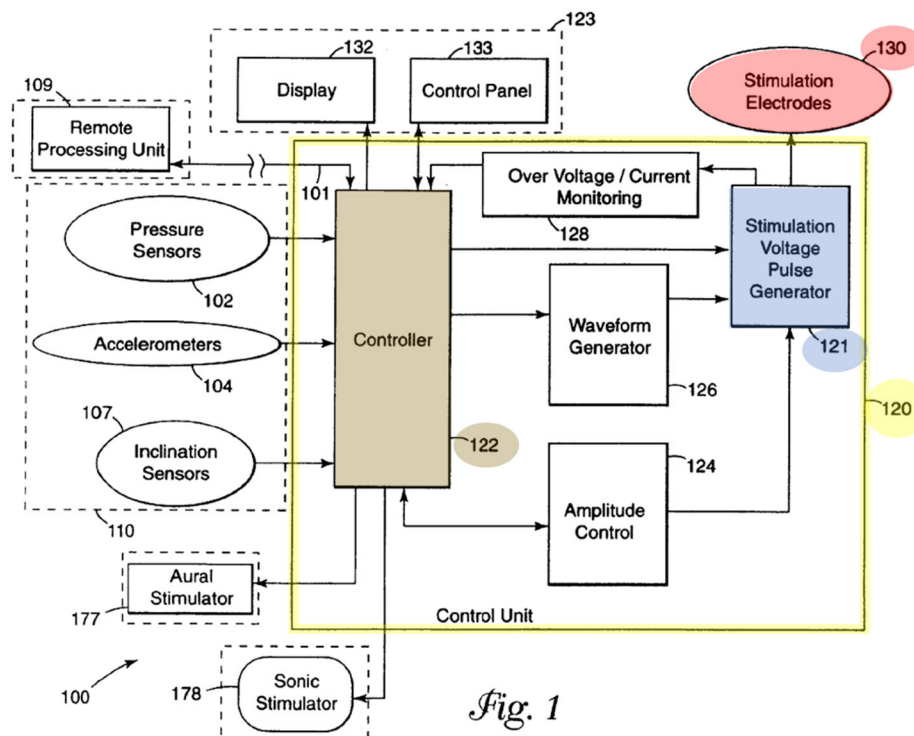


Fig. 1

Thus, the controller “transmits via the electrode an electrical stimulation.” (Ex. 1002, ¶92.)

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, 4:11-14 (emphasis added).)

Finally, as discussed in 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.”**

Gesotti discloses this limitation. (Ex. 1002, ¶¶95-97.) As explained in 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.)

As further explained in Claim 1, 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.)

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, 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.*, 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.*, 4:40-43 (emphasis added).)

8. Claim 8

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 provided in Claim 2. (*Supra* §VI.A.2.)

9. Claim 9

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

10. Claim 10

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 provided in Claim 4. (*Supra* §VI.A.4.)

11. Claim 11

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

12. Independent Claim 12

Claim 12 is anticipated or rendered obvious by Gesotti. (Ex. 1002, ¶¶102-113.)

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

If the preamble is limiting, Gesotti discloses this limitation. (Ex. 1002, ¶103.) Gesotti discloses methods of treating “Parkinson’s disease symptoms using electrical stimulation.” (Ex. 1008, 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.*, 1:32-35 (emphasis added); *see also* 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.*, 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"**

Gesotti discloses this limitation, or renders it obvious, for the reasons provided in Claim 1. (*Supra* §§VI.A.1.c-d, f; Ex. 1002, ¶¶104-108.)

Gesotti discloses transmitting an electrical stimulation from an electrical pulse generator through the electrodes in the glove and wristband. (Ex. 1002, ¶105.) As 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, 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.*, 4:44-48, Fig. 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.*, 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.*, 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.*, 9:32-34.)

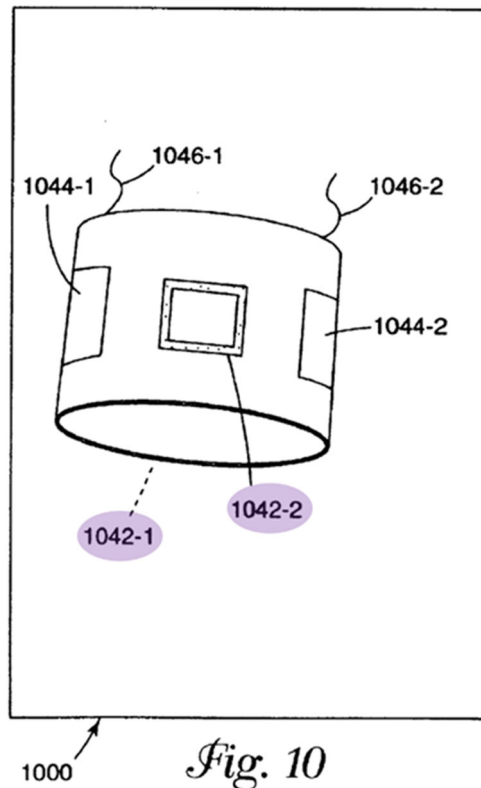
As discussed in Claim 1, if the electrodes on the wristband are not “contacted against a skin surface” of the arm, a POSITA would have found it obvious to modify the wristband so that the electrodes contact the skin surface for the reasons provided in Claim 1. (*Supra* §VI.A.1.c.)

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; Ex. 1002, ¶108.) 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, 9:29-34; Fig. 10; Ex. 1002, ¶108.)

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”**

Gesotti discloses this limitation. (Ex. 1002, ¶¶109-110.) Gesotti’s wristband (Figure 10) includes acceleration sensors that meet this limitation. As explained in 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, 9:34-37, Fig. 10; *supra* §VI.A.1.e.)



The acceleration sensors monitor for a motion of the subject. (*See e.g., id.*, 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); Ex. 1002, ¶109.) 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.*, 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; Ex. 1002, ¶109.)

Gesotti’s “integrated tactile sensor and stimulation glove” (Figures 7-9) also includes acceleration sensors that meet this limitation. As explained in Claim 1, the stimulation glove 825 incorporates “***acceleration***...sensors attached to the wrist, forearm, upper arm or the like.” (*Id.*, 8:39-43, Fig. 8 (emphasis added); *supra* §VI.A.1.e.) The acceleration sensors detect motion of the subject. (*See e.g., id.*, 4:4-6, 12:28-30; Ex. 1002, ¶110.) As further explained in 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”

Gesotti discloses this limitation. (Ex. 1002, ¶111.) As discussed in 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, 4:7-11; *see also id.*, 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.”**

Gesotti discloses this limitation. (Ex. 1002, ¶¶112-113.) As discussed in 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, claims 1-2 (claiming method of treating symptoms of Parkinson’s disease including “tremor”); *see also id.*, 1:14-16, 1:58-2:17, 2:39-50, 3:34-38, 11:46-65, 15:1-3.)

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, 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.*, 11:49-52.)

In the case of tremor, the acceleration sensor detects movement of the hand caused by the tremor. (Ex. 1002, ¶113.) 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, 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.*, 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.” (Ex. 1002, ¶113.)

13. Claim 13

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 provided in Claim 2. (*Supra* §VI.A.2.)

14. Claim 14

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 provided in Claim 3. (*Supra* §VI.A.3.)

15. Claim 15

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 provided in Claim 4. (*Supra* §VI.A.4.)

16. Claim 16

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 provided in Claim 5. (*Supra* §VI.A.5.)

17. Claim 17

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. (Ex. 1002, ¶¶118-119.)

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, 4:11-14, Fig. 1 (emphasis added); *see also id.*, 4:35-43.) As discussed above, 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

Claim 1 is rendered obvious by Burnett. (Ex. 1002, ¶¶120-147.)

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

If the preamble is limiting, Burnett discloses this limitation. (Ex. 1002, ¶¶121-122.) The ’300 patent is a continuation-in-part of Burnett (App. No. 12/508,529). (Ex. 1001, 1:20-22.) 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.)

Burnett describes electrical and magnetic stimulation devices to treat OAB and UI. (Ex. 1010, [0002, 0036, 0038, 0070].) However, Burnett includes the same list of over 100 ailments found in the '300 patent, including “tremor.” (*Id.*, [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”

Burnett discloses this limitation. (Ex. 1002, ¶¶123.) Burnett discloses that the energy emitting devices may stimulate various body regions, including the “back, leg, *arm*, neck, head, torso, etc.” (Ex. 1010, [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.*, [0107] (emphasis added), Fig. 9C.)

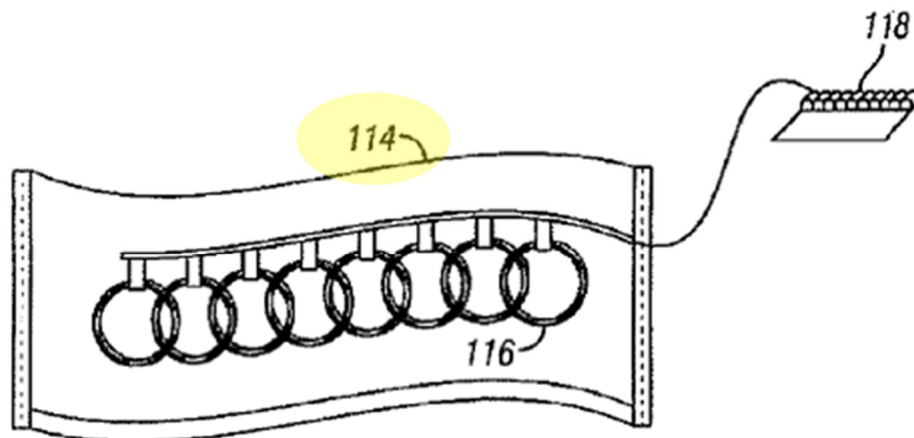


FIG. 9C

Thus, Burnett discloses an applicator configured for application to the arm. (Ex. 1002, ¶123.)

