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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/508,529	07/23/2009	Daniel Rogers Burnett	EMKNNZ00301	8186

40518 7590 02/10/2016
LEVINE BAGADE HAN LLP
2400 GENG ROAD, SUITE 120
PALO ALTO, CA 94303

EXAMINER

KUHLMAN, CATHERINE BURK

ART UNIT	PAPER NUMBER
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3735

MAIL DATE	DELIVERY MODE
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02/10/2016

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Cala Health Ex. 1014 (Part 1 of 2)
Cala v. EMKinetics
USP 11,628,300

Notice of Abandonment	Application No.	Applicant(s)
	12/508,529	BURNETT ET AL.
	Examiner	Art Unit
	CATHERINE B. KUHLMAN	3735

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

This application is abandoned in view of:

1. ☒ Applicant's failure to timely file a proper reply to the Office letter mailed on 17 July 2015.
 - (a) ☐ A reply was received on _____ (with a Certificate of Mailing or Transmission dated _____), which is after the expiration of the period for reply (including a total extension of time of _____ month(s)) which expired on _____.
 - (b) ☐ A proposed reply was received on _____, but it does not constitute a proper reply under 37 CFR 1.113 to the final rejection. (A proper reply under 37 CFR 1.113 to a final rejection consists only of: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) if this is utility or plant application, a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. Note that RCEs are not permitted in design applications.)
 - (c) ☐ A reply was received on _____ but it does not constitute a proper reply, or a bona fide attempt at a proper reply, to the non-final rejection. See 37 CFR 1.85(a) and 1.111. (See explanation in box 7 below).
 - (d) ☒ No reply has been received.

2. ☐ Applicant's failure to timely pay the required issue fee and publication fee, if applicable, within the statutory period of three months from the mailing date of the Notice of Allowance (PTOL-85).
 - (a) ☐ The issue fee and publication fee, if applicable, was received on _____ (with a Certificate of Mailing or Transmission dated _____), which is after the expiration of the statutory period for payment of the issue fee (and publication fee) set in the Notice of Allowance (PTOL-85).
 - (b) ☐ The submitted fee of \$_____ is insufficient. A balance of \$_____ is due.
The issue fee required by 37 CFR 1.18 is \$_____. The publication fee, if required by 37 CFR 1.18(d), is \$_____.
 - (c) ☐ The issue fee and publication fee, if applicable, has not been received.

3. ☐ Applicant's failure to timely file corrected drawings as required by, and within the three-month period set in, the Notice of Allowability (PTO-37).
 - (a) ☐ Proposed corrected drawings were received on _____ (with a Certificate of Mailing or Transmission dated _____), which is after the expiration of the period for reply.
 - (b) ☐ No corrected drawings have been received.

4. ☐ The letter of express abandonment which is signed by the attorney or agent of record or other party authorized under 37 CFR 1.33(b). See 37 CFR 1.138(b).

5. ☐ The letter of express abandonment which is signed by an attorney or agent (acting in a representative capacity under 37 CFR 1.34) upon the filing of a continuing application.

6. ☐ The decision by the Board of Patent Appeals and Interference rendered on _____ and because the period for seeking court review of the decision has expired and there are no allowed claims.

7. ☐ The reason(s) below:

	/CATHERINE B. KUHLMAN/ Primary Examiner, Art Unit 3735
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Petitions to revive under 37 CFR 1.137, or requests to withdraw the holding of abandonment under 37 CFR 1.181, should be promptly filed to minimize any negative effects on patent term.



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07/17/2015

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 12/508,529	Applicant(s) BURNETT ET AL.	
	Examiner CATHERINE B. KUHLMAN	Art Unit 3735	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 April 2015.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

- 5) ☒ Claim(s) 1-19 and 21-54 is/are pending in the application.
5a) Of the above claim(s) 1-18 and 35-54 is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 19 and 21-34 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

- a) ☐ All b) ☐ Some** c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) ☐ Notice of References Cited (PTO-892) | 3) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) ☐ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
Paper No(s)/Mail Date ____. | 4) ☐ Other: ____. |

DETAILED ACTION

1. This action is responsive to the amendment filed on April 29th, 2015. The examiner acknowledges the amendments to claims 19 and 34. Claims 1-19 and 21-54 are pending (claims 1-18 and 35-54 are withdrawn from consideration).

Notice of Pre-AIA or AIA Status

2. The present application is being examined under the pre-AIA first to invent provisions.

Claim Rejections - 35 USC § 112

3. The following is a quotation of 35 U.S.C. 112(b):
(b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 19 and 21-34 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention.

5. Claim 19 recites “at least one microneedle patch...configured to generate an electrical stimulus” and a controller "programmed to deliver an electrical stimulus having a frequency sufficient to stimulate the posterior tibial nerve or [a] branch thereof”. It is unclear if the electrical stimulus recited in each quoted portion of the claim is the same. Claim 19 further recites “the controller adjusts or modulates the electrical stimulus delivered through the microneedle patch...based on the feedback provided by the sensor”. It is unclear which "electrical stimulus” is referred to here. Under the broadest reasonable interpretation, multiple

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electrical stimulus signals may be provided, for example a treatment or therapy stimulus provided by a patch and an action potential-evoking stimulus by at least one additional patch.

This issue is also present in claim 34.

6. Claim 19 recites the limitation “the microneedle patch” in line 15. There is insufficient antecedent basis for this limitation in the claim.

7. Claims 21-33 incorporate the indefinite subject matter of claim 19 therein.

8. Claim 23 recites the limitation "said microneedle patch" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

9. The following is a quotation of pre-AIA 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 19, 21-25, and 27-30 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Leung (US 2006/0030845 A1) in view of Byers (US 4837049).

11. Claim 19; Leung discloses an energy emitting system for providing a medical therapy comprising at least one patch electrode 300/302. The electrodes 300 and 302 are used to provide therapy and evoke an action potential respectively [0023]; the stimulus generated by each electrode is focused on a target nerve in proximity to the electrode ([0025] electrical stimulus may be high frequency for therapy and/or lower frequency to generate an evoked potential). A sensor 306 is attachable to the skin surface in proximity to the target nerve which is configured to detect electrical conduction in the target nerve to provide feedback regarding the therapy to a

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controller 102/200 [0020-21]. The controller is coupled to the at least one patch 300/302 and is programmed to deliver an electrical stimulus having a frequency sufficient to stimulate a target nerve ([0013 and 0025], electrical stimulus delivered through patch electrode 302 configured for generating an evoked potential). The controller delivers the electrical stimulus (the therapeutic stimulus and/or the potential-evoking stimulus) through the at least one patch 300/302. The controller receives feedback from the sensor 306 based on the electrical conduction through the nerve detected by the sensor and adjusts the therapeutic electrical stimulus delivered through the microneedle patch 300 based thereon [0020 and 46]. Leung does not specifically disclose the at least one electrode patch 300/302 comprises a microneedle array deposited on the surface of an electrode. Byers discloses an electrode patch that can be used for applying electrical signals to nerve tissue (col. 2, line 58 - col. 3, line 5) comprising an array of microneedles deposited on a surface of at least one electrode (or conducting layer) (col. 10, lines 18-29). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the microneedle array patch electrode disclosed by Byers as the at least one patch electrode 300/302 in Leung's system because Byers discloses this type of electrode provides good electrical contact with subcutaneous conductive tissue (col. 5, lines 45-51).

Leung does not specifically disclose electrical stimulation focused on the posterior tibial nerve or a branch thereof or detecting electrical conduction through the posterior tibial nerve or a branch thereof and placement of the sensor on the foot. However, Leung does disclose the stimulating electrode patch 300 and sensor 306 can be placed along any neural pathway of the body [0048]. Leung also discloses detecting afferent (or sensory) nerve stimulation along the target nerve pathway [0039]. Since the patch and sensor may be surface or skin electrodes

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[0023] they could be placed anywhere on the skin of the patient, therefore the at least one patch electrode 300/302 is configured to generate an electrical stimulus focused on the posterior tibial nerve or a branch thereof if placed at an appropriate position along the foot or leg, and the sensor 306 is adapted for placement on a foot and is configured to detect conduction through the tibial nerve or a branch thereof by detecting a signal that an afferent nerve has been stimulated if also placed at an appropriate position along the foot or leg. Placement of the sensor and patch as claimed can be done without changing the structure of the prior art device, therefore the device disclosed by Leung in view of Byers obviates claim 19.

12. Claim 21; Leung discloses the electrical stimulus provided by the patch 300 is varied according to the electrical conduction detected by the sensor 306 to measure the efficacy of treatment and/or to ensure treatment has not affected the nervous system in an undesirable manner [0026]. Measuring the efficacy of treatment is a technique for ensuring adequate therapeutic stimulation [0026].

13. Claim 22; the microneedle array disclosed by Byers may be etched from a surface of the electrode (col. 10, lines 6-9, 18-22, and 55-62).

14. Claim 23; each microneedle disclosed by Byers comprises an electrically conductive material (col. 10, lines 32-38) which can transmit an electrical signal to an overlying electrode (electrical conductor material col. 10, lines 18-22).

15. Claim 24; Byers discloses the needles comprise metal (col. 10, lines 32-35).

16. Claim 25; Leung discloses the sensor 306 may have the same structure as the at least one patch electrode 300/302 [0023] which, according to the above combination of Leung in view of Byers, is a microneedle array.

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17. Claims 27-30; Byers discloses needle diameters of 5-10 microns and a length of 100 microns (col. 7, lines 37-42).

18. Claims 26 and 34 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Leung in view of Byers as applied to claim 19 above, and further in view of Surgenor (US 2006/0049957 A1).

19. Claim 26; Leung in view of Byers is silent as to a bulb extending from at least one microneedle of the array. However, Surgenor discloses microneedles of an electrode array can be provided with anchoring means such as bulbous tips [0062]. It would have been obvious to one of ordinary skill in the art at the time of the invention to include a bulbous tip on at least some of the microneedles in the system disclosed by Leung in view of Byers in order to aid in anchoring of the electrode substrate to tissue, as taught by Surgenor [0062].

20. Claim 34; Leung discloses an energy emitting system for providing a medical therapy comprising at least one patch electrode 300/302. The electrodes 300 and 302 are used to provide therapy and evoke an action potential respectively [0023]; the stimulus generated by each electrode is focused on a target nerve in proximity to the electrode ([0025] electrical stimulus may be high frequency for therapy and/or lower frequency to generate an evoked potential). A sensor 306 is attachable to the skin surface in proximity to the target nerve which is configured to detect electrical conduction in the target nerve to provide feedback regarding the therapy to a controller 102/200 [0020-21]. The controller is coupled to the at least one patch 300/302 and is programmed to deliver an electrical stimulus having a frequency sufficient to stimulate a target nerve ([0013 and 0025], electrical stimulus delivered through patch electrode 302 configured for

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generating an evoked potential). The controller delivers the electrical stimulus (the therapeutic stimulus and/or the potential-evoking stimulus) through the at least one patch 300/302. The controller receives feedback from the sensor 306 based on the electrical conduction through the nerve detected by the sensor and adjusts the therapeutic electrical stimulus delivered through the microneedle patch 300 based thereon [0020 and 46]. Leung does not specifically disclose the at least one electrode patch 300/302 comprises a microneedle array deposited on the surface of an electrode. Byers discloses an electrode patch that can be used for applying electrical signals to nerve tissue (col. 2, line 58 - col. 3, line 5) comprising an array of microneedles deposited on a surface of at least one electrode (or conducting layer) (col. 10, lines 18-29). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the microneedle array patch electrode disclosed by Byers as the at least one patch electrode 300/302 in Leung's system because Byers discloses this type of electrode provides good electrical contact with subcutaneous conductive tissue (col. 5, lines 45-51).

Leung in view of Byers is silent as to a bulb extending from at least one microneedle of the array. However, Surgenor discloses microneedles of an electrode array can be provided with anchoring means such as bulbous tips [0062]. It would have been obvious to one of ordinary skill in the art at the time of the invention to include a bulbous tip on at least some of the microneedles in the system disclosed by Leung in view of Byers in order to aid in anchoring of the electrode substrate to tissue, as taught by Surgenor [0062].

Leung does not specifically disclose electrical stimulation focused on the posterior tibial nerve or a branch thereof or detecting electrical conduction through the posterior tibial nerve or a branch thereof and placement of the sensor on the foot. However, Leung does disclose the

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stimulating electrode patch 300 and sensor 306 can be placed along any neural pathway of the body [0048]. Leung also discloses detecting afferent (or sensory) nerve stimulation along the target nerve pathway [0039]. Since the patch and sensor may be surface or skin electrodes [0023] they could be placed anywhere on the skin of the patient, therefore the patch 300 is configured to generate an electrical stimulus focused on the posterior tibial nerve or a branch thereof if placed at an appropriate position along the foot or leg, and the sensor 306 is adapted for placement on a foot and is configured to detect conduction through the tibial nerve or a branch thereof by detecting a signal that an afferent nerve has been stimulated if also placed at an appropriate position along the foot or leg. Placement of the sensor and patch as claimed can be done without changing the structure of the prior art device, therefore the device disclosed by Leung in view of Byers and Surgenor obviates claim 34.

21. Claims 31 and 32 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Leung in view of Byers as applied to claim 19 above, and further in view of Malaney (US 2002/0183804 A1).

22. Claims 31 and 32; Leung is silent as to an electrode needle coupled to the controller and inductively coupled to the patch 300/302. However, Malaney discloses an electrode needle 12 coupled to a controller 10 with an end insertable into the body in proximity to a stimulation site 15. The needle is inductively coupled to a patch electrode 14 and the patch is positioned distal to the stimulation site such that upon activation of the controller, a current traverses the stimulation site by passing from the patch to the electrode needle [0031]. It would have been obvious to one of ordinary skill in the art at the time of the invention to include an electrode needle inductively

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coupled to the patch electrode in the system taught by Leung in view of Byers, similar to the configuration taught by Malaney, because it allows for more precise targeting of the electrical stimulus provided by the electrode patch since the electrode needle can be inserted directly adjacent the target nerve.

23. Claim 33 is rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Leung in view of Byers in view of Malaney as applied to claim 32 above, and further in view of Fairbanks (US 4233965).

24. Leung, Byers, and Malaney are silent as to a conductive coil positioned distal to the stimulation site and coupled to the controller. Fairbanks discloses a modified electrical stimulation device comprising a conductive coil 14 over an electrode patch 12 connected to a controller 32 (fig. 1a). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate a conductive coil over the at least one electrode patch in the system disclosed by Leung in view of Byers and Malaney because Fairbanks discloses the coil helps focus the electric current into tissue (col. 2, lines 46-47 and col. 3, line 65 - col. 4, line 3). When a conductive coil is present over the at least one electrode patch location in the combination, it will also be located distal to the stimulation site such that upon activation of said controller, a current traverses the stimulation site by passing from the patch and the coil to the electrode needle (Malaney [0031]).

Response to Arguments

25. Applicant's arguments filed April 29th, 2015 have been fully considered but they are not persuasive.

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26. Applicant submits there is no motivation to combine the teachings of Leung and Byers because the electrode patch of Byers is designed merely to stimulate the nerve to create muscular action rather than perform electro-surgery (i.e. cut tissue) as required by Leung's electrosurgical system. The examiner respectfully disagrees. Leung states the conductive components 300, 302, 304, and/or 306 may all comprise surface or patch electrodes. Byers teaches an exemplary configuration for a patch electrode; the nature of the stimulation provided by the patch (whether therapeutic or for evoking a potential) is determined by the controller of Leung.

27. Applicant submits that a first signal, as provided by component 300, having a frequency from about 260 kHz to about 1.5 MHz is for cutting tissue and not stimulating tissue. The examiner does not dispute this and notes that the electrical stimulus recited as being provided by the at least one microneedle patch in lines 4-6 of claim 19 is not recited for any specific purpose and is not limited to only stimuli in the action-potential-evoking range.

28. Applicant submits that Leung does not teach a controller programmed to deliver an electrical stimulus having a frequency sufficient to stimulate the posterior tibial nerve. The examiner respectfully disagrees. Leung discloses delivering a stimulating frequency to the nerve using patch electrode 302. Electrode 302 is part of the "at least one microneedle patch" made up of patches 300 and 302. Claim 19 is ambiguous as to whether the electrical stimulus for stimulating the posterior tibial nerve in lines 13-14 is the same as the electrical stimulus focused on the posterior tibial nerve in line 5.

29. Applicant submits the examiner fails to show how measuring efficacy and ensuring treatment has not affected the nervous system in an undesirable manner is the same as ensuring adequate therapeutic stimulation, as stated in claim 21. The examiner notes that "measuring the

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efficacy of treatment" is a form of ensuring adequate therapeutic stimulation because it will determine whether treatment is effective. If treatment is effective, it means that therapy was adequate.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CATHERINE B. KUHLMAN whose telephone number is (571)270-7130. The examiner can normally be reached on Monday-Friday 8:30 am - 5:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CATHERINE B. KUHLMAN/
Primary Examiner, Art Unit 3735

<i>Index of Claims</i> 	Application/Control No. 12508529	Applicant(s)/Patent Under Reexamination BURNETT ET AL.
	Examiner CATHERINE B KUHLMAN	Art Unit 3735

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant										☐ CPA										☐ T.D.										☐ R.1.47									
CLAIM		DATE																																					
Final	Original	06/27/2012	01/24/2013	10/24/2013	03/19/2014	10/23/2014	07/14/2015																																
	1	÷	N	N	N	N	N																																
	2	÷	N	N	N	N	N																																
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	35	÷	N	N	N	N	N																																
	36	÷	N	N	N	N	N																																

<i>Index of Claims</i> 	Application/Control No. 12508529	Applicant(s)/Patent Under Reexamination BURNETT ET AL.
	Examiner CATHERINE B KUHLMAN	Art Unit 3735

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47									
CLAIM		DATE							
Final	Original	06/27/2012	01/24/2013	10/24/2013	03/19/2014	10/23/2014	07/14/2015		
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	54	÷	N	N	N	N	N		

Search Notes 	Application/Control No. 12508529	Applicant(s)/Patent Under Reexamination BURNETT ET AL.
	Examiner CATHERINE B KUHLMAN	Art Unit 3735

CPC- SEARCHED		
Symbol	Date	Examiner
A61N 2/00-12	7/14/2015	CBK

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
600	9-15	1/24/2013	CEB
607	2-76, 115-156	10/24/2013	CEB
601	15-22	10/24/2013	CEB
606	32-52	10/24/2013	CEB

SEARCH NOTES		
Search Notes	Date	Examiner
EAST Text	1/24/2013	CEB
IDS	1/24/2013	CEB
Inventor Names	1/24/2013	CEB
Class/Subclass	1/24/2013	CEB
Forward/Backward	1/24/2013	CEB
Updated EAST Search	10/24/2013	CEB
Updated EAST Search	3/19/2014	CBK
Updated EAST Search	10/23/2014	CBK

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner

	/C.B.K./ Primary Examiner.Art Unit 3735
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EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
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S1	761	loeb.in.	US-PGPUB; USPAT; USOCR	OR	ON	2012/06/20 15:15
S2	73	S1 and stimulator	US-PGPUB; USPAT; USOCR	OR	ON	2012/06/20 15:15
S3	1	("7798954").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/06/20 16:51
S4	1	(12/508529).APP.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/01/24 09:51
S5	1	(11/866329).APP.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/01/24 10:32
S6	102	(daniel near2 burnett).in.	US-PGPUB; USPAT; USOCR	OR	ON	2013/01/24 10:36
S7	7	S6 and (microneedle near5 (patch or array))	US-PGPUB; USPAT; USOCR	OR	ON	2013/01/24 10:36
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S16	1939	(600/9-15).CCLS.	US- PGPUB; USPAT; USOCR	OR	OFF	2013/01/24 13:08
S17	43980	electric\$5 near5 stimulat\$	US- PGPUB; USPAT; USOCR	OR	ON	2013/01/24 13:09
S18	453	S16 and S17	US- PGPUB; USPAT; USOCR	OR	ON	2013/01/24 13:09
S19	45775	(\$cutaneous\$ or skin) near5 (patch or electrode)	US- PGPUB;	OR	ON	2013/01/24 13:11

			USPAT; USOCR			
S20	8434	S17 and S19	US- PGPUB; USPAT; USOCR	OR	ON	2013/01/24 13:13
S21	6044	S20 and (nerve or neuron or neural)	US- PGPUB; USPAT; USOCR	OR	ON	2013/01/24 13:14
S22	115	S18 and S19	US- PGPUB; USPAT; USOCR	OR	ON	2013/01/24 13:14
S23	12212	(electric\$ near\$ stimulat\$) with (nerve neuron neural neuro)	US- PGPUB; USPAT; USOCR	OR	ON	2013/01/24 13:45
S24	3722	S19 and S23	US- PGPUB; USPAT; USOCR	OR	ON	2013/01/24 13:45
S25	23913	(patch or electrode) with (needle or microneedle or nanoneedle or barb or spike)	US- PGPUB; USPAT; USOCR	OR	ON	2013/01/24 13:46
S26	1081	S24 and S25	US- PGPUB; USPAT; USOCR	OR	ON	2013/01/24 13:46
S27	20089	(patch or electrode) with (needle or microneedle or nanoneedle)	US- PGPUB; USPAT; USOCR	OR	ON	2013/01/24 13:46
S28	999	S24 and S27	US- PGPUB; USPAT; USOCR	OR	ON	2013/01/24 13:46
S29	113941	(sense sensor sensed sensing detect detecting detector detected) near\$ (conduction conductiv\$ stimulat\$)	US- PGPUB; USPAT; USOCR	OR	ON	2013/01/24 13:48
S31	487	S28 and S29	US- PGPUB; USPAT; USOCR	OR	ON	2013/01/24 13:49
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S33	11	(james near\$ malaney).in.	US- PGPUB; USPAT; USOCR	OR	ON	2013/01/24 15:48
S34	22933	tip near\$ (bulb or bulbous or sphere or spheric\$ or ball)	US- PGPUB; USPAT; USOCR	OR	ON	2013/01/24 15:49

S35	542	S25 and S34	US-PGPUB; USPAT; USOCR	OR	ON	2013/01/24 15:51
S36	76	S35 and S23	US-PGPUB; USPAT; USOCR	OR	ON	2013/01/24 15:51
S37	36728	plurality with (needle or microneedle or nanoneedle or spike)	US-PGPUB; USPAT; USOCR	OR	ON	2013/01/24 16:03
S38	12318	plurality near (needle or microneedle or nanoneedle or spike)	US-PGPUB; USPAT; USOCR	OR	ON	2013/01/24 16:04
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S44	22933	tip near5 (bulb or bulbous or sphere or spheric\$ or ball)	US-PGPUB; USPAT; USOCR	OR	ON	2013/01/24 18:45
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S47	37933	S43 adn S46	US-PGPUB; USPAT; USOCR	OR	ON	2013/01/24 18:46
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S51	20587	(electrode) with (needle or microneedle or nanoneedle or spike)	US- PGPUB; USPAT; USOCR	OR	ON	2013/01/24 19:00
S52	19683	(needle or microneedle or nanoneedle or barb or spike) near10 (bulb or bulbous or sphere or spheric\$ or ball)	US- PGPUB; USPAT; USOCR	OR	ON	2013/01/24 19:01
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S54	582	S51 and S53	US- PGPUB; USPAT; USOCR	OR	ON	2013/01/24 19:01
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S56	152	S55 and (skin or \$cutaneous)	US- PGPUB; USPAT; USOCR	OR	ON	2013/01/24 19:02
S57	24933	(607/2-76).OCLS.	US- PGPUB; USPAT; USOCR	OR	OFF	2013/10/24 17:54
S58	11281	(607/115-156).OCLS.	US- PGPUB; USPAT; USOCR	OR	OFF	2013/10/24 17:56
S59	591	(607/152).OCLS.	US- PGPUB; USPAT; USOCR	OR	OFF	2013/10/24 17:57
S60	1555	(601/15-22).OCLS.	US- PGPUB; USPAT; USOCR	OR	OFF	2013/10/24 17:59
S61	12197	(606/32-52).OCLS.	US- PGPUB; USPAT; USOCR	OR	OFF	2013/10/24 18:01
S62	2075	(600/9-15).OCLS.	US- PGPUB; USPAT; USOCR	OR	OFF	2013/10/24 18:01
S63	788	S62 and (electrode or (electric\$5 near5 stimulat\$))	US- PGPUB; USPAT; USOCR	OR	ON	2013/10/24 18:02

S64	52128	stimulat\$5 with (nerve neuron\$ neural)	US-PGPUB; USPAT; USOCR	OR	ON	2013/10/24 18:03
S65	57414	stimulat\$5 with (nerve neuron\$ neural nervous)	US-PGPUB; USPAT; USOCR	OR	ON	2013/10/24 18:03
S66	48223	S57 S58 S60 S61 S62	US-PGPUB; USPAT; USOCR	OR	ON	2013/10/24 18:03
S67	14456	S65 and S66	US-PGPUB; USPAT; USOCR	OR	ON	2013/10/24 18:03
S68	79196	(sense sensor sensed sensing detect\$5 minitor\$5) with (((nerve or neuron\$ or neural or nervous) near5 (conduction or conductiv\$)) or (muscle near S61 (stimulat\$ or contract\$5)))	US-PGPUB; USPAT; USOCR	OR	ON	2013/10/24 18:05
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S70	5073	(\$needle near5 (patch or array))	US-PGPUB; USPAT; USOCR	OR	ON	2013/10/24 18:06
S71	230	S67 and S70	US-PGPUB; USPAT; USOCR	OR	ON	2013/10/24 18:06
S72	138	S69 and S70	US-PGPUB; USPAT; USOCR	OR	ON	2013/10/24 18:42
S73	122	S72 and (sensor monitor detector)	US-PGPUB; USPAT; USOCR	OR	ON	2013/10/24 18:45
S74	5	((11/105527) or (11/125247) or (11/079318)).APP.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/10/24 20:27
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S77	5172	deep near brain near stimulat\$	US-PGPUB; USPAT; USOCR	OR	ON	2014/03/19 12:40
S78	2654	S77 and (coil or microcoil)	US-PGPUB;	OR	ON	2014/03/19 12:40

			USPAT; USOCR			
S79	167	S77 and probe with (coil or microcoil or electromag\$)	US- PGPUB; USPAT; USOCR	OR	ON	2014/03/19 12:41
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S89	339	S88 with (ablate ablation ablating)	US- PGPUB; USPAT; USOCR	OR	ON	2014/10/23 13:46
S90	42849	(electric or electrical) near (stimulat\$ or stimulus)	US- PGPUB; USPAT; USOCR	OR	ON	2014/10/23 13:47
S91	417	S90 with (ablate ablation ablating)	US- PGPUB; USPAT; USOCR	OR	ON	2014/10/23 13:47
S92	78	S91 not S89	US- PGPUB; USPAT; USOCR	OR	ON	2014/10/23 13:47
S93	1	("20020183647").PN.	US- PGPUB; USPAT; USOCR	OR	OFF	2015/07/13 11:42

7/ 14/ 2015 5:52:55 PM
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I hereby certify that this correspondence is being electronically transmitted to the USPTO on the date shown below.

Date: April 29, 2015 Signature: /Kim E. Lampkins/ (Kim E. Lampkins)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.: 12/508,529
Confirmation No.: 8186
Filing Date: July 23, 2009
Inventor(s): Daniel R. BURNETT et al.
Title: METHOD AND APPARATUS FOR MAGNETIC INDUCTION
THERAPY
Examiner: Catherine B. Kuhlman
Group Art Unit: 3735

RESPONSE TO NON-FINAL OFFICE ACTION

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Madam:

This is in response to the non-final Office Action dated October 30, 2014 for which a response was due on January 30, 2015. Filed herewith is a Petition and fee for a 3-month extension of time, thereby extending the deadline for response to April 30, 2015. Accordingly, this response is timely filed. Reconsideration and allowance of the pending claims, as amended, in light of the Remarks presented herein are respectfully requested.

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks begin on page 11 of this paper.

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

In the claims

1. (Withdrawn): An energy emitting system for providing a medical therapy comprising:

at least one conductive coil disposed within or along a housing, where the at least one coil is configured to generate a magnetic field focused on a target nerve in proximity to the at least one coil;

at least one sensor configured to detect electrical conduction in the target nerve or muscle stimulation, wherein the sensor is comprised of a microneedle array attachable to a skin surface in proximity to a target nerve or muscle; and

a controller coupled to said at least one conductive coil and in communication with said at least one sensor.

2. (Withdrawn): The system of claim 1, wherein the magnetic field generated by said at least one conductive coil is varied based on the electrical conduction or muscle stimulation detected by said at least one sensor to ensure adequate therapeutic stimulation.

3. (Withdrawn): The system of claim 1, wherein the microneedle array is arrayed over a housing.

4. (Withdrawn): The system of claim 3, wherein the housing is comprised of a patch having at least one electrode and said microneedle array extends from a first surface of the electrode.

5. (Withdrawn): The system of claim 4, wherein the patch comprises a positive, negative and control electrode, each electrode comprising a microneedle array extending therefrom.

6. (Withdrawn): The system of claim 4, wherein the microneedle array is etched from a surface of the electrode.

7. (Withdrawn): The system of claim 1, wherein said microneedle array comprises at least one microneedle comprising an electrically conductive material such that it can transmit an electrical signal to an overlying electrode.

8. (Withdrawn): The system of claim 7, wherein said microneedle comprises metal, silicon, biocompatible polymers, titanium, silver, or suture material.

9. (Withdrawn): The system of claim 1, wherein said microneedle array comprises at least one microneedle coated with an electrically conductive material such that it can transmit an electrical signal to an overlying electrode.

10. (Withdrawn): The system of claim 1, wherein said microneedle array comprises at least one microneedle comprising a distal tip and a bulb extending from said distal tip to provide for anchoring of said microneedle into a subject's skin.

11. (Withdrawn): The system of claim 1, wherein said microneedle array comprises at least one microneedle having a diameter in the range of about 1 to 100 microns.

12. (Withdrawn): The system of claim 11, wherein a diameter of said microneedle is in the range of about 10 to 30 microns.

13. (Withdrawn): The system of claim 1, wherein said microneedle array comprises at least one microneedle having a length in the range of about 1 to 100 microns.

14. (Withdrawn): The system of claim 13, wherein a length of said microneedle is in the range of about 100 to 150 microns.

15. (Withdrawn): The system of claim 1, further comprising an electrode needle coupled to said controller and having an end insertable into a subject's body in proximity to a stimulation site, wherein said needle is inductively coupled to said at least one conductive coil.

16. (Withdrawn): The system of claim 15, wherein said at least one conductive coil is positioned distal to said stimulation site such that upon activation of said controller a current traverses the stimulation site by passing from said at least one conductive coil to said percutaneous electrode needle.

17. (Withdrawn): The system of claim 16, further comprising at least one conductive microneedle patch positioned distal to said stimulation site and coupled to the controller such that upon activation of said controller a current traverses the stimulation site by passing from said at least one conductive microneedle patch and said at least one conductive coil to said electrode needle.

18. (Withdrawn): An energy emitting system for providing a medical therapy comprising:

at least one conductive coil disposed within or along a housing, where the at least one coil is configured to generate a magnetic field focused on a target nerve in proximity to the at least one coil;

at least one sensor configured to detect electrical conduction in the target nerve or muscle stimulation, wherein the sensor is comprised of at least one microneedle comprising an electrically conductive material such that it can transmit an electrical signal to an overlying electrode and a distal tip having a bulb extending from said distal tip to provide for anchoring of said microneedle into a subject's skin; and

a controller coupled to said at least one conductive coil and in communication with said at least one sensor.

19. (Currently amended): An energy emitting system for providing a medical therapy comprising:

at least one microneedle patch comprised of a microneedle array deposited on a surface of at least one electrode, where said at least one microneedle patch is configured to generate an electrical stimulus focused on a posterior tibial nerve or a branch thereof in proximity to the at least one conductive microneedle patch;

at least one sensor configured to detect electrical conduction through the posterior tibial nerve or a branch thereof by detecting a signal that an afferent nerve has been stimulated to provide feedback regarding the therapy, wherein the sensor is attachable to a skin surface in proximity to a nerve or muscle, wherein the sensor is adapted for placement on a foot of a patient and

a controller coupled to said at least one microneedle patch, wherein the controller is programmed to deliver an electrical stimulus having a frequency sufficient to stimulate the posterior tibial nerve or the branch thereof, wherein the controller delivers ~~[[an]]~~ the

electrical stimulus through the microneedle patch, and[[.]] wherein the system comprises a feedback loop, wherein the controller receives feedback from the sensor based on the signal detected by the sensor, and the controller adjusts or modulates the electrical stimulus delivered through the microneedle patch to the posterior tibial nerve or a branch thereof based on the feedback provided by the sensor.

20. (Canceled)

21. (Previously presented): The system of claim 19, wherein the electrical stimulus generated by said at least one microneedle patch is varied according to the electrical conduction or a muscle stimulation detected by said at least one sensor to ensure adequate therapeutic stimulation.

