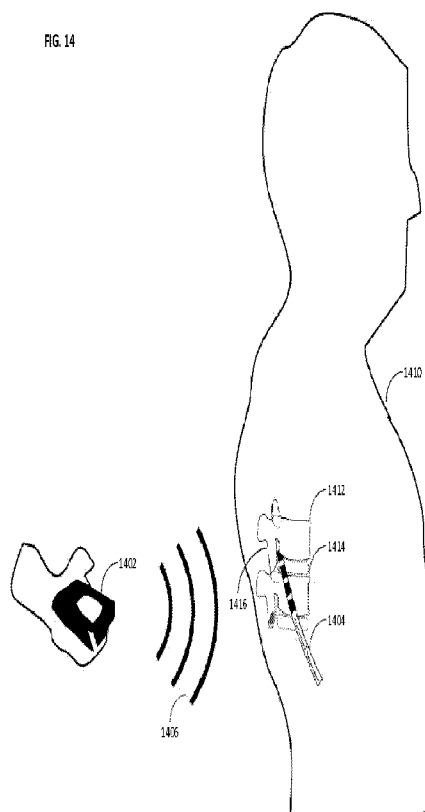




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[Continued on next page]

(54) Title: METHODS AND DEVICES FOR MODULATING EXCITABLE TISSUE OF THE EXITING SPINAL NERVES



(57) Abstract: A method for modulating nerve tissue in a body of a patient includes implanting a wireless stimulation device in proximity to a dorsal root ganglion or an exiting nerve root such that an electrode, circuitry and a receiving antenna are positioned completely within the body of the patient. An input signal containing electrical energy and waveform parameters is transmitted to the receiving antenna(s) from a control device located outside of the patient's body via radiative coupling. The circuitry within the stimulation device generates one or more electrical impulses and applies the electrical impulses to the dorsal root ganglion or the exiting nerve roots through the electrode.



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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US13/41742

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61N 1/00 (2013.01)

USPC - 607/116, 117

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)

IPC(8) - A61N 1/00 (2013.01)

USPC - 607/116, 117

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 practicable, search terms used)

MicroPatent (US-G, US-A, EP-A, EP-B, WO, JP-bib, DE-C,B, DE-A, DE-T, DE-U, GB-A, FR-A); DialogPRO; Google Scholar; Medline/PubMed: antenna, back, electrical, electrode, foramen, ganglion, impulse, kamin's triangle, lead, modulate, nerve, nervous, outside, pain, remote, root, sacrum, signal, stimulation, target, transmit

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 2007/0021803 A1 (DEEM, M, et al.) January 25, 2007; paragraphs [0026], [0048], [0064], [0065], [0069]	1 ----- 2-7, 22-32
Y	US 2002/0055761 A1 (MANN, CM, et al.) May 9, 2002; paragraph [0140]-[0148]	2, 3, 30
Y	US 2011/0098628 A1 (YEUNG, JE, et al.) April 28, 2011; paragraph [0198]	4-6, 23, 27, 31
Y	US 6104957 A (ALO, KM, et al.) August 15, 2000; claim 41	7, 25
Y	US 2010/0036445 A1 (SAKAI, JL, et al.) February 11, 2010; paragraph [0168]	22-32
Y	WO 2012/065125 A1 (HOWARD, M, et al.) May 18, 2012; figures 25, 26, 28; paragraph [0044]-[0046],[0078]-[0080]	5, 6, 24, 27, 28
Y	US 7706885 B2 (FARONE) April 27, 2010; column 9, lines 32-36	29

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

* 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 application or patent 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)

"O" 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

17 October 2013 (17.10.2013)

Date of mailing of the international search report

25 OCT 2013

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. 571-273-3201

Authorized officer:

Shane Thomas

PCT Helpdesk: 571-272-4300
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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US13/41742

Box No. 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.:
because they relate to subject matter not required to be searched by this Authority, namely:
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 No. 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:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Group I: Claims 1-7 and 22-32 are directed toward a device for modulating excitable tissue in a patient's body and a kit comprising an implantable lead and instructions on the use of the implantable lead.

Group II: Claims 8-14 are directed toward a device for treating pain in a body of a patient.

Group III: Claims 15-21 are directed toward a system for modulating excitable tissue in a body of a patient comprising a control device.

- Continued on Supplemental Page -

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 additional fees, this Authority did not invite payment of additional fees.
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.:
1-7 and 22-32

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US13/41742

- Continued from Box III - Observations where unity of invention is lacking --

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the special technical features of Group I include circuitry for generating one or more electrical impulses at the electrodes using the pulse generator as the only source of power, the electrical impulses being sufficient to modulate excitable tissue adjacent to or near the exiting nerve root or the dorsal root ganglion, which are not present in Groups II-III; the special technical features of Group II include a lead comprising a distal portion; said distal portion having a diameter less than 1.8 mm, which are not present in Groups I and III; the special technical features of Group III include a control device having a transmitter located outside of the patient's body and configured to transmit an input signal, which are not present in Groups I-II.