- 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”**

Burnett renders this limitation obvious. (Ex. 1002, ¶¶124-134.) 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):

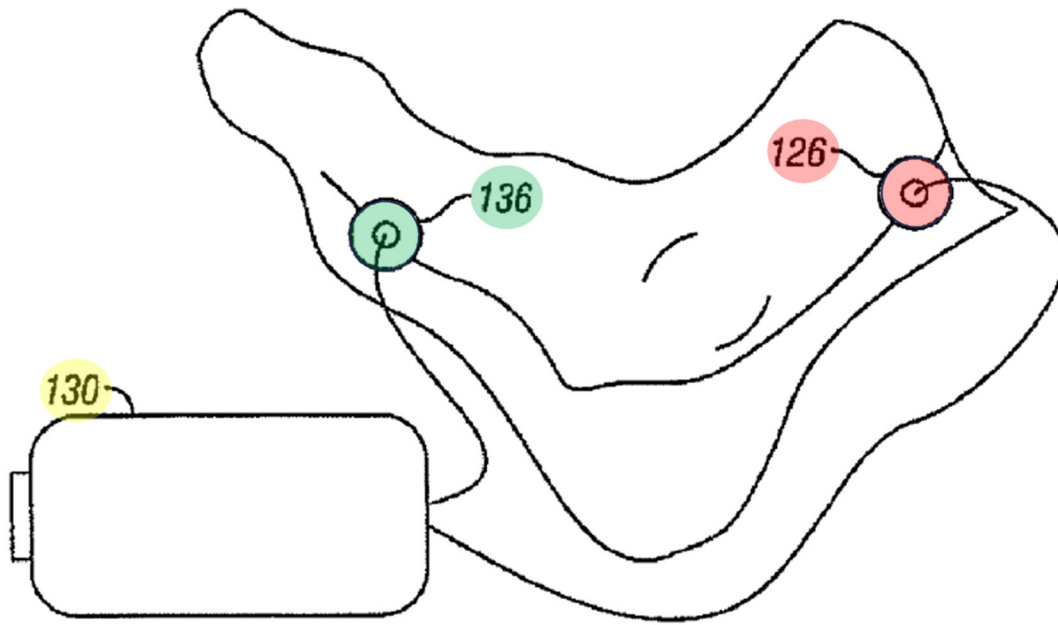


FIG. 11

(Ex. 1010, [0109], Fig. 11; *see also id.*, [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.*, [0154]; *see also id.*, [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.*, [0154].)

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.*, [0107] (emphasis added); *see also id.*, [0112] (“The transcutaneous electrical stimulation sensor may be placed in the body independently or be incorporated within the wrap....”).) While the preferred embodiments of the bands include stimulation coils (*see e.g., id.*, Fig. 9C), a POSITA would have found it obvious to substitute electrodes or microneedle patches for the coils in those embodiments. (Ex. 1002, ¶125.)

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. (*Id.*, ¶126.) 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, [0031]; *see also id.*, [0033] (similar).)

Burnett discloses several examples of energy emitting systems that use coils and electrodes interchangeably. (Ex. 1002, ¶127.) 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, [0143], [0146], Figs. 12, 21.)

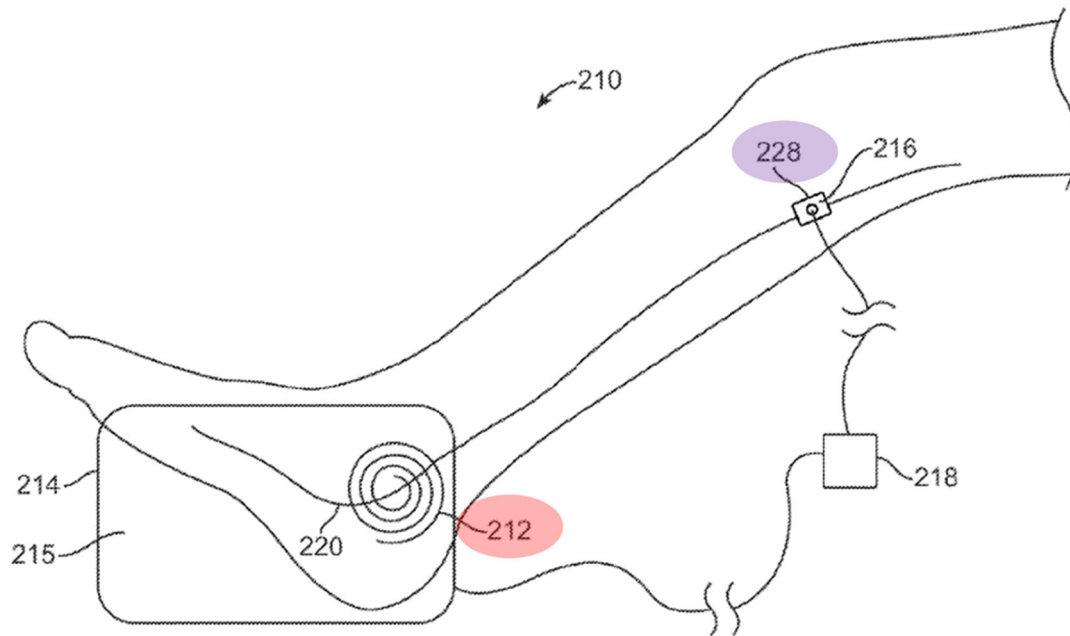


FIG. 21

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

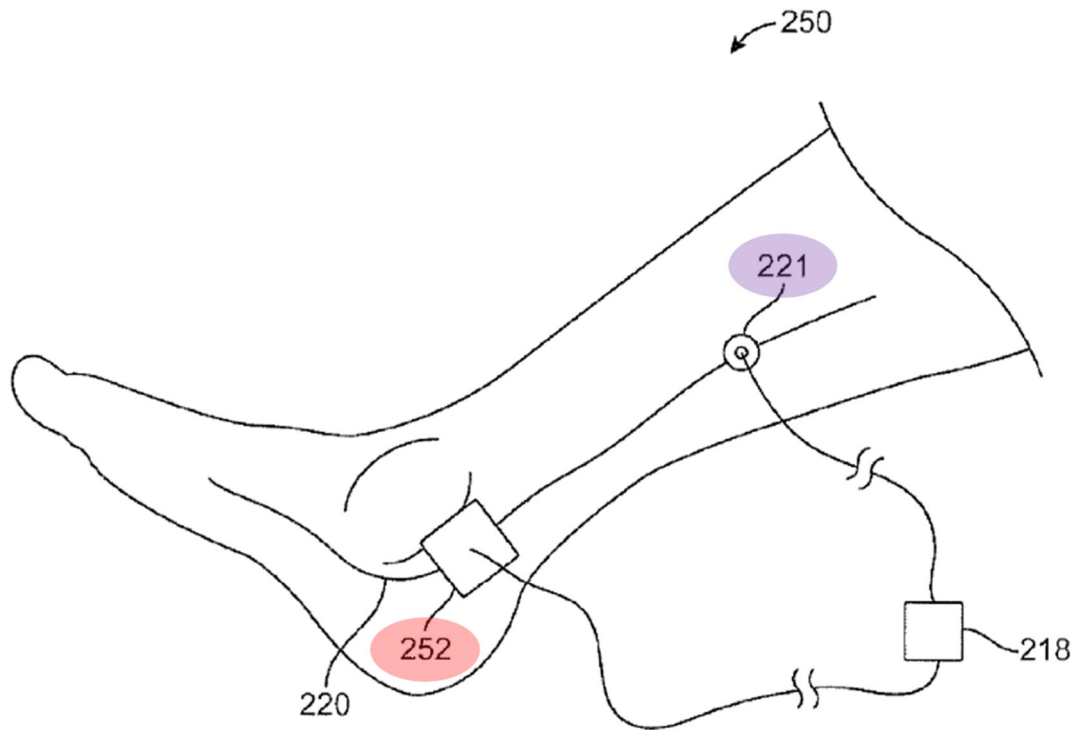


FIG. 26

(See also *id.*, Figures 6A-6B, Figs. 10-11.)

Moreover, many prior art references described the effectiveness of placing stimulation electrodes within ergonomic applicators. (See *e.g.*, Ex 1008, Figs. 7-15; Ex. 1007, Figs. 1-2, 12.) These teachings in combination with the suggestion in Burnett would have motivated a POSITA to include an electrode within the ergonomic applicator. (Ex. 1002, ¶129.) Moreover, a POSITA 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 disorders. (*Id.*)

A POSITA 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. (*Id.*, ¶130.) 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. (*Id.*) Burnett specifically discloses that the band may be retained in place using simple connectors. (Ex. 1010, [0107].)

Additionally, a POSITA would have been motivated to position the electrodes on the inside surface of the band so that the electrodes “contact the skin surface.” (Ex. 1002, ¶131.) Burnett already discloses electrodes that “contact the skin surface.” (*See e.g.*, Ex. 1010, [0166] (“In the case of a microneedle patch, the patch may be attached to a subject’s skin.”), Fig. 26.)

Moreover, a POSITA 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. (Ex. 1002, ¶132.) 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, [0140], Fig. 19.) A POSITA 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. (Ex. 1002, ¶132.)