22. (Original): The system of claim 19, wherein the microneedle array is etched from a surface of the electrode.

23. (Original): The system of claim 19, wherein said microneedle patch comprises at least one microneedle comprising an electrically conductive material such that it can transmit an electrical signal to an overlying electrode.

24. (Original): The system of claim 23, wherein said microneedle comprises metal, silicon, biocompatible polymers, titanium, silver, or suture material.

25. (Original): The system of claim 19, wherein said sensor is comprised of at least one microneedle array.

26. (Original): The system of claim 19, wherein said microneedle array comprises at least one microneedle comprising a distal tip and a bulb extending from said distal tip to provide for anchoring of said microneedle into a subject's skin.

27. (Original): The system of claim 19, wherein said microneedle array comprises at least one microneedle having a diameter in the range of about 1 to 100 microns.

28. (Original): The system of claim 27, wherein a diameter of said microneedle is in the range of about 10 to 30 microns.

29. (Original): The system of claim 19, wherein said microneedle array comprises at least one microneedle having a length in the range of about 1 to 150 microns.

30. (Original): The system of claim 29, wherein a length of said microneedle is in the range of about 100 to 150 microns.

31. (Original): The system of claim 19, further comprising an electrode needle coupled to said controller and having an end insertable into a subject's body in proximity to a stimulation site, wherein said needle is inductively coupled to said at least one conductive microneedle patch.

32. (Previously Presented): The system of claim 31, wherein said at least one microneedle patch is adapted to be positioned distal to said stimulation site such that upon activation of said controller a current traverses the stimulation site by passing from said at least one microneedle patch to said electrode needle.

33. (Original): The system of claim 32, further comprising at least one conductive coil positioned distal to said stimulation site and coupled to said controller such that upon activation of said controller a current traverses the stimulation site by passing from said at least one microneedle patch and said at least one conductive coil to said electrode needle.

34. (Currently amended): An energy emitting system for providing a medical therapy comprising:

at least one conductive microneedle patch comprised of a microneedle array deposited on a surface of at least one electrode, wherein said microneedle array comprises an electrically conductive material such that it can transmit an electrical signal to an overlying electrode wherein a distal tip of at least one microneedle of the microneedle array has a bulb extending from said distal tip to provide for anchoring of said microneedle into a subject's skin, said microneedle patch configured to deliver an electrical stimulus to a posterior tibial nerve or a branch thereof in proximity to the at least one conductive microneedle patch;

at least one sensor configured to detect electrical conduction through the posterior tibial nerve or a branch thereof by detecting a signal that an afferent nerve has been stimulated and wherein the sensor is attachable to a skin surface in proximity to a nerve or muscle, wherein the sensor is adapted for placement on a foot of a patient; and

a controller coupled to said at least one conductive microneedle patch and in communication with said at least one sensor, wherein the controller is programmed to deliver an electrical stimulus having a frequency sufficient to stimulate the posterior tibial nerve or

the branch thereof, wherein the controller delivers ~~[[an]]~~ the electrical stimulus through the microneedle patch, and~~[[,]]~~ wherein the system comprises a feedback loop, wherein the controller receives feedback from the sensor based on the signal detected by the sensor, and the controller adjusts or modulates the electrical stimulus delivered through the microneedle patch to the posterior tibial nerve or a branch thereof based on the feedback provided by the sensor.

35. (Withdrawn): An energy emitting system for providing a medical therapy comprising:

at least one conductive coil disposed within or along a housing, where the at least one coil is configured to generate a magnetic field focused on a target nerve in proximity to the at least one coil;

an electrode needle having an end insertable into a subject's body in proximity to a stimulation site, wherein said needle is inductively coupled to said at least one conductive coil; and

a controller coupled to said at least one conductive coil and said electrode needle.

36. (Withdrawn): The system of claim 35, wherein said at least one conductive coil is positioned distal to said stimulation site such that upon activation of said controller a current traverses the stimulation site by passing from said at least one conductive coil to said electrode needle.

37. (Withdrawn): The system of claim 35, further comprising at least one sensor in communication with said controller and configured to detect electrical conduction in the target nerve or muscle stimulation and attachable to a skin surface in proximity to a target nerve or muscle, wherein the magnetic field generated by said at least one conductive coil is varied based on the muscle stimulation or electrical conduction detected by said at least one sensor to ensure adequate therapeutic stimulation.

38. (Withdrawn): A method of treating a subject with urinary incontinence comprising:

positioning a first portion of a subject's body, the subject exhibiting symptoms associated with urinary incontinence, relative to an energy emitting device such that a tibial

nerve within the first portion of the body is in proximity to at least one energy generator disposed within or along the energy emitting device;

passing a current through the at least one energy generator to produce a magnetic field or electrical stimulus focused on the tibial nerve;

stimulating a nerve that innervates the pelvic floor of the subject via stimulation of the tibial nerve with the magnetic field or electrical stimulus; and

reducing symptoms associated with urinary incontinence.

39. (Withdrawn): The method of claim 38, wherein the energy generator comprises a conductive coil for generating a magnetic field.

40. (Withdrawn): The method of claim 39, wherein positioning comprises placing a foot, ankle, or leg relative to at least one conductive coil disposed within or along a housing.

41. (Withdrawn): The method of claim 39, wherein positioning comprises placing a popliteal fossa relative to at least one conductive coil disposed within or along a housing.

42. (Withdrawn): The method of claim 38, wherein the energy generator comprises a microneedle patch for producing a magnetic field or electrical stimulus.

43. (Withdrawn): The method of claim 38, wherein a nerve that innervates the pelvic floor comprises the pudendal nerve or sacral plexus.

44. (Withdrawn): The method of claim 38, wherein symptoms associated with urinary incontinence comprise urinary leakage, loss of bladder control and the inability to control urinary function.

45. (Withdrawn): The method of claim 38, further comprising detecting electrical conduction through the tibial nerve or corresponding muscle stimulation via at least one sensor positioned along a second portion of the body.

46. (Withdrawn): The method of claim 45, wherein the sensor comprises a microneedle array.

47. (Withdrawn): The method of claim 45, wherein the sensor is positioned in proximity to the tibial nerve, over a muscle innervated by the tibial nerve, or over the popliteal fossa.

48. (Withdrawn): The method of claim 45, further comprising adjusting the current via a controller in communication with the energy generator according to a signal received from the sensor indicative of the nerve conduction.

49. (Withdrawn): The method of claim 48, wherein adjusting comprises adjusting amplitude, frequency, direction of a magnetic field, or firing sequence of the energy generator.

50. (Withdrawn): The method of claim 48, wherein adjusting comprises adjusting a position of the at least one coil relative to the first portion of the subject's body to re-focus the magnetic field on the tibial nerve.

51. (Withdrawn): The method of claim 48, wherein adjusting comprises adjusting a position of the microneedle patch relative to the first portion of the subject's body to re-focus the electrical or magnetic stimulus on the tibial nerve.

52. (Withdrawn): The method of claim 48, wherein adjusting comprises varying the current according to a muscular response in the patient.

53. (Withdrawn): The method of claim 39, wherein the conductive coil is operated at about 10 to 20 hertz to generate a magnetic field of about .25 to 1.5 tesla for a duration of about 30 minutes per day.

54. (Withdrawn): A method of treating a subject with urinary incontinence comprising:

- positioning a first portion of a subject's body, the subject exhibiting symptoms associated with urinary incontinence, relative to a housing such that a posterior tibial nerve within the first portion of the body is in proximity to at least one conductive coil disposed within or along the housing;

- passing a current through the at least one conductive coil to produce a magnetic field focused on the posterior tibial nerve;

- detecting electrical conduction of the posterior tibial nerve via at least one microneedle array positioned along a second portion of the body;

- receiving a signal from the microneedle array indicative of the electrical conduction;

adjusting the current via a controller in communication with the conductive coil according to the signal received from the microneedle array; and
reducing symptoms associated with urinary incontinence.

REMARKS

Claims 1-19 and 21-54 were pending in the present application. Claims 1-18 and 35-54 were withdrawn from consideration. By virtue of this response, no claims have been cancelled, claims 19 and 34 have been amended, and no new claims have been added. Accordingly, claims 19 and 21-34 are currently under consideration. Amendment and cancellation of certain claims is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented. No new matter has been added.

Rejections under 35 U.S.C. §103(a)

A. Claims 19, 21-25 and 27-30 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Leung (U.S. Patent Publication No. 2006/0030845) in view of Byers (U.S. Patent No. 4,837,049).

Applicant respectfully traverses the rejection and contends that there is no motivation or suggestion to combine the teachings of Leung and Byers. The Office Action states “it would have been obvious to one of ordinary skill in the art at the time of the invention to use the micro needle array patch electrode disclosed by Byers as the electrode patch 300 in Leung’s system because Byers discloses this type of electrode provides good electrical contact with subcutaneous conductive tissue (col. 5, lines 45-51).” (Office Action, Page 3). However, there is no motivation to combine the micro needle array patch electrode of Byers with Leung’s electrosurgical system because the micro needle array patch electrode of Byers is designed to merely stimulate the nerve to create muscular action (Byers: Col. 1, Ln. 60-62) rather than perform electrosurgery (i.e., cut tissue) as required by Leung’s electrosurgical system.

Further, the office action states “applicant submits that Leung is directed to a system for performing and monitoring electrosurgical treatment and does not describe a system as claimed but fails to set forth any specific support for this assertion.” (Office Action, Page 8). Electrosurgery is defined as “the surgical use of high-frequency electric current for cutting or destroying tissue, as in electrocauterization.” (<http://medical-dictionary.thefreedictionary.com/electrosurgery>). Applicant points to claims 1, 15, 43, 64 and 67 of Leung which state “electrosurgical” or “electrosurgery.” Applicant points to the title of

Leung which is “Electrosurgical treatment in conjunction with monitoring.” Applicant further points to claim 2 which recites a first signal from component 300 having a frequency from about 260 kHz to about 1.5 MHz. Such a high frequency is used for cutting tissue (not stimulating tissue).

Independent claim 19 has also been amended to further distinguish the claimed subject matter such that the claim as amended now recites: “... wherein the controller is programmed to deliver an electrical stimulus having a frequency sufficient to stimulate the posterior tibial nerve or the branch thereof” Independent claim 34 has been similarly amended. The claimed controller is programmed to deliver an electrical stimulus that has a frequency sufficient to stimulate the posterior tibial nerve or branch rather than to subjecting the nerve to high-frequency electric currents for cutting or destroying the tissue.

Clearly, Leung is directed to a system for performing and monitoring electrosurgical treatment by creating a lesion in a nerve by a first signal from component 300 and sending a second signal through the nerve path to ensure the nerve path is still intact during the electrosurgical treatment. (Leung, Paragraph [0026]). Indeed, Leung does not teach a controller programmed to deliver an electrical stimulus having a frequency sufficient to stimulate the posterior tibial nerve or the branch thereof, as stated in claim 19. Byers fails to cure the defects of Leung.

With respect to dependent claim 21, the claim presently recites “wherein the electrical stimulus generated by said at least one microneedle patch is varied according to the electrical conduction or a muscle stimulation detected by said at least one sensor to ensure adequate therapeutic stimulation.” The Office Action states that “Leung discloses the electrical stimulus provided by the patch 300 is varied according to the electrical conduction detected by the sensor 306 to measure the efficacy of treatment and/or to ensure treatment has not affected the nervous system in an undesirable manner [0026]. This is considered to be ensuring adequate therapeutic stimulation [0026].” (Office Action, Page 4). The examiner fails to show how measuring efficacy and ensuring treatment has not affected the nervous system in an undesirable manner is the same as ensuring adequate therapeutic stimulation, as stated in claim 21.

Based on the above arguments, Applicant believes that the Office Action fails to establish a proper *prima facie* case of obviousness. As a result, independent claims 19 and 34

are patentable over Leung and Byers for at least these reasons. Claims 21-25 and 27-30 are dependent on claim 19 and are patentable for at least the same reasons. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the rejections under 35 U.S.C. §103.

B. Claims 26 and 34 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Leung (U.S. Patent Publication No. 2006/0030845) in view of Byers (U.S. Patent No. 4,837,049) as applied to claim 19 above, and further in view of Surgenor (U.S. Patent Publication No. 2006/0049957).

Claims 31 and 32 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Leung (U.S. Patent Publication No. 2006/0030845) in view of Byers (U.S. Patent No. 4,837,049) as applied to claim 19 above, and further in view of Malaney (U.S. Patent Publication No. 2002/0183804).

Claim 33 is rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Leung (U.S. Patent Publication No. 2006/0030845) in view of Byers (U.S. Patent No. 4,837,049) in view of Malaney (U.S. Patent Publication No. 2002/0183804) as applied to claim 32 above, and further in view of Fairbanks (U.S. Patent No. 4,233,965).

Applicant submits that Leung in view of Byers as discussed supra, do not teach or suggest all of the elements of independent claims 19 and 34 as amended. Applicant further submits that Surgenor, Malaney and Fairbanks fail to cure the defects of Leung and Byers. Claims 26 and 31-33 depend from independent claim 19 and are therefore patentable for at least the reasons discussed above.

Accordingly, Applicant respectfully requests reconsideration and withdrawal of the rejections under 35 U.S.C. §103.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections and pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the appropriate fee and/or petition is not filed herewith and the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with this filing to **Deposit Account No. 50-3973** referencing Attorney Docket No. **EMKNNZ00301**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

/Shibir H. Desai/

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PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a)		Docket Number (Optional) EMKNNZ00301
Application Number 12/508,529	Filed July 23, 2009	
For METHOD AND APPARATUS FOR MAGNETIC INDUCTION THERAPY		
Art Unit 3735	Examiner Catherine B. Kuhlman	

This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above-identified application.

The requested extension and fee are as follows (check time period desired and enter the appropriate fee below):

	Fee	Small Entity Fee	Micro Entity Fee	
☐ One month (37 CFR 1.17(a)(1))	\$200	\$100	\$50	\$ _____
☐ Two months (37 CFR 1.17(a)(2))	\$600	\$300	\$150	\$ _____
☒ Three months (37 CFR 1.17(a)(3))	\$1,400	\$700	\$350	\$ <u>700</u>
☐ Four months (37 CFR 1.17(a)(4))	\$2,200	\$1,100	\$550	\$ _____
☐ Five months (37 CFR 1.17(a)(5))	\$3,000	\$1,500	\$750	\$ _____

☒ Applicant asserts small entity status. See 37 CFR 1.27.

☐ Applicant certifies micro entity status. See 37 CFR 1.29.
Form PTO/SB/15A or B or equivalent must either be enclosed or have been submitted previously.

☐ A check in the amount of the fee is enclosed.

☐ Payment by credit card. Form PTO-2038 is attached.

☐ The Director has already been authorized to charge fees in this application to a Deposit Account.

☒ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to
Deposit Account Number 50-3973

☒ Payment made via EFS-Web.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

I am the

☐ applicant.

☒ attorney or agent of record. Registration number 45,565

☐ attorney or agent acting under 37 CFR 1.34. Registration number _____

/Johney U. Han/
Signature

April 29, 2015
Date

Johney U. Han
Typed or printed name

(650) 242-4217
Telephone Number

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. Submit multiple forms if more than one signature is required, see below*.

☒ * Total of 1 forms are submitted.

This collection of information is required by 37 CFR 1.136(a). The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 6 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Electronic Patent Application Fee Transmittal				
Application Number:		12508529		
Filing Date:		23-Jul-2009		
Title of Invention:		METHOD AND APPARATUS FOR MAGNETIC INDUCTION THERAPY		
First Named Inventor/Applicant Name:		Daniel Rogers Burnett		
Filer:		Johney U. Han/Kim Lampkins		
Attorney Docket Number:		EMKNNZ00301		
Filed as Small Entity				
Filing Fees for Utility under 35 USC 111(a)				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Extension - 3 months with \$0 paid	2253	1	700	700
Miscellaneous:				
Total in USD (\$)				700

Electronic Acknowledgement Receipt

EFS ID:	22210004
Application Number:	12508529
International Application Number:	
Confirmation Number:	8186
Title of Invention:	METHOD AND APPARATUS FOR MAGNETIC INDUCTION THERAPY
First Named Inventor/Applicant Name:	Daniel Rogers Burnett
Customer Number:	40518
Filer:	Johney U. Han/Kim Lampkins
Filer Authorized By:	Johney U. Han
Attorney Docket Number:	EMKNNZ00301
Receipt Date:	29-APR-2015
Filing Date:	23-JUL-2009
Time Stamp:	18:26:57
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	\$ 700
RAM confirmation Number	5592
Deposit Account	
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		01_EMKNNZ00301_20150429_response_to_non_final_office_action.pdf	2458252	yes	14
			b88fba69d5eaa3cacefd380b15191a85395d383b		
	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Amendment/Req. Reconsideration-After Non-Final Reject		1	1	
	Claims		2	10	
	Applicant Arguments/Remarks Made in an Amendment		11	14	
Warnings:					
Information:					
2	Extension of Time	02_EMKNNZ00301_20150429_extension_of_time.pdf	220225	no	1
			4d7a6847e344adb3c8acf3f1ea1bd598e13c463		
Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	30850	no	2
			ab312d01dcb091658375079c8d0671cfd29fb453		
Warnings:					
Information:					
Total Files Size (in bytes):			2709327		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 12/508,529	Filing Date 07/23/2009	☐ To be Mailed
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ENTITY: ☐ LARGE ☒ SMALL ☐ MICRO

APPLICATION AS FILED – PART I

(Column 1)

(Column 2)

FOR	NUMBER FILED	NUMBER EXTRA	RATE (\$)	FEE (\$)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A	N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X \$ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X \$ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$310 (\$155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	

APPLICATION AS AMENDED – PART II

(Column 1)

(Column 2)

(Column 3)

AMENDMENT	04/29/2015	CLAIMS REMAINING AFTER AMENDMENT	MINUS	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)
	Total (37 CFR 1.16(i))	* 53	Minus	** 54	= 0	X \$40 =	0
	Independent (37 CFR 1.16(h))	* 7	Minus	*** 7	= 0	X \$210 =	0
	☐ Application Size Fee (37 CFR 1.16(s))						
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
TOTAL ADD'L FEE						0	

(Column 1)

(Column 2)

(Column 3)

AMENDMENT	CLAIMS REMAINING AFTER AMENDMENT	MINUS	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)
	Total (37 CFR 1.16(i))	*	Minus	**	=	X \$ =
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X \$ =
	☐ Application Size Fee (37 CFR 1.16(s))					
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))					
TOTAL ADD'L FEE						

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

LIE
/MOLIKI MAY/

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/508,529	07/23/2009	Daniel Rogers Burnett	EMKNNZ00301	8186
40518	7590	10/30/2014		
LEVINE BAGADE HAN LLP 2400 GENG ROAD, SUITE 120 PALO ALTO, CA 94303			EXAMINER KUHLMAN, CATHERINE BURK	
			ART UNIT 3735	PAPER NUMBER
			MAIL DATE 10/30/2014	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 12/508,529	Applicant(s) BURNETT ET AL.	
	Examiner CATHERINE B. KUHLMAN	Art Unit 3735	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2014.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

- 5) ☒ Claim(s) 1-19 and 21-54 is/are pending in the application.
5a) Of the above claim(s) 1-18 and 35-54 is/are withdrawn from consideration.
- 6) ☐ Claim(s) _____ is/are allowed.
- 7) ☒ Claim(s) 1-19 and 21-34 is/are rejected.
- 8) ☐ Claim(s) _____ is/are objected to.
- 9) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

- a) ☐ All b) ☐ Some** c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) ☐ Notice of References Cited (PTO-892) | 3) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
Paper No(s)/Mail Date _____ | 4) ☐ Other: _____ |

DETAILED ACTION

Notice of Pre-AIA or AIA Status

1. The present application is being examined under the pre-AIA first to invent provisions.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 24th, 2014 has been entered.

Claim Rejections - 35 USC § 103

3. The following is a quotation of pre-AIA 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 19, 21-25, and 27-30 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Leung (US 2006/0030845 A1) in view of Byers (US 4837049).
5. Claim 19; Leung discloses an energy emitting system for providing a medical therapy comprising at least one patch or needle electrode 300 configured to generate an electrical stimulus focused on a target nerve in proximity to the electrode [0025] and at least one sensor 306 attachable to the skin surface in proximity to the target nerve configured to detect electrical conduction in the target nerve to provide feedback regarding the therapy to a controller 104 or 200 coupled to the electrode patch 300 [0020-21]. The controller delivers an electrical stimulus

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through the patch 300 and receives feedback from the sensor 306 based on the electrical conduction detected by the sensor and adjusts the electrical stimulus delivered through the microneedle patch 300 based thereon [0020 and 46]. Leung does not specifically disclose the patch 300 comprises a microneedle array deposited on the surface of an electrode. Byers discloses an electrode patch that can be used for applying electrical signals to nerve tissue (col. 2, line 58 - col. 3, line 5) comprising an array of microneedles deposited on a surface of at least one electrode (or conducting layer) (col. 10, lines 18-29). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the microneedle array patch electrode disclosed by Byers as the electrode patch 300 in Leung's system because Byers discloses this type of electrode provides good electrical contact with subcutaneous conductive tissue (col. 5, lines 45-51).

Leung does not specifically disclose electrical stimulation focused on the posterior tibial nerve or a branch thereof or detecting electrical conduction through the posterior tibial nerve or a branch thereof and placement of the sensor on the foot. However, Leung does disclose the stimulating electrode patch 300 and sensor 306 can be placed along any neural pathway of the body [0048]. Leung also discloses detecting afferent (or sensory) nerve stimulation along the target nerve pathway [0039]. Since the patch and sensor may be surface or skin electrodes [0023] they could be placed anywhere on the skin of the patient therefore the patch 300 is configured to generate an electrical stimulus focused on the posterior tibial nerve or a branch thereof if placed at an appropriate position along the foot or leg, and the sensor 306 is adapted for placement on a foot and is configured to detect conduction through the tibial nerve or a branch thereof by detecting a signal that an afferent nerve has been stimulated if also placed at an

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appropriate position along the foot or leg. Placement of the sensor and patch as claimed can be done without changing the structure of the prior art device, therefore the device disclosed by Leung in view of Byers meets claim 19.

6. Claim 21; Leung discloses the electrical stimulus provided by the patch 300 is varied according to the electrical conduction detected by the sensor 306 to measure the efficacy of treatment and/or to ensure treatment has not affected the nervous system in an undesirable manner [0026]. This is considered to be ensuring adequate therapeutic stimulation [0026].

7. Claim 22; the microneedle array disclosed by Byers may be etched from a surface of the electrode (col. 10, lines 6-9, 18-22, and 55-62).

8. Claim 23; each microneedle disclosed by Byers comprises an electrically conductive material (col. 10, lines 32-38) which can transmit an electrical signal to an overlying electrode (electrical conductor material col. 10, lines 18-22).

9. Claim 24; Byers discloses the needles comprise metal (col. 10, lines 32-35).

10. Claim 25; Leung discloses the sensor 306 may have the same structure as the patch stimulator 300 [0023] which, according to the above combination of Leung in view of Byers, is a microneedle array.

11. Claims 27-30; Byers discloses needle diameters of 5-10 microns and a length of 100 microns (col. 7, lines 37-42).

12. Claims 26 and 34 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Leung in view of Byers as applied to claim 19 above, and further in view of Surgenor (US 2006/0049957 A1).

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13. Claim 26; Leung and Byers are silent as to a bulb extending from at least one microneedle of the array. However, Surgenor discloses microneedles of an electrode array can be provided with anchoring means such as bulbous tips [0062]. It would have been obvious to one of ordinary skill in the art at the time of the invention to include a bulbous tip on at least some of the microneedles in the system disclosed by Leung in view of Byers in order to aid in anchoring of the electrode substrate to tissue, as taught by Surgenor [0062].

14. Claim 34; Leung discloses an energy emitting system for providing a medical therapy comprising at least one patch or needle electrode 300 configured to generate an electrical stimulus focused on a target nerve in proximity to the electrode [0025] and at least one sensor 306 attachable to the skin surface in proximity to the target nerve configured to detect electrical conduction in the target nerve to provide feedback regarding the therapy to a controller 104 or 200 coupled to the electrode patch 300 [0020-21]. The controller delivers an electrical stimulus through the patch 300 and receives feedback from the sensor 306 based on the electrical conduction detected by the sensor and adjusts the electrical stimulus delivered through the microneedle patch 300 based thereon [0020 and 46]. Leung does not specifically disclose the patch 300 comprises a microneedle array deposited on the surface of an electrode. Byers discloses an electrode patch that can be used for applying electrical signals to nerve tissue (col. 2, line 58 - col. 3, line 5) comprising an array of microneedles deposited on a surface of at least one electrode (or conducting layer) (col. 10, lines 18-29). Each microneedle comprises an electrically conductive material (col. 10, lines 32-38) which can transmit an electrical signal to an overlying electrode (col. 10, lines 18-22). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the microneedle array patch electrode disclosed by

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Byers as the electrode patch 300 in Leung's system because Byers discloses this type of electrode provides good electrical contact with subcutaneous conductive tissue (col. 5, lines 45-51).

Leung in view of Byers is silent as to a bulb extending from at least one microneedle of the array. However, Surgenor discloses microneedles of an electrode array can be provided with anchoring means such as bulbous tips [0062]. It would have been obvious to one of ordinary skill in the art at the time of the invention to include a bulbous tip on at least some of the microneedles in the system disclosed by Leung in view of Byers in order to aid in anchoring of the electrode substrate to tissue, as taught by Surgenor [0062].

Leung does not specifically disclose electrical stimulation focused on the posterior tibial nerve or a branch thereof or detecting electrical conduction through the posterior tibial nerve or a branch thereof and placement of the sensor on the foot. However, Leung does disclose the stimulating electrode patch 300 and sensor 306 can be placed along any neural pathway of the body [0048]. Leung also discloses detecting afferent (or sensory) nerve stimulation along the target nerve pathway [0039]. Since the patch and sensor may be surface or skin electrodes [0023] they could be placed anywhere on the skin of the patient therefore the patch 300 is configured to generate an electrical stimulus focused on the posterior tibial nerve or a branch thereof if placed at an appropriate position along the foot or leg, and the sensor 306 is adapted for placement on a foot and is configured to detect conduction through the tibial nerve or a branch thereof by detecting a signal that an afferent nerve has been stimulated if also placed at an appropriate position along the foot or leg. Placement of the sensor and patch as claimed can be

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done without changing the structure of the prior art device, therefore the device disclosed by Leung in view of Byers and Surgenor meets claim 34.

15. Claims 31 and 32 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Leung in view of Byers as applied to claim 19 above, and further in view of Malaney (US 2002/0183804 A1).

16. Claims 31 and 32; Leung is silent as to an electrode needle coupled to the controller and inductively coupled to the patch 300. However, Malaney discloses an electrode needle 12 coupled to a controller 10 with an end insertable into the body in proximity to a stimulation site

15. The needle is inductively coupled to a patch electrode 14 and the patch is positioned distal to the stimulation site such that upon activation of the controller, a current traverses the stimulation site by passing from the patch to the electrode needle [0031]. It would have been obvious to one of ordinary skill in the art at the time of the invention to include an electrode needle inductively coupled to the patch electrode in the system taught by Leung in view of Byers, similar to the configuration taught by Malaney, because it allows for more precise targeting of the electrical stimulus provided by the electrode patch since the electrode needle can be inserted directly adjacent the target nerve.

17. Claim 33 is rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Leung in view of Byers in view of Malaney as applied to claim 32 above, and further in view of Fairbanks (US 4233965).

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18. Leung, Byers, and Malaney are silent as to a conductive coil positioned distal to the stimulation site and coupled to the controller. Fairbanks discloses a modified electrical stimulation device comprising a conductive coil 14 over an electrode patch 12 connected to a controller 32 (fig. 1a). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate a conductive coil over the electrode patch in the system disclosed by Leung in view of Byers and Malaney because Fairbanks discloses the coil helps focus the electric current into tissue (col. 2, lines 46-47 and col. 3, line 65 - col. 4, line 3). When a conductive coil is present over the electrode patch location in the combination, it will also be located distal to the stimulation site such that upon activation of said controller, a current traverses the stimulation site by passing from the patch and the coil to the electrode needle (Malaney [0031]).

