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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.

IPR2024-00732
U.S. Patent 10,786,669

**PETITION FOR *INTER PARTES* REVIEW OF
U.S. PATENT 10,786,669**

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OTHER AUTHORITIES

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35 U.S.C. §325 83

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EXHIBIT LIST

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

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

Cala Health, Inc. (“Petitioner”) requests *inter partes* review (“IPR”) of claims 1-20 of U.S. Patent No. 10,786,669 (“the ’669 patent,” Ex. 1001), purportedly owned by EMKinetics Inc. (“Patent Owner” or “PO”).

I. SUMMARY OF THE ARGUMENT

Petitioner Cala Health challenges claims 1-20 of the ’669 patent, which recite a method for electrically stimulating tissue or nerves that extend through the hand to mitigate tremor. Claim 1 is the only independent claim.

The ’669 patent focuses on methods for treating overactive bladder (“OAB”) and urinary incontinence (“UI”). (*See e.g.*, Ex. 1001, 2:7-3:12 (“Background of the Invention” discusses only OAB/UI). However, the claims diverge from this central focus of the specification and instead relate to methods for treating tremor. The focus on tremor is surprising because the ’669 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.” (*Id.*, 17:46-18:22.)

Although the ’669 patent does not disclose methods of treating tremor, the prior art extensively discloses such methods. 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.” (*Id.*, 2:16-18.) 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. (Ex. 1007 ("the '707 patent"), Fig. 12.)

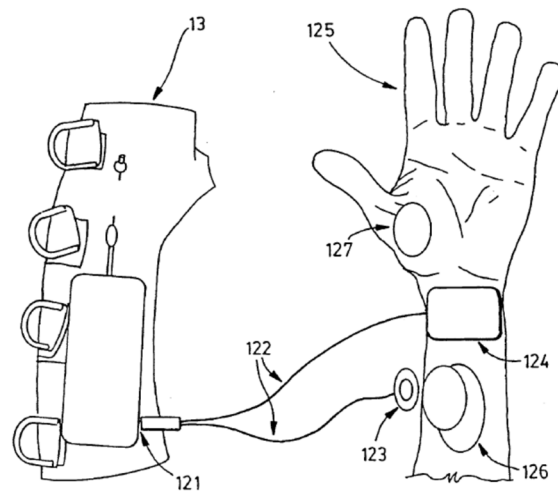


FIG. 12

The disclosed 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 on the glove to detect tremor and uses the feedback to initiate stimulation to mitigate tremor. (*Id.*)

The '707 patent was of record during prosecution of the '669 patent, but the Examiner did not apply the reference. Instead, the Examiner rejected the '669 patent claims based on Zou (Ex. 1017). (Ex. 1004, 109-112.) Zou describes placing

electrodes over nerves running through the palm and back of the hand to stimulate the underlying nerve and reduce pain. (Ex. 1017, [0015], [0032], Figs. 2, 8.)

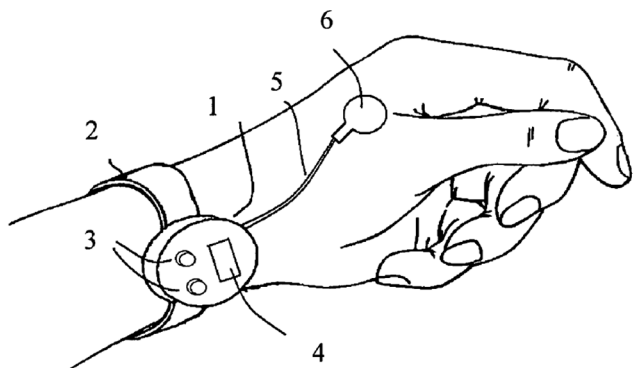


Fig. 2

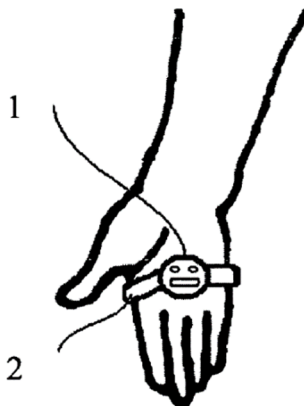


Fig. 8

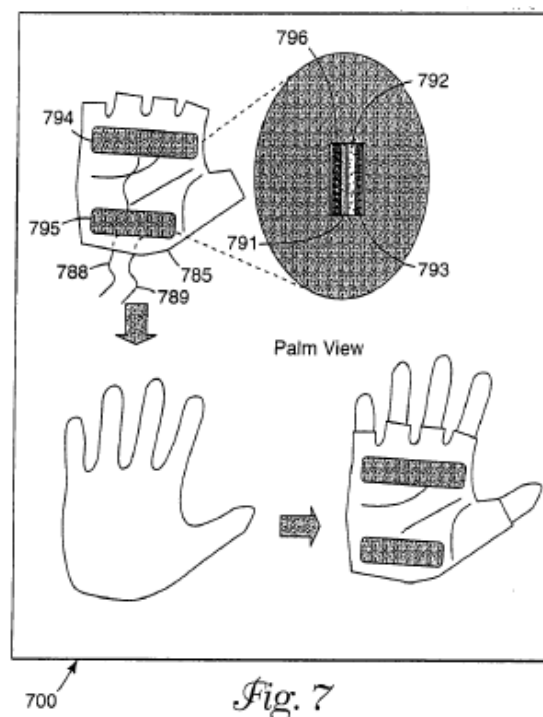
PO argued that Zou did not render the claims obvious because Zou allegedly did not disclose “electrical stimulation through the glabrous¹ skin surface which overlies the palm of the hand.” (*Infra* §III.B (prosecution history).) This argument was incorrect as evidenced by Zou’s Figure 8 above, which illustrates electrical stimulation through the patient’s palm. The Examiner did not address this inaccurate characterization by PO.

PO also argued that Zou does not describe the treatment of tremor and that a secondary reference (Ex. 1018 (“Gliner”)) that describes treating tremor was non-analogous art because it discloses implantable electrodes, as opposed to electrodes placed on skin surfaces. (*Infra* §III.B.) Unfortunately, the Examiner never combined

¹ “Glabrous” means “smooth or hairless.” (Ex. 1013.)

Zou with the '707 patent, which discloses the treatment of tremor using similar stimulation devices, or any other prior art disclosing the treatment of tremor with surface electrodes. The Examiner subsequently allowed the claims.

In this IPR, Petitioner relies on patents (Gesotti and Gesotti '896) that were not of record during prosecution of the '669 patent and that disclose the limitations allegedly missing from the examined prior art. (Exs. 1008 (U.S. Patent No. 6,704,603) -1009 (U.S. Patent No. 7,369,896).) Gesotti claims a “method of cu[r]ing an individual exhibiting one or more symptom’s [sic] of Parkinson’s disease” including “*tremor.*” (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 shown below:



(*Id.*, 8:20-26, Figs. 7-9 (emphasis added).)

Gesotti '896 discloses improvements to Gesotti and incorporates Gesotti by reference. (Ex. 1009, 1:11-17, 5:60-6:2.) Like Gesotti, Gesotti '896 discloses “systems and method for relieving symptoms of Parkinson’s disease.” (*Id.*, 1:22-24.) The system uses motion sensors to determine when electrical stimulation is required to correct neurological disorders such as tremor. (*Id.*, 3:62-4:15.)

Petitioner also relies on Burnett to demonstrate unpatentability of the '669 patent. (Ex. 1010 (“Burnett”).) The '669 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 '669 patent and Burnett. Moreover, Burnett published over one year before the earliest possible priority date for the '669 patent and, therefore, qualifies as prior art.

Burnett contains significant portions of the '669 patent specification. Like the '669 patent, Burnett discloses methods of electrically stimulating nerves and tissue using electrodes placed on skin surfaces. (Ex. 1010, [0102].) Burnett also discloses the same list of over 100 medical ailments found in the '669 patent, including tremor. (*Id.*, [0111].) Thus, if the '669 patent adequately discloses methods of treating tremor, so does Burnett.

The references relied upon herein, Gesotti, Gesotti '896, and Burnett, anticipate claims 1-20 of the '669 patent or render them obvious. As a result, the Board should institute this IPR and cancel challenged claims 1-20.

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 '669 patent.

III. THE '669 PATENT

A. Overview

The '669 patent primarily focuses on treating OAB and UI by stimulating nerves in the feet and legs. (Ex. 1001, 2:7-3:12.) Moreover, the '669 patent mostly describes “apparatus and methods for providing magnetic induction therapy,” which is not the focus of the claims. (*Id.*, 8:24-26). A smaller segment of the patent, however, describes methods for treating ailments by providing “electrical energy” to a target nerve. (*Id.*, 8:45-49.)

In one embodiment, for example, the '669 patent describes “electrodes designed for the palmar surface of the hands along with F/M wave detecting electrodes 6105.” (*Id.*, 62:15-17.) 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.*, 62:17-20.) The '669 patent states, “electrical stimulation of the hand will stimulate the Median or the Ulnar nerve or both.” (*Id.*, 62:23-25, Fig. 61A.)

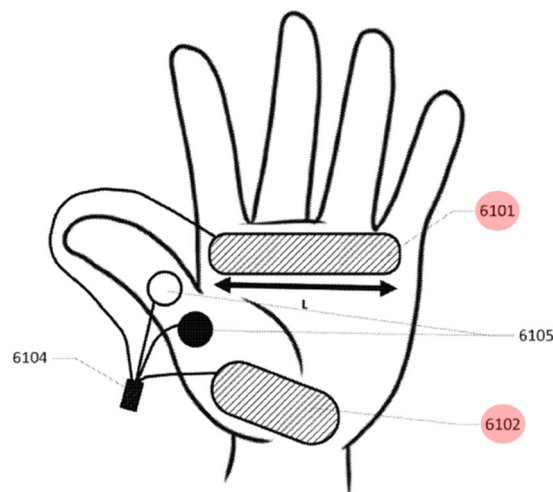


FIG. 61A

The '669 patent alleges that the electrical stimulation of the ulnar or median nerves may “treat various neurological conditions, including neuropathies, migraine, pain, headaches, depression, epilepsy, post-traumatic stress disorder, overactive bladder, incontinence, subcutaneous fat, effects of stroke, memory enhancement, etc.” (*Id.*, 59:15-24.) Notably, the list of conditions does not include tremor.

In fact, despite requiring the treatment of tremor in every claim, the '669 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 '669 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 '669 patent on March 30, 2017. The filed claims described a method of providing transdermal electrical stimulation therapy “so that pain felt by the subject is mitigated.” (Ex. 1004, 491.) PO later filed a preliminary amendment that replaced mitigating pain with “treating tremors.” (*Id.*, 230.) PO also eliminated limitations restricting the claims to “a glabrous skin surface overlying a palm.” (*Id.*)

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

positioning a stimulator electrode over a ~~glabrous~~ skin surface overlying a target nerve or tissue which extends through a hand palm of the subject; [[and]]

delivering electrical stimulation via a pulse generator transdermally through the ~~glabrous~~ skin surface and to the [[a]] target nerve or tissue ~~within the hand~~ to stimulate the target nerve or tissue ~~within the hand~~ so that tremors experienced ~~pain felt~~ by the subject are [[is]] mitigated; and

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

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

The Examiner rejected the claims under §103 based on Zou and additional references, including an article describing “Transcutaneous Electrical Nerve Stimulation” (“Chang,” Ex. 1020) and Gliner (Ex. 1018). (Ex. 1004, 108-112.) The Examiner found that Zou taught all the claim limitations except “the stimulation mitigates tremors, detecting motion using a sensor positioned on the subject, or using that sensor reading in a feedback loop to modify stimulation.” (*Id.*, 110.) However, the Examiner found that Chang and Gliner disclosed methods of mitigating tremor, and the other missing limitations, and that it would have been obvious to modify Zou to treat tremor as taught in Chang and Gliner. (*Id.*, 110-111.)

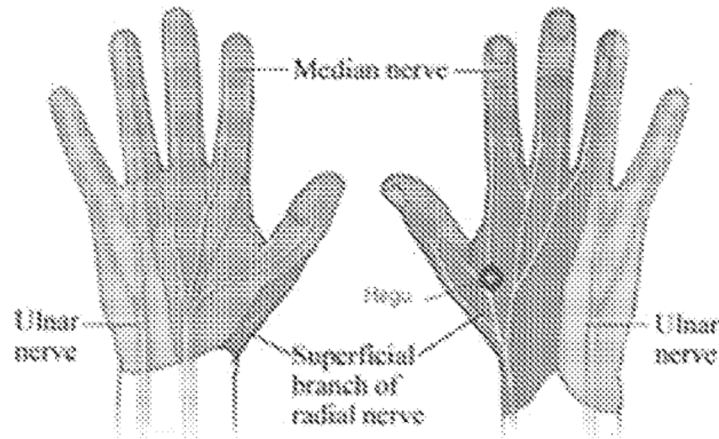
PO responded by filing substantially amended claims (below) that reintroduced certain terms PO had eliminated in the preliminary amendment, including “glabrous” and “palm.” (*Id.*, 89-92.) However, PO represented to the Examiner that the claims were “previously presented” and did not identify the amendments by underline and strikethrough as required by 37 C.F.R. §1.121(c).

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

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

(*Id.*, 89.)

PO relied on the reintroduced terms to distinguish Zou, which PO characterized as disclosing stimulation of the radial nerve along the back of the hand. (*Id.*, 94.) PO argued the “radial nerve does not extend along the palmar surface of the hand and cannot be stimulated by application of electrical stimulation through the *glabrous skin surface which overlies the palm of the hand.*” (*Id.* (emphasis added).) PO argued, “it is the median nerve and the ulnar nerves which innervate the glabrous skin surface and are wholly distinct from the radial nerve.” (*Id.*) PO included a diagram to illustrate the nerves and argued that stimulating the radial nerve “cannot [be] the same as delivering stimulation to the glabrous surfaces.” (*Id.*)



PO argued that the prior art “fail[ed] to teach delivering electrical stimulation through the *glabrous skin surface*.” (*Id.* (emphasis added).)

PO also argued that the Examiner erred in relying on Chang because the reference “fails to teach any mitigation of tremors.” (*Id.*, 95.) PO also argued that Gliner “is a completely non-analogous reference to the teachings of either Zou or Chang” because “Gliner teaches the use and implementation of a neural stimulation device which is implanted directly within the brain of a patient...” (*Id.*, 95-96.)

In the next Office Action, the Examiner made only a double-patenting rejection. (*Id.*, 76-80.) The Examiner did not make any additional prior art rejections, evidently accepting PO’s narrowing of the claims to a “glabrous skin surface” on the “palm.” Yet, in response to the double-patenting rejection, PO again amended the claims to eliminate the limitations it relied on to overcome Zou, Chang, and Gliner, including the limitations restricting the claims to electrodes placed over a “glabrous” skin surface and a target nerve or tissue that extends through a “palm”:

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

(*Id.*, 62-65.) PO did not notify the Examiner that it was attempting to withdraw its previous disclaimer of non-glabrous skin surfaces and tissue or nerves running through other parts of the hand beside the palm. PO also did not notify the Examiner that the prior art may need to be revisited. *Hakim v. Cannon Avent Grp. PLC*, 479 F.3d 1313, 1318 (Fed. Cir. 2007) (“Although a disclaimer made during prosecution can be rescinded, permitting recapture of the disclaimed scope, the prosecution history must be sufficiently clear to inform the examiner that the previous disclaimer, and the prior art that it was made to avoid, may need to be re-visited.”). Consequently, the Examiner did not revisit the prior rejections and allowed the overly broad claims. (Ex. 1004, 19-21.)

C. Applicable Priority Date

The '669 patent's priority claim is convoluted and includes three branches. Due to several defects, PO is not entitled to the earliest claimed priority date of

October 2, 2006. Instead, the earliest possible priority date for the '669 Patent is **September 20, 2011**.

The '669 patent claims priority through two different sets of continuation and continuation-in-part applications and separately to one provisional application. (Ex. 1001, 1:6-25.) The provisional application (62/350,610) was not filed until 2016 and is not relevant to this 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. (Ex. 1001, 1:6-25.) 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 patent is not entitled to the September 20, 2010 filing date of the '680 Provisional because the provisional does not disclose treating or mitigating tremor, an element of all the '669 patent claims. (Ex. 1012, [0017] (list 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 '669 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 Application No. 12/508,529 (“the '529 Application”), and then to additional prior applications. (Ex. 1001, 1:15-25.) The '529 Application published as Burnett on July 1, 2010. (Ex. 1010.) However, PO abandoned Burnett by February 10, 2016. (Ex. 1014, 1.) Because PO did not file the application that 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 '669 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 IPR “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); *Phillips v. AWH Corp.*, 415 F.3d 1303, 1309 (Fed. Cir. 2005).

PO distinguished the prior art by arguing that the ’669 patent claims require “electrical stimulation through the ***glabrous skin surface which overlies the palm of the hand.***” (*Supra* §III.B.) In doing so, PO clearly and unmistakably disclaimed electrical stimulation of non-glabrous skin surfaces and skin surfaces that are not on the palm. (*Id.*); *see Biogen Idec, Inc. v. GlaxoSmithKline LLC*, 713 F.3d 1090, 1095 (Fed. Cir. 2013) (“when the patentee unequivocally and unambiguously disavows a certain meaning to obtain a patent, the doctrine of prosecution history disclaimer narrows the meaning of the claim consistent with the scope of the claim surrendered”). Despite later amending the claims, PO never clearly disclosed that it was withdrawing its disclaimer or notified the Examiner that the disclaimer needed to be revisited. (*Supra* §III.B.) Consequently, the proper construction of “skin surface” in the ’669 patent claims is “glabrous skin surface which overlies the palm of the hand.”