A POSITA would have expected success in positioning the electrodes within the band and against the skin surface for several reasons. (*Id.*, ¶133.) 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, Figs. 7-10; Ex. 1007, Fig. 12, Ex. 1017, Fig. 3.) These prior art references would have encouraged a POSITA to try such a combination here. (Ex. 1002, ¶133.) Additionally, Burnett already describes placing electrodes directly against the skin and suggests that such positioning can improve the function of the device. (*Id.*)

Ultimately, a POSITA would have had a finite number of identified, predictable solutions for applying Burnett's electrode to the patient. *KSR*, 550 U.S. at 1416; (Ex. 1002, ¶134.) 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. (*Id.*) A POSITA would have found it obvious to try either option and would have reasonably expected success in doing so for the reasons explained above. (*Id.*)

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

Burnett discloses this limitation. (Ex. 1002, ¶135.) 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 “electrical pulse controller 130” [yellow] to “provide the desired feedback and modulate the power” to the transcutaneous stimulator, such as electrode 126 [red]. (Ex. 1010, [0109].) An electric pulse controller is a pulse generator. (Ex. 1002, ¶135.)

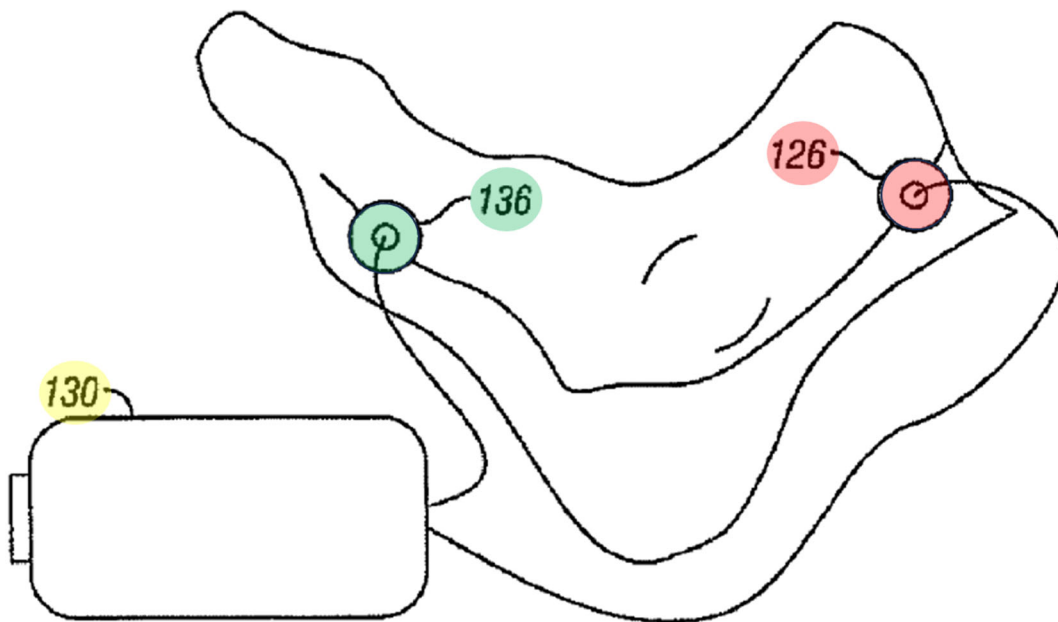


FIG. 11

(Ex. 1010, 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. (Ex. 1002, ¶135.)

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

Burnett discloses this limitation. (Ex. 1002, ¶¶136-137.) 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. (Ex. 1002, ¶136.)

Figure 26, for example, illustrates an energy emitting system 250 having a microneedle patch 252 and *sensor 221*. (Ex. 1010, [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.*, [0156].)

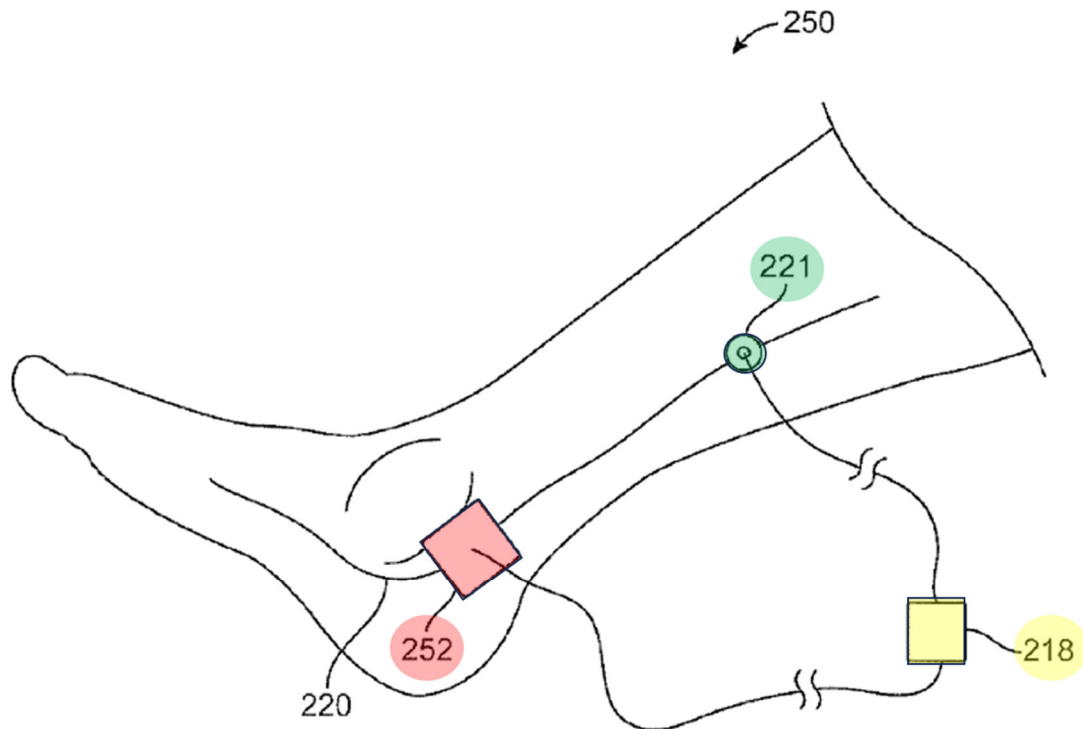


FIG. 26

(*Id.*, Fig. 26.) The controller 218 is the pulse generator. (Ex. 1002, ¶137.) “Sensor 221 detects electrical conduction through the stimulated posterior tibial nerve 220, and then transmits the signal to controller 218.” (Ex. 1010, [0156], Fig. 26.) Thus, the sensor is “positionable on the subject and in communication with the electrical pulse generator.” (Ex. 1002, ¶137.)

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

Burnett discloses this limitation. (Ex. 1002, ¶¶138-141.) Burnett discloses an electrode in communication with an electrical pulse controller, which is an electrical pulse generator. (*Supra* §VI.B.1.d.)

Burnett discloses that the electrical pulse generator provides electrical stimulation through the electrode and into a target nerve underlying the skin surface. (Ex. 1002, ¶139.) 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, [0109], Fig. 11.) The electric pulse controller is a pulse generator. (Ex. 1002, ¶139.)

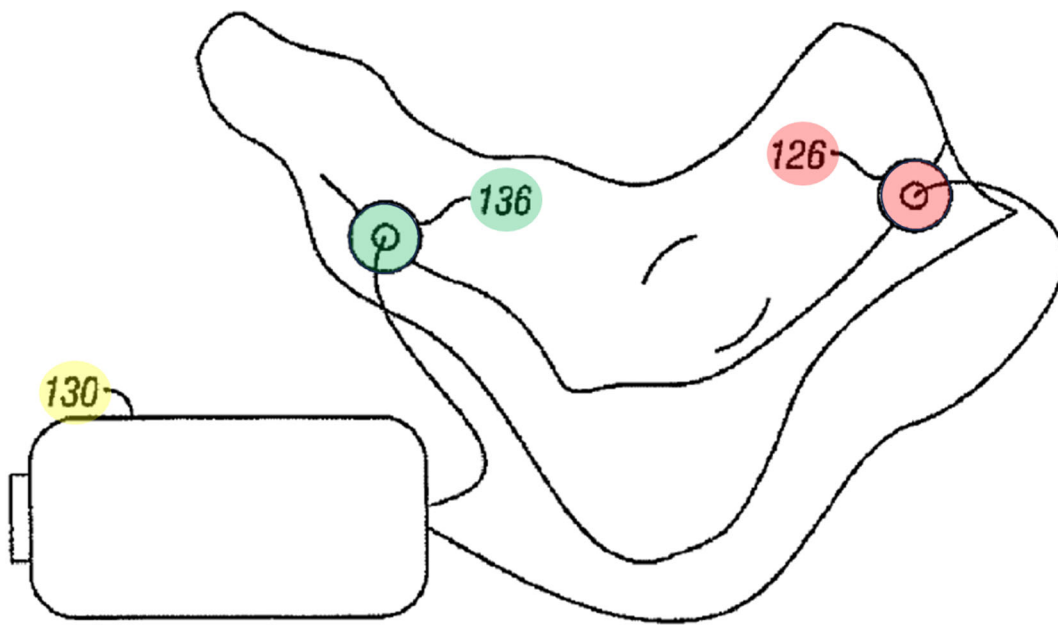


FIG. 11

Similarly, Figure 26 illustrates an energy emitting system 250 having a microneedle patch 252 and sensor 221. (Ex. 1010, [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.*, [0156].)