Response to Arguments

19. Applicant's arguments filed September 24th, 2014 have been fully considered but they are not persuasive. Applicant submits that Leung is directed to a system for performing and monitoring electrosurgical treatment and does not describe a system as claimed but fails to set forth any specific support for this assertion. Leung discloses applying an electrical stimulus with an electrode patch 300, monitoring the effect of the stimulus with a sensor 306 which senses nerve conduction through a nerve targeted by the therapy, and adjusting the electrical stimulus provided by the patch 300 in response to the sensed conduction as recited in claim 19.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CATHERINE B. KUHLMAN whose telephone number is

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(571)270-7130. The examiner can normally be reached on Monday-Friday 8:30 am - 5:00 pm Pacific Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CATHERINE B. KUHLMAN/
Primary Examiner, Art Unit 3735

Search Notes 	Application/Control No. 12508529	Applicant(s)/Patent Under Reexamination BURNETT ET AL.
	Examiner CATHERINE B KUHLMAN	Art Unit 3735

CPC- SEARCHED		
Symbol	Date	Examiner

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
600	9-15	1/24/2013	CEB
607	2-76, 115-156	10/24/2013	CEB
601	15-22	10/24/2013	CEB
606	32-52	10/24/2013	CEB

SEARCH NOTES		
Search Notes	Date	Examiner
EAST Text	1/24/2013	CEB
IDS	1/24/2013	CEB
Inventor Names	1/24/2013	CEB
Class/Subclass	1/24/2013	CEB
Forward/Backward	1/24/2013	CEB
Updated EAST Search	10/24/2013	CEB
Updated EAST Search	3/19/2014	CBK
Updated EAST Search	10/23/2014	CBK

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner

	/C.B.K./ Primary Examiner.Art Unit 3735
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EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	37184	(electric or electrical) near stimulat\$	US-PGPUB; USPAT; USOCR	OR	ON	2014/10/23 10:46
L2	339	1 with (ablate ablation ablating)	US-PGPUB; USPAT; USOCR	OR	ON	2014/10/23 10:46
L3	42849	(electric or electrical) near (stimulat\$ or stimulus)	US-PGPUB; USPAT; USOCR	OR	ON	2014/10/23 10:47
L4	417	3 with (ablate ablation ablating)	US-PGPUB; USPAT; USOCR	OR	ON	2014/10/23 10:47
L5	78	4 not 2	US-PGPUB; USPAT; USOCR	OR	ON	2014/10/23 10:47
S1	761	loeb.in.	US-PGPUB; USPAT; USOCR	OR	ON	2012/06/20 12:15
S2	73	S1 and stimulator	US-PGPUB; USPAT; USOCR	OR	ON	2012/06/20 12:15
S3	1	("7798954").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/06/20 13:51
S4	1	(12/508529).APP.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/01/24 06:51
S5	1	(11/866329).APP.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/01/24 07:32
S6	102	(daniel near2 burnett).in.	US-PGPUB; USPAT; USOCR	OR	ON	2013/01/24 07:36
S7	7	S6 and (microneedle near5 (patch or array))	US-PGPUB; USPAT; USOCR	OR	ON	2013/01/24 07:36

S8	1	("20070021803").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/01/24 07:40
S9	1	("6690959").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/01/24 07:41
S10	1	("20050143789").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/01/24 07:42
S11	1	("20060135844").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/01/24 07:46
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S15	247	S14 and \$stimulator	US- PGPUB;	OR	ON	2013/01/24 10:04

			USPAT; USOCR			
S16	1939	(600/9-15).OCLS.	US- PGPUB; USPAT; USOCR	OR	OFF	2013/01/24 10:08
S17	43980	electric\$ near\$ stimulat\$	US- PGPUB; USPAT; USOCR	OR	ON	2013/01/24 10:09
S18	453	S16 and S17	US- PGPUB; USPAT; USOCR	OR	ON	2013/01/24 10:09
S19	45775	(\$cutaneous\$ or skin) near\$ (patch or electrode)	US- PGPUB; USPAT; USOCR	OR	ON	2013/01/24 10:11
S20	8434	S17 and S19	US- PGPUB; USPAT; USOCR	OR	ON	2013/01/24 10:13
S21	6044	S20 and (nerve or neuron or neural)	US- PGPUB; USPAT; USOCR	OR	ON	2013/01/24 10:14
S22	115	S18 and S19	US- PGPUB; USPAT; USOCR	OR	ON	2013/01/24 10:14
S23	12212	(electric\$ near\$ stimulat\$) with (nerve neuron neural neuro)	US- PGPUB; USPAT; USOCR	OR	ON	2013/01/24 10:45
S24	3722	S19 and S23	US- PGPUB; USPAT; USOCR	OR	ON	2013/01/24 10:45
S25	23913	(patch or electrode) with (needle or microneedle or nanoneedle or barb or spike)	US- PGPUB; USPAT; USOCR	OR	ON	2013/01/24 10:46
S26	1081	S24 and S25	US- PGPUB; USPAT; USOCR	OR	ON	2013/01/24 10:46
S27	20089	(patch or electrode) with (needle or microneedle or nanoneedle)	US- PGPUB; USPAT; USOCR	OR	ON	2013/01/24 10:46
S28	999	S24 and S27	US- PGPUB; USPAT; USOCR	OR	ON	2013/01/24 10:46
S29	113941	(sense sensor sensed sensing detect detecting detector detected) near\$ (conduction conductiv\$ stimulat\$)	US- PGPUB; USPAT; USOCR	OR	ON	2013/01/24 10:48

S31	487	S28 and S29	US-PGPUB; USPAT; USOCR	OR	ON	2013/01/24 10:49
S32	167	("3755704" "4016886" "4350164" "4513308" "4551149" "B453031").PN. OR ("4837049").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/01/24 10:53
S33	11	(james near2 malaney).in.	US-PGPUB; USPAT; USOCR	OR	ON	2013/01/24 12:48
S34	22933	tip near5 (bulb or bulbous or sphere or spheric\$ or ball)	US-PGPUB; USPAT; USOCR	OR	ON	2013/01/24 12:49
S35	542	S25 and S34	US-PGPUB; USPAT; USOCR	OR	ON	2013/01/24 12:51
S36	76	S35 and S23	US-PGPUB; USPAT; USOCR	OR	ON	2013/01/24 12:51
S37	36728	plurality with (needle or microneedle or nanoneedle or spike)	US-PGPUB; USPAT; USOCR	OR	ON	2013/01/24 13:03
S38	12318	plurality near (needle or microneedle or nanoneedle or spike)	US-PGPUB; USPAT; USOCR	OR	ON	2013/01/24 13:04
S39	1503	S25 and S38	US-PGPUB; USPAT; USOCR	OR	ON	2013/01/24 13:04
S40	122	S39 and S29	US-PGPUB; USPAT; USOCR	OR	ON	2013/01/24 13:04
S41	114	S40 not S36	US-PGPUB; USPAT; USOCR	OR	ON	2013/01/24 13:04
S42	1	("6735474").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/01/24 13:06
S43	23913	(patch or electrode) with (needle or microneedle or nanoneedle or barb or spike)	US-PGPUB; USPAT; USOCR	OR	ON	2013/01/24 15:45
S44	22933	tip near5 (bulb or bulbous or sphere or spheric\$ or ball)	US-PGPUB; USPAT; USOCR	OR	ON	2013/01/24 15:45
S45	542	S43 and S44	US-PGPUB; USPAT;	OR	ON	2013/01/24 15:45

			USOCR			
S46	748	(needle or microneedle or nanoneedle or barb or spike) with tip near5 (bulb or bulbous or sphere or spheric\$ or ball)	US-PGPUB; USPAT; USOCR	OR	ON	2013/01/24 15:46
S47	37933	S43 adn S46	US-PGPUB; USPAT; USOCR	OR	ON	2013/01/24 15:46
S48	131	S43 and S46	US-PGPUB; USPAT; USOCR	OR	ON	2013/01/24 15:46
S49	19	("3490439" "3896790" "4353372" "4926879" "4969468" "5143079" "5184620" "5215088" "5361760" "5452718" "5482038" "5509822" "5810742" "5928159" "5928458" "6055448" "6128521" "6745062").PN. OR ("7103398").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/01/24 15:51
S50	173	("5215088").URPN.	USPAT	OR	ON	2013/01/24 15:53
S51	20587	(electrode) with (needle or microneedle or nanoneedle or spike)	US-PGPUB; USPAT; USOCR	OR	ON	2013/01/24 16:00
S52	19683	(needle or microneedle or nanoneedle or barb or spike) near10 (bulb or bulbous or sphere or spheric\$ or ball)	US-PGPUB; USPAT; USOCR	OR	ON	2013/01/24 16:01
S53	14504	(needle or microneedle or nanoneedle or barb or spike) near5 (bulb or bulbous or sphere or spheric\$ or ball)	US-PGPUB; USPAT; USOCR	OR	ON	2013/01/24 16:01
S54	582	S51 and S53	US-PGPUB; USPAT; USOCR	OR	ON	2013/01/24 16:01
S55	476	S54 not S48	US-PGPUB; USPAT; USOCR	OR	ON	2013/01/24 16:01
S56	152	S55 and (skin or \$cutaneous)	US-PGPUB; USPAT; USOCR	OR	ON	2013/01/24 16:02
S57	24933	(607/2-76).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/10/24 14:54
S58	11281	(607/115-156).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/10/24 14:56
S59	591	(607/152).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/10/24 14:57

S60	1555	(601/15-22).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/10/24 14:59
S61	12197	(606/32-52).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/10/24 15:01
S62	2075	(600/9-15).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/10/24 15:01
S63	788	S62 and (electrode or (electric\$5 near5 stimulat\$))	US-PGPUB; USPAT; USOCR	OR	ON	2013/10/24 15:02
S64	52128	stimulat\$5 with (nerve neuron\$ neural)	US-PGPUB; USPAT; USOCR	OR	ON	2013/10/24 15:03
S65	57414	stimulat\$5 with (nerve neuron\$ neural nervous)	US-PGPUB; USPAT; USOCR	OR	ON	2013/10/24 15:03
S66	48223	S57 S58 S60 S61 S62	US-PGPUB; USPAT; USOCR	OR	ON	2013/10/24 15:03
S67	14456	S65 and S66	US-PGPUB; USPAT; USOCR	OR	ON	2013/10/24 15:03
S68	79196	(sense sensor sensed sensing detect\$5 minitor\$5) with (((nerve or neuron\$ or neural or nervous) near5 (conduction or conductiv\$)) or (muscle near S61 (stimulat\$ or contract\$5)))	US-PGPUB; USPAT; USOCR	OR	ON	2013/10/24 15:05
S69	8744	S67 and S68	US-PGPUB; USPAT; USOCR	OR	ON	2013/10/24 15:05
S70	5073	(\$needle near5 (patch or array))	US-PGPUB; USPAT; USOCR	OR	ON	2013/10/24 15:06
S71	230	S67 and S70	US-PGPUB; USPAT; USOCR	OR	ON	2013/10/24 15:06
S72	138	S69 and S70	US-PGPUB; USPAT; USOCR	OR	ON	2013/10/24 15:42
S73	122	S72 and (sensor monitor detector)	US-PGPUB; USPAT; USOCR	OR	ON	2013/10/24 15:45
S74	5	((11/105527) or (11/125247) or (11/079318)).APP.	US-PGPUB;	OR	OFF	2013/10/24 17:27

			USPAT; USOCR			
S75	1	("20050275497").PN.	US- PGPUB; USPAT; USOCR	OR	OFF	2014/03/19 09:24
S76	3	((("20070027514") or ("4969468") or ("20050275497")).PN.	US- PGPUB; USPAT; USOCR	OR	OFF	2014/03/19 09:28
S77	5172	deep near brain near stimulat\$	US- PGPUB; USPAT; USOCR	OR	ON	2014/03/19 09:40
S78	2654	S77 and (coil or microcoil)	US- PGPUB; USPAT; USOCR	OR	ON	2014/03/19 09:40
S79	167	S77 and probe with (coil or microcoil or electromag\$)	US- PGPUB; USPAT; USOCR	OR	ON	2014/03/19 09:41
S80	1	("20020183804").PN.	US- PGPUB; USPAT; USOCR	OR	OFF	2014/03/19 14:43
S81	2150	(600/9-15).CCLS.	US- PGPUB; USPAT; USOCR	OR	OFF	2014/03/19 15:00

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<i>Index of Claims</i> 	Application/Control No. 12508529	Applicant(s)/Patent Under Reexamination BURNETT ET AL.
	Examiner CATHERINE B KUHLMAN	Art Unit 3735

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47										
CLAIM		DATE								
Final	Original	06/27/2012	01/24/2013	10/24/2013	03/19/2014	10/23/2014				
	1	÷	N	N	N	N				
	2	÷	N	N	N	N				
	3	÷	N	N	N	N				
	4	÷	N	N	N	N				
	5	÷	N	N	N	N				
	6	÷	N	N	N	N				
	7	÷	N	N	N	N				
	8	÷	N	N	N	N				
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	15	÷	N	N	N	N				
	16	÷	N	N	N	N				
	17	÷	N	N	N	N				
	18	÷	N	N	N	N				
	19	÷	✓	✓	✓	✓				
	20	÷	✓	-	-	-				
	21	÷	✓	✓	✓	✓				
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	26	÷	✓	✓	✓	✓				
	27	÷	✓	✓	✓	✓				
	28	÷	✓	✓	✓	✓				
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	31	÷	✓	✓	✓	✓				
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	33	÷	✓	✓	✓	✓				
	34	÷	✓	✓	✓	✓				
	35	÷	N	N	N	N				
	36	÷	N	N	N	N				

<i>Index of Claims</i> 	Application/Control No. 12508529	Applicant(s)/Patent Under Reexamination BURNETT ET AL.
	Examiner CATHERINE B KUHLMAN	Art Unit 3735

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47										
CLAIM		DATE								
Final	Original	06/27/2012	01/24/2013	10/24/2013	03/19/2014	10/23/2014				
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	38	÷	N	N	N	N				
	39	÷	N	N	N	N				
	40	÷	N	N	N	N				
	41	÷	N	N	N	N				
	42	÷	N	N	N	N				
	43	÷	N	N	N	N				
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	47	÷	N	N	N	N				
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	49	÷	N	N	N	N				
	50	÷	N	N	N	N				
	51	÷	N	N	N	N				
	52	÷	N	N	N	N				
	53	÷	N	N	N	N				
	54	÷	N	N	N	N				

CUSTOMIZED PTO/BB/06a/b (07-05)

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	12/508,529
				Filing Date	July 23, 2009
				First Named Inventor	Daniel R. BURNETT
				Art Unit	3735
				Examiner Name	Catherine B. Kuhlman
Sheet	1	of	1	Attorney Docket Number	EMKNNZ00301

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1.	5,158,080	10-27-1992	Kallik	
	2.	2002/0183647	12-05-2002	Gozani et al.	
	3.	2004/0127939	07-01-2004	Grey	
	4.	2007/0021712	01-25-2007	Bernard et al.	
	5.	2007/0265675	11-15-2007	Lund et al.	
	6.	2008/0058874	03-06-2008	Westlund et al.	
	7.	2008/0177347	07-24-2008	Tehrani et al.	
	8.	2008/0300655	12-04-2008	Cholette	
	9.	2009/0030337	01-29-2009	Gozani et al.	
	10.	2009/0054950	02-26-2009	Stephens	
	11.	2010/0057149	03-04-2010	Fahey	
	12.	2010/0318009	12-16-2010	Stanley	
	13.	2011/0264163	10-27-2011	Tracey et al.	
	14.	2012/0059432	03-08-2012	Emborg et al.	
	15.	2012/0302821	11-29-2012	Burnett	
	16.	2013/0006322	01-03-2013	Tai	

FOREIGN PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Foreign Patent Document Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	17.	WO 2006/061688	06-15-2006	STANDEN LTD.	
	18.	WO 2010/047599	04-29-2010	MED STORM INNOVATION A	

*EXAMINER: Initial if information considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. * Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature	/Catherine Kuhlman/	Date Considered	10/23/2014
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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /C.K./

REQUEST FOR CONTINUED EXAMINATION(RCE)TRANSMITTAL (Submitted Only via EFS-Web)

Application Number	12/508,529	Filing Date	2009-07-23	Docket Number (if applicable)	EMKNNZ00301	Art Unit	3735
First Named Inventor	Daniel R. BURNETT			Examiner Name	Catherine B. Kuhlman		

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.

Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. The Instruction Sheet for this form is located at WWW.USPTO.GOV

SUBMISSION REQUIRED UNDER 37 CFR 1.114

Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

☐ Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.

☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____

☐ Other _____

☒ Enclosed

☒ Amendment/Reply

☒ Information Disclosure Statement (IDS)

☐ Affidavit(s)/ Declaration(s)

☒ Other _____
Petition for Extension of Time

MISCELLANEOUS

☐ Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of months _____
(Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)

☐ Other _____

FEES

The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.

☒ The Director is hereby authorized to charge any underpayment of fees, or credit any overpayments, to
Deposit Account No 503973

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

☒ Patent Practitioner Signature

☐ Applicant Signature

Signature of Registered U.S. Patent Practitioner			
Signature	/Steven M. Giovannetti/	Date (YYYY-MM-DD)	2014-09-24
Name	Steven M. Giovannetti	Registration Number	51739

This collection of information is required by 37 CFR 1.114. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

I hereby certify that this correspondence is being electronically transmitted to the USPTO on the date shown below.

Date: September 24, 2014 Signature: /Dilora S. Haddad/ (Dilora S. Haddad)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.: 12/508,529
Confirmation No.: 8186
Filing Date: July 23, 2009
Inventor(s): Daniel R. BURNETT et al.
Title: METHOD AND APPARATUS FOR MAGNETIC INDUCTION
THERAPY
Examiner: Catherine E. Burk
Group Art Unit: 3735

RESPONSE TO FINAL OFFICE ACTION

Mail Stop RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir or Madam:

This is in response to the final Office Action dated March 24, 2014 for which a response was due on June 24, 2014. Filed herewith is a Petition and fee for a 3-month extension of time, thereby extending the deadline for response to September 24, 2014. Accordingly, this response is timely filed. Reconsideration and allowance of the pending claims, as amended, in light of the Remarks presented herein are respectfully requested.

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks begin on page 11 of this paper.

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

In the claims

1. (Withdrawn): An energy emitting system for providing a medical therapy comprising:

at least one conductive coil disposed within or along a housing, where the at least one coil is configured to generate a magnetic field focused on a target nerve in proximity to the at least one coil;

at least one sensor configured to detect electrical conduction in the target nerve or muscle stimulation, wherein the sensor is comprised of a microneedle array attachable to a skin surface in proximity to a target nerve or muscle; and

a controller coupled to said at least one conductive coil and in communication with said at least one sensor.

2. (Withdrawn): The system of claim 1, wherein the magnetic field generated by said at least one conductive coil is varied based on the electrical conduction or muscle stimulation detected by said at least one sensor to ensure adequate therapeutic stimulation.

3. (Withdrawn): The system of claim 1, wherein the microneedle array is arrayed over a housing.

4. (Withdrawn): The system of claim 3, wherein the housing is comprised of a patch having at least one electrode and said microneedle array extends from a first surface of the electrode.

5. (Withdrawn): The system of claim 4, wherein the patch comprises a positive, negative and control electrode, each electrode comprising a microneedle array extending therefrom.

6. (Withdrawn): The system of claim 4, wherein the microneedle array is etched from a surface of the electrode.

7. (Withdrawn): The system of claim 1, wherein said microneedle array comprises at least one microneedle comprising an electrically conductive material such that it can transmit an electrical signal to an overlying electrode.

8. (Withdrawn): The system of claim 7, wherein said microneedle comprises metal, silicon, biocompatible polymers, titanium, silver, or suture material.

9. (Withdrawn): The system of claim 1, wherein said microneedle array comprises at least one microneedle coated with an electrically conductive material such that it can transmit an electrical signal to an overlying electrode.

10. (Withdrawn): The system of claim 1, wherein said microneedle array comprises at least one microneedle comprising a distal tip and a bulb extending from said distal tip to provide for anchoring of said microneedle into a subject's skin.

11. (Withdrawn): The system of claim 1, wherein said microneedle array comprises at least one microneedle having a diameter in the range of about 1 to 100 microns.

12. (Withdrawn): The system of claim 11, wherein a diameter of said microneedle is in the range of about 10 to 30 microns.

13. (Withdrawn): The system of claim 1, wherein said microneedle array comprises at least one microneedle having a length in the range of about 1 to 100 microns.

14. (Withdrawn): The system of claim 13, wherein a length of said microneedle is in the range of about 100 to 150 microns.

15. (Withdrawn): The system of claim 1, further comprising an electrode needle coupled to said controller and having an end insertable into a subject's body in proximity to a stimulation site, wherein said needle is inductively coupled to said at least one conductive coil.

16. (Withdrawn): The system of claim 15, wherein said at least one conductive coil is positioned distal to said stimulation site such that upon activation of said controller a current traverses the stimulation site by passing from said at least one conductive coil to said percutaneous electrode needle.

17. (Withdrawn): The system of claim 16, further comprising at least one conductive microneedle patch positioned distal to said stimulation site and coupled to the controller such that upon activation of said controller a current traverses the stimulation site by passing from said at least one conductive microneedle patch and said at least one conductive coil to said electrode needle.

18. (Withdrawn): An energy emitting system for providing a medical therapy comprising:

at least one conductive coil disposed within or along a housing, where the at least one coil is configured to generate a magnetic field focused on a target nerve in proximity to the at least one coil;

at least one sensor configured to detect electrical conduction in the target nerve or muscle stimulation, wherein the sensor is comprised of at least one microneedle comprising an electrically conductive material such that it can transmit an electrical signal to an overlying electrode and a distal tip having a bulb extending from said distal tip to provide for anchoring of said microneedle into a subject's skin; and

a controller coupled to said at least one conductive coil and in communication with said at least one sensor.

19. (Currently Amended): An energy emitting system for providing a medical therapy comprising:

at least one microneedle patch comprised of a microneedle array deposited on a surface of at least one electrode, where said at least one microneedle patch is configured to generate an electrical stimulus focused on a posterior tibial nerve or a branch thereof in proximity to the at least one conductive microneedle patch;

at least one sensor configured to detect electrical conduction through the posterior tibial nerve or a branch thereof by detecting a signal that an afferent nerve has been stimulated to provide feedback regarding the therapy, wherein the sensor is attachable to a skin surface in proximity to a nerve or muscle, wherein the sensor is adapted for placement on a foot of a patient and

a controller coupled to said at least one microneedle patch, wherein the controller delivers an electrical stimulus through the microneedle patch and ~~wherein the controller is adjustable to modulate the therapy~~, wherein the system comprises a feedback loop, wherein

the controller receives feedback from the sensor based on the signal detected by the sensor, and the controller adjusts or modulates the electrical stimulus delivered through the microneedle patch to the posterior tibial nerve or a branch thereof based on the feedback provided by the sensor.

20. (Canceled):

21. (Currently Amended): The system of claim 19, wherein the electrical stimulus generated by said at least one microneedle patch is varied according to the electrical conduction or a muscle stimulation detected by said at least one sensor to ensure adequate therapeutic stimulation.

22. (Original): The system of claim 19, wherein the microneedle array is etched from a surface of the electrode.

23. (Original): The system of claim 19, wherein said microneedle patch comprises at least one microneedle comprising an electrically conductive material such that it can transmit an electrical signal to an overlying electrode.

24. (Original): The system of claim 23, wherein said microneedle comprises metal, silicon, biocompatible polymers, titanium, silver, or suture material.

25. (Original): The system of claim 19, wherein said sensor is comprised of at least one microneedle array.

26. (Original): The system of claim 19, wherein said microneedle array comprises at least one microneedle comprising a distal tip and a bulb extending from said distal tip to provide for anchoring of said microneedle into a subject's skin.

27. (Original): The system of claim 19, wherein said microneedle array comprises at least one microneedle having a diameter in the range of about 1 to 100 microns.

28. (Original): The system of claim 27, wherein a diameter of said microneedle is in the range of about 10 to 30 microns.

29. (Original): The system of claim 19, wherein said microneedle array comprises at least one microneedle having a length in the range of about 1 to 150 microns.

30. (Original): The system of claim 29, wherein a length of said microneedle is in the range of about 100 to 150 microns.

31. (Original): The system of claim 19, further comprising an electrode needle coupled to said controller and having an end insertable into a subject's body in proximity to a stimulation site, wherein said needle is inductively coupled to said at least one conductive microneedle patch.

32. (Previously Presented): The system of claim 31, wherein said at least one microneedle patch is adapted to be positioned distal to said stimulation site such that upon activation of said controller a current traverses the stimulation site by passing from said at least one microneedle patch to said electrode needle.

33. (Original): The system of claim 32, further comprising at least one conductive coil positioned distal to said stimulation site and coupled to said controller such that upon activation of said controller a current traverses the stimulation site by passing from said at least one microneedle patch and said at least one conductive coil to said electrode needle.

34. (Currently Amended): An energy emitting system for providing a medical therapy comprising:

at least one conductive microneedle patch comprised of a microneedle array deposited on a surface of at least one electrode, wherein said microneedle array comprises an electrically conductive material such that it can transmit an electrical signal to an overlying electrode wherein a distal tip of at least one microneedle of the microneedle array has a bulb extending from said distal tip to provide for anchoring of said microneedle into a subject's skin, said microneedle patch configured to deliver an electrical stimulus to a posterior tibial nerve or a branch thereof in proximity to the at least one conductive microneedle patch;

at least one sensor configured to detect electrical conduction through the posterior tibial nerve or a branch thereof by detecting a signal that an afferent nerve has been stimulated and wherein the sensor is attachable to a skin surface in proximity to a nerve or muscle, wherein the sensor is adapted for placement on a foot of a patient; and

a controller coupled to said at least one conductive microneedle patch and in communication with said at least one sensor, wherein the controller delivers an electrical stimulus through the microneedle patch and, wherein the system comprises a feedback loop,

wherein the controller receives feedback from the sensor based on the signal detected by the sensor, and the controller adjusts or modulates the electrical stimulus delivered through the microneedle patch to the posterior tibial nerve or a branch thereof ~~wherein the controller is adjustable to modulate the therapy based on the feedback provided by the sensor.~~

35. (Withdrawn): An energy emitting system for providing a medical therapy comprising:

at least one conductive coil disposed within or along a housing, where the at least one coil is configured to generate a magnetic field focused on a target nerve in proximity to the at least one coil;

an electrode needle having an end insertable into a subject's body in proximity to a stimulation site, wherein said needle is inductively coupled to said at least one conductive coil; and

a controller coupled to said at least one conductive coil and said electrode needle.

36. (Withdrawn): The system of claim 35, wherein said at least one conductive coil is positioned distal to said stimulation site such that upon activation of said controller a current traverses the stimulation site by passing from said at least one conductive coil to said electrode needle.

37. (Withdrawn): The system of claim 35, further comprising at least one sensor in communication with said controller and configured to detect electrical conduction in the target nerve or muscle stimulation and attachable to a skin surface in proximity to a target nerve or muscle, wherein the magnetic field generated by said at least one conductive coil is varied based on the muscle stimulation or electrical conduction detected by said at least one sensor to ensure adequate therapeutic stimulation.

38. (Withdrawn): A method of treating a subject with urinary incontinence comprising:

positioning a first portion of a subject's body, the subject exhibiting symptoms associated with urinary incontinence, relative to an energy emitting device such that a tibial nerve within the first portion of the body is in proximity to at least one energy generator disposed within or along the energy emitting device;

passing a current through the at least one energy generator to produce a magnetic field or electrical stimulus focused on the tibial nerve;

stimulating a nerve that innervates the pelvic floor of the subject via stimulation of the tibial nerve with the magnetic field or electrical stimulus; and

reducing symptoms associated with urinary incontinence.

39. (Withdrawn): The method of claim 38, wherein the energy generator comprises a conductive coil for generating a magnetic field.

40. (Withdrawn): The method of claim 39, wherein positioning comprises placing a foot, ankle, or leg relative to at least one conductive coil disposed within or along a housing.

41. (Withdrawn): The method of claim 39, wherein positioning comprises placing a popliteal fossa relative to at least one conductive coil disposed within or along a housing.

42. (Withdrawn): The method of claim 38, wherein the energy generator comprises a microneedle patch for producing a magnetic field or electrical stimulus.

43. (Withdrawn): The method of claim 38, wherein a nerve that innervates the pelvic floor comprises the pudendal nerve or sacral plexus.

44. (Withdrawn): The method of claim 38, wherein symptoms associated with urinary incontinence comprise urinary leakage, loss of bladder control and the inability to control urinary function.

45. (Withdrawn): The method of claim 38, further comprising detecting electrical conduction through the tibial nerve or corresponding muscle stimulation via at least one sensor positioned along a second portion of the body.

46. (Withdrawn): The method of claim 45, wherein the sensor comprises a microneedle array.

47. (Withdrawn): The method of claim 45, wherein the sensor is positioned in proximity to the tibial nerve, over a muscle innervated by the tibial nerve, or over the popliteal fossa.

48. (Withdrawn): The method of claim 45, further comprising adjusting the current via a controller in communication with the energy generator according to a signal received from the sensor indicative of the nerve conduction.

49. (Withdrawn): The method of claim 48, wherein adjusting comprises adjusting amplitude, frequency, direction of a magnetic field, or firing sequence of the energy generator.

50. (Withdrawn): The method of claim 48, wherein adjusting comprises adjusting a position of the at least one coil relative to the first portion of the subject's body to re-focus the magnetic field on the tibial nerve.

51. (Withdrawn): The method of claim 48, wherein adjusting comprises adjusting a position of the microneedle patch relative to the first portion of the subject's body to re-focus the electrical or magnetic stimulus on the tibial nerve.

52. (Withdrawn): The method of claim 48, wherein adjusting comprises varying the current according to a muscular response in the patient.

53. (Withdrawn): The method of claim 39, wherein the conductive coil is operated at about 10 to 20 hertz to generate a magnetic field of about .25 to 1.5 tesla for a duration of about 30 minutes per day.

54. (Withdrawn): A method of treating a subject with urinary incontinence comprising:

- positioning a first portion of a subject's body, the subject exhibiting symptoms associated with urinary incontinence, relative to a housing such that a posterior tibial nerve within the first portion of the body is in proximity to at least one conductive coil disposed within or along the housing;

- passing a current through the at least one conductive coil to produce a magnetic field focused on the posterior tibial nerve;

- detecting electrical conduction of the posterior tibial nerve via at least one microneedle array positioned along a second portion of the body;

- receiving a signal from the microneedle array indicative of the electrical conduction;

adjusting the current via a controller in communication with the conductive coil according to the signal received from the microneedle array; and
reducing symptoms associated with urinary incontinence.

REMARKS

Claims 19 and 21-34 were pending in the present application. Claims 1-18 and 35-54 were withdrawn from consideration. By virtue of this response, claims 19, 21 and 34 have been amended. Accordingly, claims 19 and 21-34 are currently under consideration. Amendment and cancellation of certain claims is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented. Support can be found in the specification and claims as originally filed, e.g., at [0169]. No new matter has been added.

Rejections under 35 USC § 112

Claim 21 is rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention.

In response, Applicants have amended claim 21 to address the rejection. Therefore, Applicants respectfully request reconsideration and withdrawal of the above rejections under 35 U.S.C. §112.

Rejections under 35 USC § 103

Claims 19, 21-25, and 27-30 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Leung (US 2006/0030845) in view of Byers (US 4837049).

In response, Applicants respectfully disagree.

Claim 19 as amended recites: An energy emitting system for providing a medical therapy comprising: at least one microneedle patch comprised of a microneedle array deposited on a surface of at least one electrode, where said at least one microneedle patch is configured to generate an electrical stimulus focused on a posterior tibial nerve or a branch thereof in proximity to the at least one conductive microneedle patch; at least one sensor configured to detect electrical conduction through the posterior tibial nerve or a branch thereof by detecting a signal that an afferent nerve has been stimulated to provide feedback regarding the therapy, wherein the sensor is attachable to a skin surface in proximity to a

nerve or muscle, wherein the sensor is adapted for placement on a foot of a patient and a controller coupled to said at least one microneedle patch, wherein the controller delivers an electrical stimulus through the microneedle patch and wherein the system comprises a feedback loop, wherein the controller receives feedback from the sensor, based on the signal detected by the sensor, and the controller adjusts or modulates the electrical stimulus delivered through the microneedle patch to the posterior tibial nerve or a branch thereof based on the feedback provided by the sensor. (Claim 34 has been similarly amended.)

In contrast, Leung is directed to a system for performing and monitoring electrosurgical treatment and forming a lesion in a nerve, and is concerned with performing monitoring during that electrosurgical treatment. For example, Leung describes a system for positioning a conductive component adjacent a facet nerve of the spine of a patient, and does not describe a system configured according to the present claims. [0039]. Indeed, Leung does not teach or suggest at least, “an energy emitting system for providing a medical therapy comprising: at least one microneedle patch comprised of a microneedle array deposited on a surface of at least one electrode, where said at least one microneedle patch is configured to generate an electrical stimulus focused on a posterior tibial nerve or a branch thereof in proximity to the at least one conductive microneedle patch; at least one sensor configured to detect electrical conduction through the posterior tibial nerve or a branch thereof by detecting a signal that an afferent nerve has been stimulated... wherein the system comprises a feedback loop, wherein the controller receives feedback from the sensor, based on the signal detected by the sensor, and the controller adjusts or modulates the electrical stimulus delivered through the microneedle patch to the posterior tibial nerve or a branch thereof based on the feedback provided by the sensor.”

Applicants further submit that Byers and Surgenor fail to cure the deficiencies of Leung.

Thus, Applicants believe that because the cited art fails to teach or suggest each and every element of the claims as amended, the claims are not rendered obvious by the cited art. Accordingly, Applicants submit that all of the independent claims and the claims dependent therefrom, are now in condition for allowance. Therefore, Applicant respectfully requests reconsideration and withdrawal of the above rejections under 35 U.S.C. §103.

Claims 26 and 34 are rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Leung in view of Byers as applied to claim 19 above, and further in view of Surgenor (US 2006/0049957 A1).

Claims 31 and 32 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Leung in view of Byers as applied to claim 19 above, and further in view of Malaney (US 2002/0183804 A1).

Claim 33 is rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Leung in view of Byers in view of Malaney as applied to claim 32 above, and further in view of Fairbanks (US 4233965).

In response, Applicants submit that Leung in view of Byers as discussed supra, do not teach or suggest all of the elements of independent claims 9 and 34 as amended. Applicants further submit that Surgenor, Malaney and Fairbanks fail to cure the defects of Leung and Byers. Claims 26, 31-33 depend from independent claim 19 and are therefore patentable for at least the reasons discussed above. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. §103.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections and pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the appropriate fee and/or petition is not filed herewith and the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with this filing to **Deposit Account No. 50-3973** referencing Attorney Docket No. **EMKNNZ00301**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

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PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a)			
Application Number 12/508,529		Filed July 23, 2009	
For METHOD AND APPARATUS FOR MAGNETIC INDUCTION THERAPY			
Art Unit 3735		Examiner Catherine B. Kuhlman	

This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above-identified application.

The requested extension and fee are as follows (check time period desired and enter the appropriate fee below):

	Fee	Small Entity Fee	Micro Entity Fee	
☐ One month (37 CFR 1.17(a)(1))	\$200	\$100	\$50	\$ _____
☐ Two months (37 CFR 1.17(a)(2))	\$600	\$300	\$150	\$ _____
☒ Three months (37 CFR 1.17(a)(3))	\$1,400	\$700	\$350	\$ <u>700</u>
☐ Four months (37 CFR 1.17(a)(4))	\$2,200	\$1,100	\$550	\$ _____
☐ Five months (37 CFR 1.17(a)(5))	\$3,000	\$1,500	\$750	\$ _____

- ☒ Applicant asserts small entity status. See 37 CFR 1.27.
- ☐ Applicant certifies micro entity status. See 37 CFR 1.29.
Form PTO/SB/15A or B or equivalent must either be enclosed or have been submitted previously.
- ☐ A check in the amount of the fee is enclosed.
- ☐ Payment by credit card. Form PTO-2038 is attached.
- ☐ The Director has already been authorized to charge fees in this application to a Deposit Account.
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I am the

- ☐ applicant.
- ☒ attorney or agent of record. Registration number 51,739
- ☐ attorney or agent acting under 37 CFR 1.34. Registration number _____

/Steven M. Giovannetti/
Signature

September 24, 2014

Date

Steven M. Giovannetti
Typed or printed name

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Telephone Number

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. Submit multiple forms if more than one signature is required; see below*.

☒ * Total of 1 forms are submitted.

This collection of information is required by 37 CFR 1.138(a). The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 5 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

I hereby certify that this correspondence is being electronically transmitted to the USPTO on the date shown below.

Date: September 24, 2014 Signature: /Dilora Haddad/ (Dilora Haddad)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.: 12/508,529
Confirmation No.: 8186
Filing Date: July 23, 2009
Inventor(s): Daniel R. BURNETT et al.
Title: METHOD AND APPARATUS FOR MAGNETIC INDUCTION
THERAPY
Examiner: Catherine B. Kuhlman
Group Art Unit: 3735

INFORMATION DISCLOSURE STATEMENT

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Dear Sir or Madam:

Pursuant to 37 C.F.R. §1.97 and §1.98, Applicants submit for consideration in the above-captioned application the documents listed on the attached Form PTO/SB/08a/b. Copies of foreign documents are submitted herewith. The Examiner is requested to make these documents of record.

This Information Disclosure Statement is submitted with the filing of a Request for Continued Examination under § 1.114; accordingly, no fee or separate requirements are required.