This construction and PO's disclaimer are consistent with the '669 patent specification. The specification describes positioning electrodes on a glabrous skin surface that overlies a palm of the hand to electrically stimulate the underlying nerves and tissue. (*Supra* §III.A; Ex. 1001, 62:15-52, Figs. 61A-61D.)

In this IPR, Petitioner relies upon prior art, such as Gesotti, that discloses stimulation through the “glabrous skin surface which overlies the palm of the hand.” However, if the Board determines that “skin surface” includes non-glabrous skin surfaces and skin surfaces not on the palm, Petitioner has also relied on Burnett, which discloses stimulating other skin surfaces (e.g., arm) in a way that satisfies the claims.

Petitioner does not believe any other terms require construction to resolve the patentability issues herein. *See* Consolidated Patent Trial Practice Guide at 44 (November 2019); *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017). 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 1-20 based on the following grounds of unpatentability:

Ground	Claims Challenged	35 U.S.C. §	References
1	1, 3-6, 9-10, 12-13, 16, 18-20	102	Gesotti
2	1, 3-7, 9-13, 16, 18-20	103	Gesotti
3	2, 8, 17	103	Gesotti and Gesotti '896
4	14-15	103	Gesotti and Stephens
5	1-12, 16, 18-20	102	Burnett
6	1-12, 16, 18-20	103	Burnett
7	13	103	Burnett and Gesotti
8	14-15	103	Burnett and Stephens
9	17	103	Burnett and Gesotti '896

B. The Asserted References Are Prior Art

The earliest possible priority date for the '669 patent is September 20, 2011. (*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, Burnett claims priority to Provisional Application 60/848720 (“the ’720 provisional,” Ex. 1015), which Burnett incorporates by reference. (Ex. 1010, [0001].)² The ’720 provisional is prior art under pre-AIA 35 U.S.C. §102(b) because the ’720 provisional was available to the public at least by July 1, 2010, the date on which Burnett published, which is more than one year before the ’669 patent’s earliest priority date (September 20, 2011).³ Members of the interested public could have located the ’720 provisional because it was expressly referenced by application number in Burnett, which was indexed and searchable in the USPTO’s database of patent publications. *See Bruckelmyer v. Ground Heaters, Inc.*, 445 F.3d 1374, 1379 (Fed. Cir. 2006) (holding figures in the public prosecution history were printed publications because the patent issuing from the application was indexed and served as a “research aid” to locate the figures).

² There was no co-pendency between the ’669 patent and ’720 provisional.

³ The ’720 provisional was also publicly available by December 11, 2008, when Patent Publication No. 2008/0306325 (“the ’325 publication,” Ex. 1016) published pursuant to 37 C.F.R. §1.14 (a)(1)(v). The ’720 provisional is prior art under §102(b) for this additional reason.

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 '669 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, 3-7, 9-13, 16, 18-20 Are Anticipated Or Rendered Obvious by Gesotti

1. Independent Claim 1

Claim 1 is anticipated or rendered obvious by Gesotti. (Ex. 1002, ¶¶46-69.)⁴

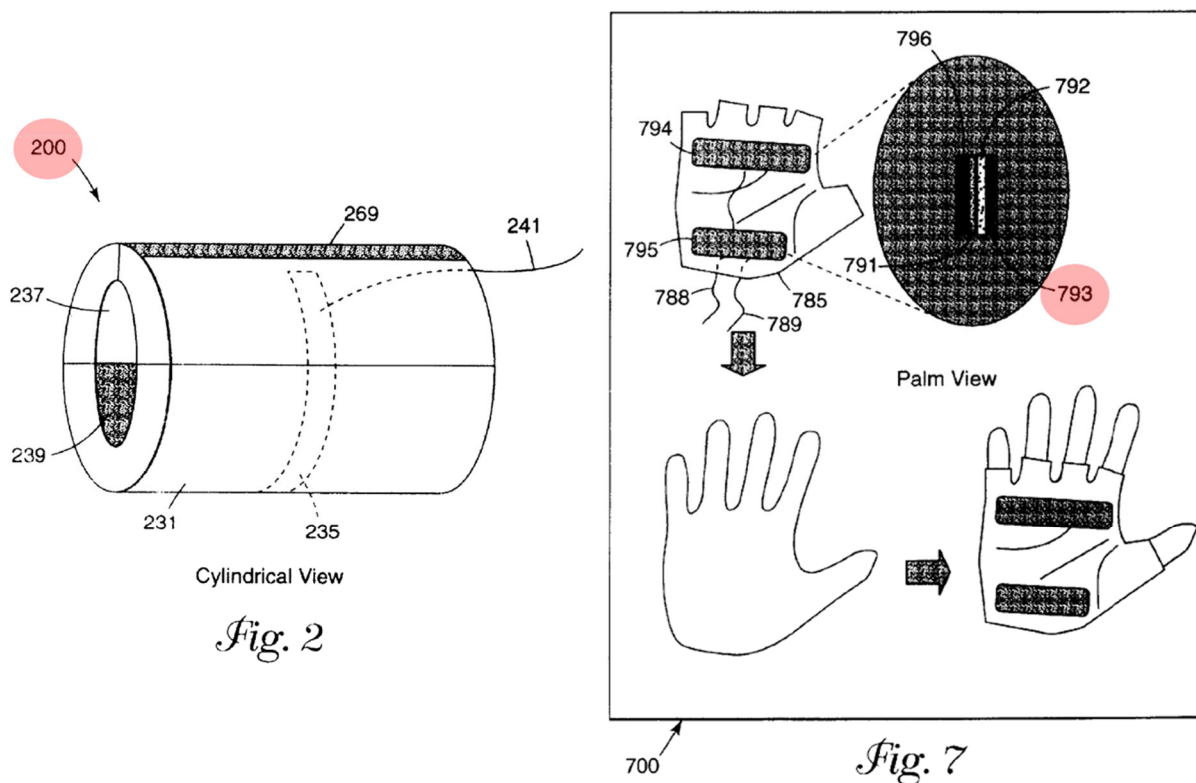
⁴ “It is well settled that a ‘disclosure that anticipates under §102 also renders the claim invalid under §103, for anticipation is the epitome of obviousness.’” *Realtime Data, LLC v. Iancu*, 912 F.3d 1368, 1373 (Fed. Cir. 2019).

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

If the preamble is limiting, Gesotti discloses this limitation. (Ex. 1002, ¶¶47-50.) 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; *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 the one or more symptoms of Parkinson’s disease comprise *tremor*, rigidity, akinesia, bradykinesia and drooping head.” (*Id.*, claims 1-2 (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 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 aspects of the electrical stimulation, such as frequency, based on the sensor information. (*Id.*, 4:11-20.)

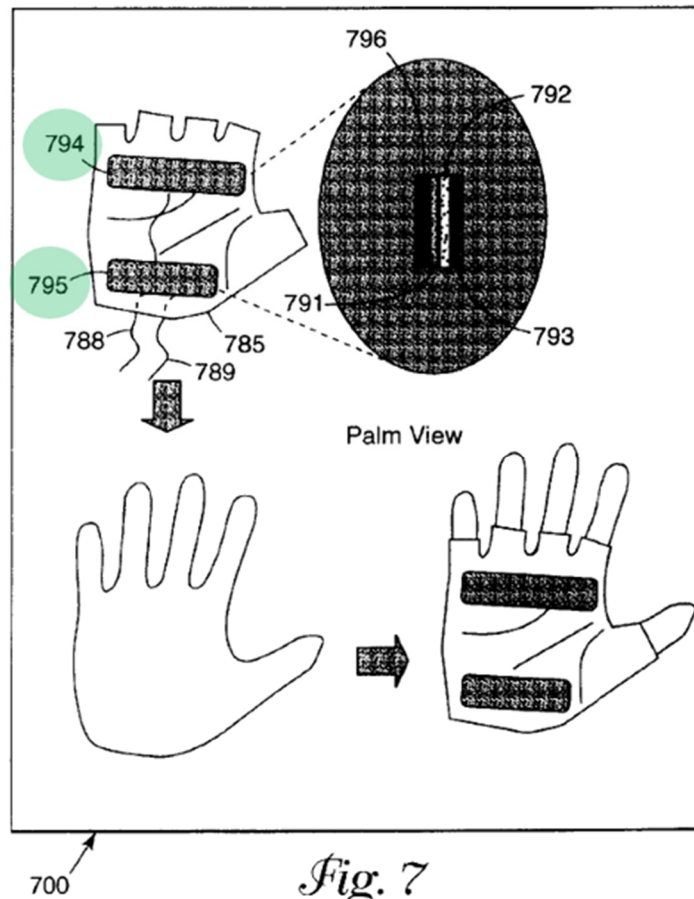
Gesotti discloses various transdermal stimulation electrodes, including “cylindrical stimulation electrode[s]” 200 [red] to fit around “fingers, thumbs, wrist, ankle, and other cylindrically shaped regions of the body” (below left) and “stimulation electrode[s] 793” [red] attached to a “tactile sensor and stimulation glove” (below right):



((*Id.*, 5:38-52, 8:16-35, Figs. 2, 7-9.)

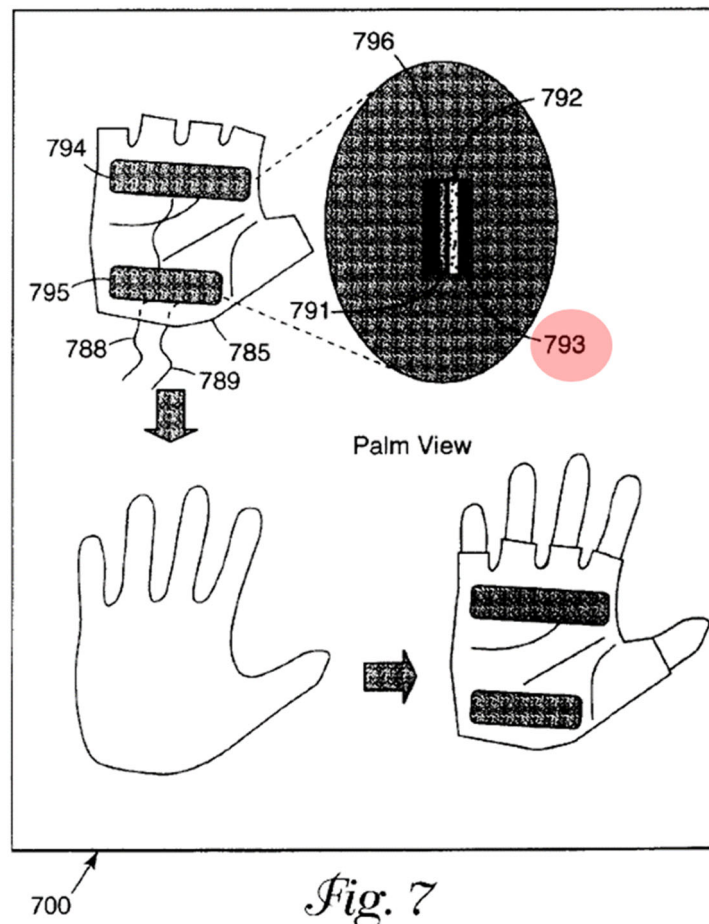
b. **Limitation [A]: “positioning a stimulator electrode over a skin surface overlying a target nerve or tissue which extends through a hand of the subject”**

Gesotti discloses this limitation. (Ex. 1002, ¶¶51-57.) Gesotti describes a “tactile sensor and stimulation glove 785” that “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).)

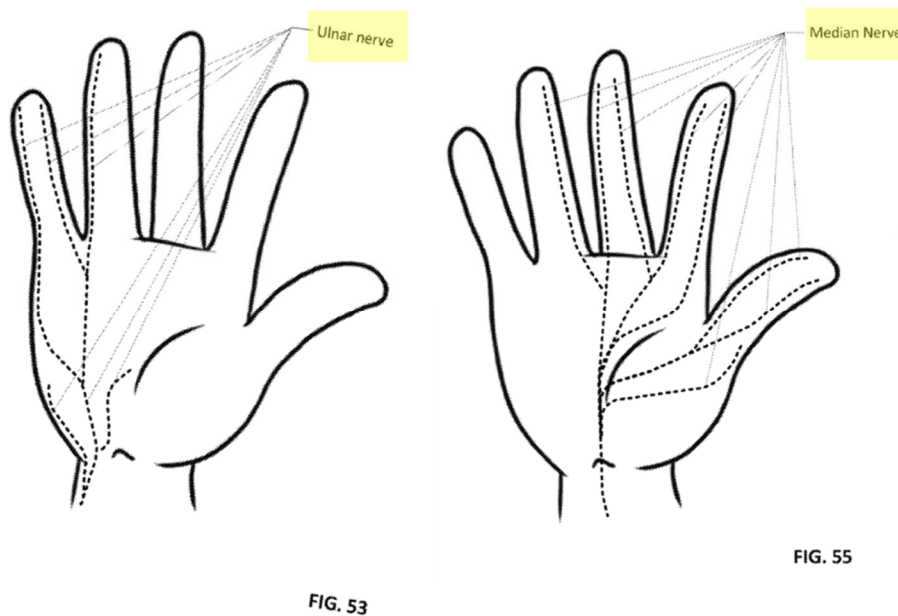


The stimulation electrodes 793 are positioned over, and in contact with, the tissue of the patient's palm and, therefore, satisfy the limitation "positioning a stimulator electrode over a skin surface overlying a target...*tissue* which extends through a hand of the subject." (Ex. 1002, ¶53.)

The stimulation electrodes 793 are also positioned "over a skin surface overlying a target *nerve*...which extends through a hand of the subject." (*Id.*, ¶54.) The ulnar and median nerves extend beneath the palm from the wrist to the fingers and pass beneath the stimulation electrodes 793 in Gesotti's stimulation glove. (*Id.*;

see Ex. 1001, Figs. 51-55 (identifying ulnar/median nerves); Ex. 1004, 94 (arguing median/ulnar nerves “innervate” the palm).)

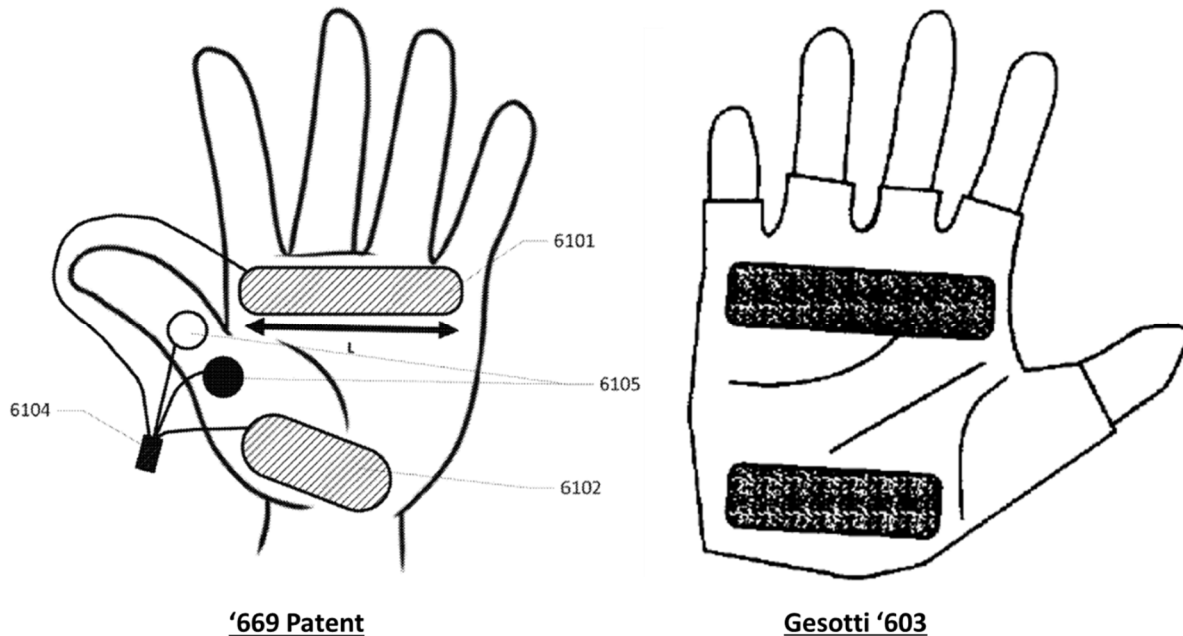
The '669 patent confirms that Gesotti's electrodes overlay the ulnar and median nerves. Figures 53 and 55 of the '669 patent illustrate the ulnar and median nerves [yellow] below the palm:



(Ex. 1001, 7:46-56, Figs. 53, 55.) Gesotti's stimulation electrodes 793 overlay both nerves because the electrodes extend across the upper and lower palm. (Ex. 1008, Fig. 7; Ex. 1002, ¶55.)