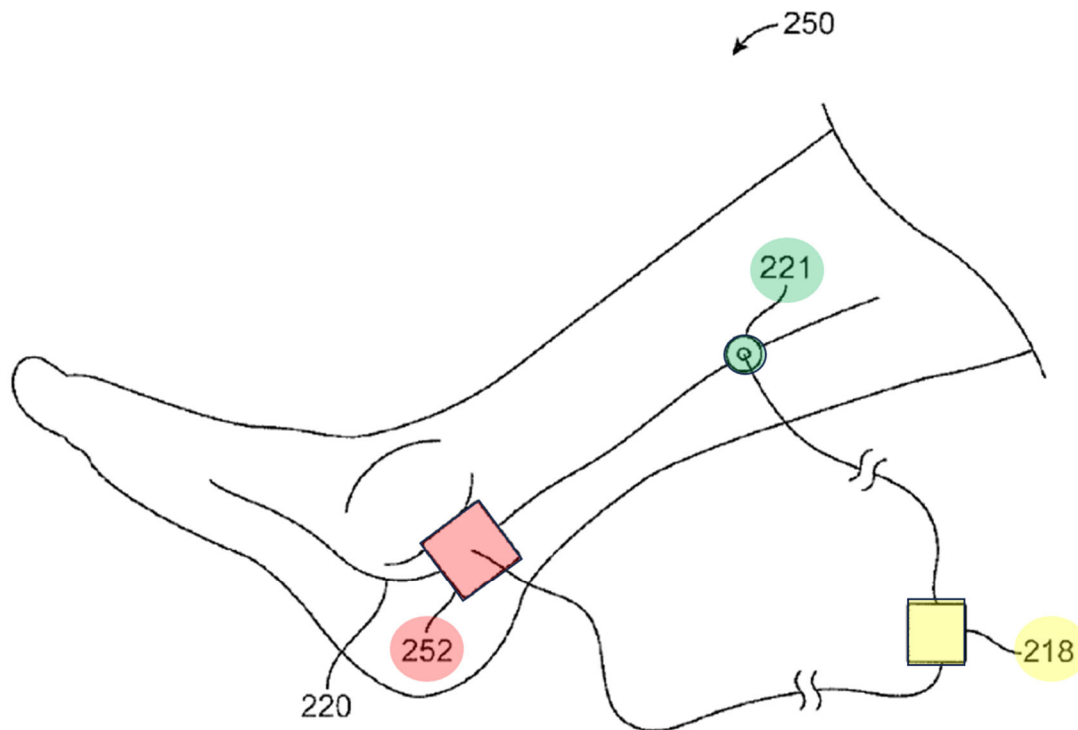


FIG. 26

(*Id.*, Fig. 26.) The controller 218 is a pulse generator. (Ex. 1002, ¶140.) 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.*, [0156]; Ex. 1002, ¶140.)

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, [0110]; Ex. 1002,

¶141; *see also* Ex. 1010, [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.”).)

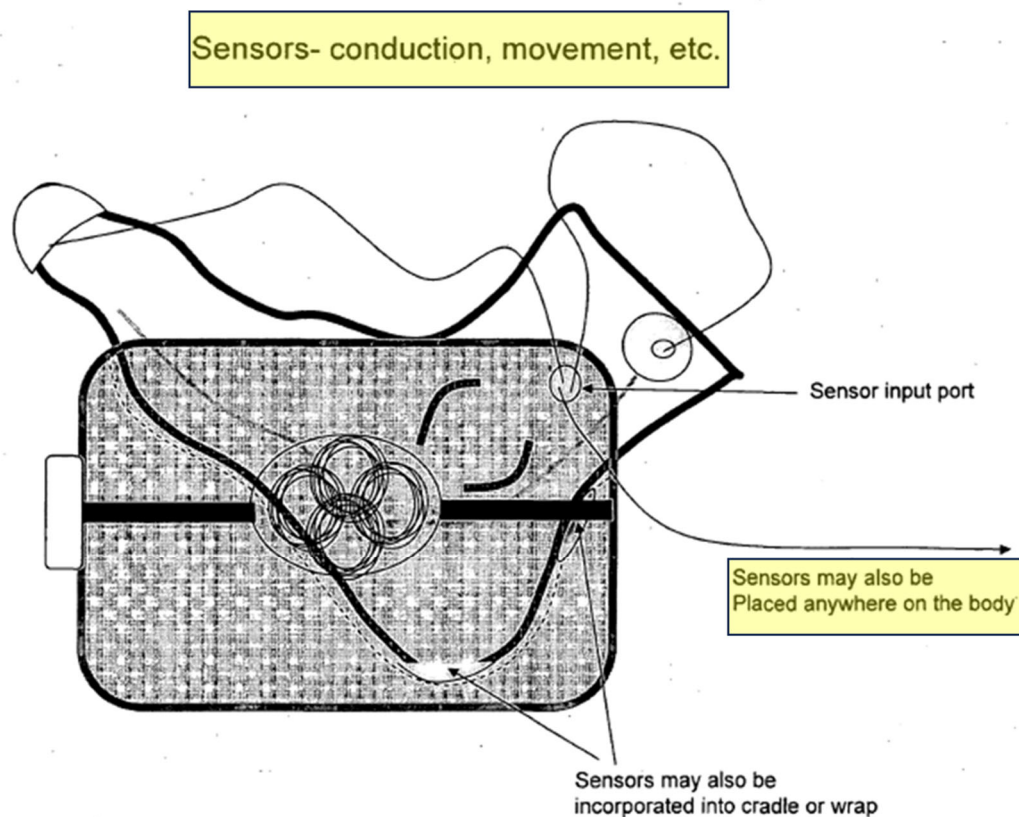
g. **Limitation [E2]: “such that the sensor detects a motion of the subject and provides a feedback signal to the electrical pulse generator”**

Burnett discloses this limitation. (Ex. 1002, ¶¶142-145.) 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, [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. (Ex. 1002, ¶142.)

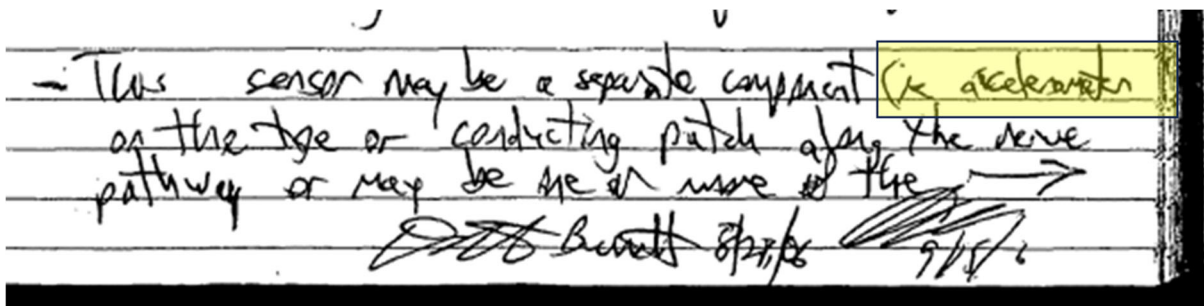
Burnett discloses that the sensor can take a variety of forms, including a microneedle patch or “a sensor type known in the art.” (Ex. 1010, [0128], [0147].) One sensor type known in the art was an accelerometer, which detects motion. (Ex. 1002, ¶143.) For example, Gesotti and Gesotti ’896 (U.S. Patent No. 7,369,896)

disclose accelerometers to detect patient motion. (*See e.g.*, Ex. 1008, Fig. 1 (identifying “accelerometer”); Ex. 1009, Fig. 1 (identifying “motion sensors”).)

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



(*Id.*, 35.)

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 electric conduction in the target nerve.” (Ex. 1010, [0032].) In this embodiment, the energy generators are the pulse generators. (Ex. 1002, ¶145.) Thus, Burnett discloses “the sensor detects a motion of the subject and provides a feedback signal to the electrical pulse generator.” (*Id.*)

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

Burnett discloses this limitation. (Ex. 1002, ¶¶146-147.) Burnett includes the same list of over 100 ailments found in the '300 patent, including “tremor.” (Ex. 1010, [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.

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, [0156]; Ex. 1002, ¶147.)

2. Claim 2

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. (Ex. 1002, ¶¶148-153.)

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):

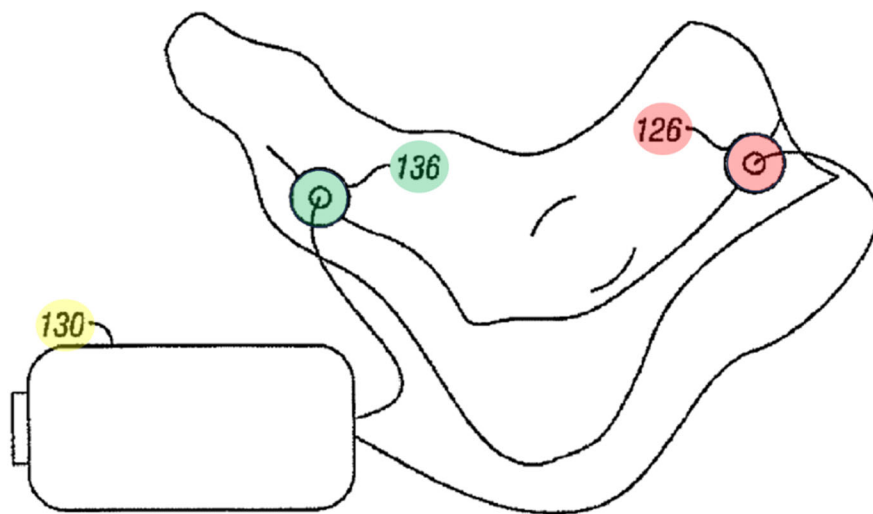


FIG. 11

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

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, [0154], [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.*, [0154].)

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.*, [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]; Ex. 1002, ¶151.) 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.” (Ex. 1010, [0126].)

Burnett discloses various body regions that may be stimulated using the disclosed devices, including the “back, leg, *arm*, neck, head, torso, etc.” (*Id.*, [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.*, [0107] (emphasis added); *see also id.*, [0112] (“The transcutaneous electrical stimulation sensor may be placed in the body independently or be incorporated within the wrap....”).)

