

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

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PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing
(day/month/year) **21 APR 2017**

Applicant's or agent's file reference
HLNR-P08-PCT

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/US17/16776

International filing date (day/month/year)

07 February 2017 (07.02.2017)

Priority date (day/month/year)

08 February 2016 (08.02.2016)

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

IPC - A61N 1/36, 1/04, 1/372 (2017.01)

CPC - A61N 1/36021, 1/0456, 1/36014, 1/37264, 1/0456, 1/36014, 1/37264; A61H 23/02, 39/002, 39/04, 39/08

Applicant Halo Neuro, Inc.

1. This opinion contains indications relating to the following items:

- Box No. I Basis of the opinion
- Box No. II Priority
- Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- Box No. IV Lack of unity of invention
- Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement
- Box No. VI Certain documents cited
- Box No. VII Certain defects in the international application
- Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

Name and mailing address of the ISA/US
Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450
Facsimile No. 571-273-8300

Date of completion of this opinion

31 March 2017 (31.03.2017)

Authorized officer

Shane Thomas

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WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US17/16776

Box No. 1 Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:
- the international application in the language in which it was filed.
 - a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).
2. This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a)).
3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing:
- a. forming part of the international application as filed:
 - in the form of an Annex C/ST.25 text file.
 - on paper or in the form of an image file.
 - b. furnished together with the international application under PCT Rule 13*ter*.1(a) for the purposes of international search only in the form of an Annex C/ST.25 text file.
 - c. furnished subsequent to the international filing date for the purposes of international search only:
 - in the form of an Annex C/ST.25 text file (Rule 13*ter*.1(a)).
 - on paper or in the form of an image file (Rule 13*ter*.1(b) and Administrative Instructions, Section 713).
4. In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that forming part of the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US17/16776

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-24	YES
	Claims	NONE	NO
Inventive step (IS)	Claims	1-24	YES
	Claims	NONE	NO
Industrial applicability (IA)	Claims	1-24	YES
	Claims	NONE	NO

2. Citations and explanations:

Claims 1-24 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest the claimed matter.

Claim 1 meets the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest; a method for providing electrical stimulation to a user, with an electrical stimulation device in communication with a controller, the method comprising: upon activation of the electrical stimulation device, transitioning the electrical stimulation device from a baseline state to a first impedance monitoring state; during the first impedance monitoring state, guiding, with the controller, an adjustment of a position of the electrical stimulation device at a head region of the user until a first impedance criterion associated with the first impedance monitoring state is satisfied; upon satisfaction of the first impedance criterion, transitioning the electrical stimulation device from the first impedance monitoring state to a stimulation regime that comprises a second monitoring state having a second criterion, wherein the stimulation regime provides an electrical stimulation session, according to a set of waveform features, to the user; upon detection of failure to satisfy the second criterion, transitioning the electrical stimulation device from the stimulation regime to the first impedance monitoring state at a first time point; and upon detecting that a third impedance criterion of the first impedance monitoring state is satisfied, transitioning the electrical stimulation device from the first impedance monitoring state to the stimulation regime at a second time point.