Under 37 C.F.R. §1.98(a)(3)(i), any patents, publications, or other information listed herein that are not in the English language are relevant, as it is understood in 37 C.F.R. §1.56(c) for reasons self-evident in the English and/or drawing portions and/or due to its citation by a foreign patent office or the U.S. Patent Office or court.

Applicants would appreciate the Examiner initialing and returning the Form PTO/SB/08a/b, indicating that the information has been considered and made of record herein.

The information contained in this Information Disclosure Statement under 37 C.F.R. §1.97 and §1.98 is not to be construed as a representation that: (i) a complete search has been made; (ii) additional information material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the above information constitutes prior art to the subject invention.

In the event the appropriate fee and/or petition is not filed herewith and the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with this filing to **Deposit Account No. 50-3973** referencing Attorney Docket No.

EMKNNZ00301. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

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Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	12/508,529
				Filing Date	July 23, 2009
				First Named Inventor	Daniel R. BURNETT
				Art Unit	3735
				Examiner Name	Catherine B. Kuhlman
Sheet	1	of	1	Attorney Docket Number	EMKNNZ00301

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	1.	5,158,080	10-27-1992	Kallik	
	2.	2002/0183647	12-05-2002	Gozani et al.	
	3.	2004/0127939	07-01-2004	Grey	
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	6.	2008/0058874	03-06-2008	Westlund et al.	
	7.	2008/0177347	07-24-2008	Tehrani et al.	
	8.	2008/0300655	12-04-2008	Cholette	
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	11.	2010/0057149	03-04-2010	Fahey	
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	15.	2012/0302821	11-29-2012	Burnett	
	16.	2013/0006322	01-03-2013	Tai	

FOREIGN PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)			
	17.	WO 2006/061688	06-15-2006	STANDEN LTD.	
	18.	WO 2010/047599	04-29-2010	MED STORM INNOVATION A	

*EXAMINER: Initial if information considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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Examiner Signature		Date Considered	
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(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
15 June 2006 (15.06.2006)

PCT

(10) International Publication Number
WO 2006/061688 A1

(51) International Patent Classification:
A61N 1/04 (2006.01) A61N 1/40 (2006.01)

(21) International Application Number:
PCT/IB2005/003670

(22) International Filing Date:
5 December 2005 (05.12.2005)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/633,871 7 December 2004 (07.12.2004) US

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(81) Designated States (unless otherwise indicated, for every
kind of national protection available): AE, AG, AL, AM,

AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN,
CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI,
GB, GD, GE, GH, GM, GR, GU, HK, HN, IL, IN, JP, KE,
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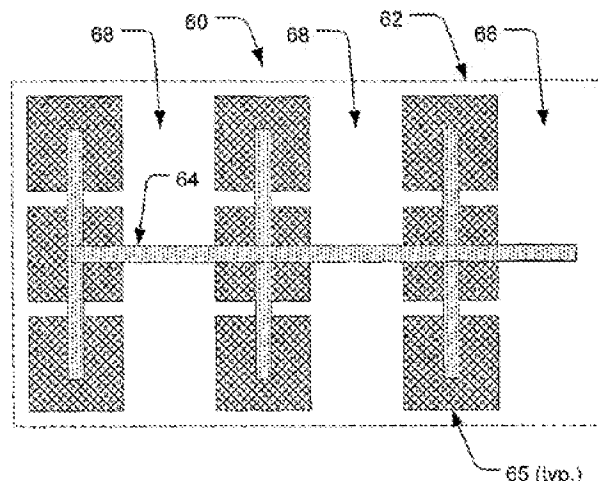
(84) Designated States (unless otherwise indicated, for every
kind of regional protection available): ARIPO (BW, GH,
GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM,
ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM),
European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI,
FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT,
RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA,
GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

- with international search report
- before the expiration of the time limit for amending the
claims and to be republished in the event of receipt of
amendments

For two-letter codes and other abbreviations, refer to the "Guid-
ance Notes on Codes and Abbreviations" appearing at the begin-
ning of each regular issue of the PCT Gazette.

(54) Title: ELECTRODES FOR APPLYING AN ELECTRIC FIELD IN-VIVO OVER AN EXTENDED PERIOD OF TIME



(57) Abstract: As compared to conventional electrodes, the electrode configurations disclosed herein minimize irritation and damage to the skin when they are placed in contact with a patient's body over extended of time. The electrodes are formed from a conductive substrate coated with a thin dielectric material, and a plurality of open spaces pass through the electrodes. Those open spaces are distributed and sized to permit moisture on the surface of the patient's body to escape when the electrode is placed in contact with the patient's body. One intended use for the electrodes is for treating tumors by applying an AC electric field with specific frequency and field strength characteristics over an extended period of time.



WO 2006/061688 A1

ELECTRODES FOR APPLYING AN ELECTRIC FIELD
IN-VIVO OVER AN EXTENDED PERIOD OF TIME

BACKGROUND

[0001] This invention concerns electrodes for applying electric fields in-vivo over an extended period of time, and methods for using such electrodes.

[0002] Living organisms proliferate by cell division, including tissues, cell cultures, microorganisms (such as bacteria, mycoplasma, yeast, protozoa, and other single-celled organisms), fungi, algae, plant cells, etc. Dividing cells of organisms can be destroyed, or their proliferation controlled, by methods that are based on the sensitivity of the dividing cells of these organisms to certain chemical or physical agents. For example, certain antibiotics stop the multiplication process of bacteria.

[0003] It is well known that tumors, particularly malignant or cancerous tumors, grow very uncontrollably compared to normal tissue. Such expedited growth enables tumors to occupy an ever-increasing space and to damage or destroy tissue adjacent thereto. Furthermore, certain cancers are characterized by an ability to spread metastases to new locations where the metastatic cancer cells grow into additional tumors.

[0004] The rapid growth of tumors, in general, and malignant tumors in particular, as described above, is the result of relatively frequent cell division or multiplication of these cells compared to normal tissue cells. The distinguishably frequent cell division of cancer cells is the basis for the effectiveness of many existing cancer treatments, e.g., irradiation therapy and the use of various chemo-therapeutic agents. Such treatments are based on the fact that cells undergoing division are more sensitive to radiation and chemo-therapeutic agents than non-dividing cells. Because tumors cells divide much more frequently than normal cells, it is possible, to a certain extent, to selectively damage or destroy tumor cells by radiation therapy and/or chemotherapy. The actual sensitivity of cells to radiation,

therapeutic agents, etc., is also dependent on specific characteristics of different types of normal or malignant cell types. Thus, unfortunately, the sensitivity of tumor cells is not sufficiently higher than that of many types of normal tissues. This diminishes the ability to distinguish between tumor cells and normal cells, and therefore, existing cancer treatments typically cause significant damage to normal tissues, thus limiting the therapeutic effectiveness of such treatments. Also, certain types of tumors are not sensitive at all to existing methods of treatment.

[0005] Electric fields and currents have been used for medical purposes for many years. The most common is the generation of electric currents in a human or animal body by application of an electric field by means of a pair of conductive electrodes between which a potential difference is maintained. These electric currents are used either to exert their specific effects, i.e., to stimulate excitable tissue, or to generate heat by flowing in the body since it acts as a resistor. Examples of the first type of application include the following: cardiac defibrillators, peripheral nerve and muscle stimulators, brain stimulators, etc. Currents are used for heating, for example, in devices for tumor ablation, ablation of malfunctioning cardiac or brain tissue, cauterization, relaxation of muscle rheumatic pain and other pain, etc.

[0006] Another use of electric fields for medical purposes involves the utilization of high frequency oscillating fields transmitted from a source that emits an electric wave, such as an RF wave or a microwave source, which is directed at the part of the body that is of interest (i.e., a target). In these instances, there is no electric energy conducting between the source and the body; but rather, the energy is transmitted to the body by radiation or induction. More specifically, the electric energy generated by the source reaches the vicinity of the body via a conductor and is transmitted from it through air or some other electric insulating material to the human body.

[0007] Electric fields that can be used in medical applications can thus be separated generally into two different modes. In the first mode, the electric fields are applied to the body or tissues by means of conducting electrodes. These electric fields can be separated into two types, namely (1) steady fields or fields that change at relatively slow rates, and alternating fields of low frequencies that induce corresponding electric currents in the body or tissues, and (2) high frequency alternating fields (above 1 MHz) applied to the body by means of the conducting electrodes or by means of insulated electrodes.

[0008] The first type of electric field is used, for example, to stimulate nerves and muscles, pace the heart, etc. In fact, such fields are used in nature to propagate signals in nerve and muscle fibers, central nervous system (CNS), heart, etc. The recording of such natural fields is the basis for the ECG, EEG, EMG, ERG, etc. The field strength in conductive electrode applications, assuming a medium of homogenous electric properties, is simply the voltage applied to the stimulating/recording electrodes divided by the distance between them. The currents thus generated can be calculated by Ohm's law and can have dangerous stimulatory effects on the heart and CNS and can result in potentially harmful ion concentration changes. Also, if the currents are strong enough, they can cause excessive heating in the tissues. This heating can be calculated by the power dissipated in the tissue (the product of the voltage and the current).

[0009] When such electric fields and currents are alternating, their stimulatory power, on nerve, muscle, etc., is an inverse function of the frequency. At frequencies above 1-10 kHz, the stimulation power of fields approaches zero. This limitation is due to the fact that excitation induced by electric stimulation is normally mediated by membrane potential changes, the rate of which is limited by the RC properties (with time constants on the order of 1 ms) of the membrane.

[0010] Regardless of the frequency, when such current inducing fields are applied, they are often associated with harmful side effects caused by currents. For example, one negative effect is the changes in ionic concentration in the various “compartments” within the system, and the harmful products of the electrolysis biological material, or the medium in which the tissues are imbedded.

[0011] Alternating fields of medium frequencies (about 50 kHz – 1 MHz), which were traditionally assumed not to have any biological effect except due to heating, can be applied to a conductive medium, such as a human body, via insulated electrodes. Under such conditions the electrodes induce in the body only capacitive currents. In contrast to the general belief that such fields have no direct biological effect, in US patent applications # 10/204,334, 10/288,562, 10/285,313 by Palti (each of which is incorporated herein by reference) and in a subsequent publication (Eilon D. Kirson, et al., Disruption of Cancer Cell Replication by Alternating Electric Fields, Cancer Res. 2004 64:3288-3295), such fields have been shown to have the capability to specifically affect cancer cells and serve, among others, for treating cancer.

[0012] Treatment of cancer, other diseases, conditions and patho-physiological states by alternating electric fields may require long term application (e.g., over weeks or months) of the fields to the target location, which involves correspondingly long contact between the electrodes and the body surface (e.g., the patient's skin). Such application may be associated with significant side effects that may result from both chemical and physical reactions. Such reactions have been reported upon application of TENS, muscle stimulation, long term body potential recording (EEG, ECG, etc.).

[0013] Chemical reaction may be due to the contact with the electrode itself, or the materials that are interposed between the electrode and the skin for improving

electric conductivity (for example gel), and the products of the current flow including electrolysis at the electrode surfaces.

[0014] The long-term physical contact of the electrodes against the skin may effect the under-laying skin by the local pressure, by keeping the skin surface wet, or by the fact that the electrodes or gel, etc. occlude the exits of the skin appendages located at the external part of the skin, such as sweat glands, hair follicles, etc. This results in accumulation of water and chemical agents within the appendages and at the skin surface, which can damage the superficial skin layers.

SUMMARY OF THE INVENTION

[0015] The present invention is designed to eliminate, or significantly reduce some of the side effects associated with long term application of electric fields to the skin by using an electrode configuration that permits the skin to "breathe."

BRIEF DESCRIPTION OF THE DRAWINGS

[0016] FIG. 1A is a plan view of a first embodiment of the present invention, which is a multi-segment electrode with the segments arranged in a rectangular array.

[0017] FIG. 1B is a cross section view of the FIG. 1A embodiment, taken along section line A-A.

[0018] FIG. 1C is a cross section view of the FIG. 1A embodiment with an optional wicking feature added.

[0019] FIG. 2 is a plan view of a second embodiment of the present invention, which is a multi-segment electrode with the segments arranged in a hexagonal array.

[0020] FIG. 3 is a plan view of a third embodiment of the present invention, which is a perforated electrode.

[0021] FIG. 4A is a plan view of a fourth embodiment of the present invention, which is an electrode made of a plurality of parallel wires.

[0022] FIG. 4B is a cross section view of the FIG. 4A embodiment, taken along section line B-B used, used with a conductive gel.

[0023] FIG. 5 is a plan view of a fifth embodiment of the present invention, which is an electrode made from a group of parallel wires, with an additional group of parallel wires that are perpendicular to the first group.

[0024] FIG. 6A is a plan view of a sixth embodiment of the present invention, with the electrode located at a first position within an overall footprint.

[0025] FIG. 6B shows the electrode of FIG. 6A located at a second position within an overall footprint.

[0026] FIG. 7A is a pictorial representation showing how a pair of any of the aforementioned electrodes are placed in contact with the skin of a patient during use.

[0027] FIG. 7B is a schematic representation of an electrical circuit that is formed when a pair of any of the aforementioned electrodes are placed in contact with the skin of a patient.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

[0028] FIGS 1A and 1B depict a first embodiment of a composite electrode that is designed for applying an electric field to an in-vivo tumor for extended periods of time. The composite electrode 10 is made up of a number of individual segments 5, with a number of open spaces 8 disposed between the segments 5. The segments 5 apply an electric field to a desired location within the patient's body. Preferred characteristics of the applied field are described in the three patent applications identified above. Those applications teach that electric fields with frequencies between about 50 kHz to about 500 kHz (and more preferably between

about 100 kHz and 300 kHz) at field strengths of between about 0.1 V/cm to about 10 V/cm (and more preferably between about 1 and about 10 V/cm) have proven effective at slowing or reversing the growth of rapidly dividing cells (e.g., cancer cells). For example, a 120 kHz, 1.4 V/cm field has been shown to be effective against melanoma, and a 170-250 kHz, 2.5 V/cm field has been shown to be effective against glioma.

[0029] Returning to FIGS. 1A and 1B, the segments 5 are preferably free to move about with respect to one another, to permit the electrode 10 to conform to the shape of the body's surface upon which the electrode 10 is placed. The segments 5 may be held together using any of a variety of suitable support structures, such as mounting them on a piece of cloth, netting, or other flexible backing (not shown). All of the segments are preferably electrically connected in parallel using appropriate wiring 4.

[0030] Each segment 5 preferably contains a conductive core 3 that is completely insulated from the surface upon which it is placed by a dielectric insulating material 2. Other surfaces of the segments 5 are preferably covered by any conventional insulating material 9. Because the dielectric insulating material 2 insulates the conductive core 3 from the surface of the patient's skin, any DC component that is present in the signal driving the electrodes will be blocked, and only the AC components at sufficiently high frequencies can pass into the patient's body. This configuration avoids the negative effects that would occur if conductive electrodes were used (e.g., ion concentration changes in the cells and the formation of harmful agents by electrolysis). This is because, in general, when capacitive electrodes are used, no actual transfer of charges takes place between the electrodes and the medium and there is no charge flow in the medium.

[0031] FIG. 7A shows how the above-described electrodes (or the electrodes of the below-described embodiments) are used to apply the desired field to the target

location. A pair of insulated electrodes 74 each contains a conducting portion 74A with an insulating dielectric portion 74B disposed thereon. When such electrodes are placed in contact with the patient's skin 6 and operatively connected to an AC voltage source 72 via leads 73, an electric field 76 is induced in the tissue 78 (which includes a tumor 79) that lies beneath the skin 6. As described in the three patent applications identified above, the equivalent electric circuit when the insulated electrodes are placed on the skin is as depicted in Figure 7B: the dielectric coated electrodes 75 act as capacitors A, E, the skin 6 acts as a resistive load B, D, and the tissue 78 also acts as a resistive load C. Under these conditions, the relative values of the impedances cause the fraction of the potential difference (electric field) that falls on the electrode insulation to be strongly dependent on the capacitance of the electrodes A, E. The potential drop across the capacitive electrode A is $A/(A+B+C+D+E)$, and a similar drop occurs across the other capacitive electrode E. At DC and low frequencies, the impedance of the capacitive electrodes A, E is high, and most of the voltage drop will be across the electrodes. In contrast, for extremely high frequencies, the capacitors have very low impedance and therefore a much larger portion of the voltage drop will appear in the tissue C. At the relevant frequency ranges identified above (i.e., from about 50 kHz to about 500 kHz), the impedance of the capacitive electrodes A, E will lie somewhere between those two extremes.

[0032] The preferred electric field intensity in the target tissue 79 is in the range of about 0.1 V/cm to about 10 V/cm. In order to achieve this voltage drop in the tissue C without increasing the voltage of the AC source 72 to undesirably high levels (which can pose a safety problem and be difficult to generate at the required parameters), the impedance of the capacitors A, E must be minimized, which occurs when the capacitance of the electrodes is maximized. Increasing the capacitance can be achieved by increasing the effective area of the "plates" of the capacitor, decreasing the thickness of the dielectric, or using a dielectric with a high dielectric

constant. Since the electrode area is limited and the insulation thickness can not be reduced in view of potential dielectric breakdown and due to the danger of mechanical damage, the best way to deliver the appropriate fields to their target locations is to use dielectrics with a very high dielectric constant. Examples of suitable dielectrics are: KTN - Potassium Tantalate ($\text{KTa}_{1-x}\text{Nb}_x\text{O}_3$), or PMNT (Lead Magnesium Niobate Titanate), which all have dielectric constants above 1000. Note that with some of these high-K materials, the dielectric constant can vary dramatically depending on the material processing procedures that are used when the material is formed (e.g., crystallization or doping), and it is more preferable to use a variety with a dielectric constant above 10,000. Note, however, that a very thin coating by a strong dielectric material with a standard dielectric constant (e.g., 3-30) may also serve well under some configurations (e.g., if a weaker field or higher voltage is not problematic).

[0033] Returning now to FIGS. 1A and 1B, the electrodes 10 include spaces 8 that are distributed throughout the surface of the electrodes 10. These spaces 8 allow the skin beneath the electrode 10 to "breathe" by allowing air to reach the skin beneath the electrodes. As a result, moisture (e.g., sweat) that might otherwise build up on the surface of the skin can evaporate. This ameliorates the detrimental effects that can accompany long term use of non-perforated electrodes (as described above in the background section). In addition, the presence of the spaces 8 between the active segments 5 of the electrode 10 helps prevent heat (due to, e.g., dielectric losses and current flow) from building up beneath the electrodes 10.

[0034] To ensure that the field is effectively strong the target location, the spacing between the segments 5 of the electrodes 10 is preferably smaller than the distance from the surface to the location that is the target of the treatment (e.g., the tumor 79, shown in FIG. 7A). On the other hand, the spacing between the segments 5 is preferably larger than about 2 mm, and more preferably larger than about 4 mm, to provide adequate ventilation. In terms of area, the area of each space 8 is

preferably larger than about 4 mm², and more preferably larger than about 16 mm². In this embodiment, the area of the segments 5 is roughly the same as the area of the spaces 8.

[0035] FIG. 2 depicts a second embodiment of an electrode 20. This electrode 20 is very similar to the electrode 10 of the FIG. 1 embodiment, except that the segments 25 and the spaces 28 of the FIG. 2 embodiment are hexagonal instead of square. Of course, other shapes besides the depicted squares and hexagons may also be used, and the spacing between the segments may be varied as required. The spacing of the segments in these embodiments is preferably selected to provide an adequate amount of field at the target region, while providing adequate ventilation to the skin. The segmented structure of these embodiments can be particularly advantageous in anatomical positions where a large degree of flexibility is needed to conform the electrodes to the skin surface.

[0036] FIG. 3 depicts a third embodiment of an electrode 30. This electrode is preferably made of a single piece of conductive material 35, with perforations or holes 38 disposed therein. The lower surface of the electrode 30 (not shown), which contacts the skin of the patient, is preferably coated with a dielectric material similar to the dielectric 2 of the FIG. 1 embodiment. The upper surface of the electrode 30, which faces away from the patient during use, is preferably coated with an insulator similar to the insulator 9 of the FIG. 1 embodiment. The spacing of the holes in this embodiment is also preferably selected to provide an adequate amount of field at the target region, while providing adequate ventilation to the skin.

[0037] FIGS. 4A and 4B are plan and section views of a fourth embodiment of an electrode 40. This electrode is made of a set of parallel elements 45 that are separated by spaces 48. Each element 45 is made of a conductive wire 43 that is surrounded by a dielectric coating 42, preferably of a material similar to the dielectric 2 of the FIG. 1 embodiment. The conductors 43 are preferably electrically

connected in parallel by wires 44. A suitable backing (not shown) may be affixed to the electrode 40 to maintain the desired spacing of the elements 45 of the electrode 40. Optionally, this backing may be designed to prevent bending of the electrode along the length of the elements 45, which could crack the dielectric coating when a brittle dielectric is used. However, the backing may be configured to permit bending of the electrode 40 about an axis that is parallel to the elements 45, as long as the bending occurs at the spaces 48. The spacing of the open spaces 48 in this embodiment is also preferably selected to provide an adequate amount of field at the target region, while providing adequate ventilation to the skin. For example, the spaces 48 may be at least 2 mm wide, or more preferably, at least 4 mm wide.

[0038] FIG. 5 is a plan view of a fifth embodiment of an electrode 50. This embodiment is similar to the FIG. 4 embodiment described above, except that in addition to the horizontal elements 55 that correspond to the horizontal elements 45 of the FIG. 4 embodiment, the fifth embodiment also contains a second set of vertical elements 55' with a similar construction. Both sets of elements 55, 55' are preferably wired up in parallel by wires 54. As with the above-described embodiments, the size of the open spaces 58 are also preferably selected to provide an adequate amount of field at the target region, while providing adequate ventilation to the skin. For example, the spaces 58 may be at least 2 mm by 2 mm, or more preferably, at least 4 mm by 4 mm.

[0039] In some embodiments, e.g., FIGS. 1 and 4, the pattern of insulated conductors and spaces is configured so that locations that are covered when the electrode is positioned in a first location will become uncovered when the electrode is repositioned to a second location that is offset slightly from the first location, wherein the overall footprint of the electrodes in both locations is substantially the same. When this arrangement is implemented, the electrodes can be shifted back and forth between two positions periodically (e.g., every 2 to 4 days), so that each small patch of skin is alternately covered (in one position) or uncovered (in the other

position). Periodically exposing each patch of skin to the air in this manner gives the skin a chance to recover from any negative effects (e.g., accumulation of moisture or field effects) than may have occurred during the period of time when the skin was covered by the electrode. In applications where the electrodes are applied to the head, the head may be shaved before the electrodes are replaced in their new position, to prevent hair growth from interfering with the fields.

[0040] FIGS. 6A and 6B are plan views of a sixth embodiment of an electrode 60 positioned, respectively, at first and second locations within an overall footprint 62. As such, FIGS. 6A and 6B depict yet another embodiment in which the electrodes can be shifted back and forth between two positions periodically, as discussed above. The electrode 60 of this embodiment is made of a set of square segments 65 that are separated by spaces 68, with the area of the segments 65 roughly the same as the area of the spaces 68. The construction of the individual segments 65 of this embodiment is preferably similar to the segments 5 described above in connection with the FIG. 1 embodiment. Each segment 65 preferably measures at least 2 mm by 2 mm, and more preferably at least 4 mm by 4 mm, with a thickness between about 0.2 and about 1 mm. Note that although square segments are depicted in FIGS. 6A and 6B, other shapes and sizes may also be used, such as rectangular segments (e.g., 5 × 15 mm or 13 × 15 mm), circular segments (e.g., 19 mm in diameter), or other shapes that are designed to conform to a particular anatomical location.

[0041] The segments 65 may be mechanically held in place by any suitable flexible support. For example, they may be mounted on a thin and flexible substrate such as DuPont Kapton® polyimide film (not shown). When such a film is used, flexible wiring 64 may also be integrated onto the substrate to provide a low impedance electrical connection between the segments 65. An adhesive bandage may be used to affix the electrode assembly to the patient's body, in which case the adhesive bandage would also provide additional mechanical support.

[0042] Optionally, temperature sensors (e.g., a thermistor, not shown) may be added to each segment in this embodiment, e.g., by mounting them through a small hole (e.g., 2.5 mm dia.) in the center of each segment. When a polyimide film with flexible wiring is used for the connections to the segments, the wiring for the sensors is preferably implemented on the same polyimide film.

[0043] Fig 1C illustrates an optional additional skin protective system. In this case the spaces between the solid coated portions 3, 2 of the electrodes are filled with a water absorbing material 12 such as cotton, polypropylene, etc. that wicks the wetness off the skin 6 so as to keep it dry, and transfers it to a water storing medium 11 such as a hygroscopic gel, polyacrylate, etc. The water storing medium 11 is preferably positioned on the back of the electrode body so that it does not touch the skin. Note that while FIG. 1C illustrates this optional feature in connection with the FIG. 1A/1B embodiment, this feature may be incorporated into any of the other embodiments described above by making appropriate changes to the shapes and sizes of the water absorbing material 12 and the water storing medium 11.

[0044] FIG. 4B illustrates the use of another option – a conductive gel. (Note that while FIG. 4B is illustrates this optional feature in connection with the FIG. 4A embodiment, this feature may be incorporated into any of the other embodiments described above.) The electric contact between the cylindrical electrodes (which are made of conductors 43 surrounded by a dielectric coating 42) and the body surface 7 or skin can be improved by placing an intervening filler such as a conductive gel 41 between the electrodes and the skin 6. Alternatively, the gel 41' may be applied so as to completely surround the dielectric coating 42 that surrounds the conductor 43, which results in an increase in the area of the effective electrode surface. Optionally, the absorbing material 12 or gel 41' may include or be coated by a medication that prevents or relieves skin irritation and inflammation, such as a steroid paste.

[0045] Unfortunately, long term application of an object or medium that is not permeable to air, such as a gel, often results in skin reaction which may be severe. In addition water based media such as gels keep the skin wet, and long term wetting of the skin causes the external corneal skin layer to swell and lose its skin protective ability. Many gels can also occlude the orifices of the sweat and sebaceous glands, thus worsening the damage to the skin. Accordingly, such gels are preferably used in combination with those above-described embodiments where the electrodes can be shifted back and forth between two positions periodically, to minimize these problems.

[0046] Optionally a temperature sensor (not shown) may be incorporated into the electrode, and an appropriate circuit (not shown) can be used to temporarily turn off the power to the electrode (or to individual affected regions, if the segments are not all wired in parallel) when the output of the sensor indicates that it is too hot.

[0047] The above-described embodiments can generate safely and effectively alternating and transient electric fields in human patients, or other objects, for prolonged periods of time, by means of skin surface electrodes without causing significant side effects. Minor skin reactions that might still occur may be eased by incorporating medication to the conductive gels used. Such medication can include steroids, anti-allergic agents, antihistamines, etc.

[0048] While the invention has been particularly shown and described with reference to preferred embodiments thereof, it will be understood by those skilled in the art that various changes in form and details can be made without departing from the spirit and scope of the invention.

I CLAIM:

1. An electrode configured for placement in contact with a surface of a patient's body, the electrode comprising:

a conductive substrate having a first side that faces the patient when the electrode is placed in contact with the patient's body, the conductive substrate having a plurality of open spaces passing therethrough that pass through the first side of the conductive substrate, wherein the open spaces are distributed and sized to permit moisture on the surface of the patient's body to escape via the open spaces when the electrode is placed in contact with the patient's body; and

a thin dielectric material disposed on the first side of the conductive substrate so as to insulate the conductive substrate from the patient's body when the electrode is placed in contact with the patient's body, wherein the dielectric coating has a dielectric constant of at least 1000.

2. The electrode of claim 1, wherein the conductive substrate is a single piece of conductive material.

3. The electrode of claim 1, wherein the conductive substrate comprises a plurality of separate sections that are attached to one another in a manner that permits the sections to move with respect to neighboring sections, by a limited amount.

4. The electrode of claim 1, wherein the conductive substrate comprises a plurality of roughly parallel wires spaced apart by at least 2 mm, and wherein the thin dielectric material surrounds each of the wires.

5. The electrode of claim 1, wherein the open spaces are at least 2 mm wide.

6. The electrode of claim 1, wherein the open spaces are at least 4 mm wide.
7. The electrode of claim 1, wherein the open spaces have an area that is least 4 square mm.
8. The electrode of claim 1, wherein the open spaces have an area that is least 16 square mm.
9. The electrode of claim 1, wherein the open spaces are arranged in a pattern that permits portions of the surface of a patient's body that are covered when the electrode is in the first position to become uncovered when the electrode is moved to a second position, with the overall footprint of the electrode in the first position substantially overlapping the overall footprint of the electrode in the second position.
10. The electrode of claim 9, wherein the combined area of all the open spaces is roughly half the area of the footprint of the electrode.
11. The electrode of claim 1, wherein the dielectric coating has a dielectric constant of at least 10,000.
12. A method of treating a patient with an AC electric field, comprising the steps of:
 - placing at least two electrodes against a patient's body, the electrodes having a conductive substrate and a thin dielectric layer located between the patient and the conductive substrate, wherein at least one of the electrodes has a plurality of open spaces passing therethrough, the open spaces being distributed and sized to permit moisture that is located beneath the electrode to escape via the open spaces; and
 - applying an AC voltage across the electrodes to induce an electric field at a target region in the patient's body, the electric field having a frequency between

about 50 kHz and about 500 kHz and a field strength between about 0.1 and about 10 V/cm at the target region.

13. The method of claim 12, wherein the applying step lasts for at least five days.

14. The method of claim 12, wherein the electric field has a frequency between about 170 kHz and about 250 kHz and a field strength between about 1 and about 10 V/cm at the target region.

15. The method of claim 12, wherein the electric field has a frequency of about 120 kHz and a field strength between about 1 and about 10 V/cm at the target region.

16. The method of claim 12, wherein the conductive substrate is a single piece of conductive material.

17. The method of claim 12, wherein the conductive substrate comprises a plurality of separate sections that are attached to one another in a manner that permits the sections to move with respect to neighboring sections, by a limited amount.

18. The method of claim 12, wherein the conductive substrate comprises a plurality of roughly parallel wires spaced apart by at least 2 mm, and wherein the thin dielectric material surrounds each of the wires.

19. The method of claim 12, wherein the open spaces are at least 2 mm wide.

20. The method of claim 12, wherein the open spaces are at least 4 mm wide.

21. The method of claim 12, wherein the open spaces have an area that is least 4 square mm.
22. The method of claim 12, wherein the open spaces have an area that is least 16 square mm.
23. The method of claim 12, further comprising the step of moving the electrodes from a first position in which first portions of the surface of a patient's body are covered by solid portions of the electrodes to a second position in which the first portions are not covered by the solid portions of the electrodes, wherein the overall footprints of the electrodes in the first position substantially overlap the overall footprints of the electrodes in the second position.
24. The method of claim 23, wherein the electrodes are switched between the first position and the second position every 2-4 days.
25. A method of treating a patient with an AC electric field, comprising the steps of:
- placing at least two electrodes against a patient's body, the electrodes having a conductive substrate and a thin dielectric layer located between the patient and the conductive substrate, the dielectric layer having a dielectric constant of at least 1000, wherein at least one of the electrodes has a plurality of open spaces passing therethrough, the open spaces being distributed and sized to permit moisture that is located beneath the electrode to escape via the open spaces; and
- applying an AC voltage across the electrodes to induce an electric field at a target region in the patient's body, the electric field having a frequency between about 50 kHz and about 500 kHz and a field strength between about 0.1 and about 10 V/cm at the target region.

26. The method of claim 25, wherein the applying step lasts for at least five days.
27. The method of claim 25, wherein the electric field has a frequency between about 170 kHz and about 250 kHz and a field strength between about 1 and about 10 V/cm at the target region.
28. The method of claim 25, wherein the electric field has a frequency of about 120 kHz and a field strength between about 1 and about 10 V/cm at the target region.
29. The method of claim 25, wherein the conductive substrate is a single piece of conductive material.
30. The method of claim 25, wherein the conductive substrate comprises a plurality of separate sections that are attached to one another in a manner that permits the sections to move with respect to neighboring sections, by a limited amount.
31. The method of claim 25, wherein the conductive substrate comprises a plurality of roughly parallel wires spaced apart by at least 2 mm, and wherein the thin dielectric material surrounds each of the wires.
32. The method of claim 25, wherein the open spaces are at least 2 mm wide.
33. The method of claim 25, wherein the open spaces are at least 4 mm wide.
34. The method of claim 25, wherein the open spaces have an area that is least 4 square mm.

35. The method of claim 25, wherein the open spaces have an area that is least 16 square mm.
36. The method of claim 25, further comprising the step of moving the electrodes from a first position in which first portions of the surface of a patient's body are covered by solid portions of the electrodes to a second position in which the first portions are not covered by the solid portions of the electrodes, wherein the overall footprints of the electrodes in the first position substantially overlap the overall footprints of the electrodes in the second position.
37. The method of claim 36, wherein the electrodes are switched between the first position and the second position every 2-4 days.
38. The method of claim 25, wherein the dielectric layer has a dielectric constant of at least 10,000.