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:

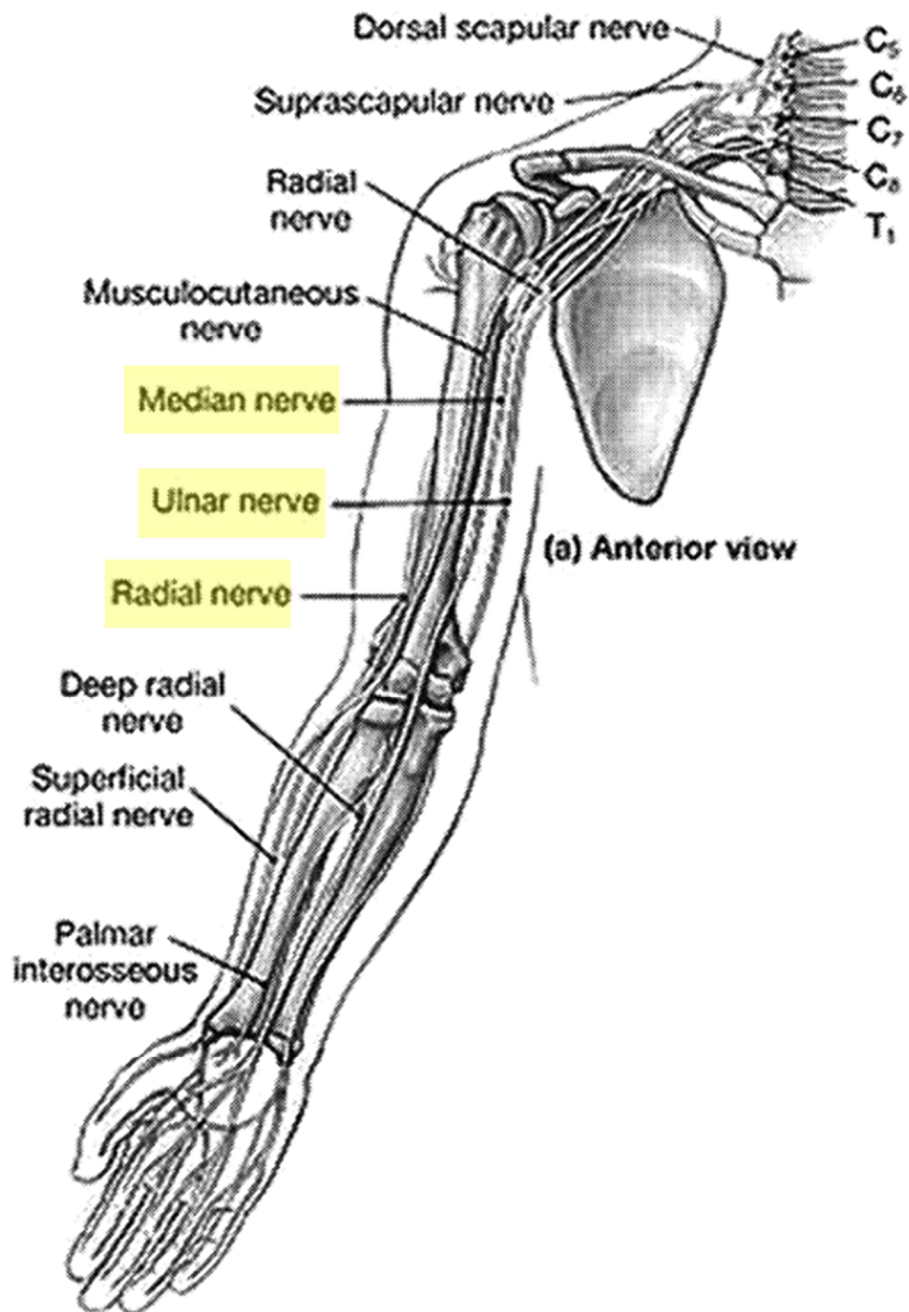


FIG. 56A

(Ex. 1001, Fig. 56A; Ex. 1002, ¶153.) Therefore, a band wrapped around the arm, or an electrode placed on the arm, as disclosed in Burnett, will overlie a target nerve

(e.g., median, ulnar, or radial) which extends through a hand of the subject. (Ex. 1002, ¶153.) Thus, Burnett discloses this limitation. (*Id.*)

3. Claim 3

Claim 3 depends from claim 1 and recites: “wherein the applicator comprises a strap or band.” Burnett discloses this claim. (Ex. 1002, ¶154.) Burnett discloses incorporating the stimulation devices into a band that “may be wrapped around a body portion (for example, an *arm*)....” (Ex. 1010, [0107] (emphasis added); *see also id.*, [0112] (“The transcutaneous electrical stimulation sensor may be placed in the body independently or be incorporated within the wrap....”).)

4. Claim 4

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 provided in Claim 1. (*Supra* §VI.B.1.c.)

5. Claim 5

Claim 5 depends from claim 1 and recites: “comprising an additional electrode separate from the electrode.” Burnett discloses this limitation. (Ex. 1002, ¶156.) 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, [0038] (emphasis added); *see also Id.*, [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

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. (Ex. 1002, ¶¶157-158.)

Burnett discloses that “[a]n apparatus according to the present invention may deliver any frequency of stimulation....” (Ex. 1010, [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.*, [0170] (emphasis added), [0175], [0181], [0186]; *see also id.*, [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

Claim 1 is rendered obvious by Burnett. (Ex. 1002, ¶¶159-167.)

a. Preamble

If the preamble is limiting, Burnett discloses the preamble for the reasons provided in Claim 1. (*Supra* VI.B.1.a.)

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

Burnett discloses this limitation for the reasons provided in 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”**

Burnett renders this limitation obvious for the reasons provided in Claim 1. (*Supra* §VI.B.1.c.)

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

Burnett discloses this limitation. (Ex. 1002, ¶¶163-164.) 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, [0032].) “The one or more energy generators produce energy focused on the target nerve upon receiving a signal from the logic controller....” (*Id.*)

Similarly, Figure 26 illustrates an energy emitting system 250 having a microneedle patch 252 and sensor 221. (*Id.*, [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.*, [0156].)

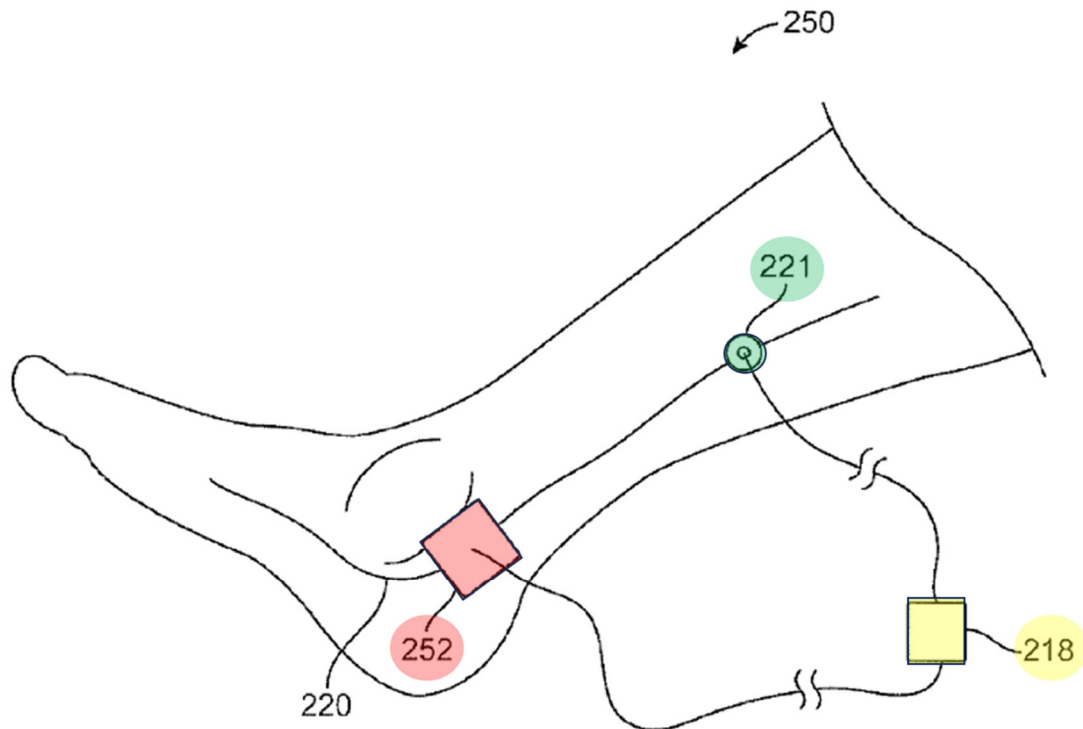


FIG. 26

(*Id.*, Fig. 26.) Thus, Burnett discloses “a controller in communication with the electrode.” (Ex. 1002, ¶164.)

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

Burnett discloses this limitation. (Ex. 1002, ¶165.) Figure 26 illustrates an energy emitting system 250 having a microneedle patch 252 and ***sensor 221***. (Ex. 1010, [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.*, [0156].)

