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- (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, BN, 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, IR, IS, JP, KE, KG, 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, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

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Declarations under Rule 4.17:

— as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))

Published:

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

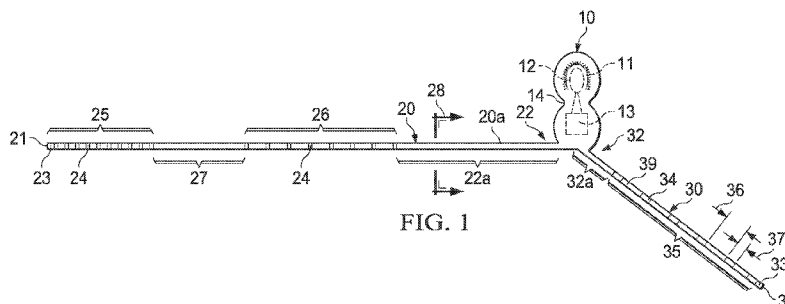
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(54) **Title:** IMPLANTABLE HEAD MOUNTED NEUROSTIMULATION SYSTEM FOR HEAD PAIN



(57) **Abstract:** An implantable head-mounted unibody peripheral neurostimulation system is provided for implantation in the head for the purpose of treating chronic head pain, including migraine. The system may include an implantable pulse generator (IPG) from which multiple stimulating leads may extend sufficient to allow for adequate stimulation over multiple regions of the head, preferably including the frontal, parietal and occipital regions. A lead may include an extended body, along which may be disposed a plurality of surface metal electrodes, which may be sub-divided into a plurality of electrode arrays. A plurality of internal metal wires may run a portion of its length and connect the IPG's internal circuit to the surface metal electrodes. The IPG may include a rechargeable battery, an antenna, and an application specific integrated circuit. The IPG may be capable of functional connection with an external radiofrequency unit for purposes that may include recharging, diagnostic evaluation, and programming.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US14/51235

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. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I: Claims 1-11 are directed toward a head implantable neurostimulator.

Group II: Claims 12-19 are directed toward a unibody implantable neurostimulator.

-Continued Within the 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.:
1-11

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/US14/51235

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61N 1/05 (2015.01)

CPC - A61N 1/0526, 1/0529, 1/36071

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 (2015.01)

CPC: A61N 1/0526, 1/0529, 1/36071; USPC: 607/46, 116

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); PatSeer (US, WO); Google; Google Scholar; Google Patent; ProQuest; PubMed/Medline. Search terms: head, skull, cranium, "cranial, implant", power, battery, process* microproces*, leads, wires; electrodes, flexible, bend*, malleable, elastic, plastic, silastic, cover*, contain*, jacket, shell, case, neuro*

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2005/0102006 A1 (WHITEHURST, TK et al.) May 12, 2005; figures 2-3; paragraphs [0035], [0060], [0063], [0067], [0069], [0091], [0070]-[0073], [0163]	1-11
Y	US 2013/0085561 A1 (MASHIACH, A) April 4, 2013; figure 4; paragraphs [0056], [0058], [0060], [0137]-[0138]	1-11
Y	US 2011/0172736 A1 (GEFEN, R et al.) July 14, 2011; figure 2B; paragraphs [0177], [0209]	7, 8
Y	US 7,729,781 B2 (SWOYER, JM et al.) June 1, 2010; claims 16-18	9
Y	US 2011/0112603 A1 (DEGIORGIO, C et al.) May 12, 2011; figures 1B, 4B; paragraph [0049]	9
A	US 2007/0112404 A1 (MANN, AE et al.) May 17, 2007; entire document	1-11

 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

20 January 2015 (20.01.2015)

Date of mailing of the international search report

19 FEB 2015

Name and mailing address of the ISA/US

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US14/51235

-Continued from Box No. III - Observations where unity of invention is lacking--

The inventions listed as Groups I-II 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 a covering over the main body fabricated from the flexible material and merged with the flexible material of the first elongated lead body to form a unibody sealed assembly comprised of the main body and the first elongated lead body, which are not present in Group II; the special technical features of Group II include an enclosure having a first enclosed portion and a second enclosed portion, the first enclosed portion and the second enclosed portion having a common interior; the first enclosed portion housing having contained therein in the associated portion of the common interior, which are not present in Group I.

The common technical features of Groups I and II are an implantable neurostimulator, comprising: a power source, and a processor, the processor operable to generate a plurality of stimulating signals for output on associated stimulating outputs; a plurality of stimulating conductors, each connected to associated ones of the stimulating outputs; and a plurality of surface electrodes disposed along the length of the first elongated lead body and connected to the stimulating conductors.

These common technical features are disclosed by US 2005/0102006 A1 to Whitehurst, et al. (hereinafter 'Whitehurst'). Whitehurst discloses an implantable neurostimulator (implanting a pulse generator within the skull, for stimulating nerves; abstract; figure 2; paragraph [0060]; claim 1), comprising: a power source (unit 110 includes a rechargeable battery as a power source 180; figure 3; paragraphs [0070]-[0071]), and a processor (110 includes a processor; paragraph [0071]), the processor operable to generate a plurality of stimulating signals for output on associated stimulating outputs (the processor generates stimulation pulses through electrodes 152; paragraph [0071]); a plurality of stimulating conductors (wires are bundled, as shown in figure 3, and contain leads 150; figure 3; paragraph [0063]), each connected to associated ones of the stimulating outputs (wires of leads 150 are connected to stimulation pulses generated by 110; paragraph [0063]); a plurality of surface electrodes disposed along the length of the first elongated lead body (surface electrodes 152 disposed along the lead body 150 thereon; figure 3; paragraph [0063]) and connected to the stimulating conductors (lead wires are connected to electrodes 152; figure 3; paragraph [0063]).

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