As per claim 1, US 2015/0360027 A1 to DJO, LLC (hereinafter 'DJO') discloses a method for providing electrical stimulation to a user (a method for electrical stimulation to a user; abstract; paragraph [0008]), with an electrical stimulation device in communication with a controller (a device includes a controller for delivering electrical stimulation therapy; paragraph [0017]), the method comprising: upon activation of the electrical stimulation device, transitioning the electrical stimulation device from a baseline state to a first impedance monitoring state (during the delivery of electrical stimulation therapy, current flows through the first electrode 402 and returns through the second electrode 406 (a baseline state), and the magnitude of the surface impedance is adjusted (a first impedance monitoring state); paragraphs [0118]-[0119]); during the first impedance monitoring state (when sensing impedance with the controller 622; paragraph [0100]), an adjustment of a position of the electrical stimulation device at a head region of the user (electrodes 402 and 406 may be positioned further apart, for applying stimulation to a therapy site with hair, such as the back of the head; figure 25; paragraphs [0119], [0159]) until a first impedance criterion associated with the first impedance monitoring state is satisfied (for effective electrical stimulation, based upon the surface impedance; paragraphs [0118]-[0120]); upon satisfaction of the first impedance criterion (the controller 622 may be programmed to sense impedance and deliver therapy accordingly; paragraph [0100]), a stimulation regime (a signal generator 660 for creating repeated stimulation pulses; paragraph [0137]), wherein the stimulation regime provides an electrical stimulation session, according to a set of waveform features (waveform 802 includes amplitude, width, intrapulse interval, interpulse interval, and shape; figures 26A-B; paragraph [0137]). DJO does not teach or fairly suggest; guiding, with the controller, an adjustment of a position of the electrical stimulation device at a head region of the user until a first impedance criterion associated with the first impedance monitoring state is satisfied; upon satisfaction of the first impedance criterion, transitioning the electrical stimulation device from the first impedance monitoring state to a stimulation regime that comprises a second monitoring state having a second criterion, wherein the stimulation regime provides an electrical stimulation session, according to a set of waveform features, to the user; upon detection of failure to satisfy the second criterion, transitioning the electrical stimulation device from the stimulation regime to the first impedance monitoring state at a first time point; and upon detecting that a third impedance criterion of the first impedance monitoring state is satisfied, transitioning the electrical stimulation device from the first impedance monitoring state to the stimulation regime at a second time point.

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WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US17/16776

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

-Continued from Box V: Citations and Explanations-

WO 2008/048471 A2 to Apnex Medical, Inc. (hereinafter 'Apnex') discloses a method for providing electrical stimulation to a user (methods for nerve stimulation of a patient; paragraphs [0007], [0046]), with an electrical stimulation device in communication with a controller (a nerve stimulator 50 in communication with a patient controller 40; paragraphs [0046], [0051]; figure 1), the method comprising: a first impedance monitoring state (stimulation lead 60 is connected to impedance electrodes 74A- 74D that monitor and/or determine the functionality of lead 60; paragraphs [0071]-[0073]); a head region of the user (the hypoglossal nerve; paragraph [0124]) second monitoring state having a second criterion (a second bio-impedance between second and third electrodes; claim 56); a third impedance criterion (a third bio-impedance between the second and third electrodes; claim 56); a set of waveform features (wave forms include pulse, pulse train, bi-phasic pulse, bi-phasic pulse train, sinusoidal, sinusoidal w/ ramping, square wave, and square w/ ramping; paragraph [0175]). Apnex does not teach or fairly suggest; the method comprising: upon activation of the electrical stimulation device, transitioning the electrical stimulation device from a baseline state to a first impedance monitoring state; during the first impedance monitoring state, guiding, with the controller, an adjustment of a position of the electrical stimulation device at a head region of the user until a first impedance criterion associated with the first impedance monitoring state is satisfied; upon satisfaction of the first impedance criterion, transitioning the electrical stimulation device from the first impedance monitoring state to a stimulation regime that comprises a second monitoring state having a second criterion, wherein the stimulation regime provides an electrical stimulation session, according to a set of waveform features, to the user; upon detection of failure to satisfy the second criterion, transitioning the electrical stimulation device from the stimulation regime to the first impedance monitoring state at a first time point; and upon detecting that a third impedance criterion of the first impedance monitoring state is satisfied, transitioning the electrical stimulation device from the first impedance monitoring state to the stimulation regime at a second time point.