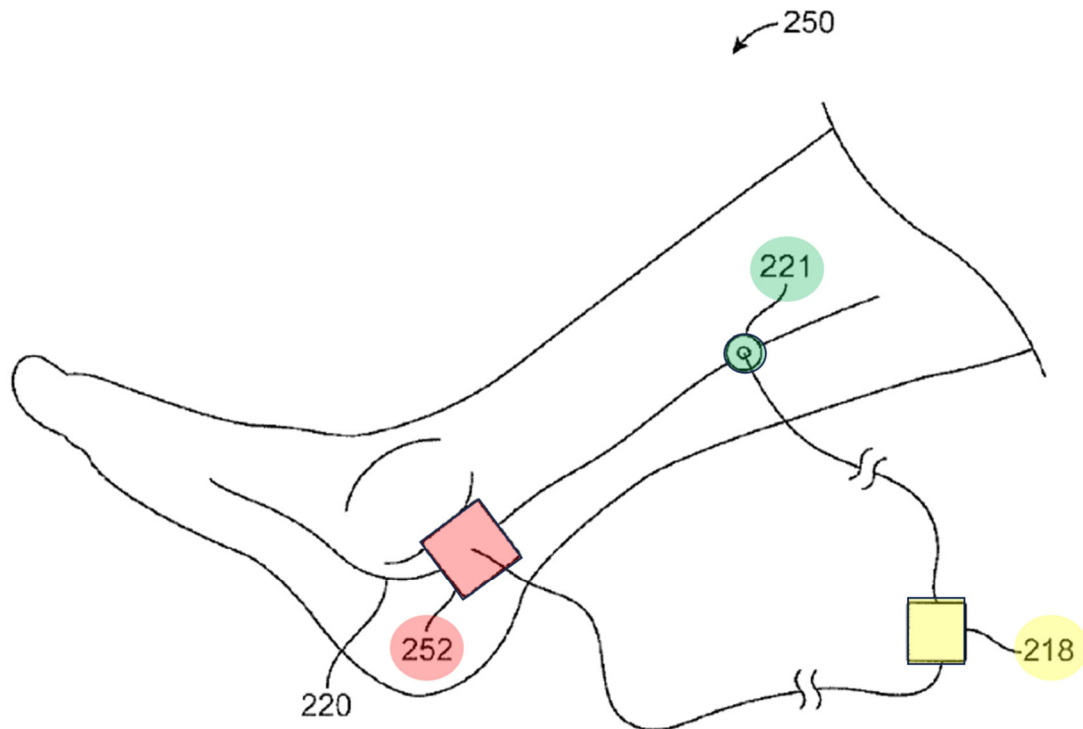


FIG. 26

(*Id.*, Fig. 26.) “Sensor 221 detects electrical conduction through the stimulated posterior tibial nerve 220, and then *transmits the signal to controller 218.*” (*Id.*, [0156] (emphasis added).) Thus, Burnett discloses “a sensor positionable on the subject and in communication with the controller.” (Ex. 1002, ¶165.)

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”**

Burnett discloses this limitation (Ex. 1002, ¶166.) Figure 26 illustrates an energy emitting system 250 having a microneedle patch 252 and sensor 221. (Ex. 1010, [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.*, [0156] (emphasis added).)

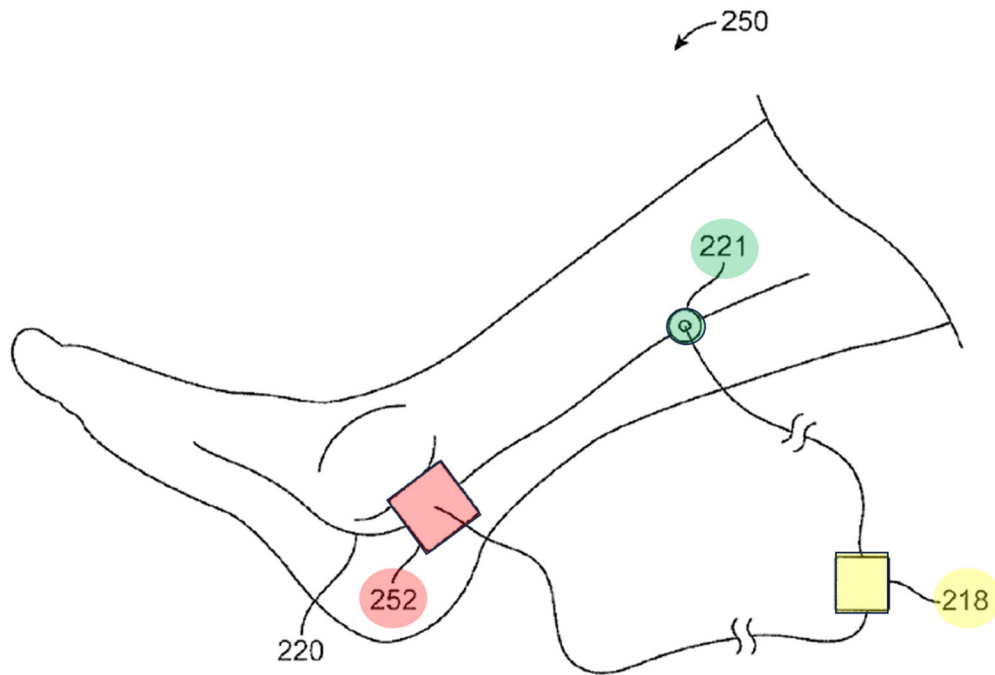


FIG. 26

(*Id.*, 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.*, [0156].) As explained in 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.”**

If the '300 patent discloses this limitation, so does Burnett. (Ex. 1002, ¶167.) As explained in Claim 1, Burnett discloses sensors that detect motion of the subject. (*Supra* §VI.B.1.g.) Likewise, as 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 to the same extent as the '300 patent. (*Supra* §VI.B.1.h.)

8. Claim 8

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 provided in Claim 2. (*Supra* §VI.B.2.)

9. Claim 9

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

10. Claim 10

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 provided in Claim 4. (*Supra* §VI.B.4.)

11. Claim 11

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

12. Independent Claim 12

Claim 12 rendered obvious by Burnett. (Ex. 1002, ¶¶172-185.)

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

If the preamble is limiting, Burnett discloses this limitation. (Ex. 1002, ¶173.) Burnett describes electrical and magnetic stimulation devices to treat OAB and UI. (Ex. 1010, [0002, 0036, 0038, 0070].) However, Burnett includes the same list of over 100 ailments found in the ’300 patent, including “tremor.” (*Id.*, [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”**

Burnett discloses this limitation. (Ex. 1002, ¶¶174-177.) 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, [0109].) An electric pulse controller is a pulse generator. (Ex. 1002, ¶174.)

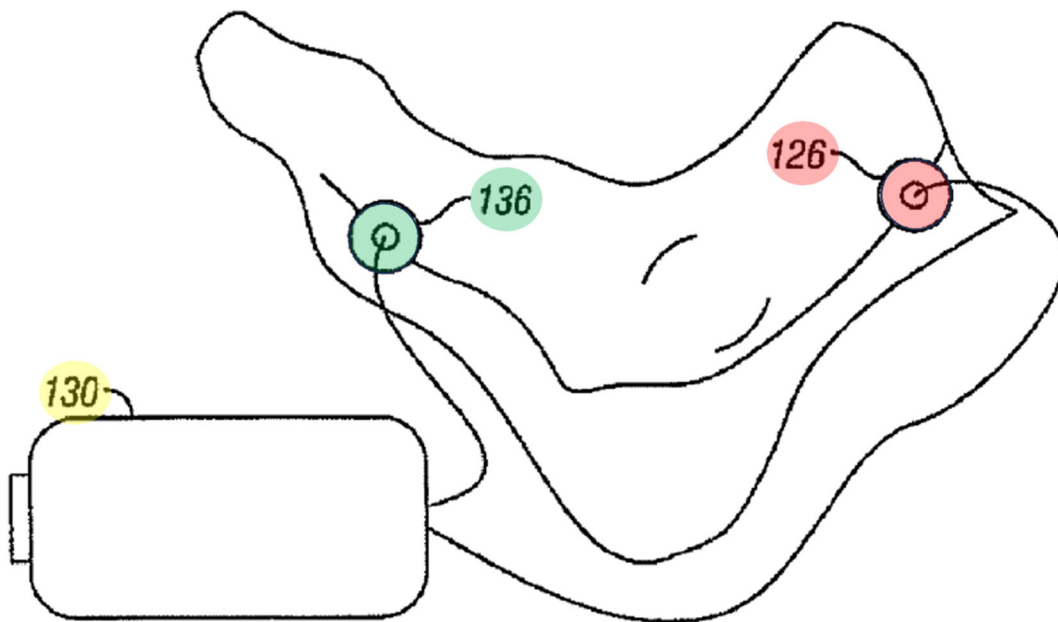


FIG. 11

(*Id.*, Fig. 11.)

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.*, [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 electric conduction in the target nerve.” (*Id.*) In these embodiments, the energy generators are the pulse generators. (Ex. 1002, ¶175.)

Additionally, Figure 26 illustrates an energy emitting system 250 having a microneedle patch 252 and sensor 221. (Ex. 1010, [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.*, [0156].)

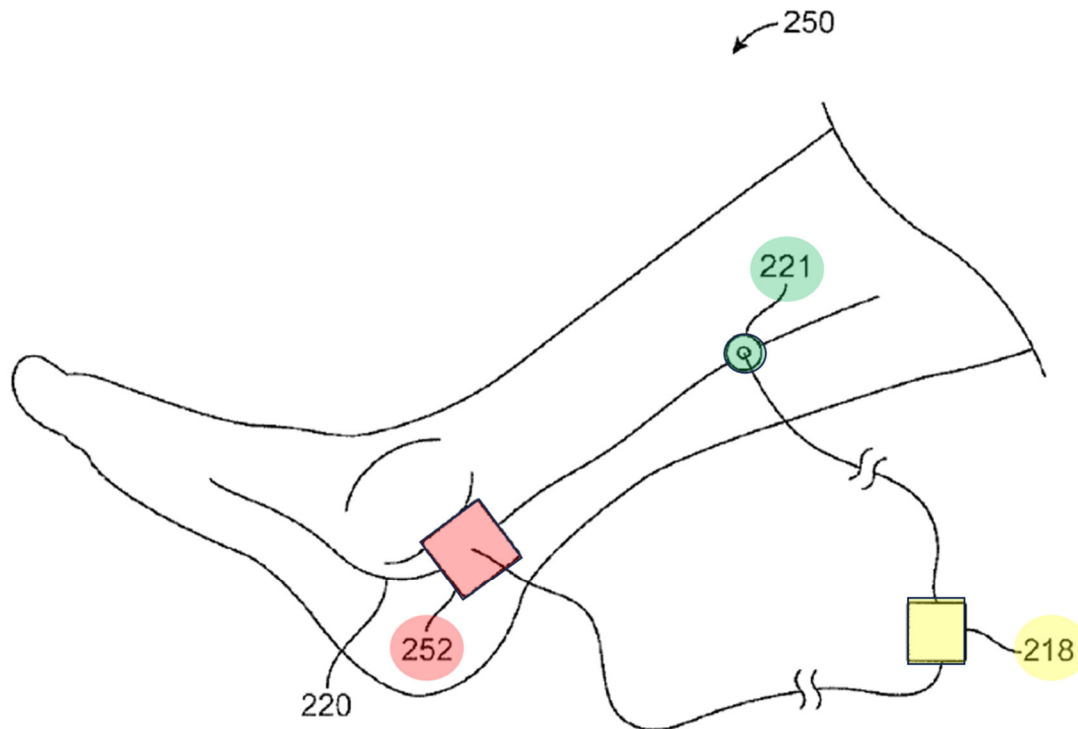


FIG. 26

(*Id.*, Fig. 26.) The controller 218 is the pulse generator in this embodiment. (Ex. 1002, ¶176.)