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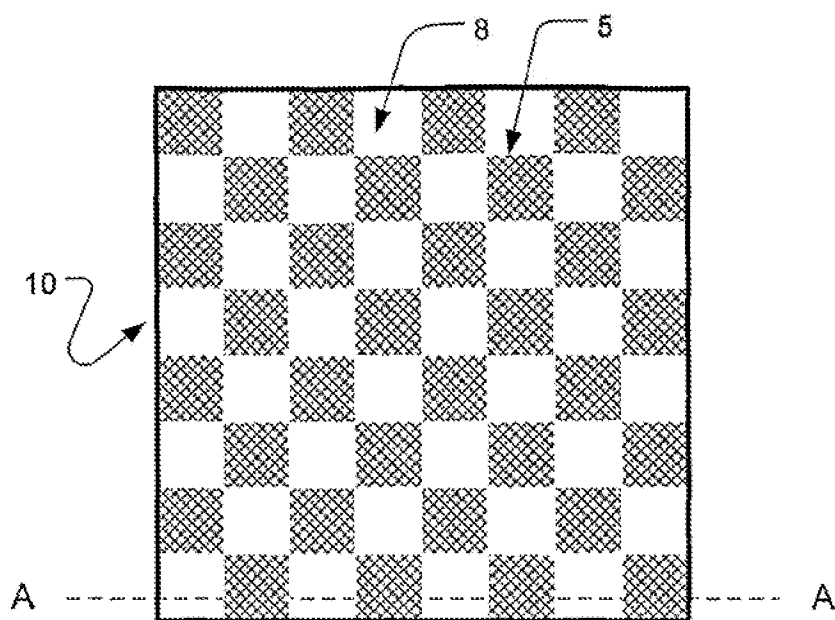


FIG. 1A

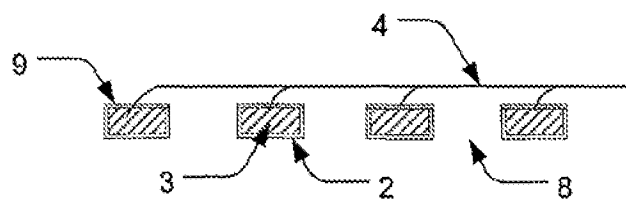


FIG. 1B

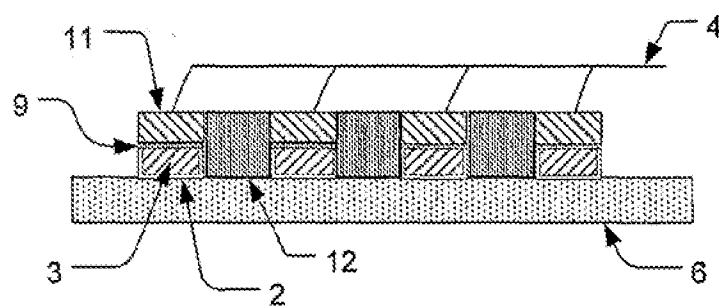


FIG. 1C

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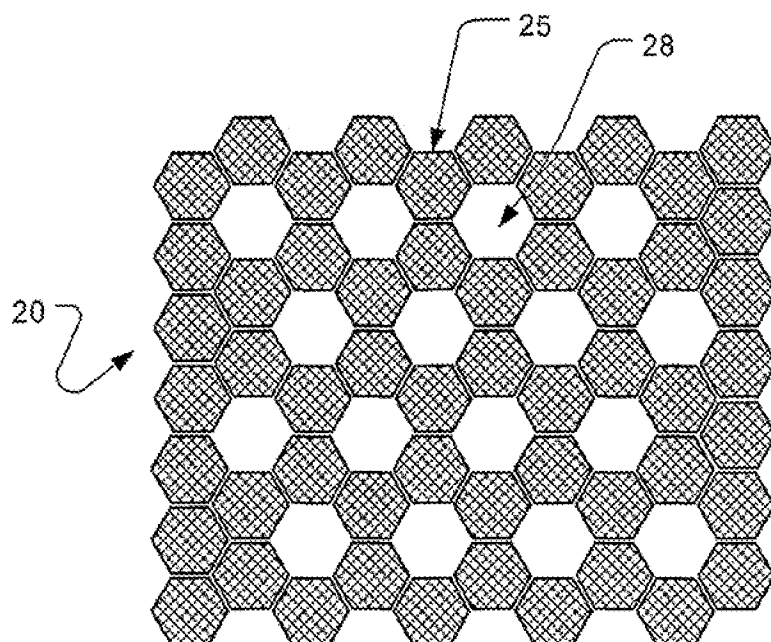


FIG. 2

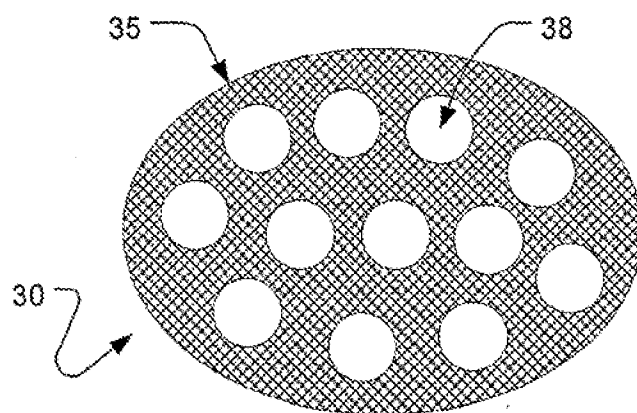


FIG. 3

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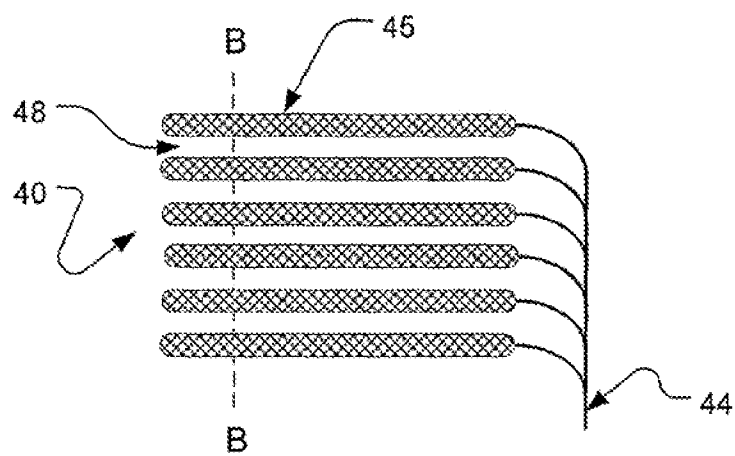


FIG. 4A

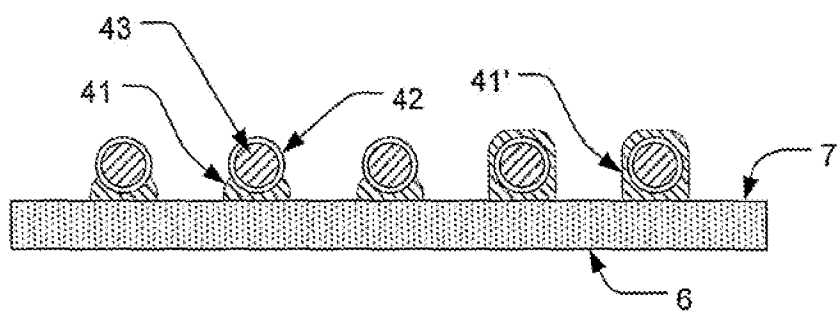
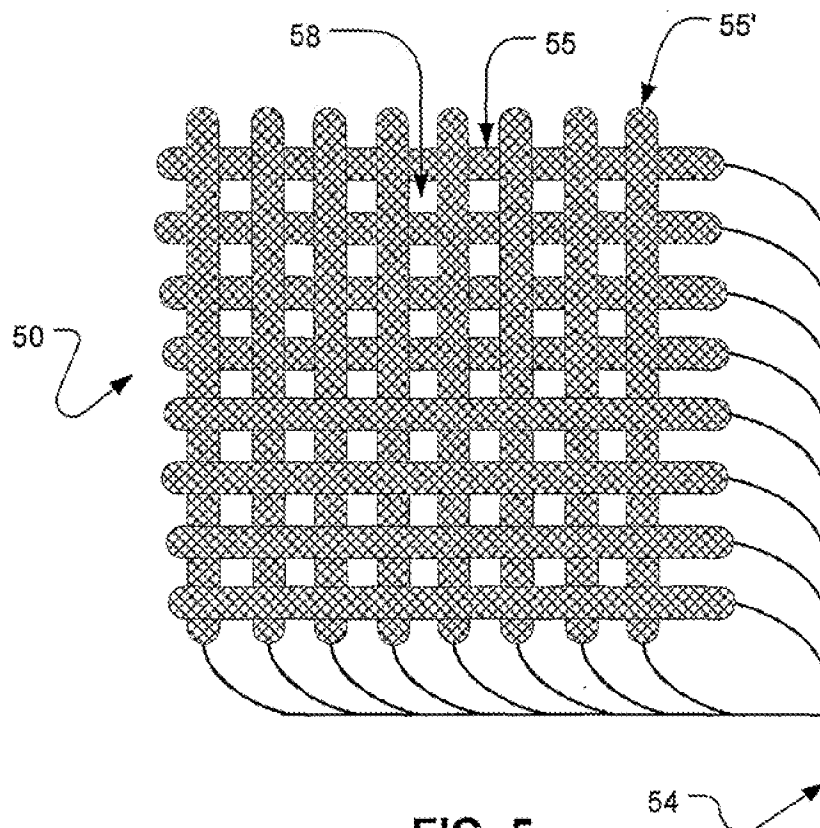
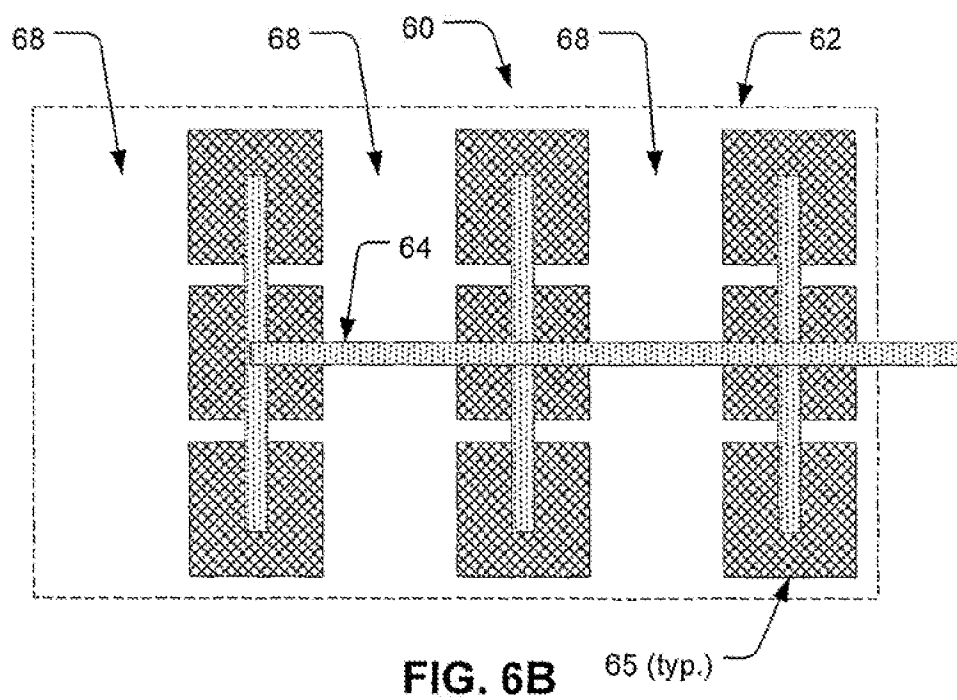
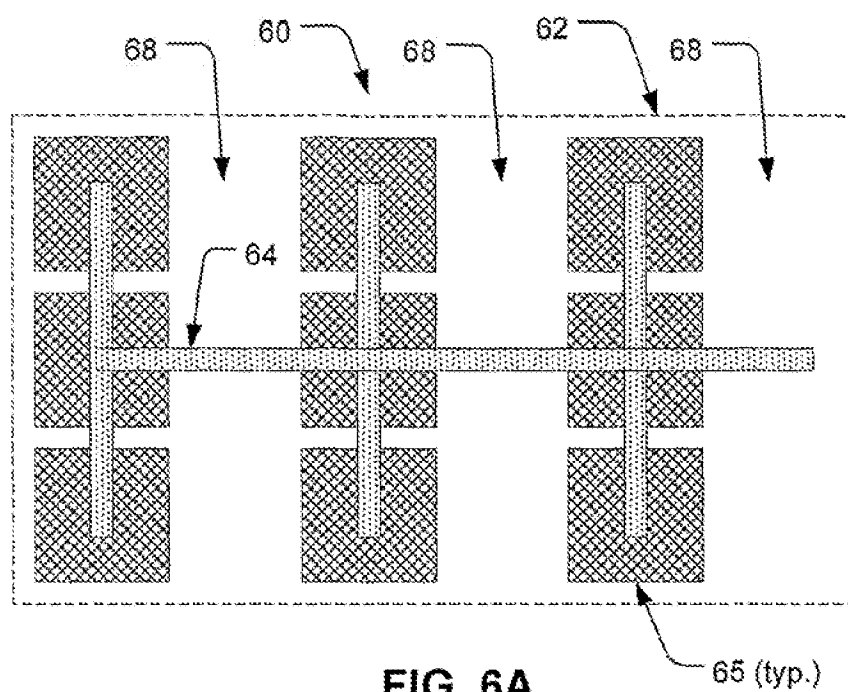


FIG. 4B

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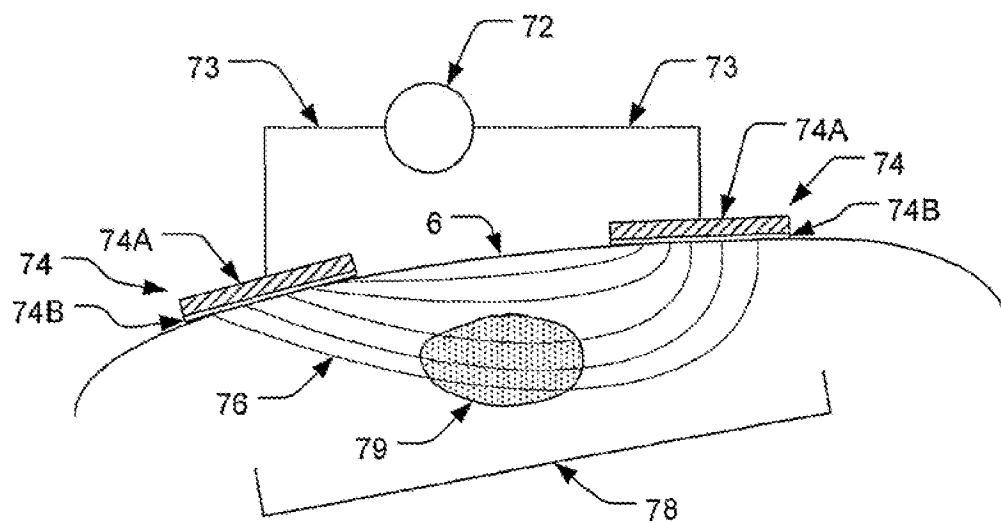


FIG. 7A



FIG. 7B

INTERNATIONAL SEARCH REPORT

International application No.

PCT/IB2005/003670

A. CLASSIFICATION OF SUBJECT MATTER
A61N1/04 A61N1/40

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2 130 759 A (ROSE EDGAR J) 20 September 1938 (1938-09-20) the whole document	1,2
A	EP 0 862 924 A (GRAPHIC CONTROLS CORPORATION) 9 September 1998 (1998-09-09) the whole document	1,5-8
A	US 2004/162602 A1 (COHEN SHLOMI) 19 August 2004 (2004-08-19) the whole document	1,2
A	US 5 974 344 A (SHOEMAKER, II ET AL) 26 October 1999 (1999-10-26) the whole document	1,5,7

☒ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents:

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Date of the actual completion of the international search

6 April 2006

Date of mailing of the international search report

25/04/2006

Name and mailing address of the ISA/

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Authorized officer

Sopelana Martínez, J

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB2005/003670

G(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4 367 755 A (BAILEY ET AL) 11 January 1983 (1983-01-11) the whole document	1
A	US 2003/055478 A1 (LYSTER THOMAS D ET AL) 20 March 2003 (2003-03-20) the whole document	1
A	US 2004/068297 A1 (PALTI YORAM) 8 April 2004 (2004-04-08) the whole document	1

Form PCT/ISA/210 (continuation of second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/182005/003670

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 12-38
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this International Application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/IB2005/003670

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 2130759	A	20-09-1938	NONE	
EP 0862924	A	09-09-1998	CA 2228163 A1	04-10-1998
			US 5961484 A	05-10-1999
			US 5848966 A	15-12-1998
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US 2004068297	A1	08-04-2004	NONE	



(43) International Publication Date
29 April 2010 (29.04.2010)

(10) International Publication Number
WO 2010/047599 A1

(51) International Patent Classification:
A61B 5/04 (2006.01) A61N 1/04 (2006.01)
A61B 5/0402 (2006.01)

(74) Agents: ONSAGERS AS et al.; P.O. Box 6963 St. Olavs
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(21) International Application Number:
PCT/NO2009/000365

(81) Designated States (unless otherwise indicated, for every
kind of national protection available): AE, AG, AL, AM,
AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ,
CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO,
DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT,
HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP,
KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD,
ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI,
NO, NZ, OM, PE, PG, PH, PL, PT, RO, RS, RU, SC, SD,
SE, SG, SK, SL, SM, ST, SV, SY, TJ, TM, TN, TR, TT,
TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(22) International Filing Date:
22 October 2009 (22.10.2009)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
20084440 22 October 2008 (22.10.2008) NO

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(84) Designated States (unless otherwise indicated, for every
kind of regional protection available): AKIPO (BW, GH,
GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM,
ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ,
TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE,
ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV,
MC, MK, MT, NL, NO, PL, PT, RO, SE, SI, SK, SM,
TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW,
ML, MR, NE, SN, TD, TG).

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[Continued on next page]

(54) Title: ELECTRODE ASSEMBLY FOR MEDICAL PURPOSES

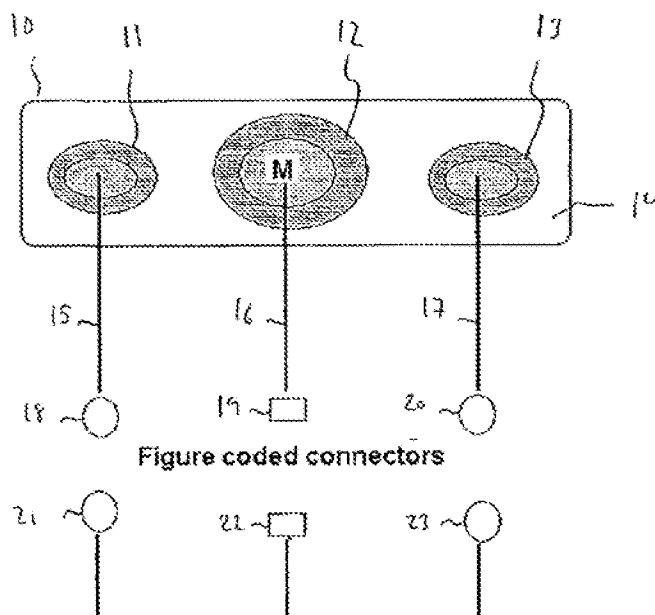


Figure coded connectors

Figure 1

(57) Abstract: An electrode assembly 10 for medical purposes comprises a first electrode 11 electrically connected to a first connecting line 15, a second electrode 12 electrically connected to a second connecting line 16, and a third electrode 13 electrically connected to a third connecting line 17. The first, second and third electrodes are arranged in a single patch 14. The shape or area of the second electrode is different from the shape or area of the first and third electrodes. The first, second and third connection lines may be coded by visible or tactile coding means.



Published:

---- with international search report (Art. 21(3))

---- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))

ELECTRODE ASSEMBLY FOR MEDICAL PURPOSES

Field of the invention

The invention relates to an electrode assembly for medical purposes, particularly to be placed on the skin of a patient.

5 Background of the invention

Medical electrodes are needed in many applications, e.g. for measurement of electrical activity in the brain (EEG), the heart (ECG), or the muscles (EMG). Medical electrodes may be used for measuring, e.g., electric current, potential/voltage, skin conductance, and skin resistance. Certain medical electrodes
10 may also be used for supplying electrical energy into the patient, e.g. in the case of defibrillators, electroconvulsive therapy and other therapy methods.

Medical electrodes are also used in the fields of electrophysiology and neuroscience. A particular class of equipment and methods utilize measurement of skin conductance for assessing the state of the autonomous nervous system of a
15 patient, such as a sedated patient, e.g. for detecting pain or awakening during anaesthesia.

WO-03/094726 is an example of an apparatus and a method for monitoring the autonomous nervous system of a sedated patient, wherein the skin conductance, measured by use of electrodes placed on the skin of the patient, is measured. Signals
20 indicating pain/discomfort in the patient and awakening in the patient are derived from the skin conductance measurements.

Summary of the invention

The invention is set forth in the appended claims.

Brief description of the drawings

25 Embodiments, aspects and principles of the invention will now be described in more detail with reference to the attached drawings, in which

figure 1 is a schematic block diagram illustrating an electrode assembly in a first embodiment, and

figure 2 is a schematic block diagram illustrating an electrode assembly in a second
30 embodiment.

Detailed description

Figure 1 is a schematic block diagram illustrating an electrode assembly in a first embodiment.

The electrode assembly 10 comprises a first electrode 11, a second electrode (M) 12, and a third electrode 13, all arranged in a patch 14.

5 In an aspect, the first electrode 11 is a counter current electrode, the second electrode 12 is a measuring electrode, and the third electrode 13 is a reference voltage electrode.

10 The first electrode 11 is electrically connected to a first connecting line 15, which is further connected to a first connection device 18. Similarly, the second electrode 12 is electrically connected to a second connecting line 16, further connected to a second connection device 19. Similarly, the third electrode 13 is electrically connected to a third connecting line 17, further connected to a third connection device 20.

In the illustrated example, the area of the second electrode 12 is different from the area of the first 11 and second 13 electrodes.

15 In an aspect, the shapes of the first and third electrodes are the same. In a particular aspect, the shape of the second electrode may be the same as the shapes of the first electrode and the third electrode. In another particular aspect, the shape of the second electrode may be different from the shapes of the first electrode and the third electrode.

20 In the illustrated example, the first 11, second 12 and third 13 electrodes have oval shapes. Alternatively, they could have circular shapes, or other shapes such as square, rectangular, triangular, etc.

In an aspect, as illustrated, the area of the first 11 and the third 13 electrodes may be the same, and the area of the second electrode 12 may be larger than the area of the first 11 and second 13 electrodes.

25 The patch 14 may have an elongated shape, e.g. a substantially rectangular shape as illustrated.

In an aspect, the second electrode 12 is a measurement electrode 12 and is arranged in between the first (counter current) electrode 11 and the third (reference voltage) electrode 13.

30 In an aspect, the first electrode 11 and the third electrode 13 are arranged substantially symmetrically about a line perpendicular to the length of the longitudinal patch 14.

In an aspect, the first electrode 11, the second electrode 12 and the third electrode 13 are arranged substantially in-line.

In another aspect, the first electrode 11, the second electrode 12 and the third voltage electrode 13 are not arranged in-line.

The first 15, the second 16 and the third 17 connection lines may be coded by visible or tactile coding means.

- 5 In an aspect, as schematically illustrated in figure 1, the coding means are both visible and tactile. In this case the first 15, second 16 and third 17 connection lines are figure coded. This is achieved by providing the first 15 and third 17 connection lines with connectors 18, 20 of a first type and by providing the second connection line 16 with a connector 19 which is incompatible with the connectors 18, 20 of the first type.

As an example, the connectors 18 and 20 may be a female connector, i.e. a socket, with a circular cross-section, while the connector 19 is a female connector, i.e. a socket, with a rectangular or square cross-section.

- 15 Correspondingly, wires for connection to measurement equipment (not shown) are provided with male connector (plug or pin type) with appropriate circular cross-section (connectors 21, 23), and a male connector (plug or pin type) with appropriate rectangular or square cross-section (connector 22).

Figure 2 is a schematic block diagram illustrating an electrode assembly in a second embodiment.

- 20 Please refer to the description of figure 1 for a detailed description of those elements of figure 2 which are identical to (and have the same reference numerals as) those illustrated in figure 1.

- In the embodiment of figure 2, the first 15, second 16 and third 17 connection lines are coded by visible coding means. This is achieved by color coding the connection lines. By example, this may be achieved by using different colors of the wires 15, 16, and 17, and/or the connectors 28, 29, 30, and/or the connectors 31, 32, 33.

By example, a blue insulation may be used for the second connection line 32, while red insulation is used for the first 31 and third 33 connection lines.

- 30 In such an embodiment, the connectors 28, 29, 30 may be of the same shape and type, e.g. female (socket) connectors, corresponding to male (plug/pin) connectors 31, 32, 33, respectively.

The electrode assembly disclosed in any of the above embodiments may be used in an arrangement for measuring skin conductance, e.g. of a patient.

- 35 In such use, the electrode assembly 10 may be placed on an area of the skin on a body part of the patient, for the purpose of measuring the skin's conductance. The

body part may, e.g., be a hand or a foot, and the area of the skin on the body part may, e.g., be the palmar side of the hand or the plantar side of the foot.

5 The first electrode 11 is a counter current electrode, the second electrode 12 is a measuring electrode 12, and the third electrode 13 is a reference voltage electrode, all arranged in the patch 14, which is placed on the skin area.

The electrode assembly 10 and its connected external equipment may ensure a constant application of voltage over the stratum corneum (the surface layer of the skin) under the measuring electrode.

10 The resulting current in a closed circuit between the measuring electrode 12 and the counter current electrode 11 may be measured by means of a measurement converter (not shown), connected between the counter current electrode 11 and the measuring electrode 12. The measurement converter may comprise a current to
15 voltage converter, such as a transresistance amplifier or simply a resistance, which converts the current from the measuring electrode 12 to a voltage.

The arrangement of a stiff patch 14 ensures that the second electrode (or measuring electrode) 12 does not suffer from undesired movement, which might lead to artefacts in the resulting measurements.

20 The arrangement of the measuring electrode 12 in the middle also contribute to reduced artefacts.

Since the skin conductance changes are monitored below the measuring electrode 12, the area below the measuring electrode 12 may be critical.

Further possible values and specifications of the electrode assembly and its elements are given below (for illustration, not for limitation):

25 Sensor:

Single use self-adhesive Ag/AgCl

Solid gel

The measuring sensor area (M) may be between 260 and 480 mm²

30 Operational principle; 3 measuring points, minimum 1 cm between the measuring points.

Dimension:

Electrode size and skin conduct size with adhesive area may have a minimum area of 260 mm²,

Connecting wire between 1 and 1000 mm.

The electrodes do not necessarily need to be on a line

Materials:

Biocompatible

5 Color coded or figure coded for ease of identification

Outer carrier, e.g. polyester

Lead-wire insulation, e.g. polyvinyl chloride

Lead-wire connector, e.g. polypropylene

10 The electrode assembly disclosed herein may also be used in an arrangement for monitoring the autonomous nervous system of a patient.

In this case a similar arrangement is used as explained above. In addition, the measuring equipment is connected to a processing device configured for monitoring the autonomous nervous system of the patient, based on measurements of the skin conductance. An example of suitable processing and monitoring means/methods has
15 been disclosed in WO-03/094726 (expressly incorporated by reference).

The inventive concept is not limited to the exemplary embodiments described above. Rather, the scope of the invention is set forth in the following patent claims.

CLAIMS

1. Electrode assembly for medical purposes,
comprising a first electrode electrically connected to a first connecting line,
a second electrode electrically connected to a second connecting line, and
5 a third electrode electrically connected to a third connecting line,
the first, second and third electrodes being arranged in a single patch,
wherein the shape or area of the second electrode is different from the shape or area
of the first and third electrodes, and
wherein the first, second and third connection lines are coded by tactile coding
10 means.
2. Electrode assembly according to claim 1,
wherein the shapes of the first and third electrodes are the same.
- 15 3. Electrode assembly according to claim 1 or 2,
wherein the area of the first and third electrodes are the same.
4. Electrode assembly according to one of the claims 1-3,
wherein the area of the second electrode is larger than the area of the first and third
20 electrodes.
5. Electrode assembly according to one of the preceding claims,
wherein said first, second and third connection lines are figure coded,
the first and third connection lines being provided with a connector of a first type
25 and the second connection line being provided with a connector which is
incompatible with the connector of the first type.
6. Electrode assembly according to claim one of the preceding claims, wherein
said first, second and third connection lines are color coded.
30
7. Electrode assembly according to one of the preceding claims, wherein
said first electrode is a counter current electrode,
said second electrode is a measuring electrode, and

said third electrode is a reference voltage electrode.

8. Use of an electrode assembly according to one of the preceding claims in an arrangement for measuring skin conductance.

5

9. Use of an electrode assembly according to one of the claims 1-7 in an arrangement for monitoring the autonomous nervous system of a patient.