The '669 patent's Figure 61A further confirms that Gesotti's electrodes overlay the ulnar and median nerves. (Ex. 1001, 62:37-41, Fig. 61D.) The '669 patent states that the electrode patches illustrated in Figure 61D (below left) “can be used to alternatively stimulation [sic] the Ulnar and Median nerve....” (*Id.*) The

electrodes in the '669 patent's Figure 61D (below left) are in the same position as the electrodes in Gesotti's Figure 7 (below right):



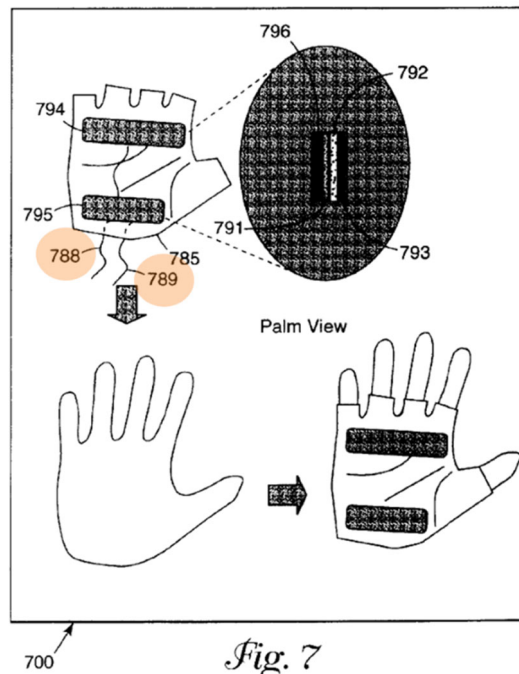
(Ex. 1001, Fig. 61A (excerpted); Ex. 1008, Fig. 7 (excerpted).)

Thus, the stimulation electrodes 793 described in Gesotti meet this limitation.

(Ex. 1002, ¶57.)

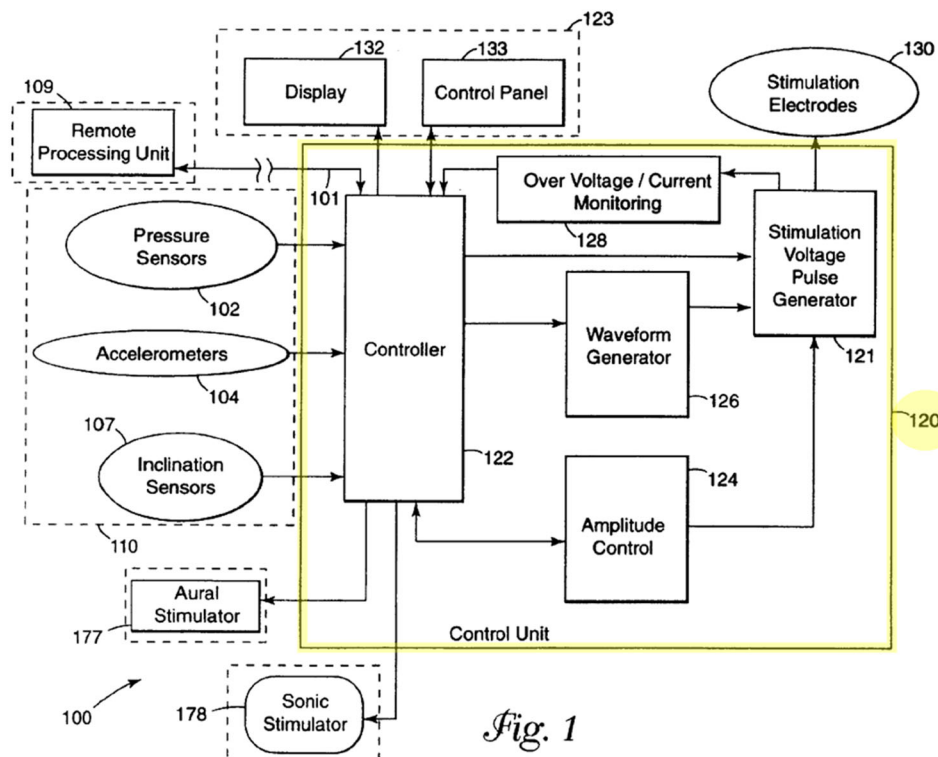
- c. **Limitation [B]: “delivering electrical stimulation via a pulse generator transdermally through the skin surface and to the target nerve or tissue to stimulate the target nerve or tissue so that tremors experienced by the subject are mitigated”**

Gesotti discloses this limitation. (Ex. 1002, ¶¶58-65.) The “first tactile sensor assembly 794 is coupled to a first electrical lead 788 [orange] and the second tactile sensor assembly 795 is coupled to a second electrical lead 789 [orange].” (Ex. 1008, 8:26-29.)



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

Control unit 120 [yellow below] is described in Figure 1. (*Id.*, 3:55-57.)



(*Id.*, 4:44-48.)

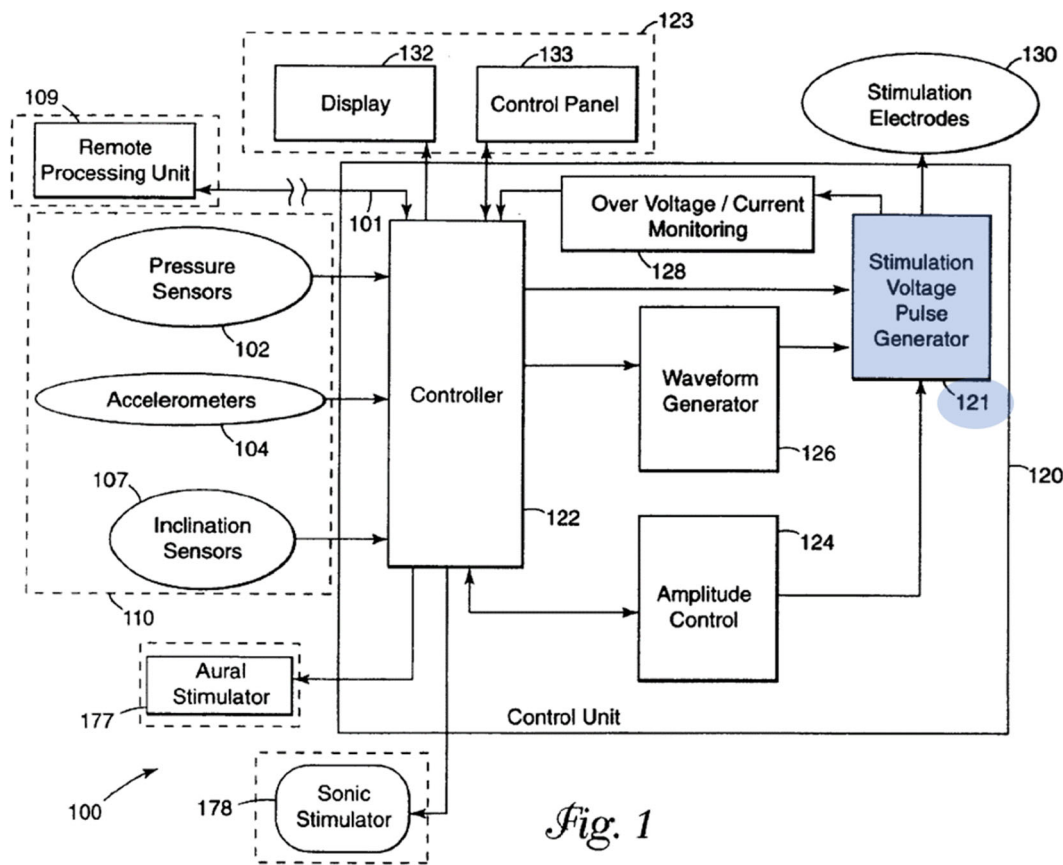


Fig. 1

The stimulation electrodes 793 attached to Gesotti's glove are positioned over target nerves and tissue in the patient's palm. (*Supra* §VI.A.1.b.) Gesotti's glove delivers electrical stimulation via the stimulation voltage pulse generator 121 transdermally through the palm (i.e., skin surface) and to the target nerve or tissue to stimulate the target nerve or tissue. (*See e.g.*, Ex. 1008, 2:18-38 ("The at least one stimulation electrode is adapted to provide stimulation to an area of the body of a living subject...The adaptive stimulator is adapted to selectively provide stimulation

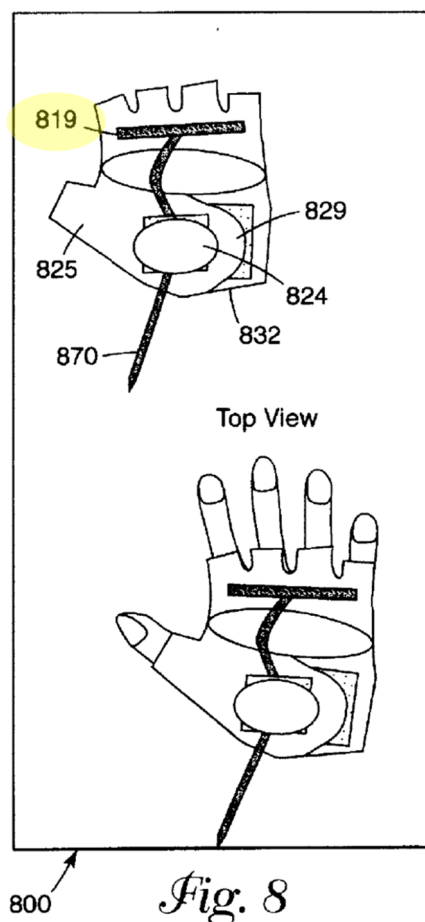
in response to the control unit.”); 4:8-11 (“Control unit 120 receives the information and uses the information to determine when electrical stimulation is required at the location of each stimulation electrode 130.”); Ex. 1002, ¶62.)

Gesotti discloses that the described inventions, including the stimulation glove, deliver electrical stimulation to mitigate the symptoms of Parkinson’s disease, including tremor. (*See e.g.*, Ex. 1008, claims 1-2, 1:14-16, 1:58-2:17, 2:39-50, 3:34-38, 11:46-65, 15:1-3.) Figure 16 provides “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 “receives one or more input signals from at least one sensor such as a pressure, inclination, acceleration or the like, wherein the input signals are based on physical stimulus.” (*Id.*, 11:49-52.) In the case of tremor, the glove detects movement of the hand through, at least, an acceleration sensor. (Ex. 1002, ¶64.) If the input signal received from the sensor meets defined criteria, the glove “generates one or more stimulation signals,” which are transmitted to the stimulators (e.g., electrodes). (Ex. 1008, 11:53-64.) The system can then further adjust the “electrical stimulation signal based on sensor information.” (*Id.*, 4:11-14.)

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

Gesotti discloses this limitation. (Ex. 1002, ¶¶66-69.) Gesotti discloses a stimulation glove that combines the features of Figures 7 and 8 (the “integrated

tactile sensor and stimulation glove”). (Ex. 1008, 8:65-9:2, Figs. 7-9.) The stimulation glove 825 includes “a wire connector 819 [yellow] for connection to additional sensors such as...acceleration or pressure sensors attached to the wrist, forearm, upper arm or the like.” (*Id.*, 8:39-43, Fig. 8.) These sensors are “positioned on the subject.” (Ex. 1002, ¶67.)



The acceleration sensor detects 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)...”) (emphasis added); 12:28-30 (“the control unit receives inputs that

indicate little or no motion (acceleration) at the wrist.”); Ex. 1002, ¶68.) Gesotti’s method of treating Parkinson’s 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.)

2. Claim 3

Claim 3 depends from claim 1 and recites: “wherein the stimulator electrode is a surface electrode.” Gesotti discloses this claim. (Ex. 1002, ¶¶70-71.)

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

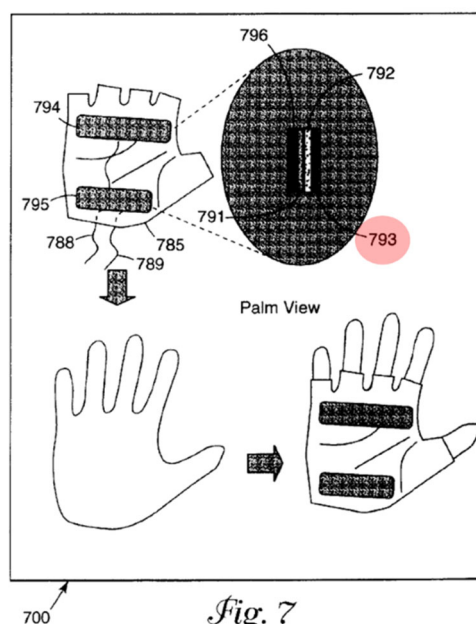


Fig. 7

Thus, the electrode is a “surface electrode” because it is in direct contact with the palm. (Ex. 1002, ¶71.)

3. Claim 4

Claim 4 depends from claim 1 and recites: “wherein the electrical stimulation is delivered intermittently or on a chronic basis.” Gesotti discloses this claim. (Ex. 1002, ¶¶72-78.)

Gesotti discloses devices that “provide patients affected with Parkinson’s disease relief from the symptoms.” (Ex. 1008, 2:5-10.) The devices are “adapted to selectively provide stimulation in response to” signals received from sensors. (*Id.*, 14:3-9.) The adaptive stimulator’s control unit 120 “selectively adjusts...modulation type and the like of each electrical stimulation signal based on sensor information.” (*Id.*, 4:11-14.) The “[m]odulation type allows selection of one of a collection of dynamic waveform changes that vary amplitude, frequency or pulse width in some predetermined manner.” (*Id.*, 4:15-20.) Gesotti explains that in “some applications, the body adapts to static waveforms decreasing sensitivity and this modulation feature prolongs stimulation effectiveness.” (*Id.*) By modulating, for example, frequency and pulse width, the electrical stimulation is provided intermittently (i.e., not between pulses). (Ex. 1002, ¶73.)

Additionally, Figure 16 illustrates “one embodiment of a method of adaptive stimulation for the treatment of the symptoms of Parkinson’s disease....” (Ex. 1008,

11:46-49.) The device receives input signals from one or more sensors based on physical stimulus and determines whether the signals meet defined criteria. (*Id.*, 11:49-64.) If the signal does not meet the criteria, the device continues to monitor the signals. (*Id.*) If the signal meets the criteria, the device generates a stimulation signal **and** “continues to monitor the input signals while the method proceeds.” (*Id.*, 11:59-64; *see also* Ex. 1008, 12:39-50 (describing methods of adjusting the “cadence” of stimulation).) Thus, the device intermittently delivers electrical stimulation based on whether the criteria is met. (Ex. 1002, ¶74.)

Figure 16 describes methods of treating symptoms of Parkinson’s disease “according to the teachings of the present invention,” and Figures 7-9 also disclose embodiments “of the present invention.” (Ex. 1008, 8:16-19, 11:46-49.) Accordingly, a POSITA would have understood that the stimulation glove may use the method in Figure 16. (Ex. 1002, ¶75.)

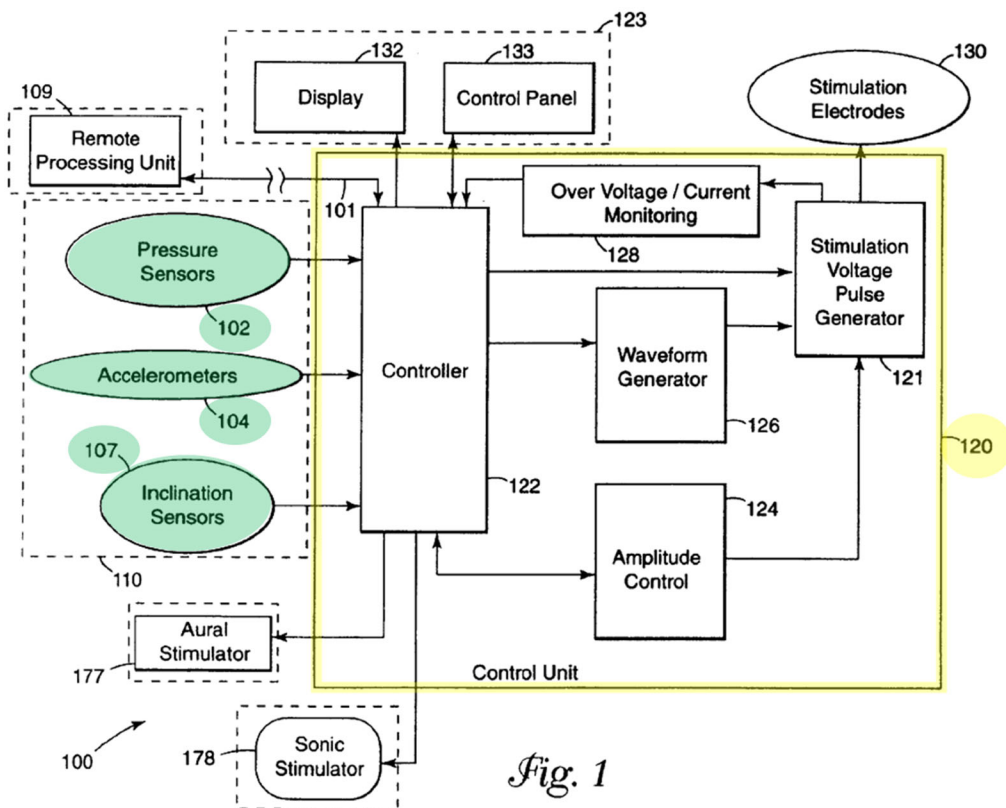
4. Claim 5

Claim 5 depends from claim 1 and recites: “adjusting or optimizing the electrical stimulation in response to a feedback signal received from the sensor indicative of the detected motion and efficacy of the applied electrical stimulation therapy.” Gesotti discloses this limitation. (Ex. 1002, ¶¶79-82.)