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 provided in Claim 1. (*Supra* §VI.B.1.b-c.)

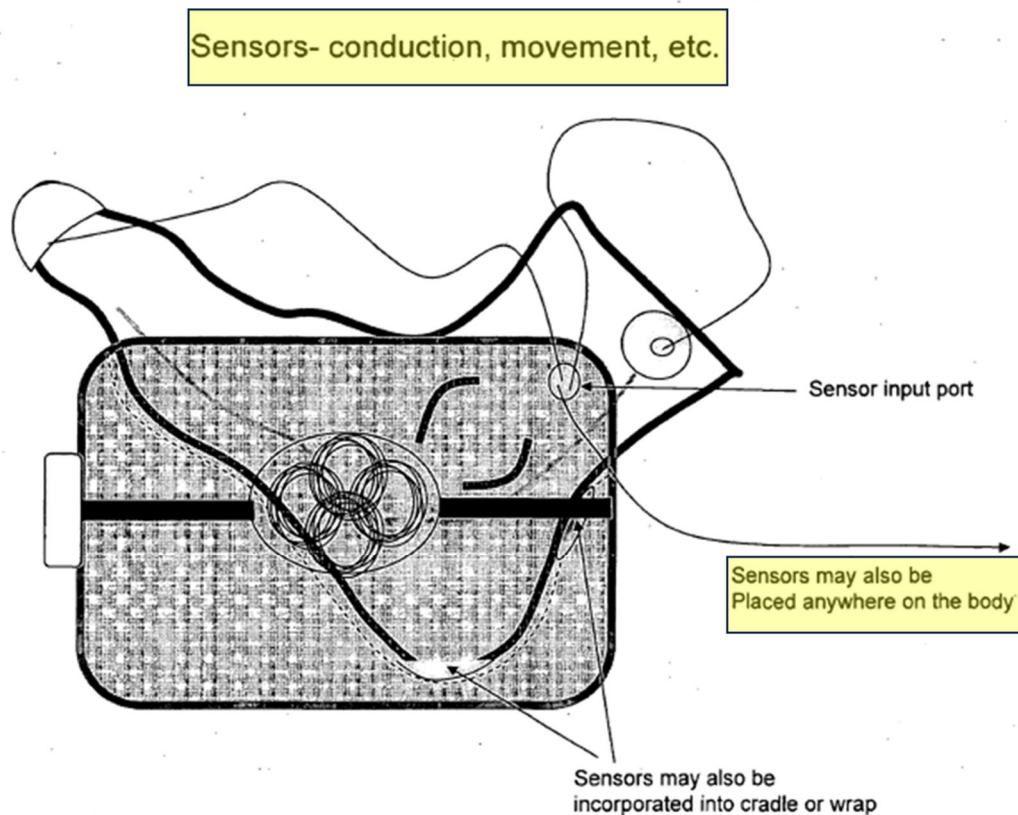
c. **Limitation [B]: “monitoring for a motion of the subject via a sensor positionable on the subject and in communication with the electrical pulse generator”**

Burnett discloses this limitation. (Ex. 1002, ¶¶178-182.) 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, [0101] (emphasis added); *see also id.*, [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. (Ex. 1002, ¶178.)

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, [0128], [0147].) One sensor type known in the art was an accelerometer, which detects motion. (Ex. 1002, ¶179.) For example, Gesotti and Gesotti ’896 disclose accelerometers to detect patient motion. (*See e.g.*, Ex. 1008, Fig. 1 (identifying “accelerometer”); Ex. 1009, Fig. 1 (identifying “motion sensors”).)

Additionally, the ’720 provisional, which is incorporated into Burnett, discloses sensors that respond to a variety of physiologic changes, including patient movements such as twitching. (Ex. 1015, [55].) Like Burnett, the ’720 provisional recognizes that sensors “may also be placed anywhere on the body” to measure physiologic changes:



(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*).”

The handwritten note on lined paper reads: "This sensor may be a separate component (i.e. accelerometer) on the leg or conducting patch along the nerve pathway or may be one or more of the". The phrase "(i.e. accelerometer)" is highlighted in a yellow box. The note is signed "Burnett" and dated "9/15/16".

(*Id.*, 35.)

Additionally, Burnett discloses that “[t]he 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 electric conduction in the target nerve.” (Ex. 1010, [0032].) In this embodiment, the energy generators are the pulse generators. (Ex. 1002, ¶181.)

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

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

Burnett discloses this limitation. (Ex. 1002, ¶¶183-184.) Burnett discloses “[t]he 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 electric conduction in the target nerve.” (Ex. 1010, [0032].)

Similarly, Figure 26 illustrates an energy emitting system 250 having a microneedle patch 252 and *sensor 221*. (Ex. 1010, [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.*, [0156].)

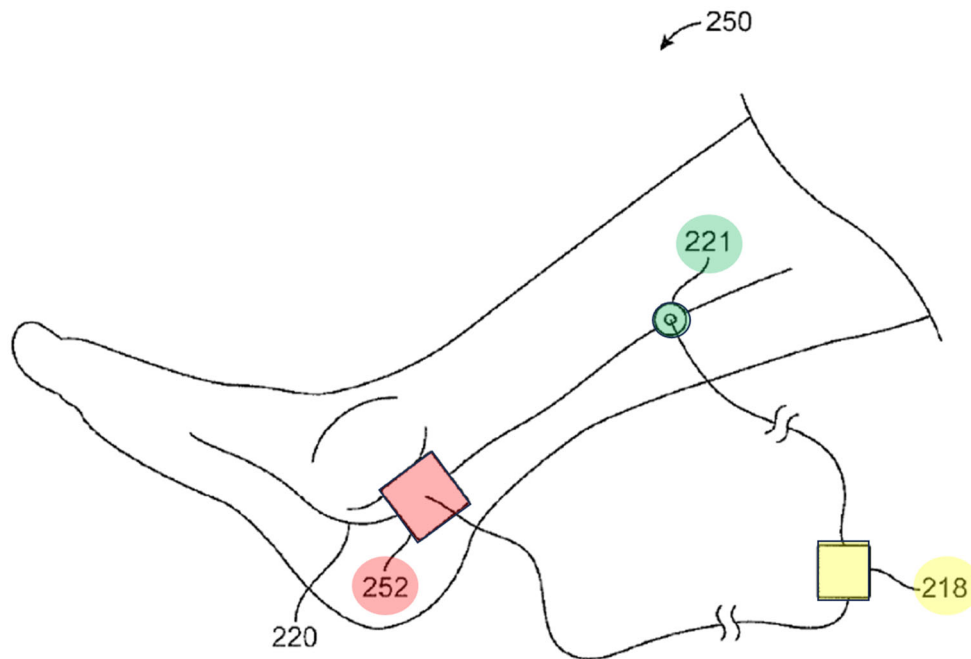


FIG. 26

(*Id.*, Fig. 26.) “Sensor 221 detects electrical conduction through the stimulated posterior tibial nerve 220, and then *transmits the signal to controller 218.*” (*Id.*, [0156] (emphasis added).) Thus, Burnett discloses “receiving a feedback signal via the sensor.” (Ex. 1002, ¶184.)

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.”**

If the '300 patent discloses this limitation, so does Burnett. (Ex. 1002, ¶185.) As explained in Claim 1, Burnett discloses sensors that detect motion of the subject. (*Supra* §VI.B.1.g.) Likewise, as 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 by adjusting or

optimizing the electrical stimulation to the same extent as the '300 patent. (*Supra* §VI.B.1.h.)

13. Claim 13

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 provided in Claim 2. (*Supra* §VI.B.2.)

14. Claim 14

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 provided in Claim 3. (*Supra* §VI.B.3.)

15. Claim 15

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 provided in Claim 4. (*Supra* §VI.B.4.)

16. Claim 16

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 provided in Claim 5. (*Supra* §VI.B.5.)

17. Claim 17

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. (Ex. 1002, ¶¶190-191.)

Figure 26 illustrates an energy emitting system 250 having a microneedle patch 252 and sensor 221. (Ex. 1010, [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.*, [0156].)