10

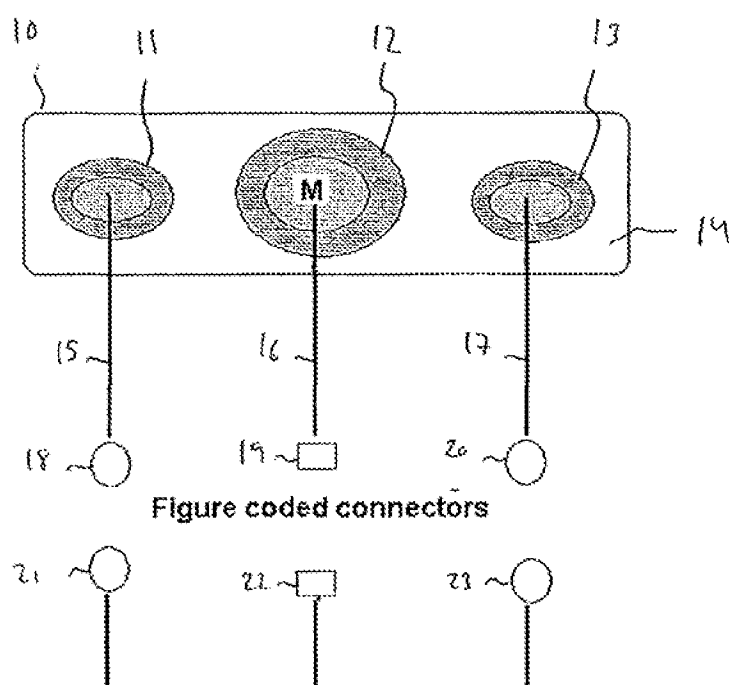


Figure 1

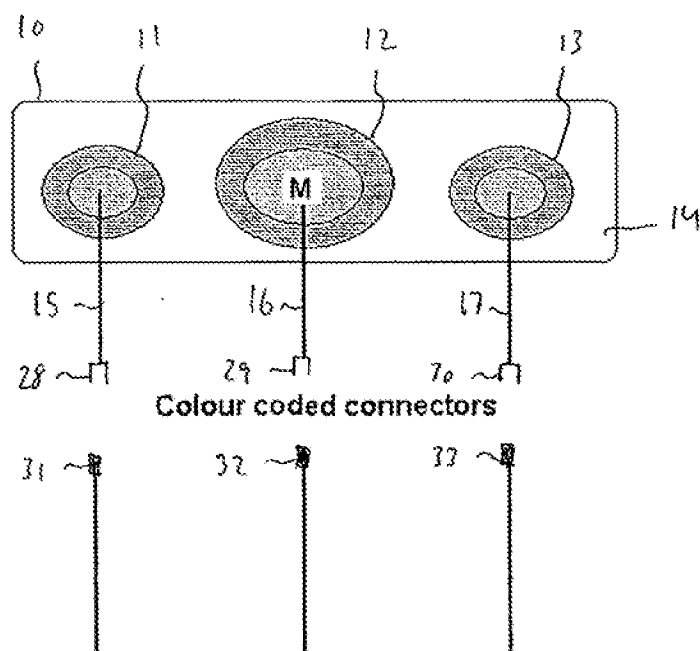


Figure 2

INTERNATIONAL SEARCH REPORT

International application No
PCT/NO2009/000365

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B5/04 A61B5/0402 A61N1/04

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61B A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2007/066876 A1 (HALLIN ROLF G [GB]) 22 March 2007 (2007-03-22) paragraphs [0014], [0038], [0039], [0048] - [0059], [0066]; figures 5,6	1-9
Y	WO 2005/114535 A (BAYER HEALTHCARE LLC [US]; THOMPSON BRIAN C [US]) 1 December 2005 (2005-12-01) page 5, line 7 - line 17; figure 1A	1-9
Y	WO 2007/096452 A (BRAINSCOPE OY [FI]; VOIPIO JUHA [FI]) 30 August 2007 (2007-08-30) page 12, lines 1-3	6

-/--

☒ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents:

- * "A" document defining the general state of the art which is not considered to be of particular relevance
- * "E" earlier document but published on or after the international filing date
- * "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- * "C" document referring to an oral disclosure, use, exhibition or other means
- * "P" document published prior to the international filing date but later than the priority date claimed

- * "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- * "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- * "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- * "&" document member of the same patent family

Date of the actual completion of the international search

26 February 2010

Date of mailing of the international search report

05/03/2010

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
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Authorized officer

Schindler, Martin

INTERNATIONAL SEARCH REPORT

International application No
PCT/NO2009/000365

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 6 334 068 B1 (HACKER DAVID C [US]) 25 December 2001 (2001-12-25) column 9, line 45 - column 10, line 3; figures 7-10 -----	1-9
A	US 6 394 953 B1 (DEVLIN PHILIP H [US] ET AL) 28 May 2002 (2002-05-28) column 4, line 66 - column 5, line 21; figures 1, 5a-c column 6, line 4 - line 13 -----	1-9
A	US 5 632 643 A (SHEPHERD DAVID J [US] ET AL) 27 May 1997 (1997-05-27) column 3, line 58 - column 4, line 24; figure 3 -----	1-9

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/NO2009/000365

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			JP 2007508100 T	05-04-2007
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			NO 970496 A	06-08-1997

Electronic Patent Application Fee Transmittal

Application Number:	12508529			
Filing Date:	23-Jul-2009			
Title of Invention:	METHOD AND APPARATUS FOR MAGNETIC INDUCTION THERAPY			
First Named Inventor/Applicant Name:	Daniel Rogers Burnett			
Filer:	Steven Michael Giovannetti/Dilora Haddad			
Attorney Docket Number:	EMKNNZ00301			
Filed as Small Entity				
Utility under 35 USC 111(a) Filing Fees				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Extension - 3 months with \$0 paid	2253	1	700	700

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous:				
Request for Continued Examination	2801	1	600	600
Total in USD (\$)				1300

Electronic Acknowledgement Receipt

EFS ID:	20236678
Application Number:	12508529
International Application Number:	
Confirmation Number:	8186
Title of Invention:	METHOD AND APPARATUS FOR MAGNETIC INDUCTION THERAPY
First Named Inventor/Applicant Name:	Daniel Rogers Burnett
Customer Number:	40518
Filer:	Steven Michael Giovannetti/Dilora Haddad
Filer Authorized By:	Steven Michael Giovannetti
Attorney Docket Number:	EMKNNZ00301
Receipt Date:	24-SEP-2014
Filing Date:	23-JUL-2009
Time Stamp:	18:20:40
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	\$ 1300
RAM confirmation Number	5108
Deposit Account	
Authorized User	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
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1	Request for Continued Examination (RCE)	01_EMKNNZ00301_20140924_rce_efs.pdf	697351 6bda30eda7ec1d0406dcf3355b0900df7a21c7ec	no	3
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Information:					
2		02_EMKNNZ00301_20140924_response_to_final_office_action.pdf	2372517 0a72407227c0a560a18fbd2f115f85a2742e25ac	yes	14
	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Amendment Submitted/Entered with Filing of CPA/RCE		1	1	
	Claims		2	10	
	Applicant Arguments/Remarks Made in an Amendment		11	14	
Warnings:					
Information:					
3	Extension of Time	03_EMKNNZ00301_20140924_extension_of_time.pdf	222889 603488fa6a0e3521cc3c01e218741207359042c7	no	1
Warnings:					
Information:					
4	Transmittal Letter	04_EMKNNZ00301_20140924_ids_cover_letter.pdf	304713 e2a606a8ec39b1d3c9a2dbc9c61f670ebe67ace3	no	2
Warnings:					
Information:					
5	Information Disclosure Statement (IDS) Form (SB08)	05_EMKNNZ00301_20140924_ids_sb08.pdf	213278 640d64b3f46310ed553e07469ceebe93b069336f	no	1
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6	Foreign Reference	06_WO2006061688.pdf	4962860 4e7280533d2c5b1fce87ceb53c63c2caca2a5be3	no	31
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7	Foreign Reference	07_WO2010047599.pdf	1639615 6c12983a27e0b0699f0635b8ed0d96c0dec5de05	no	13
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Information:					

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Information:					
Total Files Size (in bytes):				10445626	
This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503. <u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application. <u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course. <u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.					

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 12/508,529	Filing Date 07/23/2009	☐ To be Mailed
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 ENTITY: ☐ LARGE ☒ SMALL ☐ MICRO

APPLICATION AS FILED – PART I

FOR	NUMBER FILED (Column 1)	NUMBER EXTRA (Column 2)	RATE (\$)	FEE (\$)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A	N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X \$ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X \$ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$310 (\$155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT	(Column 1)	(Column 2)	(Column 3)	RATE (\$)	ADDITIONAL FEE (\$)
	09/24/2014	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	
	Total (37 CFR 1.16(i))	* 54	Minus	** 54	= 0
	Independent (37 CFR 1.16(h))	* 7	Minus	*** 7	= 0
	☐ Application Size Fee (37 CFR 1.16(s))				
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))				
TOTAL ADD'L FEE					0
AMENDMENT	(Column 1)	(Column 2)	(Column 3)	RATE (\$)	ADDITIONAL FEE (\$)
		CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	
	Total (37 CFR 1.16(i))	*	Minus	**	=
	Independent (37 CFR 1.16(h))	*	Minus	***	=
	☐ Application Size Fee (37 CFR 1.16(s))				
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))				
TOTAL ADD'L FEE					

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

 LIE
/CHERYL CLARK/

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/508,529	07/23/2009	Daniel Rogers Burnett	EMKNNZ00301	8186

40518 7590 03/24/2014
LEVINE BAGADE HAN LLP
2400 GENG ROAD, SUITE 120
PALO ALTO, CA 94303

EXAMINER

KUHLMAN, CATHERINE BURK

ART UNIT	PAPER NUMBER
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3735

MAIL DATE	DELIVERY MODE
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03/24/2014

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 12/508,529	Applicant(s) BURNETT ET AL.	
	Examiner CATHERINE B. KUHLMAN	Art Unit 3735	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/27/2014.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

- 5) ☒ Claim(s) 1-19 and 21-54 is/are pending in the application.
5a) Of the above claim(s) 1-18 and 35-54 is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 19 and 21-34 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

- a) ☐ All b) ☐ Some** c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
Paper No(s)/Mail Date ____.
- 3) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 4) ☐ Other: ____.

DETAILED ACTION

1. The present application is being examined under the pre-AIA first to invent provisions.
2. This action is responsive to the amendment filed on January 27th, 2014. The examiner acknowledges the amendments to claims 19, 21, 32 and 34. Claims 1-19 and 21-54 are pending; claims 1-18 and 35-54 remain withdrawn from consideration.

Claim Rejections - 35 USC § 112

3. The following is a quotation of 35 U.S.C. 112(b):
(b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 21 is rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention.
5. Claim 21 recites the limitation "the...muscle stimulation" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

6. The following is a quotation of pre-AIA 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 19, 21-25, and 27-30 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Leung (US 2006/0030845) in view of Byers (US 4837049).

8. Claim 19; Leung discloses an energy emitting system for providing a medical therapy comprising a least one patch or needle electrode 300 configured to generate an electrical stimulus focused on a target nerve in proximity to the electrode [0023 and 31] and at least one sensor 306 attachable to the skin surface in proximity to the target nerve configured to detect electrical conduction in the target nerve to provide feedback regarding the therapy to a controller 104 or 200 coupled to the electrode patch 300 [0020-21]. The controller delivers an electrical stimulus through the patch 300 and is adjustable to modulate therapy based on feedback from the sensor 306 [0020 and 46]. Leung does not specifically disclose the patch 300 comprises a microneedle array deposited on the surface of an electrode. Byers discloses an electrode patch that can be used for applying electrical stimulus to nerve tissue (col. 2, line 58 - col. 3, line 5) comprising an array of microneedles deposited on a surface of at least one electrode (or conducting layer) (col. 10, lines 18-29). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the microneedle array patch electrode disclosed by Byers as the electrode patch in Leung's system because Byers discloses this type of electrode provides good electrical contact with subcutaneous conductive tissue (col. 5, lines 45-51).

Leung does not specifically disclose electrical stimulation focused on the posterior tibial nerve or a branch thereof or detecting electrical conduction through the posterior tibial nerve or a branch thereof and placement of the sensor on the foot. However, Leung does disclose the stimulating electrode patch 300 and sensor 306 can be placed along any neural pathway of the body [0048]. Leung also discloses detecting afferent (or sensory) nerve stimulation along the

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target nerve pathway [0039]. Since the patch and sensor may be surface or skin electrodes [0023] they could be placed anywhere on the skin of the patient therefore the patch 300 is configured to generate an electrical stimulus focused on the posterior tibial nerve or a branch thereof if placed at an appropriate position along the foot or leg, and the sensor 306 is adapted for placement on a foot and is configured to detect conduction through the tibial nerve or a branch thereof by detecting a signal that an afferent nerve has been stimulated if also placed at an appropriate position along the foot or leg. Placement of the sensor and patch as claimed can be done without changing the structure of the prior art device, therefore the device disclosed by Leung in view of Byers meets claim 19.

9. Claim 21; Leung discloses the electrical stimulus provided by the patch 302 is varied according to the electrical conduction detected by the sensor 306 to ensure adequate therapeutic stimulation [0026].

10. Claim 22; the microneedle array disclosed by Byers may be etched from a surface of the electrode (col. 10, lines 6-9, 18-22, and 55-62).

11. Claim 23; each microneedle disclosed by Byers comprises an electrically conductive material (col. 10, lines 32-38) which can transmit an electrical signal to an overlying electrode (electrical conductor material col. 10, lines 18-22).

12. Claim 24; Byers discloses the needles comprise metal (col. 10, lines 32-35).

13. Claim 25; Leung discloses the sensor 306 may have the same structure as the patch stimulator 300 [0023] which, according to the above combination of Leung in view of Byers, is a microneedle array.

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14. Claims 27-30; Byers discloses needle diameters of 5-10 microns and a length of 100 microns (col. 7, lines 37-42).

15. Claims 26 and 34 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Leung in view of Byers as applied to claim 19 above, and further in view of Surgenor (US 2006/0049957 A1).

16. Claim 26; Leung in view of Byers is silent as to a bulb extending from at least one microneedle of the array. However, Surgenor discloses microneedles of an electrode array can be provided with anchoring means such as bulbous tips [0062]. It would have been obvious to one of ordinary skill in the art at the time of the invention to include a bulbous tip on at least some of the microneedles in the system disclosed by Leung in view of Byers in order to aid in anchoring of the electrode substrate to tissue, as taught by Surgenor [0062].

17. Claim 34; Leung discloses an energy emitting system for providing a medical therapy comprising a least one patch or needle electrode 300 configured to generate an electrical stimulus focused on a target nerve in proximity to the electrode [0023 and 31] and at least one sensor 306 attachable to the skin surface in proximity to the target nerve configured to detect electrical conduction in the target nerve to provide feedback regarding the therapy to a controller 104 or 200 coupled to the electrode patch 300 [0020-21]. The controller delivers an electrical stimulus through the patch 300 and is adjustable to modulate therapy based on feedback from the sensor 306 [0020 and 46]. Leung does not specifically disclose the patch 300 comprises a microneedle array deposited on the surface of an electrode. However, Byers discloses an electrode patch that can be used for applying electrical stimulus to nerve tissue (col. 2, lines 58-68) comprising an

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array of microneedles deposited on a surface of at least one electrode (or conducting layer) (col. 10, lines 18-29). Each microneedle comprises an electrically conductive material (col. 10, lines 32-38) which can transmit an electrical signal to an overlying electrode (col. 10, lines 18-22). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the microneedle array patch electrode disclosed by Byers as the electrode patch in Leung's system because Byers discloses this type of electrode provides good electrical contact with subcutaneous conductive tissue (col. 5, lines 45-51).

Leung in view of Byers is silent as to a bulb extending from at least one microneedle of the array. However, Surgenor discloses microneedles of an electrode array can be provided with anchoring means such as bulbous tips [0062]. It would have been obvious to one of ordinary skill in the art at the time of the invention to include a bulbous tip on at least some of the microneedles in the system disclosed by Leung in view of Byers in order to aid in anchoring of the electrode substrate to tissue, as taught by Surgenor [0062].

Leung does not specifically disclose electrical stimulation focused on the posterior tibial nerve or a branch thereof or detecting electrical conduction through the posterior tibial nerve or a branch thereof and placement of the sensor on the foot. However, Leung does disclose the stimulating electrode patch 300 and sensor 306 can be placed along any neural pathway of the body [0048]. Leung also discloses detecting afferent (or sensory) nerve stimulation along the target nerve pathway [0039]. Since the patch and sensor may be surface or skin electrodes [0023] they could be placed anywhere on the skin of the patient therefore the patch 300 is configured to generate an electrical stimulus focused on the posterior tibial nerve or a branch thereof if placed at an appropriate position along the foot or leg, and the sensor 306 is adapted

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for placement on a foot and is configured to detect conduction through the tibial nerve or a branch thereof by detecting a signal that an afferent nerve has been stimulated if also placed at an appropriate position along the foot or leg. Placement of the sensor and patch as claimed can be done without changing the structure of the prior art device, therefore the device disclosed by Leung in view of Byers and Surgenor meets claim 34.

18. Claims 31 and 32 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Leung in view of Byers as applied to claim 19 above, and further in view of Malaney (US 2002/0183804 A1).

19. Claims 31 and 32; Leung is silent as to an electrode needle coupled to the controller and inductively coupled to the patch. However, Malaney discloses an electrode needle 12 coupled to a controller 10 with an end insertable into the body in proximity to a stimulation site 15. The needle is inductively coupled to a patch electrode 14 and the patch is positioned distal to the stimulation site such that upon activation of the controller, a current traverses the stimulation site by passing from the patch to the electrode needle [0031]. It would have been obvious to one of ordinary skill in the art at the time of the invention to include an electrode needle inductively coupled to the patch electrode in the system taught by Leung in view of Byers, similar to the configuration taught by Malaney, because it allows for more precise targeting of the stimulation current provided by the electrode patch since the electrode needle can be inserted directly adjacent the target nerve.

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20. Claim 33 is rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Leung in view of Byers in view of Malaney as applied to claim 32 above, and further in view of Fairbanks (US 4233965).

21. Leung, Byers, and Malaney are silent as to a conductive coil positioned distal to the stimulation site and coupled to the controller. Fairbanks discloses a modified electrical stimulation device comprising a conductive coil 14 over an electrode patch 12 connected to a controller 32 (fig. 1a). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate a conductive coil over the electrode patch in the system disclosed by Leung in view of Byers and Malaney because Fairbanks discloses the coil helps focus the electric current in to tissue (col. 2, lines 46-47 and col. 3, line 65 - col. 4, line 3). When a conductive coil is present over the electrode patch location in the combination, it will also be located distal to the stimulation site such that upon activation of said controller, a current traverses the stimulation site by passing from the patch and the coil to the electrode needle (Malaney [0031]).

Response to Arguments

22. Applicant's arguments filed January 27th, 2014 have been fully considered but they are not persuasive.

23. In response to applicant's argument that Leung does not teach electrical stimulus of the posterior tibial nerve or a branch thereof or a sensor configured to detect electrical conduction through the posterior tibial nerve or a branch thereof by detecting a signal that an afferent nerve has been stimulated, the examiner notes that this is an intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention

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and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Since the patch electrode and sensor taught by Leung can be placed along any neural pathway and may be configured as surface electrodes, they are capable of being placed as claimed to stimulate and detect conduction in the posterior tibial nerve without any structural modifications.

24. Leung further teaches a controller as claimed which is adjustable to modulate therapy in response to feedback provided by the sensor [0020 and 46].

Conclusion

25. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CATHERINE B. KUHLMAN whose telephone number is (571)270-7130. The examiner can normally be reached on Monday-Friday 8:30 am - 5:00 pm Pacific Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CATHERINE B KUHLMAN/
Examiner, Art Unit 3735

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L14	1	("20020183804").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2014/03/19 14:43
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S1	761	loeb.in.	US-PGPUB; USPAT; USOCR	OR	ON	2012/06/20 12:15
S2	73	S1 and stimulator	US-PGPUB; USPAT; USOCR	OR	ON	2012/06/20 12:15
S3	1	("7798954").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/06/20 13:51
S4	1	(12/508529).APP.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/01/24 06:51
S5	1	(11/866329).APP.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/01/24 07:32
S6	102	(daniel near2 burnett).in.	US-PGPUB; USPAT; USOCR	OR	ON	2013/01/24 07:36
S7	7	S6 and (microneedle near5 (patch or array))	US-PGPUB; USPAT; USOCR	OR	ON	2013/01/24 07:36
S8	1	("20070021803").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/01/24 07:40
S9	1	("6690959").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/01/24 07:41
S10	1	("20050143789").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/01/24 07:42

S11	1	("20060135844").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/01/24 07:46
S12	257	("20020099323" "20050277998" "20060122660" "20080063866" "20080114199" "20090073991" "20090076345" "20090076559" "20090227831" "20100161005" "5690693" "6029090" "6086525" "6088619" "6200259" "6603987" "6611707" "6654636" "6663820" "6808506" "6931277" "7117034" "7320664" "7591806" "7658728" "20050283202" "7032302" "20020082465" "20030028072" "20060122454" "20070027353" "20070276318" "20090076336" "20090234410" "20110021863" "4915110" "6349233" "6471903" "6493588" "6743211" "6908453" "7130696" "7226439" "7497980" "7530968" "D571920" "20060199159" "20070282246" "20080262287" "4456012" "5314453" "5449378" "5518495" "5984854" "6491620" "6511463" "6533949" "6582393" "6652478" "6684106" "6701185" "6866659" "6941171" "6972013" "7013179" "7416541" "7500911" "7556615" "7572405" "7578954" "7627938" "20040010276" "20040122787" "20050021104" "20060276702" "20080004484" "20100022864" "20040147964" "20060052839" "20070027355" "20070208212" "20080177128" "20080183070" "20080306325" "20090118777" "20090264792" "20090292194" "20100056881" "20100160712" "20100222630" "3817254" "4428366" "4940453" "5000178" "5401233" "5792209" "6179770" "6451240" "6503231" "6591124" "6623457" "6770480" "6899838" "6926660" "6939311" "6960193" "7027478" "7048723" "7115108" "7285113" "7396326" "7410476" "7582069" "20030144625" "20050143783" "20110295100" "5978712" "2893392" "20040092860" "20040111139" "20060016452" "20090076565" "20090162570" "20100204538" "4804054" "5725471" "5766124" "6024691" "6066084" "6143035" "6256533" "6261221" "6334856" "6500110" "6527694" "6565532" "6671527" "6790372" "6881203" "6962772" "6980855" "7079355" "7104947" "7315758" "7415299" "7473244" "7647112" "7648484" "20020111777" "20040138517" "20040210282" "20050029223" "20060004244"	US-PGPUB; USPAT; USOCR	OR	ON	2013/01/24 07:50

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S13	1	("6161039").PN.	US- PGPUB; USPAT; USOCR	OR	OFF	2013/01/24 08:03
S14	1386	(whitehurst or loeb).in.	US- PGPUB; USPAT; USOCR	OR	ON	2013/01/24 10:04
S15	247	S14 and \$stimulator	US- PGPUB; USPAT; USOCR	OR	ON	2013/01/24 10:04
S16	1939	(600/9-15).OCLS.	US- PGPUB; USPAT; USOCR	OR	OFF	2013/01/24 10:08
S17	43980	electric\$5 near5 stimulat\$	US- PGPUB; USPAT; USOCR	OR	ON	2013/01/24 10:09
S18	453	S16 and S17	US- PGPUB;	OR	ON	2013/01/24 10:09

			USPAT; USOCR			
S19	45775	((\$cutaneous\$ or skin) near5 (patch or electrode)	US- PGPUB; USPAT; USOCR	OR	ON	2013/01/24 10:11
S20	8434	S17 and S19	US- PGPUB; USPAT; USOCR	OR	ON	2013/01/24 10:13
S21	6044	S20 and (nerve or neuron or neural)	US- PGPUB; USPAT; USOCR	OR	ON	2013/01/24 10:14
S22	115	S18 and S19	US- PGPUB; USPAT; USOCR	OR	ON	2013/01/24 10:14
S23	12212	(electric\$5 near5 stimulat\$) with (nerve neuron neural neuro)	US- PGPUB; USPAT; USOCR	OR	ON	2013/01/24 10:45
S24	3722	S19 and S23	US- PGPUB; USPAT; USOCR	OR	ON	2013/01/24 10:45
S25	23913	(patch or electrode) with (needle or microneedle or nanoneedle or barb or spike)	US- PGPUB; USPAT; USOCR	OR	ON	2013/01/24 10:46
S26	1081	S24 and S25	US- PGPUB; USPAT; USOCR	OR	ON	2013/01/24 10:46
S27	20089	(patch or electrode) with (needle or microneedle or nanoneedle)	US- PGPUB; USPAT; USOCR	OR	ON	2013/01/24 10:46
S28	999	S24 and S27	US- PGPUB; USPAT; USOCR	OR	ON	2013/01/24 10:46
S29	113941	(sense sensor sensed sensing detect detecting detector detected) near5 (conduction conductiv\$ stimulat\$)	US- PGPUB; USPAT; USOCR	OR	ON	2013/01/24 10:48
S31	487	S28 and S29	US- PGPUB; USPAT; USOCR	OR	ON	2013/01/24 10:49
S32	167	("3755704" "4016886" "4350164" "4513308" "4551149" "B453031").PN. OR ("4837049").URPN.	US- PGPUB; USPAT; USOCR	OR	ON	2013/01/24 10:53
S33	11	(james near2 malaney).in.	US- PGPUB; USPAT; USOCR	OR	ON	2013/01/24 12:48

S34	22933	tip near5 (bulb or bulbous or sphere or spheric\$ or ball)	US-PGPUB; USPAT; USOCR	OR	ON	2013/01/24 12:49
S35	542	S25 and S34	US-PGPUB; USPAT; USOCR	OR	ON	2013/01/24 12:51
S36	76	S35 and S23	US-PGPUB; USPAT; USOCR	OR	ON	2013/01/24 12:51
S37	36728	plurality with (needle or microneedle or nanoneedle or spike)	US-PGPUB; USPAT; USOCR	OR	ON	2013/01/24 13:03
S38	12318	plurality near (needle or microneedle or nanoneedle or spike)	US-PGPUB; USPAT; USOCR	OR	ON	2013/01/24 13:04
S39	1503	S25 and S38	US-PGPUB; USPAT; USOCR	OR	ON	2013/01/24 13:04
S40	122	S39 and S29	US-PGPUB; USPAT; USOCR	OR	ON	2013/01/24 13:04
S41	114	S40 not S36	US-PGPUB; USPAT; USOCR	OR	ON	2013/01/24 13:04
S42	1	("6735474").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/01/24 13:06
S43	23913	(patch or electrode) with (needle or microneedle or nanoneedle or barb or spike)	US-PGPUB; USPAT; USOCR	OR	ON	2013/01/24 15:45
S44	22933	tip near5 (bulb or bulbous or sphere or spheric\$ or ball)	US-PGPUB; USPAT; USOCR	OR	ON	2013/01/24 15:45
S45	542	S43 and S44	US-PGPUB; USPAT; USOCR	OR	ON	2013/01/24 15:45
S46	748	(needle or microneedle or nanoneedle or barb or spike) with tip near5 (bulb or bulbous or sphere or spheric\$ or ball)	US-PGPUB; USPAT; USOCR	OR	ON	2013/01/24 15:46
S47	37933	S43 adn S46	US-PGPUB; USPAT; USOCR	OR	ON	2013/01/24 15:46
S48	131	S43 and S46	US-PGPUB; USPAT;	OR	ON	2013/01/24 15:46

			USOCR			
S49	19	("3490439" "3896790" "4353372" "4926879" "4969468" "5143079" "5184620" "5215088" "5361760" "5452718" "5482038" "5509822" "5810742" "5928159" "5928458" "6055448" "6128521" "6745062").PN. OR ("7103398").URPN.	US- PGPUB; USPAT; USOCR	OR	ON	2013/01/24 15:51
S50	173	("5215088").URPN.	USPAT	OR	ON	2013/01/24 15:53
S51	20587	(electrode) with (needle or microneedle or nanoneedle or spike)	US- PGPUB; USPAT; USOCR	OR	ON	2013/01/24 16:00
S52	19683	(needle or microneedle or nanoneedle or barb or spike) near10 (bulb or bulbous or sphere or spheric\$ or ball)	US- PGPUB; USPAT; USOCR	OR	ON	2013/01/24 16:01
S53	14504	(needle or microneedle or nanoneedle or barb or spike) near5 (bulb or bulbous or sphere or spheric\$ or ball)	US- PGPUB; USPAT; USOCR	OR	ON	2013/01/24 16:01
S54	582	S51 and S53	US- PGPUB; USPAT; USOCR	OR	ON	2013/01/24 16:01
S55	476	S54 not S48	US- PGPUB; USPAT; USOCR	OR	ON	2013/01/24 16:01
S56	152	S55 and (skin or \$cutaneous)	US- PGPUB; USPAT; USOCR	OR	ON	2013/01/24 16:02
S57	24933	(607/2-76).CCLS.	US- PGPUB; USPAT; USOCR	OR	OFF	2013/10/24 14:54
S58	11281	(607/115-156).CCLS.	US- PGPUB; USPAT; USOCR	OR	OFF	2013/10/24 14:56
S59	591	(607/152).CCLS.	US- PGPUB; USPAT; USOCR	OR	OFF	2013/10/24 14:57
S60	1555	(601/15-22).CCLS.	US- PGPUB; USPAT; USOCR	OR	OFF	2013/10/24 14:59
S61	12197	(606/32-52).CCLS.	US- PGPUB; USPAT; USOCR	OR	OFF	2013/10/24 15:01
S62	2075	(600/9-15).CCLS.	US- PGPUB; USPAT; USOCR	OR	OFF	2013/10/24 15:01

S63	788	S62 and (electrode or (electric\$5 near5 stimulat\$))	US-PGPUB; USPAT; USOCR	OR	ON	2013/10/24 15:02
S64	52128	stimulat\$5 with (nerve neuron\$ neural)	US-PGPUB; USPAT; USOCR	OR	ON	2013/10/24 15:03
S65	57414	stimulat\$5 with (nerve neuron\$ neural nervous)	US-PGPUB; USPAT; USOCR	OR	ON	2013/10/24 15:03
S66	48223	S57 S58 S60 S61 S62	US-PGPUB; USPAT; USOCR	OR	ON	2013/10/24 15:03
S67	14456	S65 and S66	US-PGPUB; USPAT; USOCR	OR	ON	2013/10/24 15:03
S68	79196	(sense sensor sensed sensing detect\$5 minitor\$5) with (((nerve or neuron\$ or neural or nervous) near5 (conduction or conductiv\$)) or (muscle near S61 (stimulat\$ or contract\$5)))	US-PGPUB; USPAT; USOCR	OR	ON	2013/10/24 15:05
S69	8744	S67 and S68	US-PGPUB; USPAT; USOCR	OR	ON	2013/10/24 15:05
S70	5073	(\$needle near5 (patch or array))	US-PGPUB; USPAT; USOCR	OR	ON	2013/10/24 15:06
S71	230	S67 and S70	US-PGPUB; USPAT; USOCR	OR	ON	2013/10/24 15:06
S72	138	S69 and S70	US-PGPUB; USPAT; USOCR	OR	ON	2013/10/24 15:42
S73	122	S72 and (sensor monitor detector)	US-PGPUB; USPAT; USOCR	OR	ON	2013/10/24 15:45
S74	5	((11/105527) or (11/125247) or (11/079318)).APP.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/10/24 17:27
S75	1	("20050275497").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2014/03/19 09:24
S76	3	((("20070027514") or ("4969468") or ("20050275497")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2014/03/19 09:28
S77	5172	deep near brain near stimulat\$	US-PGPUB;	OR	ON	2014/03/19 09:40

			USPAT; USOCR			
S78	2654	S77 and (coil or microcoil)	US- PGPUB; USPAT; USOCR	OR	ON	2014/03/19 09:40
S79	167	S77 and probe with (coil or microcoil or electromag\$)	US- PGPUB; USPAT; USOCR	OR	ON	2014/03/19 09:41

3/ 19/ 2014 3:10:32 PM
C:\ Users\ cburk\ Documents\ EAST\ Workspaces\ 12508529.wsp

<i>Index of Claims</i> 	Application/Control No. 12508529	Applicant(s)/Patent Under Reexamination BURNETT ET AL.
	Examiner CATHERINE B KUHLMAN	Art Unit 3735

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant						☐ CPA		☐ T.D.		☐ R.1.47	
CLAIM		DATE									
Final	Original	06/27/2012	01/24/2013	10/24/2013	03/19/2014						
	1	÷	N	N	N						
	2	÷	N	N	N						
	3	÷	N	N	N						
	4	÷	N	N	N						
	5	÷	N	N	N						
	6	÷	N	N	N						
	7	÷	N	N	N						
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	11	÷	N	N	N						
	12	÷	N	N	N						
	13	÷	N	N	N						
	14	÷	N	N	N						
	15	÷	N	N	N						
	16	÷	N	N	N						
	17	÷	N	N	N						
	18	÷	N	N	N						
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	20	÷	✓	-	-						
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	31	÷	✓	✓	✓						
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	33	÷	✓	✓	✓						
	34	÷	✓	✓	✓						
	35	÷	N	N	N						
	36	÷	N	N	N						

<i>Index of Claims</i> 	Application/Control No. 12508529	Applicant(s)/Patent Under Reexamination BURNETT ET AL.
	Examiner CATHERINE B KUHLMAN	Art Unit 3735

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant						☐ CPA		☐ T.D.		☐ R.1.47	
CLAIM		DATE									
Final	Original	06/27/2012	01/24/2013	10/24/2013	03/19/2014						
	37	÷	N	N	N						
	38	÷	N	N	N						
	39	÷	N	N	N						
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	41	÷	N	N	N						
	42	÷	N	N	N						
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	45	÷	N	N	N						
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	52	÷	N	N	N						
	53	÷	N	N	N						
	54	÷	N	N	N						

Search Notes 	Application/Control No. 12508529	Applicant(s)/Patent Under Reexamination BURNETT ET AL.
	Examiner CATHERINE B KUHLMAN	Art Unit 3735

CPC- SEARCHED		
Symbol	Date	Examiner

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
600	9-15	1/24/2013	CEB
607	2-76, 115-156	10/24/2013	CEB
601	15-22	10/24/2013	CEB
606	32-52	10/24/2013	CEB

SEARCH NOTES		
Search Notes	Date	Examiner
EAST Text	1/24/2013	CEB
IDS	1/24/2013	CEB
Inventor Names	1/24/2013	CEB
Class/Subclass	1/24/2013	CEB
Forward/Backward	1/24/2013	CEB
Updated EAST Search	10/24/2013	CEB
Updated EAST Search	3/19/2014	CBK

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner

/C.B.K./
Examiner.Art Unit 3735

CUSTOMIZED PTO/SB/08a/b (07-05)

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	12/508,529
				Filing Date	July 23, 2009
				First Named Inventor	Daniel R. BURNETT
				Art Unit	3735
				Examiner Name	Catherine E. Burk
Sheet	1	of	1	Attorney Docket Number	EMKNNZ00301

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1.	6,319,241	11-20-2001	King et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
	2.					

*EXAMINER: Initial if information considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	3.		

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature	/Catherine Kuhlman/	Date Considered	03/19/2014
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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /C.K./

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	12/508,529
				Filing Date	July 23, 2009
				First Named Inventor	Daniel R. BURNETT
				Art Unit	3735
				Examiner Name	Catherine E. Burk
Sheet	1	of	1	Attorney Docket Number	EMKNNZ00301

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1.	6,319,241	11-20-2001	King et al.	

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Examiner Initials*	Cite No. ¹	Foreign Patent Document Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
	2.					

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NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	3.		