Gesotti discloses using acceleration sensors for detecting motion of the subject. (*See* Ex. 1008, 4:4-7, Fig. 1 (“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.”); *supra* §VI.A.1.d.)

“Each sensor [green] provides information to control unit 120” [yellow]:



(*Id.*, 4:7-8, Fig. 1.) The “[c]ontrol unit 120 receives the information and uses the information to determine when electrical stimulation is required at the location of each stimulation electrode 130.” (*Id.*, 4:8-11.) For example, control unit 120 selectively adjusts “each electrical stimulation signal based on sensor information.” (*Id.*, 4:11-14.)

Gesotti specifically discloses providing stimulation based on the detection of “*little* or no motion (acceleration).” (*Id.*, 12:28-33 (emphasis added).) The “control

unit is programmable for each patient to respond based on a set of criteria.” (*Id.*, 12:39-50.) “In one embodiment, a control unit is programmed to provide electrical stimulation and if the electrical stimulation does not produce the desired result the control unit will adapt to change the voltage, frequency, pulse width, amplitude, waveform and/or the like of the electrical stimulation signals.” (*Id.*) “In a further embodiment, the control unit changes the sequence or the cadence of the stimulation.” (*Id.*)

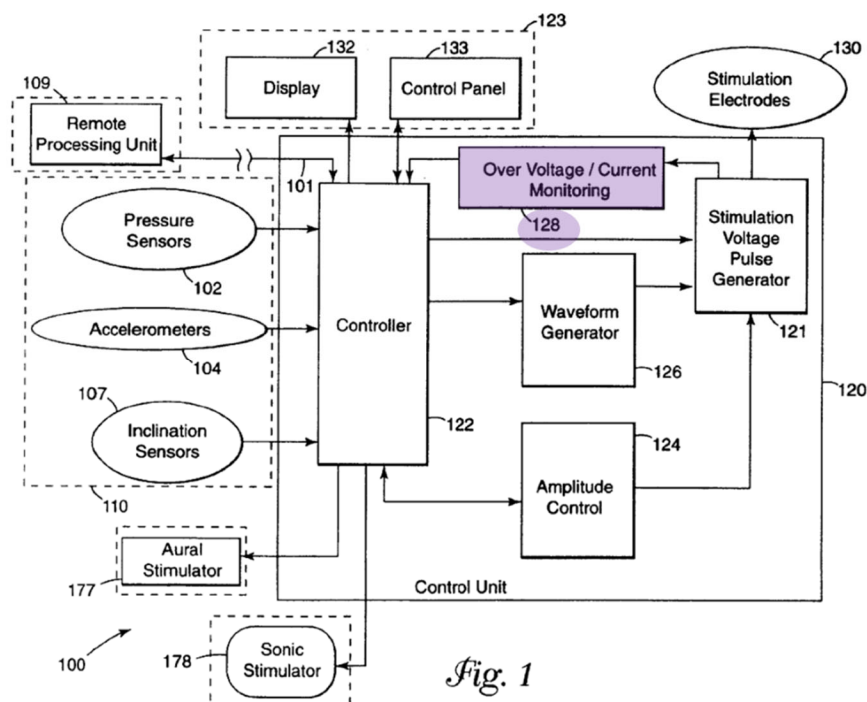
The stimulation glove (Figures 7-9) “is coupled to a control unit such as control unit 120” and, therefore, the above disclosure applies to the sensors included with the stimulation glove. (*Id.*, 8:29-30.) In fact, Gesotti discloses using signals received from sensors in the stimulation glove to adjust the stimulation level. (*See id.*, 8:31-33 (“In one embodiment, the electrical leads provide pressure information to a control unit for a determination of the need for stimulation.”).)

5. Claim 6

Claim 6 depends from claim 5 and recites: “wherein the feedback is queried such that the electrical stimulation therapy is adjusted to ensure that a minimum amount of energy is being applied to stimulate the target nerve while reducing the risk of burns or intolerance.” Gesotti discloses this claim. (Ex. 1002, ¶¶83-85.)

Gesotti discloses “monitoring stimulation electrode voltage and current to prevent exposure of the patient to uncomfortable stimulation levels.” (Ex 1008,

11:65-67.) The control unit 120 includes “an over voltage/current monitoring circuit 128 [purple] coupled between stimulation voltage pulse generator 121 and controller 128.” (*Id.*, 4:55-58.) The “[m]onitoring circuit 128 monitors stimulation electrode voltage and current and provides information to controller 122 to prevent exposure of the patient to uncomfortable stimulation levels.” (*Id.*, 4:58-61, Fig. 1.)



Gesotti’s reference to “uncomfortable stimulation levels” includes patient intolerance to stimulation. (Ex. 1002, ¶84.)

The stimulation glove (Figures 7-9) “is coupled to a control unit such as control unit 120” and, therefore, the above disclosures apply to the stimulation glove. (Ex. 1008, 8:29-30.)

6. Claim 7

Claim 7 depends from claim 5 and recites: “wherein the feedback is queried such that the positioning of the stimulator electrode is adjusted to optimize the electrical stimulation therapy.” Gesotti renders this claim obvious. (Ex. 1002, ¶¶86-88.)

Gesotti discloses methods of querying the sensor feedback to optimize the electrical stimulation, including selectively adjusting the “stimulation voltage, frequency, pulse width, waveform shape, amplitude, modulation type and the like of each electrical stimulation signal based on sensor information.” (Ex. 1008, 4:11-14.) Gesotti also recognizes that the sensors must be “strategically positioned” across the patient’s body, including the hand, fingers, head, wrist, and ankle. (*See e.g., id.*, 12:1-15.) A POSITA would have found it obvious to adjust the position of the stimulation electrode based on the sensor feedback if other methods for optimizing the electrical stimulation were ineffective. *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.”) (internal quotes omitted) (Ex. 1002, ¶87.) A POSITA would have understood that there were a finite number of predictable adjustments that could be made to the stimulation electrode to improve its function. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007); Ex. 1002, ¶87.) The predictable options would have

included electrical adjustments (*e.g.*, stimulation voltage, frequency, etc.) and moving the electrode to a more effective location. (*Id.*)

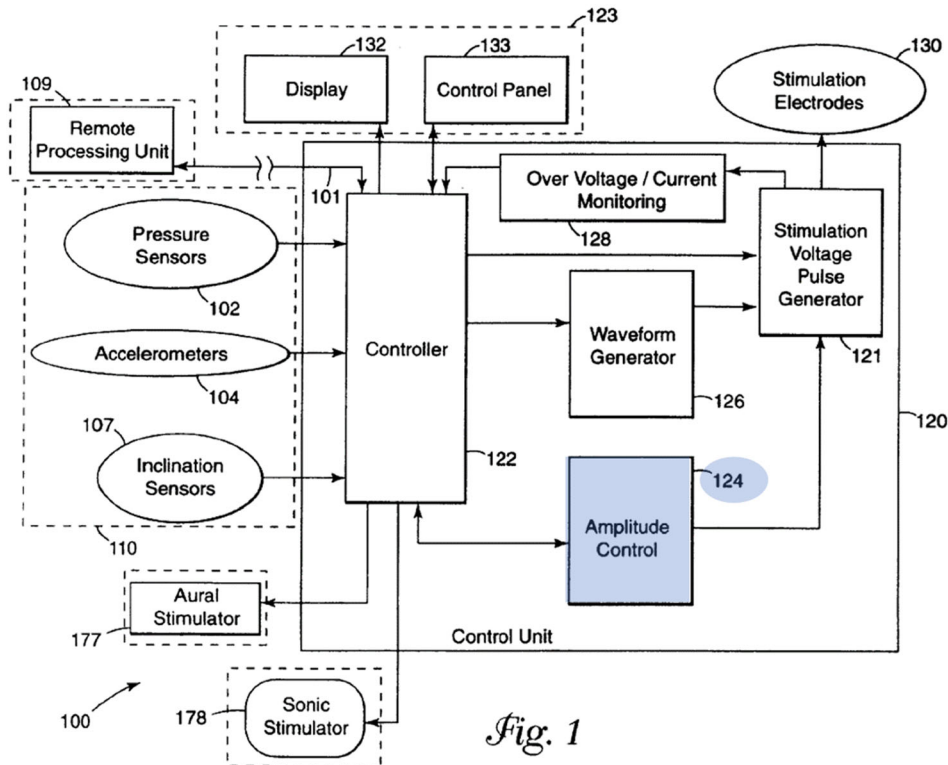
A POSITA would have reasonably expected success in moving the stimulator electrode because Gesotti discloses placing stimulator electrodes at various positions on the body. (*Id.*, ¶88; Ex. 1008, 6:49-53 (“cylindrical electrode 300 adjusts to fit a variety of different sized body parts for example one size that fits a variety of upper arms, forearms, wrists, torsos, ankles, knees, calves, thighs, or the like”).) Gesotti also discloses positioning electrodes at various locations on the hand, including the top and bottom of the palm and along the fingers. (Ex. 1008, 8:16-19, Figs. 7-8.) If a stimulation electrode was ineffective at the bottom of the palm, a POSITA would have reasonably expected success in moving the stimulation electrode to the top of the palm or to the fingers based on Gesotti. (Ex. 1002, ¶88.)

7. **Claim 9**

Claim 9 depends from claim 1 and recites: “wherein the pulses generated during the electrical stimulation therapy include pulses of a first amplitude and pulses of a second amplitude, where the first amplitude is different from the second amplitude.” Gesotti discloses this claim. (Ex. 1002, ¶¶90-91.)

Gesotti’s “[c]ontrol unit 120 selectively adjusts stimulation voltage, frequency, pulse width, waveform shape, ***amplitude***, modulation type and the like of each electrical stimulation signal based on sensor information.” (Ex. 1008, 4:11-

14 (emphasis added); 4:15-17.) The control unit 120 includes an “amplitude control device 124” to adjust the amplitude. (*Id.*, 4:61-64, Fig. 1.)



(*Id.*, Fig. 1, 13:29-38, Fig. 17.) By selectively adjusting the pulse amplitude, the control unit creates pulses having a first amplitude (original amplitude) and a second amplitude (amplitude after change) where the amplitudes are different. (Ex. 1002, ¶91.) Thus, Gesotti discloses this claim. (*Id.*)

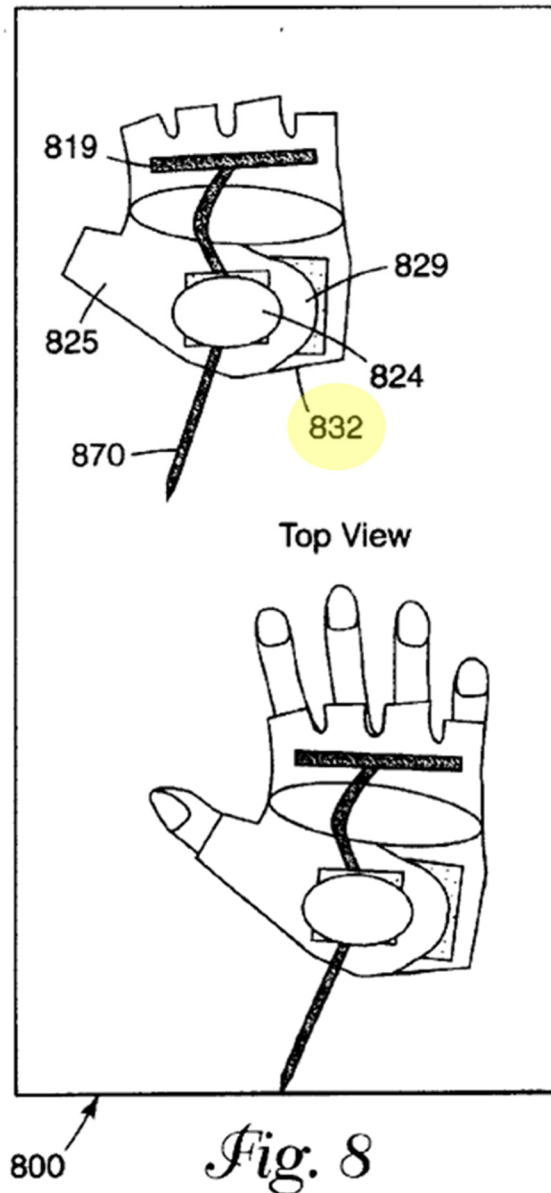
8. Claim 10

Claim 10 depends from claim 1 and recites: “positioning a return electrode on the subject to facilitate penetration of an electrical current through the surface to stimulate the target nerve.” Gesotti discloses this claim. (Ex. 1002, ¶¶92-96.)

Gesotti discloses that “[e]ach stimulation electrode 130” connected to the control unit 120 “include[s] a common return electrode.” (Ex. 1008, 3:63-64, Fig. 1.) “The common return electrode is in direct contact with the skin and provides the return path for each of the electrical stimulation electrodes....” (*Id.*, 3:65-67.) The common return electrode has “a large surface area and as a result a lower impedance than each of the stimulation electrodes” and, therefore, aids “in keeping the current at the contact location at a comfortable level for the patient.” (*Id.*, 3:67-4:4.) Thus, Gesotti’s return electrode is “on the subject” and “facilitates penetration of an electrical current through the surface to stimulate the target nerve.” (Ex. 1002, ¶93.)

The description of the return electrode in Figure 1 applies to the electrodes on the stimulation glove. The stimulation electrodes on the glove are connected to control unit 120 and, therefore, the “stimulation electrodes” 130 in Figure 1 encompass the electrodes in the stimulation glove. (Ex. 1008, 8:29-30; Ex. 1002, ¶94.)

Gesotti also describes the “integrated tactile sensor and stimulation glove which is coupled to a control unit such as control unit 120 of FIG. 1.” (Ex. 1008, 8:65-9:2.) “[S]timulation glove 825 includes a common return electrode 832 [yellow].” (*Id.*, 8:48-49, Fig. 8.)



The “[c]ommon return electrode 832 is in direct contact with the skin and provides the return path for each of the electrical stimulation electrodes attached to the body.” (*Id.*, 8:49-51.) Further, the return electrode 832 “provides a large surface and as a result a lower impedance than each of the stimulation electrodes, this is adapted to aid in keeping the current at the contact location at a comfortable level for the

patient.” (*Id.*, 8:52-55.) Thus, the common return electrodes facilitate penetration of an electrical current through the surface to stimulate a target nerve. (Ex. 1002, ¶96.)

9. Claim 11

Claim 11 depends from claim 1 and recites: “wherein the stimulator electrode is attached to the skin surface with an adhesive.” Gesotti renders this claim obvious. (Ex. 1002, ¶¶97-101.)

Gesotti discloses stimulator electrodes attached to the patient’s skin with a “conductive adhesive gel.” (*See e.g.*, Ex. 1008, 6:30-41, 5:56-65, 10:9-12, 11:5-8.) However, Gesotti does not expressly state whether the stimulator electrodes in the stimulation glove are adhered to the skin surface, although Gesotti states that the electrodes are “in direct contact with the palm of the hand.” (*Id.*, 8:20-25.)

Based on Gesotti’s disclosure of using adhesives to attach stimulator electrodes to a patient’s skin, a POSITA would have found it obvious to attach the stimulator electrode coupled to the glove to the patient’s palm using an adhesive. (Ex. 1002, ¶99.) Gesotti discloses that the “conductive gel is adhesive in nature so that it may perform a dual function by both electrically coupling the electrode to the body and adhering the electrode to the body.” (Ex. 1008, 5:59-62.) A POSITA would have been motivated to try attaching the stimulation electrode to the palm with the adhesive to achieve an enhanced connection between the electrode and skin and enhanced electrical coupling. (Ex. 1002, ¶99.) This coupling with the gel would be

superior, in some circumstances, to positioning the electrode against the skin. (*Id.*) Additionally, adhering the stimulation electrode to the skin would provide additional flexibility by allowing the glove to be removed or replaced without disturbing the stimulation electrode. (*Id.*)

Moreover, a POSITA would have recognized there are only a finite number of predictable ways to position the stimulator electrode on the palm. (*Id.*, ¶100.) Either the electrode is adhered to the palm, or the electrode is adhered to the glove such that it contacts the palm. (*Id.*) Either arrangement would have required a simple adhesive and would have been well within the skill and knowledge of a POSITA. (*Id.*)

A POSITA would have reasonably expected success in attaching the electrode to the patient’s palm with the conductive adhesive gel because Gesotti encourages using adhesive gels on various body parts and adhesive gels were well known and common for electrodes and sensors in 2011. (*Id.*, ¶101.)

10. Claim 12

Claim 12 depends from claim 1 and recites: “wherein the stimulator electrode is positioned over the skin surface with an ergonomic applicator.” Gesotti discloses this claim. (Ex. 1002, ¶¶102-103.)