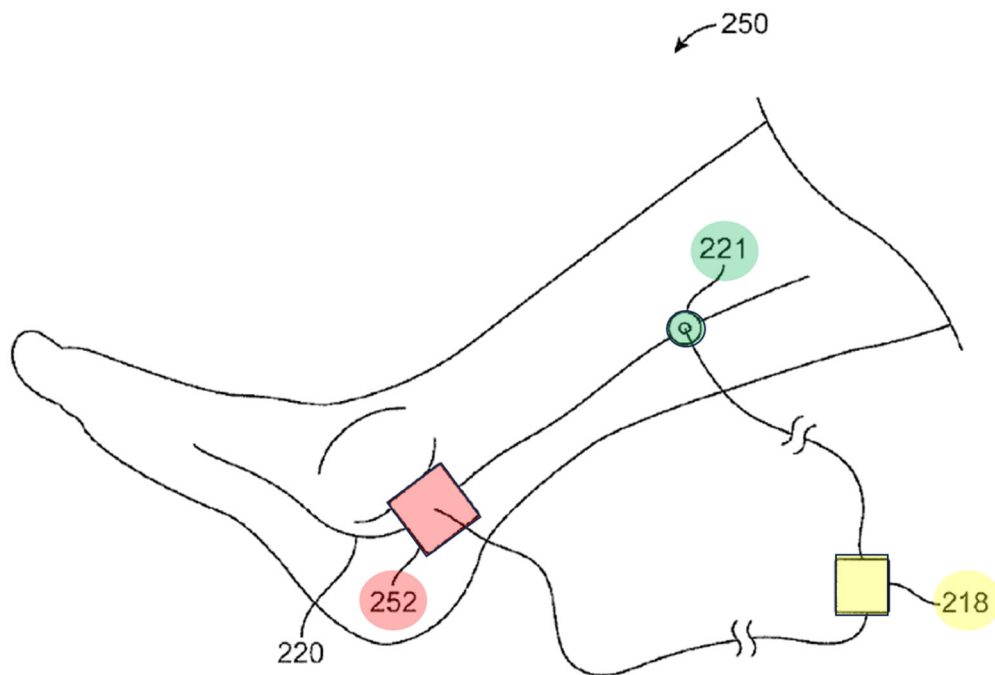


FIG. 26

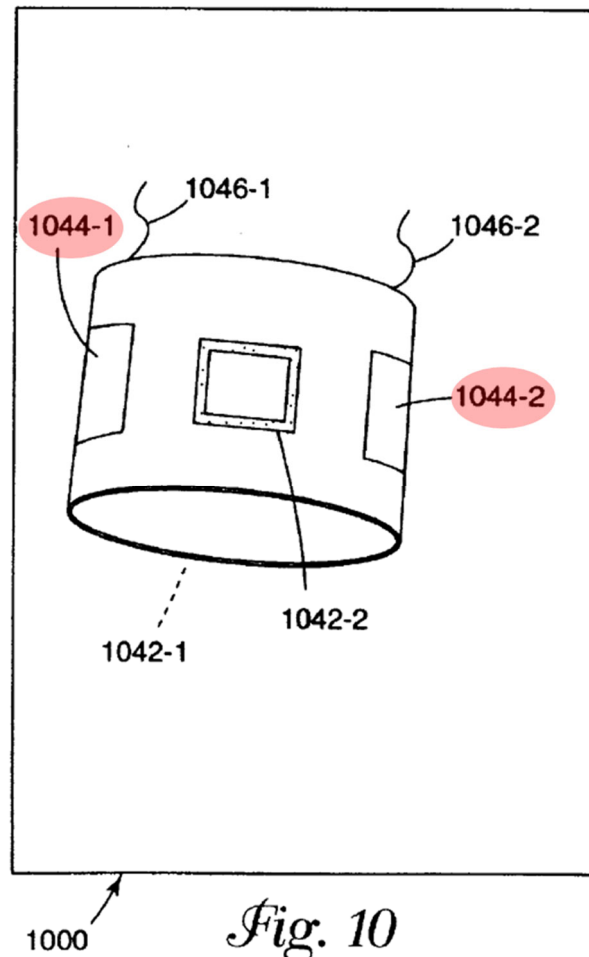
(*Id.*, Fig. 26.) Additionally, the “controller can then be varied or adjusted based on the signal from the sensor 221 to ensure that adequate conduction of the posterior

tibial nerve 220 occurs and an adequate and accurate dosage of treatment is being received.” (*Id.*, [0156].) As explained in 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

As explained in Claim 1, a POSITA 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 POSITA would have also found it obvious to include the electrodes in Burnett’s ergonomic applicators based on Gesotti. (Ex. 1002, ¶192.)

Gesotti discloses “a stimulation and sensing wristband, shown generally at 1000, constructed according to the teachings of the present invention.” (Ex. 1008, 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.*, 9:32-34.)



The wristband in Gesotti is like the ergonomic bands for use on a patient's arm described in Burnett. (Ex. 1010, [0107], Fig. 9C; Ex. 1002, ¶193.) Gesotti would have motivated a POSITA implementing Burnett's devices to place the electrodes within the band, and led to a reasonable expectation of success, because Gesotti's bands are effective for treating tremor. (Ex. 1002, ¶193.)

Alternatively, a POSITA would have been motivated to use the wristband in Gesotti with Burnett's stimulation systems. (Ex. 1002, ¶194.) Gesotti's wristband includes electrical leads that can couple the device to a controller or pulse generator,

as disclosed in Burnett. (*Id.*) Thus, no significant modifications would be necessary to adapt the wristband for use with Burnett’s stimulation systems. (*Id.*)

VII. SECONDARY CONSIDERATIONS

Secondary considerations should be evaluated, but do not control an obviousness conclusion, particularly where, as here, a strong *prima facie* showing of obviousness exists. *Leapfrog Enters. v. Fisher-Price, Inc.*, 485 F.3d 1157, 1162 (Fed. Cir. 2007); *Newell Cos. v. Kenney Mfg. Co.*, 864 F.2d 757, 768 (Fed. Cir. 1988). Petitioner understands that PO does not practice the ’300 patent or sell any products covered by the ’300 patent. Therefore, Petitioner is not aware of any evidence of secondary considerations. (Ex. 1002, ¶21.) Even if PO were to present alleged evidence of secondary considerations, the evidence cannot outweigh the strong *prima facie* case of obviousness. If PO identifies any alleged evidence of secondary considerations in the future, Petitioner respectfully requests an opportunity to respond.

VIII. DISCRETIONARY FACTORS FAVOR INSTITUTION

The Board should not exercise its discretion to deny institution under 35 U.S.C. §§ 314(a) or 325(d). While PO recently filed a lawsuit alleging that Petitioner infringes the ’300 patent, PO has not yet served the complaint on Petitioner and no case schedule has been set. Further, the combination of prior art and arguments set forth above have not previously been considered by the Patent Office. Finally, the

Petition makes a strong showing that claims 1-17 are unpatentable. Accordingly, none of the factors favoring discretionary denial are present here.

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

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

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

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

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

PO recently filed suit against Petitioner alleging infringement of the '300 patent. *EMKinetics, Inc. v. Cala Health, Inc.*, No. 1-24-cv-00250 (D. Del.). PO has not served the Complaint and no case schedule has been set.

Petitioner is not aware of any other judicial or administrative matter that would affect, or be affected by, a decision in this proceeding.

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

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

Lead Counsel	Back-up Counsel
Joshua J. Stowell (Reg. No. 64,096) 2jys@knobbe.com BoxCalaHealth300@knobbe.com	William R. Zimmerman (<i>pro hac vice</i> admission request pending filing) 2wrz@knobbe.com
Knobbe, Martens, Olson, & Bear, LLP <u>Postal and Hand-Delivery Address:</u> 2040 Main St., 14th Floor Irvine, CA 92614 Telephone: 949-760-0404 Facsimile: 949-760-9502	Knobbe, Martens, Olson, & Bear, LLP <u>Postal and Hand-Delivery Address:</u> 2040 Main St., 14th Floor Irvine, CA 92614 Telephone: 949-760-0404 Facsimile: 949-760-9502

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

Please direct all correspondence to lead counsel and back-up counsel at the addresses shown above. Petitioner also consents to electronic service by email to BoxCalaHealth300@knobbe.com.

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

The undersigned authorize the Office to charge the fee set forth in 37 C.F.R. §42.15(a) for this Petition to Deposit Account No. 11-1410. Payment for any additional fees may be charged to the same Deposit Account.

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

Petitioner certifies that the '300 Patent is available for IPR and that Petitioner is not barred or estopped from requesting IPR challenging the patent claims on the identified grounds.

XII. CONCLUSION

Petitioner has established a reasonable likelihood of prevailing in showing that at least one challenged claim is unpatentable, and therefore requests that the Board institute an IPR trial to cancel challenged claims 1-17.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: March 29, 2024

By: /Joshua J. Stowell/

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

Customer No. 20,995

Attorney for Petitioner,
CALA HEALTH, INC.

CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. §42.24(d), the undersigned certifies that the foregoing
PETITION FOR INTER PARTES REVIEW OF U.S. PATENT 11,628,300,
exclusive of the parts exempted as provided in 37 C.F.R. §42.24(a), contains 13,966
words and therefore complies with the type-volume limitations of 37 C.F.R.
§42.24(a).

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: March 29, 2024

By: /Joshua J. Stowell/

Joshua J. Stowell (Reg. No. 64,096)
Customer No. 20,995

Attorney for Petitioner,
CALA HEALTH, INC.

CERTIFICATE OF SERVICE

I hereby certify that, pursuant to 37 C.F.R. §42.105, a true and correct copy of the foregoing **PETITION FOR INTER PARTES REVIEW OF U.S. PATENT 11,628,300 AND EXHIBITS 1001-2017 and 2021** are being served on March 29, 2024, via FedEx Priority Overnight to the correspondence address of record for the subject patent **11,628,300** found on the USPTO's Patent Center webpage.

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KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: March 29, 2024

By: /Joshua J. Stowell/

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

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

Customer No. 20,995

Attorney for Petitioner,
CALA HEALTH, INC.