US 2015/0352357 A1 to Medtronic, Inc. (hereinafter 'Medtronic') discloses a method for providing electrical stimulation to a user (delivering external electrical stimulation to a patient; paragraph [0004]), with an electrical stimulation device in communication with a controller (a stimulation generator 42 is controlled by processor 40; figure 1; paragraph [0058]), the method comprising: a baseline state (a baseline impedance; paragraph [0102]), a first impedance monitoring state (an electrical impedance change is observed across the sensing electrodes 114; paragraph [0088]); a second monitoring state having a second criterion (a second level of sensed impedance; paragraph [0102]), a third impedance criterion (a third level of sensed impedance less than the second level; paragraph [0102]). Medtronic does not teach or fairly suggest; the method comprising: upon activation of the electrical stimulation device, transitioning the electrical stimulation device from a baseline state to a first impedance monitoring state; during the first impedance monitoring state, guiding, with the controller, an adjustment of a position of the electrical stimulation device at a head region of the user until a first impedance criterion associated with the first impedance monitoring state is satisfied; upon satisfaction of the first impedance criterion, transitioning the electrical stimulation device from the first impedance monitoring state to a stimulation regime that comprises a second monitoring state having a second criterion, wherein the stimulation regime provides an electrical stimulation session, according to a set of waveform features, to the user; upon detection of failure to satisfy the second criterion, transitioning the electrical stimulation device from the stimulation regime to the first impedance monitoring state at a first time point; and upon detecting that a third impedance criterion of the first impedance monitoring state is satisfied, transitioning the electrical stimulation device from the first impedance monitoring state to the stimulation regime at a second time point.

Thus, it would not have been obvious to one of ordinary skill in the art at the time of the invention to modify DJO, Apnex and Medtronic, such that the during the first impedance monitoring state, guiding, with the controller, an adjustment of a position of the electrical stimulation device at a head region of the user until a first impedance criterion associated with the first impedance monitoring state is satisfied, as described, because the references of record fail to disclose all of the elements of the inventive method.

Claims 2-17 meet the criteria set out in PCT Article 33(2)-(3), because of direct or indirect dependencies upon claim 1.

Claim 18 meets the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest; a system for providing electrical stimulation to a head region of a user, the system comprising: an electrical stimulation device having a head-mountable portion and a set of electrodes reversibly coupled to the head-mountable portion, the electrical stimulation device operable between a baseline state, a first impedance monitoring state, and a stimulation regime having a second monitoring state, wherein: the first impedance monitoring state comprises a first set of impedance criteria and is enterable upon at least one of: a) detection of activation of the electrical stimulation device and b) failure to satisfy an impedance criterion of the second monitoring state, during the stimulation regime; the stimulation regime provides a stimulation session with a waveform definition to the head region of the user upon satisfaction of at least one of the first set of impedance criteria of the first impedance monitoring state; and a controller that transmits the stimulation waveform definition and guides adjustment of the set of electrodes at the head region of the user in cooperation with the first impedance monitoring state.

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WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US17/16776

Supplemental Box

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As per claim 18, DJO discloses a system for providing electrical stimulation to a head region of a user (electrical stimulation to a neck of a user; abstract; figure 5A; paragraph [0008]), the system comprising: an electrical stimulation device (a device for delivering electrical stimulation therapy; paragraph [0017]), the electrical stimulation device operable between a baseline state (during the delivery of electrical stimulation therapy, current flows through the first electrode 402 and returns through the second electrode 406 (a baseline state); paragraphs [0118]-[0119]), a first impedance monitoring state (and the magnitude of the surface impedance is adjusted (a first impedance monitoring state); paragraphs [0118]-[0119]), and a stimulation regime (a signal generator 660 for creating repeated stimulation pulses; paragraph [0137]) having a second monitoring state (upon detection of an open circuit; paragraph [0100]), wherein: the first impedance monitoring state comprises a first set of impedance criteria and is enterable upon at least one of: a) detection of activation of the electrical stimulation device and b) failure to satisfy an impedance criterion of the second monitoring state, during the stimulation regime (a controller 622 controller is programmed to sense impedance and deliver therapy such that if an electrode loses electrical contact with the patient's tissue during therapy, the controller 622 detects the open circuit and modifies the applied electrical stimulation appropriately until the lead makes contact; paragraph [0100]). DJO does not teach or fairly suggest; the electrical stimulation device having a head-mountable portion (DJO teaches that the device is a hand-held device that is held by a user and placed on the neck when being held by the user, as shown in figure 5A, but does not teach that the device is head-mountable) and a set of electrodes reversibly coupled to the head-mountable portion; the stimulation regime provides a stimulation session with a waveform definition to the head region of the user upon satisfaction of at least one of the first set of impedance criteria of the first impedance monitoring state; and a controller that transmits the stimulation waveform definition and guides adjustment of the set of electrodes at the head region of the user in cooperation with the first impedance monitoring state (DJO teaches that the site impedance can be adjusted by a variety of therapeutic parameters, including the distance between the electrodes 402 and 406; paragraph [0118], which in turn is a function of the amount of top surface of skin 84 between the electrodes 402 and 406, and the degree to which the electrodes are depressed into the skin surface by the hand of a user; figures 5A, 9A-B, 21A-B; paragraphs [0100], [0104], and further that the controller 622 adjusts the amount of current, based upon the subsequent surface impedance; paragraph [0100], but DJO does not teach that an adjustment of the set of electrodes at the head region of the user is guided by the controller in cooperation with the first impedance monitoring state).