Gesotti discloses positioning a stimulator electrode over the patient's palm with a stimulator glove (i.e., ergonomic applicator). (Ex. 1008, 8:16-35, Fig. 7; Ex. 1002, ¶103.)

11. Claim 13

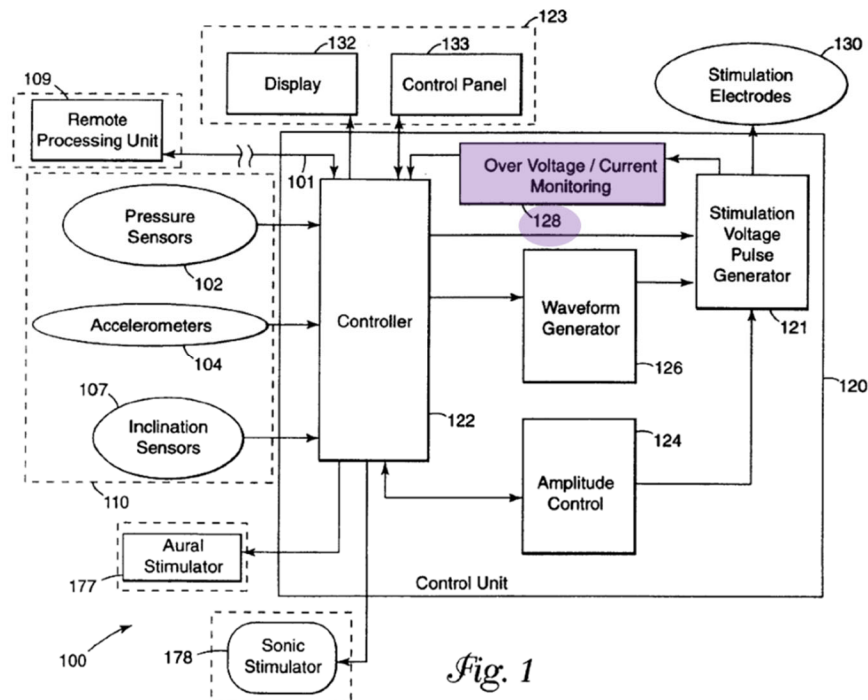
Claim 13 depends from claim 12 and recites: “wherein the applicator is a glove or brace configured to be positioned against a skin surface such that the electrode delivers electrical stimulation to the target nerve or tissue.” Gesotti discloses this claim for the reasons provided in Claims 1 and 12.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

12. Claim 16

Claim 16 depends from claim 1 and recites: “wherein once tetany is detected in a patient, indicating that a threshold frequency of the applied stimulation has been reached, the strength of the applied stimulation is automatically or manually decreased.” Gesotti anticipates this claim or renders it obvious. (Ex. 1002, ¶¶105-107.)

Tetany is the overstimulation of neuromuscular activity characterized by muscle twitches, spasms, and cramps. (Ex. 1013, 1966.) Gesotti does not expressly mention “tetany.” However, Gesotti discloses “monitoring stimulation electrode voltage and current to prevent exposure of the patient to uncomfortable stimulation levels.” (Ex 1008, 11:65-67.) In one embodiment, the control unit 120 includes “an

over voltage/current monitoring circuit 128 [purple] coupled between stimulation voltage pulse generator 121 and controller 122.” (*Id.*, 4:55-58.) The “[m]onitoring circuit 128 monitors stimulation electrode voltage and current and provides information to controller 122 to prevent exposure of the patient to uncomfortable stimulation levels.” (*Id.*, 4:58-61, Fig. 1.)



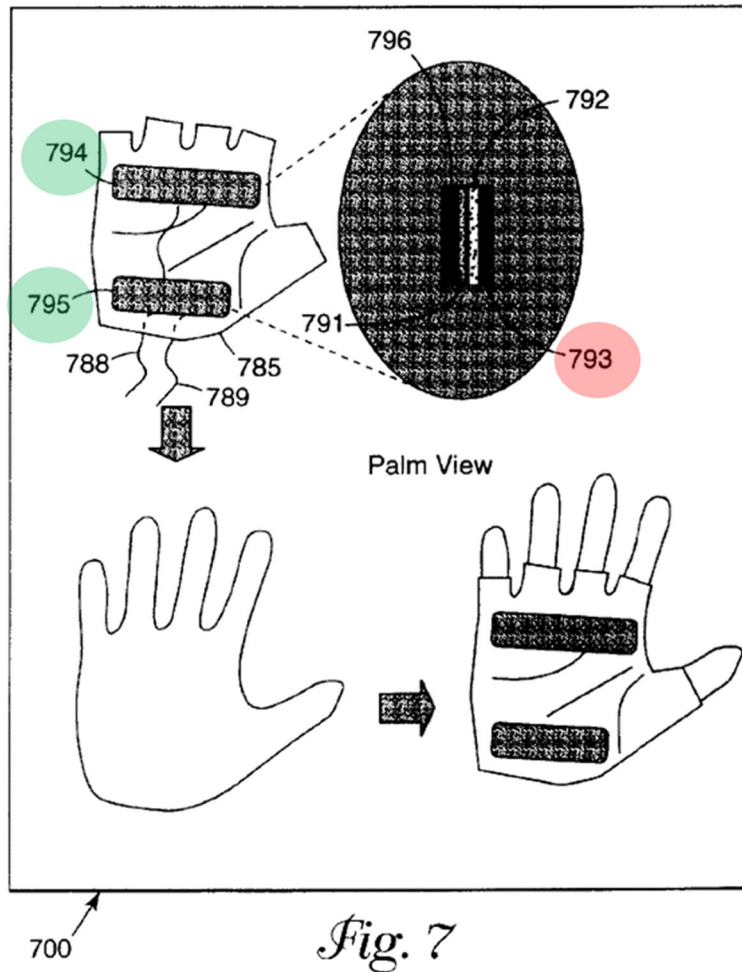
The symptoms of tetany reflect “uncomfortable stimulation levels,” which would cause Gesotti’s controller to decrease the stimulation signal strength. (Ex. 1002, ¶107.) Likewise, a POSITA would have found it obvious, and been motivated, to use the functionality of Gesotti’s device to decrease the stimulation strength (e.g., voltage or current) when the patient experiences tetany. (*Id.*) Gesotti explains that “a control unit is programmed to provide electrical stimulation and if the electrical stimulation does not produce the desired result the control unit will adapt to change

the voltage, frequency, pulse width, amplitude, waveform and/or the like of electrical stimulation signals.” (Ex. 1008, 12:40-45.) Tetany is not a “desired result.” (Ex. 1002, ¶107.) Thus, the control unit will automatically reduce the stimulation strength and, if it does not, a POSITA would have been motivated to adjust the programming and reduce the stimulation strength so that the patient does not experience pain. (*Id.*) A POSITA would have expected success in reducing the stimulation strength because Gesotti suggests altering the stimulation voltage or current to prevent uncomfortable stimulation levels. (*Id.*)

13. Claim 18

Claim 18 depends from claim 1 and recites: “wherein positioning a stimulator electrode comprises positioning at least two electrodes over the skin surface.” Gesotti discloses this claim. (Ex. 1002, ¶¶108-109.)

Gesotti’s stimulation glove includes two stimulation electrodes 793 in each “tactile sensor assembly” 794 and 795:



(Ex. 1008, 8:16-35, Fig. 7.) Each stimulation electrode 793 “is in direct contact with the palm of the hand,” and, therefore, positioned over a skin surface. (*Id.*; Ex. 1002, ¶108.)

14. Claim 19

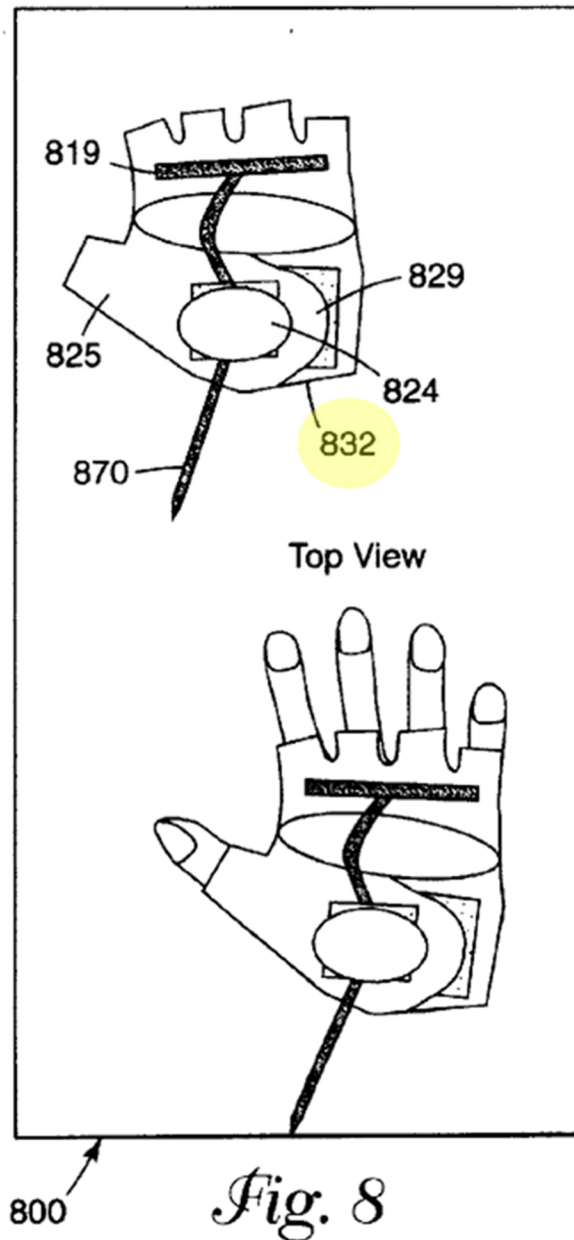
Claim 19 depends from claim 18 and recites: “wherein the at least two electrodes are positioned to stimulate an Ulnar or Median nerve.” Gesotti discloses this claim for the reasons explained in Claim 1. (*Supra*, §VI.A.1.b.)

15. Claim 20

Claim 20 depends from claim 18 and recites: “wherein the at least two electrodes are positioned in opposition relative to one another.” Gesotti discloses this claim. (Ex. 1002, ¶¶111-113.)

Gesotti discloses a stimulation glove (Figures 7-9) having stimulation electrodes positioned on the upper and lower palm. (Ex. 1008, 8:16-35, Fig. 7.) These electrodes are “in opposition relative to one another” because they are on opposing surfaces of the palm (i.e., upper and lower). (Ex. 1002, ¶112.)

Gesotti also describes “an integrated tactile sensor and stimulation glove which is coupled to a control unit such as control unit 120 of FIG. 1.” (Ex. 1008, 8:65-9:2.) “[S]timulation glove 825 includes a common return electrode 832 [yellow].” (*Id.*, 8:48-49, Fig. 8.)



The “[c]ommon return electrode 832 is in direct contact with the skin and provides the return path for each of the electrical stimulation electrodes attached to the body.” (*Id.*, 8:49-51.) The return electrode 832, which is located on the back of the hand, is “positioned in opposition relative” to the stimulation electrode 793, which is located

on the palm of the hand. (*Id.*, 9:29-34, 10:31-36, Figs. 10, 13 (disclosing opposing stimulator electrodes); Ex. 1002, ¶113.)

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

1. Motivation To Combine Gesotti and Gesotti '896

Gesotti '896 describes variations of the stimulation systems described in Gesotti. Gesotti '896 “is related to copending application[] U.S. Ser. No. 09/659,351 (the '351 Application),” which matured into Gesotti, and incorporates the '351 Application. (Ex. 1009, 1:11-17.) Gesotti '896 also expressly describes using Gesotti's sensors and stimulators. (*Id.*, 5:60-6:2.) Based on this relationship, POSITAs would have been motivated to combine the teachings of Gesotti '896 with Gesotti. (Ex. 1002, ¶114.)

Moreover, like Gesotti, Gesotti '896 discloses methods for relieving symptoms of Parkinson's disease, including tremors. (*See e.g.*, Ex. 1009, 1:20-44, 1:55-2:10, 2:3-40, Tables 11-12.) Both Gesotti patents use similar adaptive stimulators to provide stimulation and monitor feedback from the patient. (*Compare* Ex. 1008, Fig. 1 *and* Ex. 1009, Fig. 1.) Thus, in addition to the express suggestion to combine the patents, a POSITA would have been motivated to combine the teachings because the patents address the same problem (*e.g.*, symptoms of Parkinson's disease, including tremor) and use similar devices (*e.g.*, stimulation electrodes, sensors, and control units). (Ex. 1002, ¶115.) A POSITA would have

reasonably expected success in using the methods described in Gesotti '896 with Gesotti because Gesotti '896 suggests the combination and the systems are similar.

(*Id.*)

2. Claim 2

Claim 2 depends from claim 1 and recites “wherein the electrical stimulation is delivered at a frequency of about 5 Hz to about 60 Hz, while remaining safe and tolerable to the subject.” Gesotti and Gesotti '896 render this claim obvious. (Ex. 1002, ¶¶116-120.)

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

Gesotti '896 discloses the frequency values. Gesotti '896 explains that the stimulation periods for the described devices are “typically 12-20 milliseconds,” which correspond to a frequency of 50-83 Hz. (Ex. 1009, 11:1-4.) This stimulation period is within the range of Claim 2.

Gesotti '896 also discloses “relieving bradykinesia, akinesia and freezing in Parkinson's Disease” using a pulse period of 14 milliseconds (approximately 71 Hz). (Ex. 1009, 11:37-44.) However, Gesotti '896 explains that this frequency is

“significantly higher than the 40 Hz frequency *normally used for neuromuscular electrical stimulation and functional electrical stimulation....*” (*Id.*, 11:40-44 (emphasis added).) This “normal frequency” is within the range of Claim 2. Because the claimed ranges (10-60 Hz) “overlap or lie inside ranges disclosed by the prior art” (Gesotti ’896), the claimed ranges are obvious. *In re Wertheim*, 541 F.2d 257, 267 (CCPA 1976).

A POSITA would have been motivated, and reasonably expected success, in using the frequency ranges described in Gesotti ’896 with the stimulation device in Gesotti. (Ex. 1002, ¶120.) Gesotti ’896 incorporates the adaptive stimulator in ’Gesotti and specifically suggests using the frequency ranges (e.g., 12-20 milliseconds) with the described stimulator. (Ex. 1009, 5:60-6:2, 11:1-4.) Additionally, a POSITA would have been motivated to try the “normal” frequency for neurostimulation described in Gesotti ’896 because the frequency had been commonly used and proven effective in the past. (Ex 1002, ¶120.)

3. Claim 8

Claim 8 depends from claim 5 and recites: “wherein the sensor is a surface electrode.” Gesotti and Gesotti ’896 render this claim obvious. (Ex. 1002, ¶121.)

Gesotti ’896 discloses using electromyography in conjunction with motion sensors to detect patient motion. (*See e.g.*, Ex. 1009, 6:3-22, 6:38-56, Fig. 1.) The electromyography includes surface electrodes. (Ex. 1002, ¶121.) A POSITA would

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

4. Claim 17

Claim 17 depends from claim 1 and recites: “wherein electrical stimulation is provided by delivering a cycle comprising a preset number of pulses followed by a pause in stimulation, followed by a preset number of pulses, and repeating the cycle as necessary.” Gesotti and Gesotti ’896 render this claim obvious. (Ex. 1002, ¶¶122-124.)

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

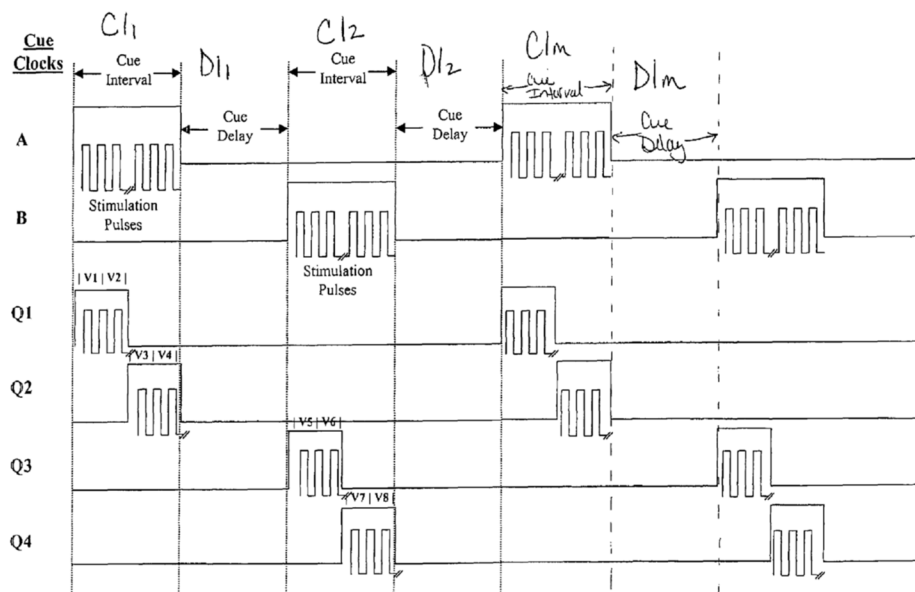


Figure 4

(Ex. 1009, Fig. 4; Ex. 1002 ¶123.)