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature		Date Considered	
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Electronic Patent Application Fee Transmittal				
Application Number:		12508529		
Filing Date:		23-Jul-2009		
Title of Invention:		METHOD AND APPARATUS FOR MAGNETIC INDUCTION THERAPY		
First Named Inventor/Applicant Name:		Daniel Rogers Burnett		
Filer:		Steven Michael Giovannetti/Kym Moore		
Attorney Docket Number:		EMKNNZ00301		
Filed as Small Entity				
Utility under 35 USC 111(a) Filing Fees				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous:				
Submission- Information Disclosure Stmt	2806	1	90	90
Total in USD (\$)				90

Electronic Acknowledgement Receipt

EFS ID:	18038216
Application Number:	12508529
International Application Number:	
Confirmation Number:	8186
Title of Invention:	METHOD AND APPARATUS FOR MAGNETIC INDUCTION THERAPY
First Named Inventor/Applicant Name:	Daniel Rogers Burnett
Customer Number:	40518
Filer:	Steven Michael Giovannetti/Kym Moore
Filer Authorized By:	Steven Michael Giovannetti
Attorney Docket Number:	EMKNNZ00301
Receipt Date:	27-JAN-2014
Filing Date:	23-JUL-2009
Time Stamp:	18:13:10
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	\$90
RAM confirmation Number	5847
Deposit Account	
Authorized User	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
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1		1_EMKNZ00301_20140127_response_to_non_final_office_action.pdf	113323 748a96266769548236dd45eee2845dd06d0cb62a	yes	13
	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Amendment/Req. Reconsideration-After Non-Final Reject		1	1	
	Claims		2	9	
	Applicant Arguments/Remarks Made in an Amendment		10	13	
Warnings:					
Information:					
2	Transmittal Letter	2_EMKNZ00301_20140127_ids_cover_letter.pdf	74785 86ff5b3cb98c52e1d573b1bc0d9724c7e4010b65	no	2
Warnings:					
Information:					
3	Information Disclosure Statement (IDS) Form (SB08)	3_EMKNZ00301_20140127_ids_sb08.pdf	91082 ca775b00a806bdfdc25af8afa3d0c4efd86ee49e	no	1
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Information:					
This is not an USPTO supplied IDS fillable form					
4	Fee Worksheet (SB06)	fee-info.pdf	30481 fbd039b9d3c7eba0cc95d2686595549ae480b064	no	2
Warnings:					
Information:					
Total Files Size (in bytes):			309671		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

I hereby certify that this correspondence is being electronically transmitted to the USPTO on the date shown below.

Date: January 27, 2014

Signature: /Kym Y. Moore/ (Kym Y. Moore)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.: 12/508,529
Confirmation No.: 8186
Filing Date: July 23, 2009
Inventor(s): Daniel R. BURNETT et al.
Title: METHOD AND APPARATUS FOR MAGNETIC INDUCTION
THERAPY
Examiner: Catherine E. Burk
Group Art Unit: 3735

RESPONSE TO NON-FINAL OFFICE ACTION

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is in response to the non-final Office Action dated October 25, 2013 for which a response was due on January 25, 2014 (which fell on a Saturday). Accordingly, this response is timely filed. Reconsideration and allowance of the pending claims, as amended, in light of the Remarks presented herein are respectfully requested.

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks begin on page 10 of this paper.

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

In the claims

1. (Withdrawn): An energy emitting system for providing a medical therapy comprising:

at least one conductive coil disposed within or along a housing, where the at least one coil is configured to generate a magnetic field focused on a target nerve in proximity to the at least one coil;

at least one sensor configured to detect electrical conduction in the target nerve or muscle stimulation, wherein the sensor is comprised of a microneedle array attachable to a skin surface in proximity to a target nerve or muscle; and

a controller coupled to said at least one conductive coil and in communication with said at least one sensor.

2. (Withdrawn): The system of claim 1, wherein the magnetic field generated by said at least one conductive coil is varied based on the electrical conduction or muscle stimulation detected by said at least one sensor to ensure adequate therapeutic stimulation.

3. (Withdrawn): The system of claim 1, wherein the microneedle array is arrayed over a housing.

4. (Withdrawn): The system of claim 3, wherein the housing is comprised of a patch having at least one electrode and said microneedle array extends from a first surface of the electrode.

5. (Withdrawn): The system of claim 4, wherein the patch comprises a positive, negative and control electrode, each electrode comprising a microneedle array extending therefrom.

6. (Withdrawn): The system of claim 4, wherein the microneedle array is etched from a surface of the electrode.

7. (Withdrawn): The system of claim 1, wherein said microneedle array comprises at least one microneedle comprising an electrically conductive material such that it can transmit an electrical signal to an overlying electrode.

8. (Withdrawn): The system of claim 7, wherein said microneedle comprises metal, silicon, biocompatible polymers, titanium, silver, or suture material.

9. (Withdrawn): The system of claim 1, wherein said microneedle array comprises at least one microneedle coated with an electrically conductive material such that it can transmit an electrical signal to an overlying electrode.

10. (Withdrawn): The system of claim 1, wherein said microneedle array comprises at least one microneedle comprising a distal tip and a bulb extending from said distal tip to provide for anchoring of said microneedle into a subject's skin.

11. (Withdrawn): The system of claim 1, wherein said microneedle array comprises at least one microneedle having a diameter in the range of about 1 to 100 microns.

12. (Withdrawn): The system of claim 11, wherein a diameter of said microneedle is in the range of about 10 to 30 microns.

13. (Withdrawn): The system of claim 1, wherein said microneedle array comprises at least one microneedle having a length in the range of about 1 to 100 microns.

14. (Withdrawn): The system of claim 13, wherein a length of said microneedle is in the range of about 100 to 150 microns.

15. (Withdrawn): The system of claim 1, further comprising an electrode needle coupled to said controller and having an end insertable into a subject's body in proximity to a stimulation site, wherein said needle is inductively coupled to said at least one conductive coil.

16. (Withdrawn): The system of claim 15, wherein said at least one conductive coil is positioned distal to said stimulation site such that upon activation of said controller a current traverses the stimulation site by passing from said at least one conductive coil to said percutaneous electrode needle.

17. (Withdrawn): The system of claim 16, further comprising at least one conductive microneedle patch positioned distal to said stimulation site and coupled to the controller such that upon activation of said controller a current traverses the stimulation site by passing from said at least one conductive microneedle patch and said at least one conductive coil to said electrode needle.

18. (Withdrawn): An energy emitting system for providing a medical therapy comprising:

at least one conductive coil disposed within or along a housing, where the at least one coil is configured to generate a magnetic field focused on a target nerve in proximity to the at least one coil;

at least one sensor configured to detect electrical conduction in the target nerve or muscle stimulation, wherein the sensor is comprised of at least one microneedle comprising an electrically conductive material such that it can transmit an electrical signal to an overlying electrode and a distal tip having a bulb extending from said distal tip to provide for anchoring of said microneedle into a subject's skin; and

a controller coupled to said at least one conductive coil and in communication with said at least one sensor.

19. (Currently Amended): An energy emitting system for providing a medical therapy comprising:

at least one microneedle patch comprised of a microneedle array deposited on a surface of at least one electrode, where said at least one microneedle patch is configured to generate an electrical stimulus focused on a ~~target~~ posterior tibial nerve or a branch thereof in proximity to the at least one conductive microneedle patch;

at least one sensor configured to detect ~~the~~ electrical conduction ~~in~~ through the ~~target nerve~~ posterior tibial nerve or a branch thereof by detecting a signal that an afferent nerve has been stimulated ~~or muscle stimulation~~ to provide feedback regarding the therapy, wherein the sensor is attachable to a skin surface in proximity to a ~~target~~ nerve or muscle, wherein the sensor is adapted for placement on a foot of a patient and

a controller coupled to said at least one microneedle patch, wherein the controller delivers an electrical stimulus through the microneedle patch and wherein the controller is adjustable to modulate the therapy based on the feedback provided by the sensor.

20. (Canceled):
21. (Currently amended): The system of claim 19, wherein the electrical ~~or~~ magnetic stimulus generated by said at least one microneedle patch is varied according to the electrical conduction or muscle stimulation detected by said at least one sensor to ensure adequate therapeutic stimulation.
22. (Original): The system of claim 19, wherein the microneedle array is etched from a surface of the electrode.
23. (Original): The system of claim 19, wherein said microneedle patch comprises at least one microneedle comprising an electrically conductive material such that it can transmit an electrical signal to an overlying electrode.
24. (Original): The system of claim 23, wherein said microneedle comprises metal, silicon, biocompatible polymers, titanium, silver, or suture material.
25. (Original): The system of claim 19, wherein said sensor is comprised of at least one microneedle array.
26. (Original): The system of claim 19, wherein said microneedle array comprises at least one microneedle comprising a distal tip and a bulb extending from said distal tip to provide for anchoring of said microneedle into a subject's skin.
27. (Original): The system of claim 19, wherein said microneedle array comprises at least one microneedle having a diameter in the range of about 1 to 100 microns.
28. (Original): The system of claim 27, wherein a diameter of said microneedle is in the range of about 10 to 30 microns.
29. (Original): The system of claim 19, wherein said microneedle array comprises at least one microneedle having a length in the range of about 1 to 150 microns.
30. (Original): The system of claim 29, wherein a length of said microneedle is in the range of about 100 to 150 microns.
31. (Original): The system of claim 19, further comprising an electrode needle coupled to said controller and having an end insertable into a subject's body in proximity to a

stimulation site, wherein said needle is inductively coupled to said at least one conductive microneedle patch.

32. (Currently Amended): The system of claim 31, wherein said at least one microneedle patch is adapted to be positioned distal to said stimulation site such that upon activation of said controller a current traverses the stimulation site by passing from said at least one microneedle patch to said electrode needle.

33. (Original): The system of claim 32, further comprising at least one conductive coil positioned distal to said stimulation site and coupled to said controller such that upon activation of said controller a current traverses the stimulation site by passing from said at least one microneedle patch and said at least one conductive coil to said electrode needle.

34. (Currently Amended): An energy emitting system for providing a medical therapy comprising:

at least one conductive microneedle patch comprised of a microneedle array deposited on a surface of at least one electrode, wherein said microneedle array comprises an electrically conductive material such that it can transmit an electrical signal to an overlying electrode ~~and a~~ wherein a distal tip of at least one microneedle of the microneedle array has having a bulb extending from said distal tip to provide for anchoring of said microneedle into a subject's skin, said microneedle patch configured to deliver an electrical ~~or magnetic~~ stimulus to ~~a target nerve~~ a posterior tibial nerve or a branch thereof in proximity to the at least one conductive microneedle patch;

at least one sensor configured to detect electrical conduction ~~[[in]]~~ through the ~~target nerve~~ posterior tibial nerve or a branch thereof by detecting a signal that an afferent nerve has been stimulated ~~or muscle stimulation~~ and wherein the sensor is attachable to a skin surface in proximity to a ~~target~~ nerve or muscle, wherein the sensor is adapted for placement on a foot of a patient; and

a controller coupled to said at least one conductive microneedle patch and in communication with said at least one sensor, wherein the controller delivers an electrical stimulus through the microneedle patch and wherein the controller is adjustable to modulate the therapy based on feedback provided by the sensor.

35. (Withdrawn): An energy emitting system for providing a medical therapy comprising:

at least one conductive coil disposed within or along a housing, where the at least one coil is configured to generate a magnetic field focused on a target nerve in proximity to the at least one coil;

an electrode needle having an end insertable into a subject's body in proximity to a stimulation site, wherein said needle is inductively coupled to said at least one conductive coil; and

a controller coupled to said at least one conductive coil and said electrode needle.

36. (Withdrawn): The system of claim 35, wherein said at least one conductive coil is positioned distal to said stimulation site such that upon activation of said controller a current traverses the stimulation site by passing from said at least one conductive coil to said electrode needle.

37. (Withdrawn): The system of claim 35, further comprising at least one sensor in communication with said controller and configured to detect electrical conduction in the target nerve or muscle stimulation and attachable to a skin surface in proximity to a target nerve or muscle, wherein the magnetic field generated by said at least one conductive coil is varied based on the muscle stimulation or electrical conduction detected by said at least one sensor to ensure adequate therapeutic stimulation.

38. (Withdrawn): A method of treating a subject with urinary incontinence comprising:

positioning a first portion of a subject's body, the subject exhibiting symptoms associated with urinary incontinence, relative to an energy emitting device such that a tibial nerve within the first portion of the body is in proximity to at least one energy generator disposed within or along the energy emitting device;

passing a current through the at least one energy generator to produce a magnetic field or electrical stimulus focused on the tibial nerve;

stimulating a nerve that innervates the pelvic floor of the subject via stimulation of the tibial nerve with the magnetic field or electrical stimulus; and

reducing symptoms associated with urinary incontinence.

39. (Withdrawn): The method of claim 38, wherein the energy generator comprises a conductive coil for generating a magnetic field.

40. (Withdrawn): The method of claim 39, wherein positioning comprises placing a foot, ankle, or leg relative to at least one conductive coil disposed within or along a housing.

41. (Withdrawn): The method of claim 39, wherein positioning comprises placing a popliteal fossa relative to at least one conductive coil disposed within or along a housing.

42. (Withdrawn): The method of claim 38, wherein the energy generator comprises a microneedle patch for producing a magnetic field or electrical stimulus.

43. (Withdrawn): The method of claim 38, wherein a nerve that innervates the pelvic floor comprises the pudendal nerve or sacral plexus.

44. (Withdrawn): The method of claim 38, wherein symptoms associated with urinary incontinence comprise urinary leakage, loss of bladder control and the inability to control urinary function.

45. (Withdrawn): The method of claim 38, further comprising detecting electrical conduction through the tibial nerve or corresponding muscle stimulation via at least one sensor positioned along a second portion of the body.

46. (Withdrawn): The method of claim 45, wherein the sensor comprises a microneedle array.

47. (Withdrawn): The method of claim 45, wherein the sensor is positioned in proximity to the tibial nerve, over a muscle innervated by the tibial nerve, or over the popliteal fossa.

48. (Withdrawn): The method of claim 45, further comprising adjusting the current via a controller in communication with the energy generator according to a signal received from the sensor indicative of the nerve conduction.

49. (Withdrawn): The method of claim 48, wherein adjusting comprises adjusting amplitude, frequency, direction of a magnetic field, or firing sequence of the energy generator.

50. (Withdrawn): The method of claim 48, wherein adjusting comprises adjusting a position of the at least one coil relative to the first portion of the subject's body to re-focus the magnetic field on the tibial nerve.

51. (Withdrawn): The method of claim 48, wherein adjusting comprises adjusting a position of the microneedle patch relative to the first portion of the subject's body to re-focus the electrical or magnetic stimulus on the tibial nerve.

52. (Withdrawn): The method of claim 48, wherein adjusting comprises varying the current according to a muscular response in the patient.

53. (Withdrawn): The method of claim 39, wherein the conductive coil is operated at about 10 to 20 hertz to generate a magnetic field of about .25 to 1.5 tesla for a duration of about 30 minutes per day.

54. (Withdrawn): A method of treating a subject with urinary incontinence comprising:

- positioning a first portion of a subject's body, the subject exhibiting symptoms associated with urinary incontinence, relative to a housing such that a posterior tibial nerve within the first portion of the body is in proximity to at least one conductive coil disposed within or along the housing;

- passing a current through the at least one conductive coil to produce a magnetic field focused on the posterior tibial nerve;

- detecting electrical conduction of the posterior tibial nerve via at least one microneedle array positioned along a second portion of the body;

- receiving a signal from the microneedle array indicative of the electrical conduction;

- adjusting the current via a controller in communication with the conductive coil according to the signal received from the microneedle array; and

- reducing symptoms associated with urinary incontinence.

REMARKS

Claims 1-19 and 21-54 were pending in the present application. Claims 1-18 and 35-54 were withdrawn from consideration. By virtue of this response, claims 19, 21, 32 and 34 have been amended. Accordingly, claims 19-34 are currently under consideration. Amendment and cancellation of certain claims is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented. Support for the amendments can be found in the claims and specification as originally filed, see, e.g., [0036], [0109], [0154], [0167]-[0168] of 2010/0168501. No new matter has been added.

Claim Objections

Claims 32 and 34 are objected to because of informalities.

In response, Applicants have amended claims 32 and 34. Thus, Applicants respectfully request reconsideration and withdrawal of the above objections.

Rejections under 35 USC § 112

Claim 21 is rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention.

In response, Applicants have amended claim 21 to address the rejection.

Thus, Applicants respectfully request reconsideration and withdrawal of the above rejections.

Rejections under 35 USC § 103

Claims 19, 21-25, and 27-30 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Leung (US 2006/0030845) in view of Byers (US 4837049).

Claims 26 and 34 are rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Leung in view of Byers as applied to claim 19 above, and further in view of Surgenor (US 2006/0049957 A1).

In response, Applicants respectfully disagree. Applicants submit that Leung fails to teach or suggest all of the elements of the claims as amended.

Claim 19 has been amended to recite: An energy emitting system for providing a medical therapy comprising: at least one microneedle patch comprised of a microneedle array deposited on a surface of at least one electrode, where said at least one microneedle patch is configured to generate an electrical stimulus focused on a posterior tibial nerve or a branch thereof in proximity to the at least one conductive microneedle patch; at least one sensor configured to detect electrical conduction through the posterior tibial nerve or a branch thereof by detecting a signal that an afferent nerve has been stimulated to provide feedback regarding the therapy, wherein the sensor is attachable to a skin surface in proximity to a nerve or muscle, wherein the sensor is adapted for placement on a foot of a patient and a controller coupled to said at least one microneedle patch, wherein the controller delivers an electrical stimulus through the microneedle patch and wherein the controller is adjustable to modulate the therapy based on the feedback provided by the sensor.

(Claim 34 has been similarly amended.)

In contrast, Leung is directed to a system for performing and monitoring electrosurgical treatment, and is concerned with performing monitoring during electrosurgical treatment. Leung does not teach or suggest at least, an energy emitting system for providing a medical therapy comprising at least one microneedle patch where said at least one microneedle patch is “configured to generate an electrical stimulus focused on a posterior tibial nerve or a branch thereof in proximity to the at least one conductive microneedle patch; at least one sensor configured to detect electrical conduction through the posterior tibial nerve or a branch thereof by detecting a signal that an afferent nerve has been stimulated to provide feedback regarding the therapy, wherein the sensor is attachable to a skin surface in proximity to a nerve or muscle, wherein the sensor is adapted for placement on a foot of a patient and a controller coupled to said at least one microneedle patch, wherein the controller delivers an electrical stimulus through the microneedle patch and wherein the controller is adjustable to modulate the therapy based on the feedback provided by the sensor.” Applicants further submit that Byers and Surgenor fail to cure the deficiencies of Leung.

Thus, Applicants believe that because the cited art fails to teach or suggest all of the elements of the claims as amended, the claims are not rendered obvious by the cited art. Accordingly, Applicants submit that all of the independent claims and the claims dependent therefrom, are now in condition for allowance. Therefore, Applicant respectfully requests reconsideration and withdrawal of the above rejections under 35 U.S.C. §103.

Claims 31 and 32 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Leung in view of Byers as applied to claim 19 above, and further in view of Malaney (US 2002/0183804 A1).

Claim 33 is rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Leung in view of Byers in view of Malaney as applied to claim 32 above, and further in view of Fairbanks (US 4233965).

In response, Applicants submit that Leung in view of Byers as discussed supra, do not teach or suggest all of the elements of the independent claims as amended. Applicants further submit that Malaney and Fairbanks fail to cure the defects of Leung and Byers. Claims 31-33 depend from independent claim 19 and are therefore patentable for at least the reasons discussed above. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. §103.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections and pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the appropriate fee and/or petition is not filed herewith and the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with this filing to **Deposit Account No. 50-3973** referencing Attorney Docket No. **EMKNNZ00301**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

/Steven M. Giovannetti/

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I hereby certify that this correspondence is being electronically transmitted to the USPTO on the date shown below.

Date: January 27, 2014

Signature: /Kym Y. Moore/ (Kym Y. Moore)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.: 12/508,529
Confirmation No.: 8186
Filing Date: July 23, 2009
Inventor(s): Daniel R. BURNETT
Title: METHOD AND APPARATUS FOR MAGNETIC INDUCTION
THERAPY
Examiner: Catherine E. Burk
Group Art Unit: 3735

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir or Madam:

Pursuant to 37 C.F.R. §1.97 and §1.98, Applicants submit for consideration in the above-captioned application the documents listed on the attached Form PTO/SB/08a/b. The Examiner is requested to make these documents of record.

This Information Disclosure Statement is submitted after receipt of a first Office Action on the merits but before mailing of a final Office Action or Notice of Allowance. The required fee is being concurrently submitted via EFS-Web.

Applicants would appreciate the Examiner initialing and returning the Form PTO/SB/08a/b, indicating that the information has been considered and made of record herein.

The information contained in this Information Disclosure Statement under 37 C.F.R. §1.97 and §1.98 is not to be construed as a representation that: (i) a complete search has been made; (ii) additional information material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are

accurate or enabling; or (iv) the above information constitutes prior art to the subject invention.

In the event the appropriate fee and/or petition is not filed herewith and the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with this filing to **Deposit Account No. 50-3973** referencing Attorney Docket No.

EMKNNZ00301. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

/Steven M. Giovannetti/

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Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 12/508,529	Filing Date 07/23/2009	☐ To be Mailed
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ENTITY: ☐ LARGE ☒ SMALL ☐ MICRO**APPLICATION AS FILED – PART I**

(Column 1)

(Column 2)

FOR	NUMBER FILED	NUMBER EXTRA	RATE (\$)	FEE (\$)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X \$ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X \$ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$310 (\$155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	

APPLICATION AS AMENDED – PART II

(Column 1)

(Column 2)

(Column 3)

AMENDMENT	01/27/2014	CLAIMS REMAINING AFTER AMENDMENT	MINUS	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)
	Total (37 CFR 1.16(i))	* 53	Minus	** 54	= 0	X \$40 =	0
	Independent (37 CFR 1.16(h))	* 7	Minus	*** 7	= 0	X \$210 =	0
	☐ Application Size Fee (37 CFR 1.16(s))						
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
TOTAL ADD'L FEE						0	

(Column 1)

(Column 2)

(Column 3)

AMENDMENT	CLAIMS REMAINING AFTER AMENDMENT	MINUS	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)
	Total (37 CFR 1.16(i))	*	Minus	**	=	X \$ =
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X \$ =
	☐ Application Size Fee (37 CFR 1.16(s))					
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))					
TOTAL ADD'L FEE						

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

LIE
/YUVANNA CHAPHIV/

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/508,529	07/23/2009	Daniel Rogers Burnett	EMKNNZ00301	8186

40518 7590 10/25/2013
LEVINE BAGADE HAN LLP
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EXAMINER

BURK, CATHERINE E

ART UNIT	PAPER NUMBER
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3735

MAIL DATE	DELIVERY MODE
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10/25/2013

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 12/508,529	Applicant(s) BURNETT ET AL.	
	Examiner CATHERINE E. BURK	Art Unit 3735	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7/26/2013.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 1-19 and 21-54 is/are pending in the application.
5a) Of the above claim(s) 1-18 and 35-54 is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 19 and 21-34 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

- a) ☐ All b) ☐ Some c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) ☒ Notice of References Cited (PTO-892) | 3) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 4) ☐ Other: ____. |

DETAILED ACTION

1. The present application is being examined under the pre-AIA first to invent provisions.
2. This action is responsive to the amendment filed on July 26th, 2013. The examiner acknowledges the amendments to claims 19 and 21 and the cancellation of claim 20. Claims 1-19 and 21-54 are pending, claims 1-18 and 35-54 were previously withdrawn from consideration.

Claim Objections

3. Claim 32 is objected to because of the following informalities: the microneedle patch is recited as being positioned distal to the stimulation site. Since the stimulation site is a region of the body, this claim should be amended to recite the patch is adapted to be positioned distal to the stimulation site in order to avoid a 35 U.S.C. 101 rejection for claiming a part of the body. Appropriate correction is required.
4. Claim 34 is objected to because of the following informalities: lines 4-6 recite "said microneedle array comprises...a distal tip having a bulb extending from said distal tip..." This language implies the array as a single unit has a bulbous distal tip rather than a microneedle of the array having a bulbous distal tip. Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of 35 U.S.C. 112(b):
(b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 21 is rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention.

7. Claim 21 recites the limitation "the...magnetic stimulus" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

8. The following is a quotation of pre-AIA 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 19, 21-25, and 27-30 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Leung (US 2006/0030845) in view of Byers (US 4837049).

10. Claim 19; Leung discloses an energy emitting system for providing a medical therapy comprising a least one patch or needle electrode 302 configured to generate an electrical stimulus focused on a target nerve in proximity to the electrode [0023 and 31] and at least one sensor 306 attachable to the skin surface in proximity to the target nerve configured to detect electrical conduction in the target nerve to provide feedback regarding the therapy to a controller 104 coupled to the electrode patch [0020-21]. Leung discloses a variety of stimulators including an electrode patch, needle electrodes, and probes but does not specifically describe a microneedle array deposited on the surface of an electrode. Byers discloses an electrode patch that can be used for applying electrical stimulus to nerve tissue (col. 2, lines 58-68) comprising an array of

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microneedles deposited on a surface of at least one electrode (or conducting layer) (col. 10, lines 18-29). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the microneedle array patch electrode disclosed by Byers as the electrode patch in Leung's system because Byers discloses this type of electrode provides good electrical contact with subcutaneous conductive tissue (col. 5, lines 45-51) and Leung discloses several embodiments wherein the electrode structure penetrates the skin.

11. Claim 21; Leung discloses the electrical stimulus provided by the patch 302 is varied according to the electrical conduction detected by the sensor 306 to ensure adequate therapeutic stimulation [0026].

12. Claim 22; the microneedle array disclosed by Byers may be etched from a surface of the electrode (col. 10, lines 6-9, 18-22, and 55-62).

13. Claim 23; each microneedle disclosed by Byers comprises an electrically conductive material (col. 10, lines 32-38) which can transmit an electrical signal to an overlying electrode (electrical conductor material col. 10, lines 18-22).

14. Claim 24; Byers discloses the needles comprise metal (col. 10, lines 32-35).

15. Claim 25; Leung discloses the sensor 306 may have the same structure as the patch stimulator 302 [0023]. According to the combination of Leung in view of Byers, this may be a microneedle array.

16. Claims 27-30; Byers discloses needle diameters of 5-10 microns and a length of 100 microns (col. 7, lines 37-42).

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17. Claims 26 and 34 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Leung in view of Byers as applied to claim 19 above, and further in view of Surgenor (US 2006/0049957 A1).

18. Claim 26; Leung in view of Byers are silent as to bulbous tips on the microarray needles. However, Surgenor discloses microneedles of an electrode array can be provided with anchoring means such as bulbous tips [0062]. It would have been obvious to one of ordinary skill in the art at the time of the invention to include a bulbous tip on at least some of the microneedles in the system disclosed by Leung in view of Byers because Surgenor discloses they help anchor the electrode substrate to tissue [0062].

19. Claim 34; Leung discloses an energy emitting system for providing a medical therapy comprising a least one patch or needle electrode 302 configured to generate an electrical stimulus focused on a target nerve in proximity to the electrode [0023 and 31] and at least one sensor 306 attachable to the skin surface in proximity to the target nerve configured to detect electrical conduction in the target nerve to provide feedback regarding the therapy [0020-21]. The system further comprises a controller 104 coupled to the electrode patch and in communication with the sensor. Leung discloses a variety of stimulators including an electrode patch, needle electrodes, and probes but does not specifically describe a microneedle array deposited on the surface of an electrode. However, Byers discloses an electrode patch that can be used for applying electrical stimulus to nerve tissue (col. 2, lines 58-68) comprising an array of microneedles deposited on a surface of at least one electrode (or conducting layer) (col. 10, lines 18-29). Each microneedle comprises an electrically conductive material (col. 10, lines 32-38) which can transmit an electrical signal to an overlying electrode (col. 10, lines 18-22). It would have been obvious to

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one of ordinary skill in the art at the time of the invention to use the microneedle array patch electrode disclosed by Byers as the electrode patch in Leung's system because Byers discloses this type of electrode provides good electrical contact with subcutaneous conductive tissue (col. 5, lines 45-51) and Leung discloses several embodiments wherein the electrode structure penetrates the skin.

20. Claims 31 and 32 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Leung in view of Byers as applied to claim 19 above, and further in view of Malaney (US 2002/0183804 A1).

21. Claims 31 and 32; Leung discloses additional conducting devices 300 and 304 may be included and may have the form of an electrode needle [0023] but does not disclose the needle and patch are inductively coupled. However, Malaney discloses an electrode needle 12 coupled to a controller 10 with an end insertable into the body in proximity to a stimulation site 15. The needle is inductively coupled to a patch electrode and the patch is positioned distal to the stimulation site such that upon activation of the controller, a current traverses the stimulation site by passing from the patch to the electrode needle [0031]. It would have been obvious to one of ordinary skill in the art at the time of the invention to include an electrode needle inductively coupled to the patch electrode in the system taught by Leung in view of Byers, similar to the configuration taught by Malaney, because it allows for more precise targeting of the stimulation current provided by the electrode patch since the electrode needle can be inserted directly adjacent the target nerve.

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22. Claim 33 is rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Leung in view of Byers in view of Malaney as applied to claim 32 above, and further in view of Fairbanks (US 4233965).

23. Leung, Byers, and Malaney are silent as to a conductive coil positioned distal to the stimulation site and coupled to the controller. Fairbanks discloses a modified electrical stimulation device comprising a conductive coil 14 over an electrode patch 12 connected to a controller 32 (fig. 1a). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate a conductive coil over the electrode patch in the system disclosed by Leung in view of Byers and Malaney because Fairbanks discloses the coil helps focus the electric current in to tissue (col. 2, lines 46-47 and col. 3, line 65 - col. 4, line 3). When a conductive coil is present over the electrode patch location in the combination, it will also be located distal to the stimulation site such that upon activation of said controller, a current traverses the stimulation site by passing from the patch and the coil to the electrode needle (Malaney [0031]).

Response to Arguments

24. Applicant's arguments with respect to claims 19 and 21-34 have been considered but are moot because the arguments do not apply to any of the references being used in the current rejection.