The common technical features of Groups I and II are a lead comprising one or more electrodes; circuitry; a receiving antenna; wherein the receiving antenna is configured to receive an input signal containing electrical energy and waveform parameters through radiative coupling from a transmitter located outside of the patient's body; and wherein the circuitry is configured to generate an electrical impulse from the input signal sufficient to modulate a nerve or a nerve ganglion at a target site.

These common technical features are disclosed by US 2007/0021803 A1 to Deem, et al. (hereinafter 'Deem'). Deem discloses a lead comprising one or more electrodes (systems may include electrodes; paragraph [0064]); circuitry (systems may include electrodes (circuitry); paragraph [0064]); a receiving antenna (systems may include electrodes (antenna); paragraph [0051]); wherein the receiving antenna is configured to receive an input signal containing electrical energy (a partially implantable system 120 includes a receiver 124; figure 7; paragraph [0065]) and waveform parameters (energy delivery parameters; paragraph [0058]) through radiative coupling (relies upon radio frequency to transmit the energy to the lead or electrode; paragraph [0065]) from a transmitter located outside of the patient's body (transmitters are carried outside the body, while the receiver is implanted inside the body; paragraph [0065]); and wherein the circuitry is configured to generate an electrical impulse from the input signal sufficient to modulate a nerve or a nerve ganglion at the target site (nerve modulation utilizing pulsed electric fields; stellate ganglion; root nerves; paragraphs [0026], [0048]; [0051]).

Since the common technical features are previously disclosed by the Deem reference, the common features are not special and so Groups I and II lack unity.

The common technical features of Groups I and III are a lead comprising one or more electrodes; circuitry; a receiving antenna; being sized and configured for placement adjacent to or near a target site at an exiting nerve root or a dorsal root ganglion; an input signal containing electrical and waveform parameters through radiative coupling; and wherein the lead is configured to generate an electrical impulse from the input signal sufficient to modulate a nerve or a nerve ganglion at a target site.

These common technical features are disclosed by the Deem reference. Deem discloses a lead comprising one or more electrodes (systems may include electrodes; paragraph [0064]); circuitry (systems may include electrodes (circuitry); paragraph [0064]); a receiving antenna (systems may include electrodes (antenna); paragraph [0051]); being sized and configured for placement adjacent to or near a target site at an exiting nerve root or a dorsal root ganglion (target tissue may be treated from one or more locations either adjacent to or at a distance from target tissue; stellate ganglion and associated nerves; root nerves, the dorsal root nerves; paragraphs [0026], [0048], [0064]); an input signal containing electrical (a partially implantable system 120 includes a receiver 124; figure 7; paragraph [0065]) and waveform parameters (energy delivery parameters; paragraph [0058]) through radiative coupling (relies upon radio frequency to transmit the energy to the lead or electrode; paragraph [0065]); and wherein the lead is configured to generate an electrical impulse from the input signal sufficient to modulate a nerve or a nerve ganglion at a target site (nerve modulation utilizing pulsed electric fields; stellate ganglion; root nerves; paragraphs [0026], [0048]; [0051]).

Since the common technical features are previously disclosed by the Deem reference, the common features are not special and so Groups I and III lack unity.

The common technical features of Groups II and III are a lead comprising one or more electrodes; a receiving antenna; an input signal containing electrical energy and waveform parameters to the receiving antenna through radiative coupling; and wherein the circuitry is configured to generate an electrical impulse from the input signal sufficient to modulate a nerve or a nerve ganglion at a target site within the patient's body.

These common technical features are disclosed by the Deem reference. Deem discloses a lead comprising one or more electrodes (systems may include electrodes; paragraph [0064]); a receiving antenna (systems may include electrodes (antenna); paragraph [0051]); an input signal containing electrical (a partially implantable system 120 includes a receiver 124; figure 7; paragraph [0065]) and waveform parameters (energy delivery parameters; paragraph [0058]) through radiative coupling (relies upon radio frequency to transmit the energy to the lead or electrode; paragraph [0065]); and wherein the circuitry is configured to generate an electrical impulse from the input signal sufficient to modulate a nerve or a nerve ganglion at a target site within the patient's body (nerve modulation utilizing pulsed electric fields; stellate ganglion; root nerves; paragraphs [0026], [0048]; [0051]).

Since the common technical features are previously disclosed by the Deem reference, the common features are not special and so Groups II and III lack unity.