Gesotti '896 further explains that the preset number of pulses is a “burst” that has a preset pulse count. (Ex. 1009, 8:35-55, Fig. 2.) The preset number of pulses (burst count) can be customized for each channel. (*Id.*, 8:41-43.) Likewise, the cue delay between each burst can be preset for each channel or random and adjusted depending on the treatment plan. (*Id.*, 8:52-56.) For example, exemplary cue intervals and cue delays to reduce tremor are shown in Table 11. (*Id.*, 17:15-25; Ex. 1002, ¶124.) A POSITA would have been motivated to combine the treatment protocols of Gesotti '896 with Gesotti, and expected success in doing so, for the reasons previously provided. (*Supra* §VI.B.1.)

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

1. Claim 14

Claim 14 depends from claim 1 and recites: “wherein the electrical stimulation is automatically paused for a preset amount of time every 10 minutes to overcome habituation.” Gesotti and Stephens render this claim obvious. (Ex. 1002, ¶¶125-129.)

Gesotti recognizes that habituation and decreasing sensitivity to static waveforms occurs. (Ex. 1008, 4:13-20.) Thus, Gesotti discloses different modulation features to prolong “stimulation effectiveness.” (*Id.*) The modulation features permit the control unit to select “one of a collection of dynamic waveform changes that vary amplitude, frequency or pulse width in some predetermined manner.” (*Id.*) Gesotti

also discloses that the control unit can make additional modifications to the stimulation based on sensor information, including modifying “the type of stimulation, duration, frequency, amplitude and the like in order to produce the desired results....” (*Id.*, 13:7-16.) While Gesotti recognizes the problem caused by habituation and adjusts stimulation, Gesotti does not expressly disclose the timing of the adjustments.

Stephens discloses methods of electrically stimulating nerves to treat UI. (Ex. 1019, abstract, 1:9-13.) “In an embodiment, rather than constant stimulation of the one or more nerves, stimulation may be by way of a duty cycle, the nerve stimulation being on for a period and off for a period.” (*Id.*, 6:1-4, 9:19-22.) The “[d]uty cycle and other signal characteristics may be adjusted to provide the most effective stimulation.” (*Id.*, 21:28-30.) Stephens specifically claims generating a stimulation signal “wherein the on period is 10 minutes or more and the off period is 20 minutes or more.” (*Id.*, 42:6:8; *see also id.*, 42:9-14 (claiming on periods of “8 minutes or more” and “5 minutes or more”).) Stephens also discloses that the on and off periods may be the same. (*See e.g., id.*, 20:7-9 (“The signal may be a long duty cycle stimulation (e.g. five minutes on, five minutes off.”).) Thus, Stephens discloses automatically pausing stimulation for a preset amount of time every 10 minutes (e.g., 10 minutes on/10 minute off or 10 minutes on/20 minutes off). (Ex. 1002, ¶127.)

A POSITA would have been motivated to intermittently pause Gesotti's pulse signal as disclosed in Stephens to address the known problem of habituation. (Ex. 1002, ¶128.) Both references disclose methods of using electrical stimulation to treat neurological disorders. (*Id.*) While Stephens focuses on a treating UI, POSITAs using electrical stimulation for one application regularly consulted the use of electrical stimulation in other applications. (*Id.*) In fact, the '669 patent assumes that methods of treating UI are applicable to treating tremor. While the '669 patent extensively discusses using electrical stimulation to treat UI, it mentions "tremor" only once and still claims that the disclosed devices may treat "tremor." Ultimately, the use of Stephens stimulation durations with Gesotti is merely the application of a known technique (Stephens' timing) to a known device (Gesotti's stimulator) ready for improvement to yield predictable results. (*Id.*)

A POSITA would have expected success in adjusting the duration of Gesotti's system using the timing set forth in Stephens. (*Id.*, ¶129.) Gesotti already discloses that adjustments to the stimulation may be necessary to avoid habituation. (Ex. 1008, 4:11-19.) Moreover, Gesotti discloses that the stimulation may be turned on and off based on feedback from sensors and that the duration of the signal may be changed. (*Id.*, 13:7-19, 12:9-21.) A POSITA would have recognized that 10 minutes falls within a typical range for stimulating a patient and would not have expected any negative results from that duration of treatment. (Ex. 1002, ¶129.)

2. Claim 15

Claim 15 depends from claim 1 and recites: “wherein the electrical stimulation is automatically paused for a preset amount of time every 10 minutes based on feedback provided by the at least one sensor.” Gesotti and Stephens render this claim obvious for the reasons provided in Claim 14. (*Supra* §VI.C.1.)

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

1. Independent Claim 1

Claim 1 is anticipated or rendered obvious by Burnett. (Ex. 1002, ¶¶132-154.)

a. Preamble

If the preamble is limiting, Burnett discloses this limitation. (Ex. 1002, ¶¶133-137.) The ’669 patent is a continuation-in-part of Burnett (App. No. 12/508,529). (Ex. 1001, 1:15-17.) Consequently, Burnett includes significant portions of the ’669 patent, including Figures 1-30b of the ’669 patent. (*Compare* Ex. 1001, 10:18-63:63, 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].) However, Burnett includes the same list of over 100 ailments found in the ’669 patent, including “tremor.” (*Id.*, [0111].) Thus, if the ’669 patent discloses a “method...for treating tremors,” then so does Burnett. (Ex. 1002, ¶135.)

Burnett also describes transdermal electrical stimulation therapy. For example, Burnett discloses embodiments for nerve stimulation where electrical energy is dispensed through “a transcutaneous stimulator, such as an electrode 126 [red].” (Ex. 1010, [0109], Fig. 11.)

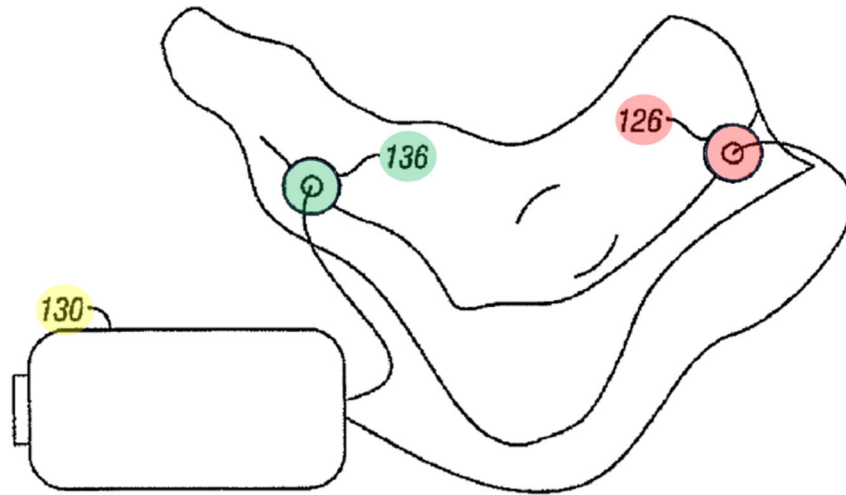


FIG. 11

As shown, the transcutaneous stimulator (electrode) is a transdermal patch placed on the patient’s skin. (Ex. 1002, ¶136.) An “electrical pulse controller 130 [yellow] is connected to both electrode 126 and to sensor 136 [green]” “to provide the desired feedback and modulate the power to” the electrode 126. (Ex. 1010, [0109].) Thus, the transcutaneous stimulator (electrode 126) provides transdermal electrical stimulation therapy. (Ex. 1002, ¶136; *see also* Ex. 1010, [0032, 0036, 0038, 0088 (other embodiments).)

While Figure 11 illustrates the stimulation of the “posterior tibial nerve,” Burnett discloses that the stimulation devices may be used to treat “other peripheral

nerves,” which would include the nerves in the arm and hand. (Ex. 1010, [0110]; Ex. 1002, ¶137; *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] (similar).)

b. Limitation [A]

If “skin surface” is not limited to a “glabrous skin surface which overlies the palm of the hand,” and instead has its ordinary and customary meaning, then Burnett discloses this limitation or renders it obvious. (Ex. 1002, ¶¶138-146.)

Burnett discloses positioning “a transcutaneous stimulator, such as an electrode 126 [red],” over a skin surface overlying a target nerve:

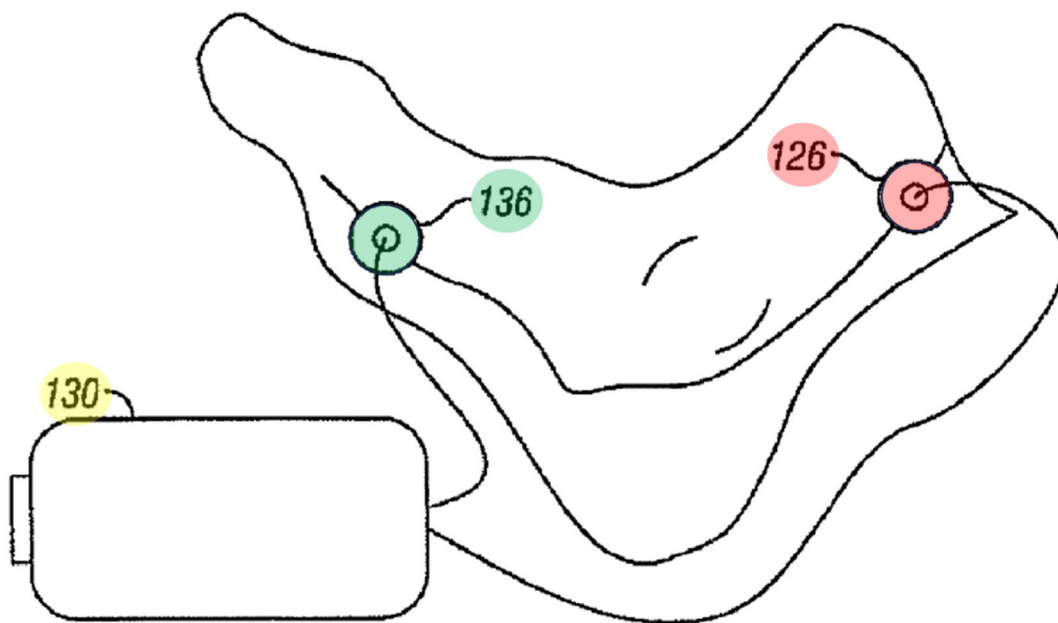


FIG. 11

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

Burnett discloses other electrodes for placement over a skin surface including “a microneedle patch 252...having one or more microneedle arrays deposited on a surface of one or more electrodes.” (Ex. 1010, [0154]; *see also id.*, [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 Burnett’s embodiments illustrate electrical stimulation of nerves in the feet, Burnett describes those applications as exemplary. (*See id.*, [0153] (“e.g., on the leg as shown”); [0154] (“e.g., the tibial nerve”).) Burnett discloses the stimulation electrodes may treat “other peripheral nerves,” which 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], [0126]; Ex. 1002, ¶141.)

Burnett also discloses stimulating 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 '669 patent acknowledges that peripheral nerves extend along the arm and through the hand. Figure 56A, for example, illustrates that the radial, median, and ulnar nerves traverse the arm:

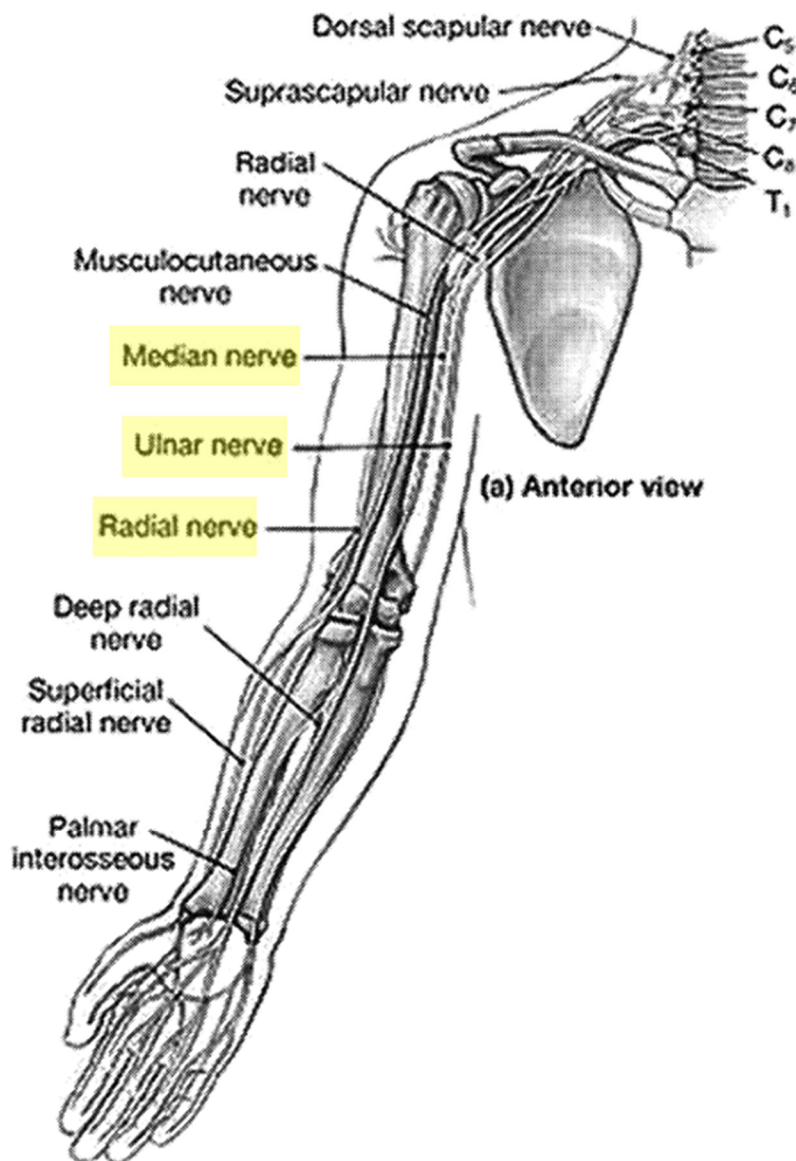


FIG. 56A

(Ex. 1001, Fig. 56A; Ex. 1002, ¶143.) Therefore, a band wrapped around the arm, or an electrode placed on the arm, as disclosed in Burnett, will overlie a target nerve that extends through a hand. (Ex. 1002, ¶143.) Thus, Burnett discloses this limitation. (*Id.*)

If PO argues that Burnett does not disclose this limitation, it renders the limitation obvious. (*Id.*, ¶144.) Burnett discloses methods of stimulating peripheral nerves. (Ex. 1010, [0110].) Additionally, Burnett discloses using the stimulation electrodes to stimulate nerves and muscles on a patient's arm. (*Id.*, [0102], [0107].) A POSITA would have understood that the median, ulnar, and radial nerves are peripheral nerves extending through a patient's arm/hand. (Ex. 1002, ¶144.)

A POSITA would have been motivated to use the stimulation devices described in Burnett to stimulate the nerves in the arms to treat tremor, as claimed. (Ex. 1002, ¶145.) Burnett discloses that the described systems treat “tremor,” but does not disclose how. (Ex. 1010, [0111].) Thus, POSITAs would have consulted other references describing methods to treat tremor. (Ex. 1002, ¶145.) Many prior-art references disclosed treating tremor by stimulating nerves running through the arm. For example, the Prochazka articles disclose methods of treating tremor by stimulating the biceps and triceps. (*See* Ex. 1005, 207, Fig. 2 (“Triceps and biceps brachii are selectively stimulated with surface electrodes.”).) Similarly, Gesotti discloses devices for treating “Parkinson's disease symptoms,” including cylindrical

electrodes for “upper arms, forearms, [and] wrists.” (Ex. 1008, 6:1-17; *see also id.*, 6:42-53, 9:25-28.) Likewise, Gesotti ’896 discloses methods of reducing “arm tremor” by placing electrodes at different positions along the arm, including at the brachioradialis (forearm). (Ex. 1009, 4:16-28, 5:1-2, 16:46-67, Tables 11-12; Ex. 1002, ¶145.) These references, in conjunction with the teachings in Burnett, would have motivated a POSITA to try using Burnett’s stimulation electrodes to stimulate nerves running through the arm and hand. (Ex. 1002, ¶145.)

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

c. Limitation [B]

Burnett discloses this limitation. (Ex. 1002, ¶147-150.) Burnett includes the same list of over 100 ailments found in the ’669 patent. (Ex. 1010, [0111].) Further, like the ’669 patent, Burnett mentions “tremor” only in this list of ailments. If the

single mention of tremor in the '669 patent is sufficient to disclose mitigating tremors, then so is the mention of tremor in Burnett. (Ex. 1002, ¶148.)

Burnett discloses delivering electrical stimulation transdermally through a skin surface to stimulate a target nerve. (*Supra* §VI.D.1.a-b.) Burnett also discloses delivering the electrical stimulation via an “electrical pulse controller 130” to “provide the desired feedback and modulate the power” to electrode 126 [red]. (Ex. 1010, [0109], Fig. 11.) The electric pulse controller is a pulse generator. (Ex. 1002, ¶149.)