Apnex discloses a system for providing electrical stimulation to a head region of a user (hypoglossal nerve stimulation of a patient; paragraphs [0007], [0046], [0124]), the system comprising: a first impedance monitoring state (stimulation lead 60 is connected to impedance electrodes 74A-74D that monitor and/or determine the functionality of lead 60; paragraphs [0071]-[0073]), and a stimulation regime (wave forms include a bi-phasic pulse train; paragraph [0175]). Apnex does not teach or fairly suggest; the system comprising: an electrical stimulation device having a head-mountable portion (Apnex teaches that the device is implanted; paragraph [0010]; figure 2), and a set of electrodes reversibly coupled to the head-mountable portion, the electrical stimulation device operable between a baseline state, a first impedance monitoring state, and a stimulation regime having a second monitoring state, wherein: the first impedance monitoring state comprises a first set of impedance criteria and is enterable upon at least one of: a) detection of activation of the electrical stimulation device and b) failure to satisfy an impedance criterion of the second monitoring state, during the stimulation regime; the stimulation regime provides a stimulation session with a waveform definition to the head region of the user upon satisfaction of at least one of the first set of impedance criteria of the first impedance monitoring state; and a controller that transmits the stimulation waveform definition and guides adjustment of the set of electrodes at the head region of the user in cooperation with the first impedance monitoring state.

Medtronic discloses a system for providing electrical stimulation (delivering external electrical stimulation to a patient; paragraph [0004]), a baseline state (a baseline impedance; paragraph [0102]), a first impedance monitoring state (an electrical impedance change is observed across the sensing electrodes 114; paragraph [0088]). Medtronic does not teach or fairly suggest; a system for providing electrical stimulation to a head region of a user, the system comprising: an electrical stimulation device having a head-mountable portion and a set of electrodes reversibly coupled to the head-mountable portion, the electrical stimulation device operable between a baseline state, a first impedance monitoring state, and a stimulation regime having a second monitoring state, wherein: the first impedance monitoring state comprises a first set of impedance criteria and is enterable upon at least one of: a) detection of activation of the electrical stimulation device and b) failure to satisfy an impedance criterion of the second monitoring state, during the stimulation regime; the stimulation regime provides a stimulation session with a waveform definition to the head region of the user upon satisfaction of at least one of the first set of impedance criteria of the first impedance monitoring state; and a controller that transmits the stimulation waveform definition and guides adjustment of the set of electrodes at the head region of the user in cooperation with the first impedance monitoring state.

Thus, it would not have been obvious to one of ordinary skill in the art at the time of the invention to modify DJO, Apnex and Medtronic, such that a controller guides adjustment of the set of electrodes at the head region of the user in cooperation with the first impedance monitoring state, as described, because the references of record fail to disclose all of the elements of the inventive system.

Claims 19-24 meet the criteria set out in PCT Article 33(2)-(3), because of direct or indirect dependencies upon claim 18.

Claims 1-24 have industrial applicability as defined by PCT Article 33(4) because the subject matter can be made or used in industry.