25. The examiner notes that Malaney is used to teach the addition of a probe electrode to a patch stimulating system, therefore the arguments provided by applicant pertaining to the Malaney in view of Byers combination are moot since the examiner is no longer asserting it would have been obvious to modify the Malaney patch electrode in view of the Byers electrode.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CATHERINE E. BURK whose telephone number is (571)270-7130. The examiner can normally be reached on Monday-Friday 8:30 am - 5:00 pm Pacific Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CATHERINE E BURK/
Examiner, Art Unit 3735

Notice of References Cited	Application/Control No. 12/508,529	Applicant(s)/Patent Under Reexamination BURNETT ET AL.	
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U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-2006/0030845 A1	02-2006	Leung et al.	606/041
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Search Notes 	Application/Control No. 12508529	Applicant(s)/Patent Under Reexamination BURNETT ET AL.
	Examiner CATHERINE E BURK	Art Unit 3735

CPC- SEARCHED		
Symbol	Date	Examiner

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
600	9-15	1/24/2013	CEB
607	2-76, 115-156	10/24/2013	CEB
601	15-22	10/24/2013	CEB
606	32-52	10/24/2013	CEB

SEARCH NOTES		
Search Notes	Date	Examiner
EAST Text	1/24/2013	CEB
IDS	1/24/2013	CEB
Inventor Names	1/24/2013	CEB
Class/Subclass	1/24/2013	CEB
Forward/Backward	1/24/2013	CEB
Updated EAST Search	10/24/2013	CEB

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner

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✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant		☐ CPA		☐ T.D.		☐ R.1.47			
CLAIM		DATE							
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	3	÷	N	N					
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	34	÷	✓	✓					
	35	÷	N	N					
	36	÷	N	N					

<i>Index of Claims</i> 	Application/Control No. 12508529	Applicant(s)/Patent Under Reexamination BURNETT ET AL.
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✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47										
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EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
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L2	11281	(607/115-156).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/10/24 14:56
L3	591	(607/152).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/10/24 14:57
L4	1555	(601/15-22).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/10/24 14:59
L5	12197	(606/32-52).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/10/24 15:01
L6	2075	(600/9-15).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/10/24 15:01
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L8	52128	stimulat\$5 with (nerve neuron\$ neural)	US-PGPUB; USPAT; USOCR	OR	ON	2013/10/24 15:03
L9	57414	stimulat\$5 with (nerve neuron\$ neural nervous)	US-PGPUB; USPAT; USOCR	OR	ON	2013/10/24 15:03
L10	48223	1 2 4 5 6	US-PGPUB; USPAT; USOCR	OR	ON	2013/10/24 15:03
L11	14456	9 and 10	US-PGPUB; USPAT; USOCR	OR	ON	2013/10/24 15:03
L12	79196	(sense sensor sensed sensing detect\$5 minitor\$5) with (((nerve or neuron\$ or neural or nervous) near5 (conduction or conductiv\$)) or (muscle near 5 (stimulat\$ or contract\$5)))	US-PGPUB; USPAT; USOCR	OR	ON	2013/10/24 15:05

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L16	138	13 and 14	US-PGPUB; USPAT; USOCR	OR	ON	2013/10/24 15:42
L17	122	16 and (sensor monitor detector)	US-PGPUB; USPAT; USOCR	OR	ON	2013/10/24 15:45
L18	5	((11/105527) or (11/125247) or (11/079318)).APP.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/10/24 17:27
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S3	1	("7798954").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/06/20 13:51
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S5	1	(11/866329).APP.	US-PGPUB; USPAT; USOCR	OR	OFF	2013/01/24 07:32
S6	102	(daniel near2 burnett).in.	US-PGPUB; USPAT; USOCR	OR	ON	2013/01/24 07:36
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S16	1939	(600/9-15).CCLS.	US- PGPUB; USPAT; USOCR	OR	OFF	2013/01/24 10:08

S17	43980	electric\$5 near5 stimulat\$	US-PGPUB; USPAT; USOCR	OR	ON	2013/01/24 10:09
S18	453	S16 and S17	US-PGPUB; USPAT; USOCR	OR	ON	2013/01/24 10:09
S19	45775	(\$cutaneous\$ or skin) near5 (patch or electrode)	US-PGPUB; USPAT; USOCR	OR	ON	2013/01/24 10:11
S20	8434	S17 and S19	US-PGPUB; USPAT; USOCR	OR	ON	2013/01/24 10:13
S21	6044	S20 and (nerve or neuron or neural)	US-PGPUB; USPAT; USOCR	OR	ON	2013/01/24 10:14
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S23	12212	(electric\$5 near5 stimulat\$) with (nerve neuron neural neuro)	US-PGPUB; USPAT; USOCR	OR	ON	2013/01/24 10:45
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S27	20089	(patch or electrode) with (needle or microneedle or nanoneedle)	US-PGPUB; USPAT; USOCR	OR	ON	2013/01/24 10:46
S28	999	S24 and S27	US-PGPUB; USPAT; USOCR	OR	ON	2013/01/24 10:46
S29	113941	(sense sensor sensed sensing detect detecting detector detected) near5 (conduction conductiv\$ stimulat\$)	US-PGPUB; USPAT; USOCR	OR	ON	2013/01/24 10:48
S31	487	S28 and S29	US-PGPUB; USPAT; USOCR	OR	ON	2013/01/24 10:49
S32	167	("3755704" "4016886" "4350164" "4513308" "4551149" "B453031").PN. OR ("4837049").URPN.	US-PGPUB; USPAT;	OR	ON	2013/01/24 10:53

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S35	542	S25 and S34	US-PGPUB; USPAT; USOCR	OR	ON	2013/01/24 12:51
S36	76	S35 and S23	US-PGPUB; USPAT; USOCR	OR	ON	2013/01/24 12:51
S37	36728	plurality with (needle or microneedle or nanoneedle or spike)	US-PGPUB; USPAT; USOCR	OR	ON	2013/01/24 13:03
S38	12318	plurality near (needle or microneedle or nanoneedle or spike)	US-PGPUB; USPAT; USOCR	OR	ON	2013/01/24 13:04
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S44	22933	tip near5 (bulb or bulbous or sphere or spheric\$ or ball)	US-PGPUB; USPAT; USOCR	OR	ON	2013/01/24 15:45
S45	542	S43 and S44	US-PGPUB; USPAT; USOCR	OR	ON	2013/01/24 15:45
S46	748	(needle or microneedle or nanoneedle or barb or spike) with tip near5 (bulb or bulbous or sphere or spheric\$ or ball)	US-PGPUB; USPAT; USOCR	OR	ON	2013/01/24 15:46
S47	37933	S43 and S46	US-	OR	ON	2013/01/24

			PGPUB; USPAT; USOCR			15:46
S48	131	S43 and S46	US- PGPUB; USPAT; USOCR	OR	ON	2013/01/24 15:46
S49	19	("3490439" "3896790" "4353372" "4926879" "4969468" "5143079" "5184620" "5215088" "5361760" "5452718" "5482038" "5509822" "5810742" "5928159" "5928458" "6055448" "6128521" "6745062").PN. OR ("7103398").URPN.	US- PGPUB; USPAT; USOCR	OR	ON	2013/01/24 15:51
S50	173	("5215088").URPN.	USPAT	OR	ON	2013/01/24 15:53
S51	20587	(electrode) with (needle or microneedle or nanoneedle or spike)	US- PGPUB; USPAT; USOCR	OR	ON	2013/01/24 16:00
S52	19683	(needle or microneedle or nanoneedle or barb or spike) near10 (bulb or bulbous or sphere or spheric\$ or ball)	US- PGPUB; USPAT; USOCR	OR	ON	2013/01/24 16:01
S53	14504	(needle or microneedle or nanoneedle or barb or spike) near5 (bulb or bulbous or sphere or spheric\$ or ball)	US- PGPUB; USPAT; USOCR	OR	ON	2013/01/24 16:01
S54	582	S51 and S53	US- PGPUB; USPAT; USOCR	OR	ON	2013/01/24 16:01
S55	476	S54 not S48	US- PGPUB; USPAT; USOCR	OR	ON	2013/01/24 16:01
S56	152	S55 and (skin or \$cutaneous)	US- PGPUB; USPAT; USOCR	OR	ON	2013/01/24 16:02

CUSTOMIZED PTO/SB/08a/b (07-05)

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	12/508,529
				Filing Date	July 23, 2009
				First Named Inventor	Daniel R. BURNETT
				Art Unit	3735
				Examiner Name	Catherine E. Burk
Sheet	1	of	1	Attorney Docket Number	EMKNNZ00301

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	1.	6,622,035	09-16-2003	Merilainen et al.	
	2.	6,782,283	08-24-2004	Schmidt et al.	
	3.	7,522,061	04-21-2009	Rondoni et al.	
	4.	7,536,226	05-19-2009	Williams et al.	
	5.	7,941,201	05-10-2011	Chiou et al.	
	6.	8,430,805	04-30-2013	Burnett et al.	
	7.	2002/0028991	03-07-2002	Thompson	
	8.	2003/0217754	11-27-2003	Thomas et al.	
	9.	2004/0054393	03-18-2004	Stemme et al.	
	10.	2004/0082875	04-29-2004	Donoghue et al.	
	11.	2006/0047316	03-02-2006	Fischell et al.	
	12.	2006/0173261	08-03-2006	Kall et al.	
	13.	2008/0288035	11-20-2008	Gill et al.	
	14.	2013/0072746	03-21-2013	Burnett et al.	

*EXAMINER: Initial if information considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04.

Examiner Signature	/Catherine Burk/	Date Considered	10/24/2013
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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /C.B./

I hereby certify that this correspondence is being electronically transmitted to the USPTO on the date shown below.

Date: July 26, 2013

Signature: /Kym Y. Moore/ (Kym Y. Moore)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.: 12/508,529

Confirmation No.: 8186

Filing Date: July 23, 2009

Inventor(s): Daniel R. BURNETT et al.

Title: METHOD AND APPARATUS FOR MAGNETIC INDUCTION
THERAPY

Examiner: Catherine E. Burk

Group Art Unit: 3735

RESPONSE TO NON-FINAL OFFICE ACTION

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is in response to the non-final Office Action dated January 31, 2013 for which a response was due on April 31, 2013. Filed herewith is a Petition and fee for a 3-month extension of time, thereby extending the deadline for response to July 30, 2013.

Accordingly, this response is timely filed. Reconsideration and allowance of the pending claims, as amended, in light of the Remarks presented herein are respectfully requested.

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks begin on page 10 of this paper.

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

In the claims

1. (Withdrawn): An energy emitting system for providing a medical therapy comprising:

at least one conductive coil disposed within or along a housing, where the at least one coil is configured to generate a magnetic field focused on a target nerve in proximity to the at least one coil;

at least one sensor configured to detect electrical conduction in the target nerve or muscle stimulation, wherein the sensor is comprised of a microneedle array attachable to a skin surface in proximity to a target nerve or muscle; and

a controller coupled to said at least one conductive coil and in communication with said at least one sensor.

2. (Withdrawn): The system of claim 1, wherein the magnetic field generated by said at least one conductive coil is varied based on the electrical conduction or muscle stimulation detected by said at least one sensor to ensure adequate therapeutic stimulation.

3. (Withdrawn): The system of claim 1, wherein the microneedle array is arrayed over a housing.

4. (Withdrawn): The system of claim 3, wherein the housing is comprised of a patch having at least one electrode and said microneedle array extends from a first surface of the electrode.

5. (Withdrawn): The system of claim 4, wherein the patch comprises a positive, negative and control electrode, each electrode comprising a microneedle array extending therefrom.

6. (Withdrawn): The system of claim 4, wherein the microneedle array is etched from a surface of the electrode.

7. (Withdrawn): The system of claim 1, wherein said microneedle array comprises at least one microneedle comprising an electrically conductive material such that it can transmit an electrical signal to an overlying electrode.

8. (Withdrawn): The system of claim 7, wherein said microneedle comprises metal, silicon, biocompatible polymers, titanium, silver, or suture material.

9. (Withdrawn): The system of claim 1, wherein said microneedle array comprises at least one microneedle coated with an electrically conductive material such that it can transmit an electrical signal to an overlying electrode.

10. (Withdrawn): The system of claim 1, wherein said microneedle array comprises at least one microneedle comprising a distal tip and a bulb extending from said distal tip to provide for anchoring of said microneedle into a subject's skin.

11. (Withdrawn): The system of claim 1, wherein said microneedle array comprises at least one microneedle having a diameter in the range of about 1 to 100 microns.

12. (Withdrawn): The system of claim 11, wherein a diameter of said microneedle is in the range of about 10 to 30 microns.

13. (Withdrawn): The system of claim 1, wherein said microneedle array comprises at least one microneedle having a length in the range of about 1 to 100 microns.

14. (Withdrawn): The system of claim 13, wherein a length of said microneedle is in the range of about 100 to 150 microns.

15. (Withdrawn): The system of claim 1, further comprising an electrode needle coupled to said controller and having an end insertable into a subject's body in proximity to a stimulation site, wherein said needle is inductively coupled to said at least one conductive coil.

16. (Withdrawn): The system of claim 15, wherein said at least one conductive coil is positioned distal to said stimulation site such that upon activation of said controller a current traverses the stimulation site by passing from said at least one conductive coil to said percutaneous electrode needle.

17. (Withdrawn): The system of claim 16, further comprising at least one conductive microneedle patch positioned distal to said stimulation site and coupled to the controller such that upon activation of said controller a current traverses the stimulation site by passing from said at least one conductive microneedle patch and said at least one conductive coil to said electrode needle.

18. (Withdrawn): An energy emitting system for providing a medical therapy comprising:

at least one conductive coil disposed within or along a housing, where the at least one coil is configured to generate a magnetic field focused on a target nerve in proximity to the at least one coil;

at least one sensor configured to detect electrical conduction in the target nerve or muscle stimulation, wherein the sensor is comprised of at least one microneedle comprising an electrically conductive material such that it can transmit an electrical signal to an overlying electrode and a distal tip having a bulb extending from said distal tip to provide for anchoring of said microneedle into a subject's skin; and

a controller coupled to said at least one conductive coil and in communication with said at least one sensor.

19. (Currently Amended): An energy emitting system for providing a medical therapy comprising:

at least one microneedle patch comprised of a microneedle array deposited on a surface of at least one electrode, where said at least one microneedle patch is configured to generate an electrical ~~or magnetic~~ stimulus focused on a target nerve in proximity to the at least one conductive microneedle patch;

at least one sensor configured to detect the electrical conduction in the target nerve or muscle stimulation to provide feedback regarding the therapy, wherein the sensor is attachable to a skin surface in proximity to a target nerve or muscle, and

a controller coupled to said at least one microneedle patch.

20. (Canceled):

21. (Currently Amended): The system of claim 19 ~~20~~, wherein the electrical or magnetic stimulus generated by said at least one microneedle patch is varied according to the

electrical conduction or muscle stimulation detected by said at least one sensor to ensure adequate therapeutic stimulation.

22. (Original): The system of claim 19, wherein the microneedle array is etched from a surface of the electrode.

23. (Original): The system of claim 19, wherein said microneedle patch comprises at least one microneedle comprising an electrically conductive material such that it can transmit an electrical signal to an overlying electrode.

24. (Original): The system of claim 23, wherein said microneedle comprises metal, silicon, biocompatible polymers, titanium, silver, or suture material.

25. (Original): The system of claim 19, wherein said sensor is comprised of at least one microneedle array.

26. (Original): The system of claim 19, wherein said microneedle array comprises at least one microneedle comprising a distal tip and a bulb extending from said distal tip to provide for anchoring of said microneedle into a subject's skin.

27. (Original): The system of claim 19, wherein said microneedle array comprises at least one microneedle having a diameter in the range of about 1 to 100 microns.

28. (Original): The system of claim 27, wherein a diameter of said microneedle is in the range of about 10 to 30 microns.

29. (Original): The system of claim 19, wherein said microneedle array comprises at least one microneedle having a length in the range of about 1 to 150 microns.

30. (Original): The system of claim 29, wherein a length of said microneedle is in the range of about 100 to 150 microns.

31. (Original): The system of claim 19, further comprising an electrode needle coupled to said controller and having an end insertable into a subject's body in proximity to a stimulation site, wherein said needle is inductively coupled to said at least one conductive microneedle patch.

32. (Original): The system of claim 31, wherein said at least one microneedle patch is positioned distal to said stimulation site such that upon activation of said controller a

current traverses the stimulation site by passing from said at least one microneedle patch to said electrode needle.

33. (Original): The system of claim 32, further comprising at least one conductive coil positioned distal to said stimulation site and coupled to said controller such that upon activation of said controller a current traverses the stimulation site by passing from said at least one microneedle patch and said at least one conductive coil to said electrode needle.

34. (Original): An energy emitting system for providing a medical therapy comprising:

at least one conductive microneedle patch comprised of a microneedle array deposited on a surface of at least one electrode, wherein said microneedle array comprises an electrically conductive material such that it can transmit an electrical signal to an overlying electrode and a distal tip having a bulb extending from said distal tip to provide for anchoring of said microneedle into a subject's skin, said microneedle patch configured to deliver an electrical or magnetic stimulus to a target nerve in proximity to the at least one conductive microneedle patch;

at least one sensor configured to detect electrical conduction in the target nerve or muscle stimulation and attachable to a skin surface in proximity to a target nerve or muscle; and

a controller coupled to said at least one conductive microneedle patch and in communication with said at least one sensor.

35. (Withdrawn): An energy emitting system for providing a medical therapy comprising:

at least one conductive coil disposed within or along a housing, where the at least one coil is configured to generate a magnetic field focused on a target nerve in proximity to the at least one coil;

an electrode needle having an end insertable into a subject's body in proximity to a stimulation site, wherein said needle is inductively coupled to said at least one conductive coil; and

a controller coupled to said at least one conductive coil and said electrode needle.

36. (Withdrawn): The system of claim 35, wherein said at least one conductive coil is positioned distal to said stimulation site such that upon activation of said controller a current traverses the stimulation site by passing from said at least one conductive coil to said electrode needle.

37. (Withdrawn): The system of claim 35, further comprising at least one sensor in communication with said controller and configured to detect electrical conduction in the target nerve or muscle stimulation and attachable to a skin surface in proximity to a target nerve or muscle, wherein the magnetic field generated by said at least one conductive coil is varied based on the muscle stimulation or electrical conduction detected by said at least one sensor to ensure adequate therapeutic stimulation.

38. (Withdrawn): A method of treating a subject with urinary incontinence comprising:

- positioning a first portion of a subject's body, the subject exhibiting symptoms associated with urinary incontinence, relative to an energy emitting device such that a tibial nerve within the first portion of the body is in proximity to at least one energy generator disposed within or along the energy emitting device;

- passing a current through the at least one energy generator to produce a magnetic field or electrical stimulus focused on the tibial nerve;

- stimulating a nerve that innervates the pelvic floor of the subject via stimulation of the tibial nerve with the magnetic field or electrical stimulus; and

- reducing symptoms associated with urinary incontinence.

39. (Withdrawn): The method of claim 38, wherein the energy generator comprises a conductive coil for generating a magnetic field.

40. (Withdrawn): The method of claim 39, wherein positioning comprises placing a foot, ankle, or leg relative to at least one conductive coil disposed within or along a housing.

41. (Withdrawn): The method of claim 39, wherein positioning comprises placing a popliteal fossa relative to at least one conductive coil disposed within or along a housing.

42. (Withdrawn): The method of claim 38, wherein the energy generator comprises a microneedle patch for producing a magnetic field or electrical stimulus.

43. (Withdrawn): The method of claim 38, wherein a nerve that innervates the pelvic floor comprises the pudendal nerve or sacral plexus.

44. (Withdrawn): The method of claim 38, wherein symptoms associated with urinary incontinence comprise urinary leakage, loss of bladder control and the inability to control urinary function.

45. (Withdrawn): The method of claim 38, further comprising detecting electrical conduction through the tibial nerve or corresponding muscle stimulation via at least one sensor positioned along a second portion of the body.

46. (Withdrawn): The method of claim 45, wherein the sensor comprises a microneedle array.

47. (Withdrawn): The method of claim 45, wherein the sensor is positioned in proximity to the tibial nerve, over a muscle innervated by the tibial nerve, or over the popliteal fossa.

48. (Withdrawn): The method of claim 45, further comprising adjusting the current via a controller in communication with the energy generator according to a signal received from the sensor indicative of the nerve conduction.

49. (Withdrawn): The method of claim 48, wherein adjusting comprises adjusting amplitude, frequency, direction of a magnetic field, or firing sequence of the energy generator.

50. (Withdrawn): The method of claim 48, wherein adjusting comprises adjusting a position of the at least one coil relative to the first portion of the subject's body to re-focus the magnetic field on the tibial nerve.

51. (Withdrawn): The method of claim 48, wherein adjusting comprises adjusting a position of the microneedle patch relative to the first portion of the subject's body to re-focus the electrical or magnetic stimulus on the tibial nerve.

52. (Withdrawn): The method of claim 48, wherein adjusting comprises varying the current according to a muscular response in the patient.

53. (Withdrawn): The method of claim 39, wherein the conductive coil is operated at about 10 to 20 hertz to generate a magnetic field of about .25 to 1.5 tesla for a duration of about 30 minutes per day.

54. (Withdrawn): A method of treating a subject with urinary incontinence comprising:

positioning a first portion of a subject's body, the subject exhibiting symptoms associated with urinary incontinence, relative to a housing such that a posterior tibial nerve within the first portion of the body is in proximity to at least one conductive coil disposed within or along the housing;

passing a current through the at least one conductive coil to produce a magnetic field focused on the posterior tibial nerve;

detecting electrical conduction of the posterior tibial nerve via at least one microneedle array positioned along a second portion of the body;

receiving a signal from the microneedle array indicative of the electrical conduction;

adjusting the current via a controller in communication with the conductive coil according to the signal received from the microneedle array; and

reducing symptoms associated with urinary incontinence.

REMARKS

Claims 1-54 were pending in the present application. Claims 1-18 and 35-54 were withdrawn from consideration. By virtue of this response, claim 20 has been cancelled and claims 19 and 21 have been amended. Accordingly, claims 19 and 21-34 are currently under consideration. Amendment and cancellation of certain claims is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented. Support for the amendments can be found throughout the specification and claims as originally filed. No new matter has been added.

Rejections under 35 USC § 112

Claim 24 is rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention.

In response, Applicants submit that claim 24 does not recite “said sensor,” and as such, Applicants submit that the above rejection is improper and misplaced. Regardless, claim 19 has been amended to recite a sensor.

Thus, Applicants respectfully request reconsideration and withdrawal of the above rejections.

Rejections under 35 USC § 103

Claims 19, 22-24, and 27-32 are rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Malaney (US Pub. No. 2002/0183804 A1) in view of Byers (US Pat. No. 4,837,049).

Claims 20, 21, and 25 are rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Malaney in view of Byers as applied to claim 19 above, and further in view of Loeb (US Pat. No. 6,735,474 B1).

In response, Applicants respectfully disagree.

Claim 19 has been amended to recite: An energy emitting system for providing a medical therapy comprising: at least one microneedle patch comprised of a microneedle array

deposited on a surface of at least one electrode, where said at least one microneedle patch is configured to generate an electrical stimulus focused on a target nerve in proximity to the at least one conductive microneedle patch; at least one sensor configured to detect the electrical conduction in the target nerve or muscle stimulation to provide feedback regarding the therapy, wherein the sensor is attachable to a skin surface in proximity to a target nerve or muscle, and a controller coupled to said at least one microneedle patch.

First, the Office Action at page 3 states, “It would have been obvious to one of ordinary skill in the art at the time of the invention to use the microneedle array patch electrode disclosed by Byers as the transcutaneous electrode in Malaney’s system because Byers discloses this type of electrode provides better electrical contact with subcutaneous conductive tissue (col. 5, lines 45-51).” Malaney, however, states “the load impedance through the surface of the skin is much higher than the internal impedance. This relatively high load impedance lessens the likelihood of damage to tissue and nerves due to high current pulses. The transcutaneous electrode also creates a capacitive interface which attenuates harmful DC currents.” [0032], see also [0003], [0005]. According to Malaney’s system, “current pulses traverse the internal stimulation site by passing from the transcutaneous electrode 14 to the internal percutaneous electrode needle 12.” [0031]; Fig. 1.

Applicants submit that it would not have been obvious to a person having ordinary skill in the art to substitute the transcutaneous electrode of Malaney’s system with the microneedle array patch electrode of Byers. As stated supra, Malaney’s system is designed to deliver high current pulses, and the use of their transcutaneous electrode (which does not physically penetrate the skin surface, e.g., Fig 4.) is required to take advantage of the high load impedance through the surface of the skin to lessen the likelihood of damage to tissue and nerves due to the high current pulses.

It would not have been obvious to a person having ordinary skill in the art to modify the transcutaneous electrode of Malaney with an electrode array having protuberances or needles for penetrating nerves, organs, muscle or skin according to Byers. The penetrating array of Byers would result in a lowering of the impedance and could potentially cause tissue damage from the high current pulses. This would change the principle of operation of the Malaney system, and such a modification would render the Malaney system unsatisfactory

for its intended purpose. Therefore, there is no suggestion or motivation to make the proposed modification and the cited art does not render the claims obvious.

Additionally, the Office action states at page 4 that Malaney in view of Byers is silent as to a sensor for detecting muscle stimulation and states that while Loeb discloses using an implanted electrical stimulator/sensor to detect muscle contractions “it would have been obvious to one of ordinary skill in the art at the time of the invention to use a skin-mounted microneedle sensor in the combination taught by Malaney in view of Byers in view of Loeb because they are less invasive than implanted sensors.”

Loeb, however, is directed to a method that requires an implantable microstimulator to stimulate a nerve, describing a method for treatment of incontinence which includes implanting a microstimulator beneath the skin adjacent the tibial nerve. (Abstract). Loeb states that in order to help determine the strength of the implanted electrical stimulation required to produce the desired therapeutic effect, the muscle activity produced in response to stimulation may be detected, e.g., via recording of the associated electromyograph (EMG). Col. 9, ll. 23-27. Loeb discloses using an implanted microstimulator sensor (e.g., implanted near the dorsal nerve of the clitoris or introduced into the bladder) for, e.g., sensing changes in bladder or sphincter pressure or sensing muscular activity associated with the sphincter, bladder or colon via electromyograph. Col. 9, ll. 34-42.

As stated supra, it would not have been obvious to modify the system of Malaney with the electrode array of Byers. Furthermore, Loeb requires that the sensor be implanted. Applicants submit that it would not have been obvious to modify an implantable sensor according to Loeb by changing it to an electrode array sensor according to Byers, and it would not have been obvious to incorporate such a sensor in the system of Malaney. Such a modification and combination of systems would change the principal of operation of the systems of Loeb and Malaney, and the basis for the combination would amount to impermissible hindsight reasoning. Therefore, such a modification would not have been obvious to a person of ordinary skill in the art, and the cited art does not render the present claims obvious.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. §103.

Claims 26 is rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Malaney in view of Byers in view of Surgenor.

Claim 33 is rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Malaney in view of Byers in view of Loeb in view of Fairbanks.

Claims 34 is rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Malaney in view of Byers in view of Loeb in view of Surgenor.

In response, Applicants respectfully disagree and Applicants submit that it would not have been obvious to combine the teachings of Malaney in view of Byers and/or in view of Loeb, for at least the reasons discussed above. Applicants further submit that Surgenor and Fairbanks fail to cure the defects of Malaney, Byers and Loeb.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. §103.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections and pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the appropriate fee and/or petition is not filed herewith and the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with this filing to **Deposit Account No. 50-3973** referencing Attorney Docket No. **EMKNNZ00301**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

/Steven M. Giovannetti/

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PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a)		Docket Number (Optional) EMKNNZ00301
Application Number 12/508,529	Filed July 23, 2009	
For METHOD AND APPARATUS FOR MAGNETIC INDUCTION THERAPY		
Art Unit 3735	Examiner Catherine E. Burk	

This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above-identified application.

The requested extension and fee are as follows (check time period desired and enter the appropriate fee below):

	<u>Fee</u>	<u>Small Entity Fee</u>	<u>Micro Entity Fee</u>	
☐ One month (37 CFR 1.17(a)(1))	\$200	\$100	\$50	\$ _____
☐ Two months (37 CFR 1.17(a)(2))	\$600	\$300	\$150	\$ _____
☒ Three months (37 CFR 1.17(a)(3))	\$1,400	\$700	\$350	\$ 700
☐ Four months (37 CFR 1.17(a)(4))	\$2,200	\$1,100	\$550	\$ _____
☐ Five months (37 CFR 1.17(a)(5))	\$3,000	\$1,500	\$750	\$ _____

☒ Applicant asserts small entity status. See 37 CFR 1.27.

☐ Applicant certifies micro entity status. See 37 CFR 1.29.
Form PTO/SB/15A or B or equivalent must either be enclosed or have been submitted previously.

☐ A check in the amount of the fee is enclosed.

☐ Payment by credit card. Form PTO-2038 is attached.

☐ The Director has already been authorized to charge fees in this application to a Deposit Account.

☒ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to
Deposit Account Number 50-3973

☒ Payment made via EFS-Web.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

I am the

☐ applicant.

☒ attorney or agent of record. Registration number 51,739

☐ attorney or agent acting under 37 CFR 1.34. Registration number _____

/Steven M. Giovannetti/

July 26, 2013

Signature

Date

Steven M. Giovannetti

(650) 646-2570

Typed or printed name

Telephone Number

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. Submit multiple forms if more than one signature is required, see below*.

☒ * Total of 1 forms are submitted.

This collection of information is required by 37 CFR 1.136(a). The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 6 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

I hereby certify that this correspondence is being electronically transmitted to the USPTO on the date shown below.

Date: July 26, 2013

Signature: /Kym Y. Moore/ (Kym Y. Moore)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.: 12/508,529
Confirmation No.: 8186
Filing Date: July 23, 2009
Inventor(s): Daniel R. BURNETT et al.
Title: METHOD AND APPARATUS FOR MAGNETIC INDUCTION
THERAPY
Examiner: Catherine E. Burk
Group Art Unit: 3735

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Pursuant to 37 C.F.R. §1.97 and §1.98, Applicants submit for consideration in the above-captioned application the documents listed on the attached Form PTO/SB/08a/b. The Examiner is requested to make these documents of record.

This Information Disclosure Statement is submitted after receipt of a first Office Action on the merits but before mailing of a final Office Action or Notice of Allowance. The required fee is being concurrently submitted via EFS-Web.

Applicants would appreciate the Examiner initialing and returning the Form PTO/SB/08a/b, indicating that the information has been considered and made of record herein.

The information contained in this Information Disclosure Statement under 37 C.F.R. §1.97 and §1.98 is not to be construed as a representation that: (i) a complete search has been made; (ii) additional information material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are

accurate or enabling; or (iv) the above information constitutes prior art to the subject invention.

In the event the appropriate fee and/or petition is not filed herewith and the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with this filing to **Deposit Account No. 50-3973** referencing Attorney Docket No.

EMKNNZ00301. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

/Steven M. Giovannetti/

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Fax: (650) 284-2180

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	12/508,529
				Filing Date	July 23, 2009
				First Named Inventor	Daniel R. BURNETT
				Art Unit	3735
				Examiner Name	Catherine E. Burk
Sheet	1	of	1	Attorney Docket Number	EMKNNZ00301

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	1.	6,622,035	09-16-2003	Merilainen et al.	
	2.	6,782,283	08-24-2004	Schmidt et al.	
	3.	7,522,061	04-21-2009	Rondoni et al.	
	4.	7,536,226	05-19-2009	Williams et al.	
	5.	7,941,201	05-10-2011	Chiou et al.	
	6.	8,430,805	04-30-2013	Burnett et al.	
	7.	2002/0028991	03-07-2002	Thompson	
	8.	2003/0217754	11-27-2003	Thomas et al.	
	9.	2004/0054393	03-18-2004	Stemme et al.	
	10.	2004/0082875	04-29-2004	Donoghue et al.	
	11.	2006/0047316	03-02-2006	Fischell et al.	
	12.	2006/0173261	08-03-2006	Kall et al.	
	13.	2008/0288035	11-20-2008	Gill et al.	
	14.	2013/0072746	03-21-2013	Burnett et al.	

*EXAMINER: Initial if information considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04.

Examiner Signature		Date Considered	
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Electronic Patent Application Fee Transmittal

Application Number:	12508529			
Filing Date:	23-Jul-2009			
Title of Invention:	METHOD AND APPARATUS FOR MAGNETIC INDUCTION THERAPY			
First Named Inventor/Applicant Name:	Daniel Rogers Burnett			
Filer:	Steven Michael Giovannetti/Kym Moore			
Attorney Docket Number:	EMKNNZ00301			
Filed as Small Entity				
Utility under 35 USC 111(a) Filing Fees				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Extension - 3 months with \$0 paid	2253	1	700	700

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous:				
Submission- Information Disclosure Stmt	2806	1	90	90
Total in USD (\$)				790

Electronic Acknowledgement Receipt

EFS ID:	16424562
Application Number:	12508529
International Application Number:	
Confirmation Number:	8186
Title of Invention:	METHOD AND APPARATUS FOR MAGNETIC INDUCTION THERAPY
First Named Inventor/Applicant Name:	Daniel Rogers Burnett
Customer Number:	40518
Filer:	Steven Michael Giovannetti/Kym Moore
Filer Authorized By:	Steven Michael Giovannetti
Attorney Docket Number:	EMKNNZ00301
Receipt Date:	26-JUL-2013
Filing Date:	23-JUL-2009
Time Stamp:	11:14:04
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	\$790
RAM confirmation Number	9599
Deposit Account	
Authorized User	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
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1		1_EMKNNZ00301_20130726_response_to_non_final.pdf	114523 e731a9c820d18adc65d05a0505b873c9ed0abc0	yes	14
	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Amendment/Req. Reconsideration-After Non-Final Reject		1	1	
	Claims		2	9	
	Applicant Arguments/Remarks Made in an Amendment		10	14	
Warnings:					
Information:					
2	Extension of Time	2_EMKNNZ00301_20130726_extension_of_time.pdf	27608 031f0fa276e11c2f0026a181eb29fc1b1fcee56b	no	1
Warnings:					
Information:					
3	Transmittal Letter	3_EMKNNZ00301_20130726_ids_cover_letter.pdf	74777 5fda4a99cd4e421556b994cdb4e66091744cb6de	no	2
Warnings:					
Information:					
4	Information Disclosure Statement (IDS) Form (SB08)	4_EMKNNZ00301_20130726_ids_sb08.pdf	88371 978f6fea141bf5451572af7e2bd29dbb334c57d4	no	1
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
5	Fee Worksheet (SB06)	fee-info.pdf	32573 af1a99af055a9dc4f9d7291f910e77ceb258820b	no	2
Warnings:					
Information:					
Total Files Size (in bytes):			337852		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 12/508,529	Filing Date 07/23/2009	☐ To be Mailed
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ENTITY: ☐ LARGE ☒ SMALL ☐ MICRO

APPLICATION AS FILED – PART I

(Column 1)

(Column 2)

FOR	NUMBER FILED	NUMBER EXTRA		RATE (\$)	FEE (\$)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A		N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*		X \$ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		X \$ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$310 (\$155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).				
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))					
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL	

APPLICATION AS AMENDED – PART II

(Column 1)

(Column 2)

(Column 3)

	07/26/2013	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE (\$)	ADDITIONAL FEE (\$)
AMENDMENT	Total (37 CFR 1.16(i))	* 54	Minus	** 54	= 0		x \$40 =	0
	Independent (37 CFR 1.16(h))	* 7	Minus	*** 7	= 0		x \$210 =	0
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
	TOTAL ADD'L FEE							0

(Column 1)

(Column 2)

(Column 3)

		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE (\$)	ADDITIONAL FEE (\$)
AMENDMENT	Total (37 CFR 1.16(i))	*	Minus	**	=		X \$ =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=		X \$ =	
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
	TOTAL ADD'L FEE							

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

LIE
/ROLITA WIMBUSH/

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.