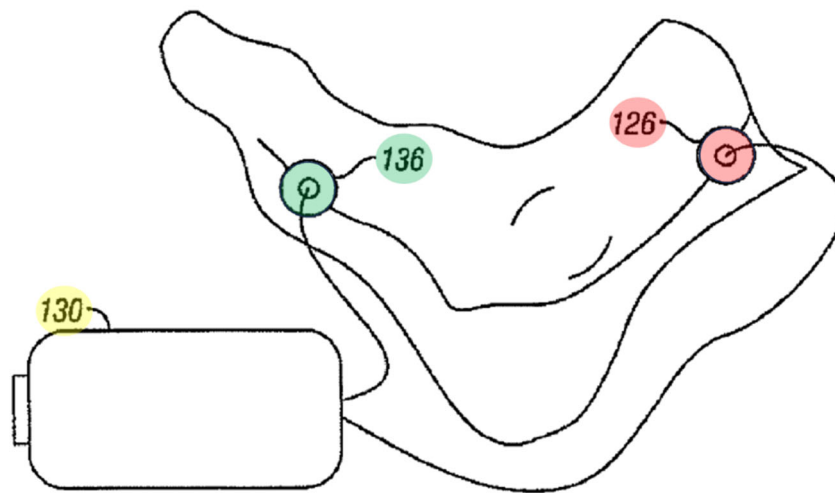


FIG. 11

Burnett also illustrates an energy emitting system 250 having a microneedle patch 252 and sensor 221. (Ex. 1010, [0155], Fig. 26.) “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.)

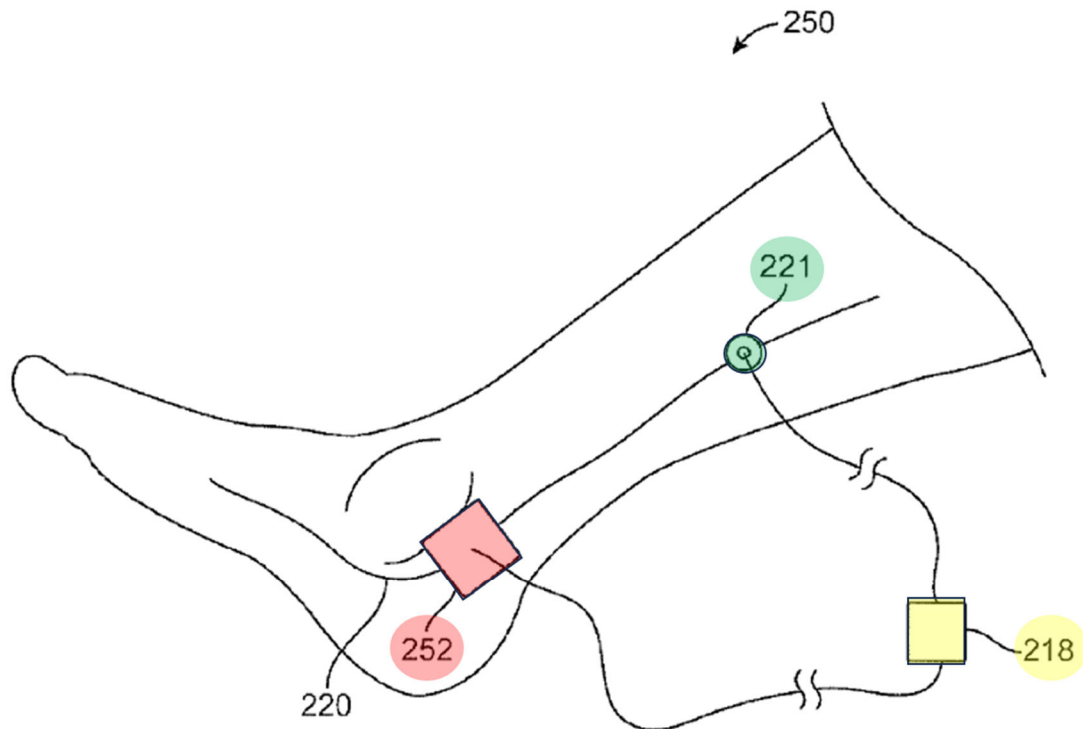


FIG. 26

The controller 218 is a pulse generator. (Ex. 1002, ¶150.) 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,” confirming that the controller generates the pulses. (*Id.*, [0156].)

d. **Limitation [C]**

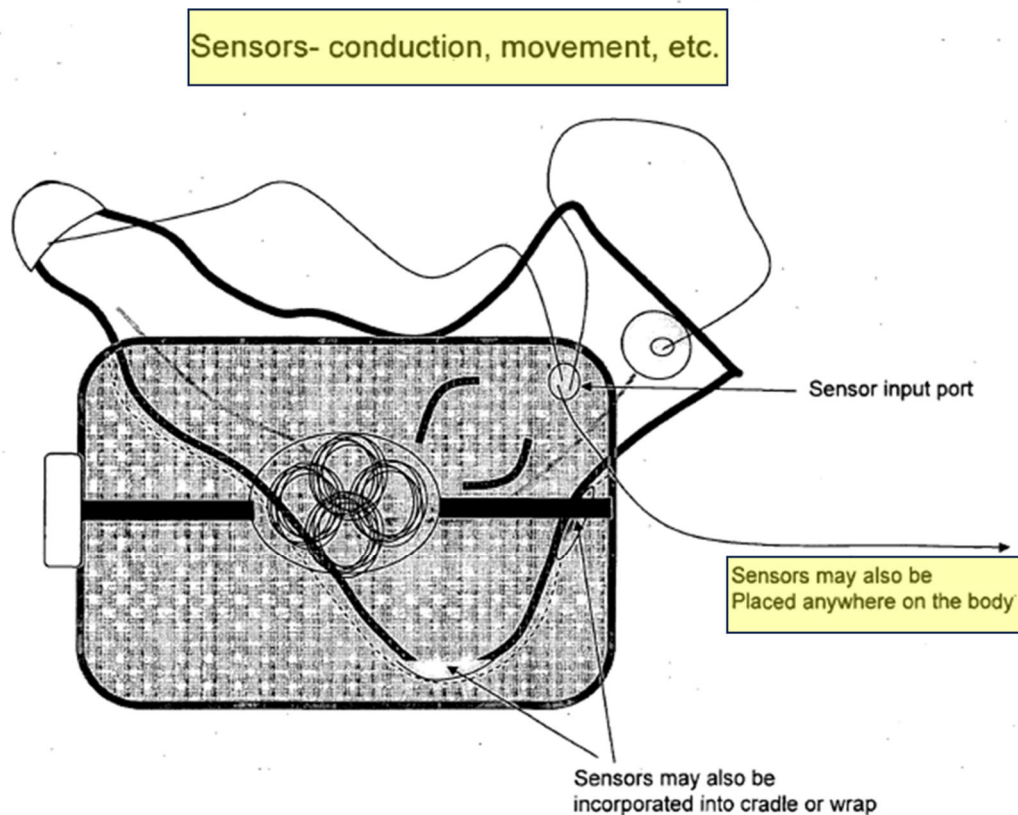
Burnett discloses this limitation. (Ex. 1002, ¶¶151-154.) Burnett’s sensors “may detect a variety of physiological changes, including neural impulses, muscular contraction, *twitching*, etc. that may occur with neural or muscular stimulation.” (Ex. 1010, [0101] (emphasis added); *see also id.*, [0145] (“Microneedle patch 228 detects

corresponding muscle stimulation or twitching or electrical conduction through the stimulated posterior tibial nerve.”); [0173] (similar); [0179] (same), [0184] (same).)

In the case of twitching, the sensor detects motion of the subject. (Ex. 1002, ¶152.)

Burnett discloses a variety of sensors, including a microneedle patch or “a sensor type known in the art.” (Ex. 1010, [0128], [0147].) One known sensor was an accelerometer, which detects motion. (Ex. 1002, ¶153.) Gesotti and Gesotti ’896 both disclose accelerometers to detect patient motion. (Ex. 1008, Fig. 1; Ex. 1009, Fig. 1.)

Additionally, the ’720 provisional, which is incorporated into Burnett, discloses sensors that are responsive to patient movement such as twitching. (Ex. 1015, [0055].) Like Burnett, the ’720 provisional discloses that sensors “may also be placed anywhere on the body” to measure physiologic changes in the patient:



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

- This sensor may be a separate component (i.e. accelerometer) on the toe or conducting patch along the nerve pathway or may be one or more of the

Burnett 8/2/16 9/15/16

(*Id.*, 35 (emphasis added).) Thus, Burnett discloses detecting a motion from the subject via at least one sensor positioned on the subject. (Ex. 1002, ¶154.)

2. Claim 2

Burnett renders this claim obvious. (Ex. 1002, ¶¶155-157.) Burnett discloses that the “optimal stimulation may be determined by a variety of manners,” including operating the stimulation device “at a frequency of 10-30 Hz at the targeted tissue depth.” (Ex. 1010, [0122].) Burnett also discloses operating the stimulation devices “at about 10 to 20 hertz” or “about 5 to 100 hertz.” (*Id.*) Because the claimed ranges (10-60 Hz) “overlap or lie inside ranges disclosed by the prior art,” the claimed ranges are obvious. *In re Wertheim*, 541 F.2d at 267.

Burnett also discloses methods of delivering the electrical stimulation at the identified frequencies while remaining safe and tolerable. (Ex 1002, ¶157.) Burnett discloses using sensors with the electrodes so stimulation “may be tailored to provide optimal therapy and, in the case of electrode migration or other electrode malfunction, to report lack of stimulation of the bodily tissues.” (Ex. 1010, [0109], [0170].) Additionally, Burnett discloses methods of controlling the stimulation “through a combination of feedback from sensor 30 and feedback based on perceptions of the patient.” (*Id.*, [0078].) For example, “the patient may activate a switch once she perceives an excessive stimulation, in particular, an excessive level of muscular stimulation.” (*Id.*) This patient control ensures that the treatment remains safe and tolerable. (*Id.*; Ex. 1002, ¶157.)

3. Claim 3

Burnett discloses this claim. (Ex. 1002, ¶¶158-160.) Burnett describes a “transcutaneous stimulator, such as an electrode 126 [red]” and Figure 11 illustrates that electrode 126 is a surface electrode applied to the patient’s foot. (Ex. 1010, [0109], Fig. 11; *see also id.*, [0164] (describing “electrode patch” placed on patient’s skin); [0126].)

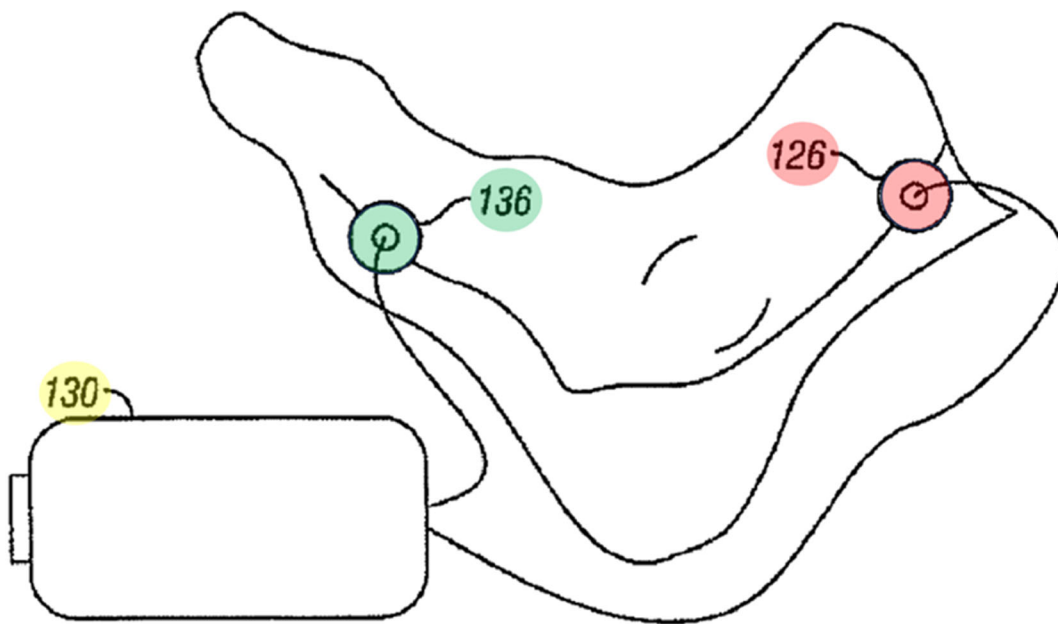


FIG. 11

Similarly, Burnett discloses embodiments having “a microneedle patch 252...having one or more microneedle arrays deposited on a surface of one or more electrodes.” (*Id.*, [0154].) As shown in Figure 26, the microneedle patch is a surface electrode placed on the patient’s skin. (Ex. 1002, ¶160.) Burnett also discloses that the microneedle patch may be “utilized to provide superior anchoring properties

such that a microneedle patch may effectively adhere or attaché [sic] to a subject's skin.” (Ex. 1010, [0134]; [0128]; [0166] (similar).)

4. Claim 4

Burnett discloses this claim. (Ex. 1002, ¶¶161-162.) Burnett discloses “[e]xemplary treatment parameters for treating various conditions,” including stimulating the patient “for a duration of about 30 minutes/day or 30 minutes per week, depending on the severity of the symptoms, until symptoms subside.” (Ex. 1010, [0187].) Burnett discloses other treatment periods, including “for about 15 minutes to 2 hours per day or week” and “for 30 minutes/week or 30 minutes/month.” (*Id.*; *see also id.*, [0122-0125] (describing intermittent treatments).) Burnett further discloses that “[a]ny treatment parameter may be varied or modified based on the effect on the patient or sensor or patient feedback regarding stimulation, until the desired result of treating or preventing a condition is achieved.” (*Id.*, [0187].) Thus, Burnett discloses intermittent treatment. (Ex. 1002, ¶162.)

5. Claim 5

Burnett discloses this claim. (Ex. 1002, ¶¶163-164.) Burnett discloses sensors for detecting patient motion including “twitching.” (*Supra* §VI.D.1.d.) For example, Burnett discloses that “[m]icroneedle patch 228 detects corresponding muscle stimulation or twitching” and relays the signal to a controller. (*Id.*, [0145], [0035].) “The controller can then be varied or adjusted (to adjust the current or magnetic

field) based on the signal received from the microneedle patch 228 to ensure that...an adequate and accurate dosage of treatment is being received.” (*Id.*; *see also id.*, [0168-0169] (detecting motion and adjusting energy generator based on sensor signal to improve efficacy).)

6. Claim 6

Burnett discloses this claim. (Ex. 1002, ¶¶165-167.) Burnett discloses the “electrical pulse controller 130 [yellow] is connected both to electrode 126 [red] and to sensor 136 [green]” “to provide the desired feedback and modulate the power” to the electrode 126. (Ex. 1010, [0109].)

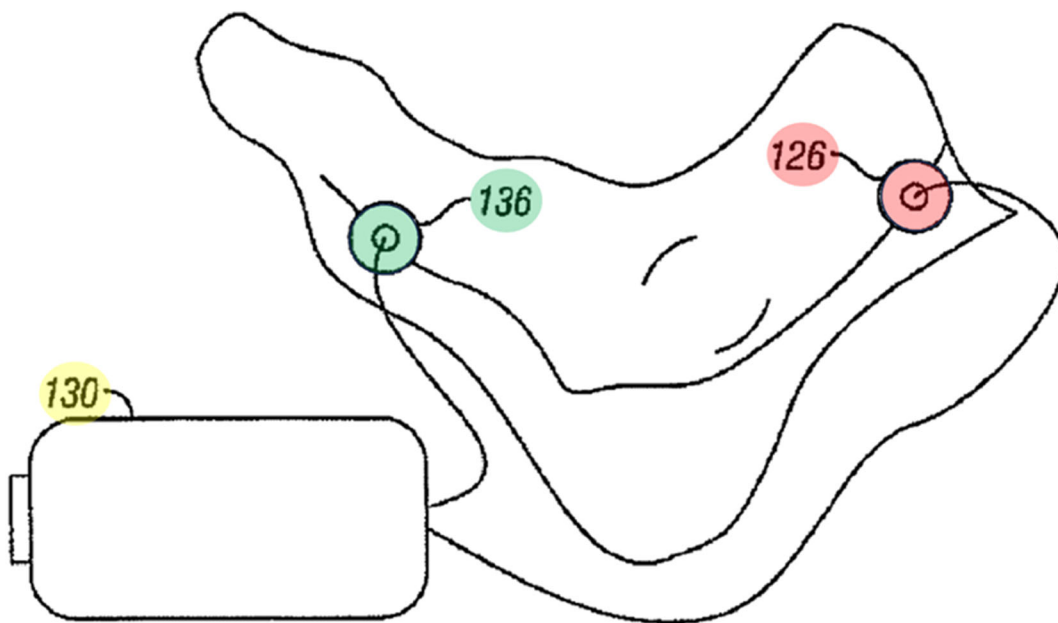


FIG. 11

In this configuration, “direct electrical stimulation of nerve and muscle may be tailored to provide optimal therapy and, in the case of electrode migration or other

electrode malfunction, to report lack of stimulation of the bodily tissues.” (*Id.*) Moreover, “these embodiments enable a ***reduction in power requirement***, because control of the signal is provided by the sensor to signal generator loop.” (*Id.* (emphasis added).) Thus, Burnett discloses querying the sensor feedback so that the electrical stimulation therapy is adjusted to ensure that a minimum amount of energy is applied to stimulate the target nerve. (Ex. 1002, ¶166.)

