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(54) Title: METHOD AND APPARATUS FOR NEUROMODULATION TREATMENTS OF PAIN AND OTHER CONDITIONS

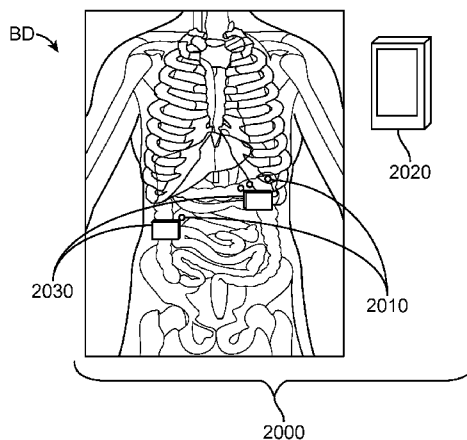


Fig. 20

(57) Abstract: Systems, devices, and methods for neurostimulation using a combination of implantable and external devices to treat pain are disclosed.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US15/36821

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61N 1/05, 1/372, 1/378 (2015.01)

CPC - A61N 1/05, 1/0551, 1/372

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 1/05, 1/36, 1/372, 1/378 (2015.01)

CPC - A61N 1/05, 1/0551, 1/36, 1/372

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)

PatSeer (US, EP, WO, JP, DE, GB, CN, FR, KR, ES, AU, IN, CA, Other Countries (INPADOC), RU, AT, CH, TH, BR, PH), ProQuest, Google, Google Patent, Google Scholar, Medline/Pubmed. Search terms: amplitude, anatomical, cycle, data, duration, duty, frequency, interface, modulat*, nerve, neural, number, pain, polarity, pulse, record, select, shape, stimulate, store, suppress, tissue, width

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2006/0074450 A1 (BOVEJA, BR et al.) 06 April 2006; figures 2, 22, 23; paragraphs [0029], [0079], [0080], [0107], [0108], [0137]	1-3, 4/2-3
X	US 2014/0142507 A1 (ARMES, CK) 22 May 2014; figures 5, 11; paragraphs [0131], [0236], [0262]; claim 3	1-3, 4/2-3
X	US 2009/0187230 A1 (DILORENZO, DJ) 23 July 2009; figures 1-6, 11; paragraphs [0025], [0061]-[0070], [0169], [0310]	1-3, 4/2-3
X	US 2013/0310901 A1 (PERRYMAN, LT et al.) 21 November 2013; figure 14; paragraphs [0012]-[0017]; [0021]; [0069], [0073], [0172], [0176]	1-3, 4/2-3

☐ 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 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

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US15/36821

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.: 5-21, 25-34, 39, 43-47, 51-227, 231-434
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. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I: Claims 1-4 are directed toward a method of treating pain with targeted modulation of tissue.

Group II: 22-24 and 35 are directed toward an apparatus for attaching to tissue and/or a structure comprising: extensions which interface with the tissue and/or structure; wherein the extensions expand and compress to secure and/or fix the apparatus to the tissue and/or structure.

Group III: Claims 36-38 are directed toward a method for attaching to a tissue.

Group IV: Claims 40-42 are directed towards a method of modulating tissue and/or collecting information.

Group V: Claims 48-50 and 228-230 are directed towards an system for a patient including wireless transcutaneous transmissions.

Group VI: Claims 435-464 is directed towards methods of ensuring charge balance safety in stimulating tissue.

-Continued Within the Next Extra Sheet-

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.:
1-4

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.

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

The inventions listed as Groups I-VI 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 includes a method of treating pain with targeted modulation of tissue comprising: placing an interface on, around, proximate, and/or inside anatomical structures and/or tissues which contain nerves and/or tissue that experience and/or communicate pain signals; wherein the interface modulates the anatomical structures and/or tissue to suppress and/or mask the pain signals and/or collects information, which are not present in Groups II-VI; and

the special technical features of Group II includes an apparatus for attaching to tissue and/or a structure comprising: extensions which interface with the tissue and/or structure; wherein the extensions expand and compress to secure and/or fix the apparatus to the tissue and/or structure, which are not present in Groups I or III-IV; and

the special technical features of Group III includes a method for attaching to a tissue and/or structure comprising: a rigid and/or semi-rigid structure and a flexible substrate, wherein the rigid and/or semirigid structure guides the flexible substrate to a target site; wherein the flexible substrate becomes attached to the target site and the rigid and/or semi-rigid structure is removed, which are not present in Groups I-II or IV-VI; and

the special technical features of Group IV includes placing multiple modulators, transducers and/or sensors on multiple anatomical structures and/or tissue; wherein one or more of the multiple modulators, transducers and/or sensors can be activated separately, sequentially, simultaneously, which are not present in Groups I-III or V-VI; and

the special technical features of Group V include at least one external device configured to transmit and receive wireless transcutaneous transmissions; and at least one implantable device configured to be implantable in the patient and receive wireless transcutaneous transmissions from the at least one external device and/or to transmit wireless transcutaneous transmissions to the at least one external device, which are not present in Groups I-IV or VI; and

the special technical features of Group VI include maintaining an active charge balance between a first current source to stimulate tissue and a second current source to stimulate the tissue by matching the first and second current sources to operate in an H-bridge-like configuration; and stimulating the tissue with the charged balanced first and second current sources, which are not present in Groups I-V.

The common technical features of Groups I-VI are forming and/or using electrical interfaces with live tissue.

The common technical features of Groups I and IV-VI are forming and/or using electrical interfaces with live tissue, and then modulating or stimulating tissue with electricity.

These common technical features are disclosed by US 2006/0074450 A1 to Boveja, et al. (hereinafter 'Boveja'). Boveja discloses a method of treating pain (therapy or alleviate symptoms of intractable pain; paragraph [0029]) with targeted modulation of tissue (providing electrical pulses to the spinal chord; paragraph [0029]) comprising: placing an interface on, around, proximate, and/or inside anatomical structures and/or tissues which contain nerves and/or tissue that experience and/or communicate pain signals (dorsal column stimulation for pain; electrode array 67 (interface) is implanted (interface) in the epidural space of the spinal cord; figure 22; paragraph [0107]); wherein the interface modulates the anatomical structures and/or tissue to suppress and/or mask the pain signals and/or collects information (distal end of electrode array 67 comprises stimulating electrodes; spinal cord stimulation to provide pain relief; figure 23; paragraphs [0107], [0108]).

Since the common technical features are previously disclosed by Boveja, these common features are not special and so Groups I-VI lack unity.