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

7. Claim 7

Burnett discloses this claim. (Ex. 1002, ¶¶168-170.) Burnett alleges the prior art failed to ensure “that the nerve was actually being stimulated or to adjust the device in response to commonly occurring psychological and anatomic variations in

nerve locations.” (Ex. 1010, [0014].) Burnett purports to address this issue by positioning sensors on an “appropriate portion of the patient’s body[] in order to detect conductivity...in another target nerve.” (*Id.*, [0091].) Conductivity may, for example, be detected by muscle movement (e.g., twitching). (*See id.*, [0127] (“The sensor may be placed over a muscle to detect muscle stimulation resulting from stimulating the target nerve (as shown in FIG. 12)....”); Ex. 1002, ¶170.) Burnett discloses that a healthcare provider analyzes conductivity measurements provided by the sensor and adjusts the positioning of the stimulator until conduction in the nerve is detected. (Ex. 1010, [0092]; *see also id.*, [0047], Figs. 6A-6D.)

While Burnett describes adjusting the location of magnetic coils in many embodiments, Burnett also establishes that the position of electrical stimulators, like the electrodes in Figures 11-12 and 26-27, can be adjusted based on sensor feedback. (Ex. 1002, ¶170.) For example, Burnett discloses that the “positioning of the microneedle patch relative to the first portion of the subject’s body may be adjusted to re-focus the electrical or magnetic stimulus or field on the posterior tibial nerve [or other target nerve] as needed.” (Ex. 1010, [0167], [0172], claims 50-51; *see also id.*, [0170] (“In certain embodiments, the amplitude, frequency, ***direction of a generated...electrical...stimulus***, or firing sequence of the...microneedles making up the microneedle array may be adjusted.”) (emphasis added).)

8. Claim 8

Burnett discloses this claim. (Ex. 1002, ¶171.) Burnett discloses “sensor 54 may be a sensor patch that is [] applied to the skin of the patient.” (Ex. 1010, [0088]; *see also id.*, [0128].) Thus, the sensor is a surface electrode. (Ex. 1002, ¶171.)

9. Claim 9

Burnett discloses this claim. (Ex. 1002, ¶¶172-173.) Burnett changes the stimulation amplitude based on sensor input. (Ex. 1010, [0033, 0121].) Burnett discloses that “sensor input may cause logic controller 28 to alter the strength or *pulse amplitude* of the magnetic field based on sensor input....” (*Id.*, [0074] (emphasis added); *see also id.*, [0078], [0121], [0170], claim 49 (adjusting amplitude.) Where the pulse amplitude is adjusted, the system operates at a first amplitude (original) and a second, different amplitude (after adjustment). (Ex. 1002, ¶173.)

10. Claim 10

Burnett discloses this claim. (Ex. 1002, ¶¶174-175.) Burnett discloses “a microneedle patch or applicator” that includes “multiple electrodes on a single patch or applicator, e.g., positive, negative, and/or control or ground electrodes, where the microneedles will be grouped in multiple arrays such that they conduct to the appropriate electrode.” (Ex. 1010, [0142], Figs. 20a-2, claim 5.) Alternatively, the positive and negative electrodes may be separate patches. (*Id.*) The negative

electrode is a return electrode and facilitates penetration of an electrical current through the surface to stimulate the target nerve. (Ex. 1002, ¶175.)

11. Claim 11

Burnett discloses this claim. (Ex. 1002, ¶¶176-177.) Burnett discloses that “a microneedle patch may include an *adhesive electrode pad* and may utilize a conductive gel to help hold the microneedles in place to prevent shear forces from breaking or bending the microneedles.” (Ex. 1010, [0141] (emphasis added); *see also id.*, [0134] (“a microneedle patch may effectively adhere or attaché [sic] to a subject’s skin”); [0164].)

12. Claim 12

Burnett renders this claim obvious. (Ex. 1002, ¶¶178-188.) Burnett discloses incorporating 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 for the coils in those embodiments. (Ex. 1002, ¶179.)

Burnett repeatedly suggests that the substitution of magnetic coils and electrodes. For example, “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, ¶181.) For example, Figure 21 discloses any energy emitting system 210 that includes a conductive coil 212 [red] disposed within housing 214 and a microneedle patch 228 [purple] to sense electrical conduction caused by the magnetic coil. (Ex. 1010, [0143], [0146], Figs. 12, 21.)

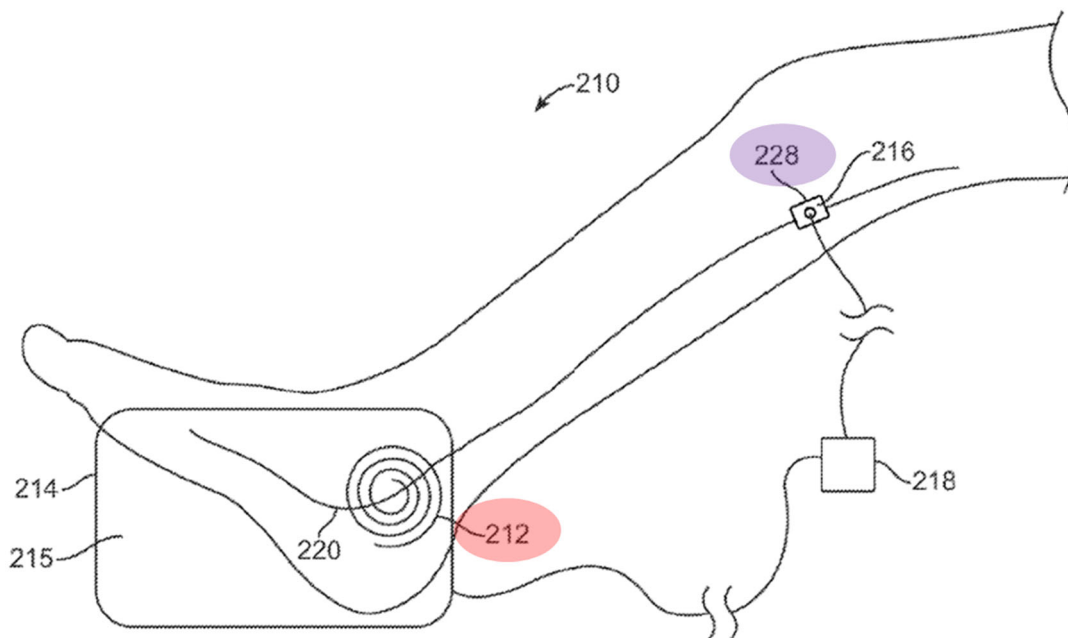


FIG. 21

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

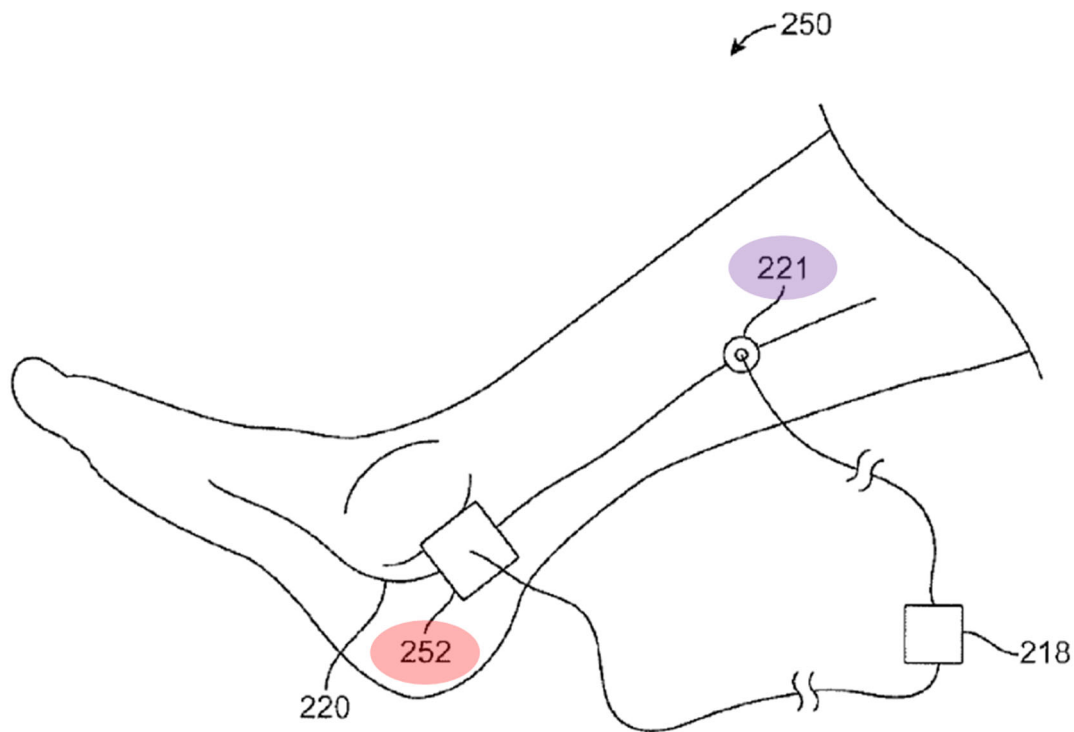


FIG. 26

(Compare Figs. 6A-6B with Figs. 10-11.)

Moreover, many prior art references described positioning stimulation electrodes within ergonomic applicators. (See *e.g.*, Ex 1008, Figs. 7-15; Ex. 1007, Figs. 1-2, 12.) These teachings combine with the suggestion in Burnett would have motivated a POSITA to try including the electrode within the ergonomic applicator. (Ex. 1002, ¶183.) Moreover, POSITAs would have expected success in combining

the electrode with an applicator because the prior art discloses the combination can 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. (Ex. 1002, ¶184.) Rather than separately applying each electrode/sensor to the skin, the band allows the patient to apply the electrodes/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 band's inner surface so the electrodes "contact the skin surface." (Ex. 1002, ¶185.) Burnett already discloses electrodes that "contact the skin surface." (*See e.g.*, Ex. 1010, [0166] ("the patch may be attached to a subject's skin"), Fig. 26.) 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 electrode. (Ex. 1002, ¶186.) Burnett discloses that placing an electrode 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 could disrupt or weaken the transmission of the electrical pulses. (Ex. 1002, ¶186.)

A POSITA would have expected success in positioning the electrodes within the band and against the skin surface. (*Id.*, ¶187.) The prior art discloses 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.) This prior art would have encouraged POSITAs to try such a combination here. (Ex. 1002, ¶187.) Additionally, Burnett already describes placing electrodes directly against the skin and suggests that such an attachment can improve the device’s function. (*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 421; (Ex. 1002, ¶188.) Burnett discloses two options: (1) placing the electrodes on the skin, or (2) incorporating the electrodes into an applicator. (*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.*)

13. Claim 16

Burnett discloses this claim. (Ex. 1002, ¶¶189-190.) Burnett discloses manually or automatically decreasing stimulation once the symptoms of tetany, such as twitching, are detected. Burnett discloses that “the patient may activate a switch

once she perceives an excessive stimulation, in particular, an excessive level of muscular stimulation.” (Ex. 1010, [0078].) “In one instance, the patient may be asked to push a button or turn a knob when she feels her toe twitching or when she experiences paresthesia over the sole of her foot.” (*Id.*) The patient then decreases the stimulation strength until reaching the appropriate treatment level is reached. (*Id.*; Ex. 1002, ¶190.)

14. Claim 18

Burnett discloses this claim. (Ex. 1002, ¶¶191-192.) Burnett discloses “one or more microneedle patches having...one or more electrodes....” (Ex. 1010, [0038]; *see also supra* §VI.D.10; [0144] (“Microneedle patch 228 may be composed of...one or more electrodes.”), [0154] (same).)

15. Claim 19

Burnett renders this claim obvious for the reasons provided with respect to Claim 1. (*Supra* §VI.D.1.b.)

16. Claim 20

Burnett renders this claim obvious. (Ex. 1002, ¶¶194-195.) Burnett explains: “When a plurality of coils is utilized, such coils may be disposed on a single side of the ankle 22, or may be disposed on more than one side, for example, *on opposing sides*, strengthening and directionalizing the flow of the magnetic field through tibial nerve 24 or other peripheral nerves of interest.” (Ex. 1010, [0072] (emphasis

added).) A POSITA would have recognized the same benefits could be achieved by placing electrodes in opposition to each other. (Ex. 1002, ¶195.) For example, Burnett discloses that the described system may use a control/ground electrode placed on a different body part, such as “above or near bone,” while the positive or negative electrodes “may be attached above a nerve or muscle.” (Ex. 1010, [0142].) Based on this description, a POSITA would have understood that a system for treating tremor could use a ground electrode placed near the elbow (i.e., a bone) and a positive/negative electrode placed on the opposite side of the arm (forearm) above the target nerve. (Ex. 1002, ¶195; *supra* §VI.D.1.b.) A POSITA would have expected success in using opposing electrodes based on Burnett and the Gesotti patents, the latter of which describes treating tremor by stimulating different portions of the arm. (Ex. 1002, ¶195.)

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

Burnett and Gesotti render claim 13 obvious. (Ex. 1002, ¶¶196-197.) Burnett does not expressly disclose a glove. However, the '720 provisional discloses that “the device may be designed to target the nerve, or other nerves, via alternative ergonomic applicators including wraps, cradles, supports for the...arm, *hand*...etc.” (Ex. 1015, [0053] (emphasis added).) Gesotti discloses stimulation gloves. (*See supra* §VI.A.12.) A POSITA would have been motivated, and expected success, in using a glove to stimulate the “hand” based on Gesotti. (Ex. 1002, ¶197.) Moreover,

a POSITA designing an ergonomic applicator for the “hand,” as described in the ’720 provisional, would have had a finite number of predictable options. (*Id.*) One option for such an ergonomic applicator would have been a glove. (*Id.*) For this additional reason, a POSITA would have found it obvious to try using Burnett’s electrodes with a glove. (*Id.*)

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

1. Claim 14

Burnett and Stephens render this claim obvious. (Ex. 1002, ¶¶198-201.) Burnett discloses methods of using information received from sensors “to vary or adjust the controller to ensure that adequate conduction of a target nerve...or muscle stimulation occurs and an adequate and accurate dosage of treatment is being received.” (Ex. 1010, [0188].) To ensure accurate treatment, Burnett discloses that “[c]ontrols may also be included to affect the following:...start/pause and cancellation of therapy....” (*Id.*) While Burnett does not expressly disclose pausing every 10 minutes, Stephens does. (*See supra* §VI.C.1 (describing Stephens).)

A POSITA would have been motivated to vary the duration of Burnett’s pulse signal according to Stephens’ timing to address the known problem of habituation. (Ex. 1002, ¶200.) Both references disclose methods of using electrical stimulation to treat neurological disorders. (*Id.*)

A POSITA would have expected success in adjusting the duration of Burnett's system using the timing set forth in Stephens. (*Id.*, ¶201.) Burnett already discloses that the stimulation may be paused. (Ex. 1010, [0188].) A POSITA would have recognized that 10 minutes falls within a typical range for stimulating a patient and would not have expected any negative results from that duration of treatment. (Ex. 1002, ¶201.)

2. Claim 15

Burnett and Stephens render this claim obvious. (Ex. 1002, ¶¶202-203.) Burnett's stimulators may be paused and the signal duration may be changed based on sensor feedback. (*Supra* §VI.F.1.) Stephens discloses automatically pausing electrical stimulation for a preset amount every 10 minutes. (*Id.*) A POSITA would have found it obvious to combine Burnett and Stephens, and expected success in doing so, for the reasons provided above. (Ex. 1002, ¶203.)

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

Burnett and Gesotti '896 render this claim obvious. (Ex. 1002, ¶¶204-205.) Gesotti '896 discloses providing electrical stimulation through a preset number of pulses. (*See supra* §VI.B.3.) A POSITA would have been motivated to combine this treatment protocol with Burnett, and expected success in doing so, because both references disclose methods of treating neurological disorders with electrical stimulation. (Ex. 1002, ¶205.) Moreover, Burnett does not expressly describe the

treatment protocols necessary to address tremor, so a POSITA would have naturally looked to a reference like Gesotti '896 that includes those protocols. (*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 '669 patent or sell any products covered by the '669 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, 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)/325(d). While PO recently filed a lawsuit alleging that Petitioner infringes the '669 patent, PO has not served the complaint and no case schedule has been set. Further, the prior-art combinations and arguments set forth herein were not previously considered by the Patent Office. Finally, the Petition makes a strong

showing that claims 1-20 are unpatentable. Accordingly, none of the factors favoring discretionary denial are present.

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 '669 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 BoxCalaHealth669@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: 206-405-2000 Facsimile: 206-405-2001

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 BoxCalaHealth669@knobbe.com.

X. PAYMENT OF FEES

The undersigned authorizes 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 '669 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 1-20.

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 10,786,669**, exclusive of the parts exempted as provided in 37 C.F.R. §42.24(a), contains 13,845 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/
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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 10,786,669 AND EXHIBITS 1001-2020** are being served on March 29, 2024, via FedEx Priority Overnight to the correspondence address of record for the subject patent **10,786,669** found on the USPTO's Patent Center webpage.

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By: /Joshua J. Stowell/

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