

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
24 July 2008 (24.07.2008)

PCT

(10) International Publication Number
WO 2008/088985 A3

(51) International Patent Classification:
A61N 1/00 (2006.01)

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(21) International Application Number:
PCT/US2008/050562

(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, 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, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(22) International Filing Date: 9 January 2008 (09.01.2008)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/880,026 12 January 2007 (12.01.2007) US
11/927,597 29 October 2007 (29.10.2007) US

(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, HR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL, NO, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

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Published:
— with international search report

(88) Date of publication of the international search report:
20 November 2008



WO 2008/088985 A3

(54) Title: SYSTEM AND METHOD FOR NEURO-STIMULATION

(57) Abstract: A neuro-stimulation system employs a includes a stimulator which may include electrode devices and/or vibration elements. A controller may be employed to drive the stimulating elements with an electrical signal. In response to the electrical signal, the stimulating elements deliver electrical and/or mechanical stimulation to the body part. The stimulation may be an aperiodic stimulation and/or may be a subthreshold stimulation. In one embodiment, the stimulator is disposable and the processor determines usage of the stimulator and ensures that the stimulator is limited to a certain amount of use. Neuro-stimulation systems may be applied to sensory cells of body parts during movement of the body parts to induce neuroplastic changes. Such movement may involve a variety of therapeutic applications, e.g. in stroke patient therapy.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 08/50562

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61N 1/00 (2008.04)

USPC - 607/2; 607/72

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 (2008.04)

USPC: 607/2; 607/72

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

USPC: 600/544

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

Electronic Databases Searched: PubWEST; Google; Google Scholar; Google Patents

Search Terms: electrical, stimulat\$, n-pin, electrode\$, mesh, vibrat\$, connector\$, usage, indicat\$, flex circuit, time, limit\$, neuro\$.

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 6,032,074 A (Collins) 29 Feb 2000 (29.02.2000); col 2, ln 51-60; col 6, ln 22-34; col 6, ln 61-65	52 and 55 ----- 1-14, 53, 54, 56, 57
Y	US 2006/0190057 A1 (Reese) 24 Aug 2006 (24.08.2006); Abstract; Figs. 1, 1A; para[0031]-[0036], [0045]	1-14
Y	US 2004/0116995 A1 (Dadd) 17 Jun 2004 (17.06.2004); Abstract	54
Y	US 2006/0129218 A1 (Swoyer et al.) 15 Jun 2006 (15.06.2006); para [0018], [0035]	53, 56, 57
Y	US 5,620,483 (Minogue) 15 Apr 1997 (15.04.1997); col 3, ln 16-45	5-13
Y	US 2004/0171971 A1 (Ravikumar et al.) 02 Sep 2004 (02.09.2004); para [0037]	13

Further documents are listed in the continuation of Box C.

* Special categories of cited documents:	"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
"A" document defining the general state of the art which is not considered to be of particular relevance	"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
"E" earlier application or patent but published on or after the international filing date	"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
"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)	"&" document member of the same patent family
"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	

Date of the actual completion of the international search 01 August 2008 (01.08.2008)	Date of mailing of the international search report 11 AUG 2008
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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: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774
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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 08/50562

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:

- Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
- 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:
- 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:
Group I, claims 1-14 and 52-57, drawn to a system for providing neuro-stimulation to a body part, the system comprising:
-- a controller including:
-- a user interface;
-- a power supply;
-- at least one electrical connector; and
-- a processor with software; and
-- a stimulator adapted to be detachably coupled to the controller via the at least one electrical connector, the stimulator including:
---- a plurality of stimulating elements, including at least one electrode device and at least one vibration element; and
---- an attachment element to attach the stimulator to a body part,
---- wherein the controller is operable to drive at least one of the stimulating elements with an electrical signal.

***** SEE SUPPLEMENTAL BOX TO CONTINUE *****

- As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
- As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
- 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.:
- 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.:
1-14, 52-57

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.

SEE SUPPLEMENTAL BOX TO CONTINUE

Continuation of BOX III. Observations where unity of invention is lacking:

Group II, claims 15-48, 79 and 80 drawn to a method of enhancing sensorimotor performance in a subject comprising the steps of:

- inputting an aperiodic signal to at least one sensory cell area of the subject;
- moving at least one body segment,
- wherein the at least one body segment utilizes sensory cells within the sensory cell area that is involved in the sensorimotor performance to be enhanced; and
- inducing neuroplastic changes in the nervous system of the subject by inputting the aperiodic signal for a period of time long enough that the subject's sensorimotor performance is enhanced; a method for providing neuro-stimulation to a body part with a neuro-stimulation device having a stimulator configured to provide at least one of an aperiodic stimulation and a subthreshold stimulation (claims 15-34, 79 and 80); a method for enhancing sensory function in a subject, the method comprising:
 - providing a stimulation source to an external device; and
 - receiving, with the external device, an interaction with a body part,
 - wherein the stimulation source applies the stimulation to sensory cells of the body part during the contact (claims 35- 48).

Group III, claims 49-51, drawn to a firearm for enhancing accuracy in shooting applications, the firearm comprising:

- a controller including:
 - a power supply;
 - an electrical connector; and
 - a processor determining an electrical signal directed from the power supply to the electrical connector; and
 - at least one stimulator operably coupled to the controller via the electrical connector and positioned on at least one of a trigger and a gun stock, the at least one stimulator including at least one of an electrode device and a vibration element,
 - wherein, the processor is operable to drive the electrode device and the vibration element with the electrical signal, and
 - in response to the electrical signal, at least one of the electrode device and the vibration element provides a stimulation to sensory cells in contact with at least one of the trigger and the gun stock.

Group IV, claims 58 and 59, drawn to a mat comprising:

- a top surface for contact a foot of a subject;
- a bottom surface for contact with a floor;
- a controller including:
 - a power supply;
 - an electrical connector; and
 - a circuit determining an electrical signal directed from the power supply to the electrical connector; and
- a stimulator operably coupled to the controller via the electrical connector and operably coupled to the top surface,
- wherein the processor is operable to drive the stimulator with the electrical signal.

Group V, claims 60, drawn to a catheter comprising:

- an elongate body,
- a plurality of stimulators positioned along the elongate body,
- wherein the one or more of the stimulators are configured to provide a stimulation,
- wherein the stimulation is at least one of an aperiodic stimulation or subthreshold stimulation.

Group VI, claims 61-68 and 71-78, drawn to a system for enhancing sensorimotor performance (claims 61-68) and improving neuroplasticity (claims 71-78) in a subject comprising:

- a wearable device to which is secured at least one signal input device; and
- a signal generator for generating a bias signal (claims 61-68).

Group VII, claims 69 and 70, drawn to a method of increasing growth hormone release in a subject comprising the step of increasing afferent signaling to the pituitary gland and growth hormone release by inputting a bias signal to a sensory cell area of a subject.

The inventions listed as Groups I-VII 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:

Although Groups I -VII do share the technical feature of a stimulator operably coupled to the controller via the electrical connector for delivering electric aperiodic signal, said stimulator is not a contribution over the prior art. Specifically, US 4,862,359 A (29 Aug 1989) to Trivedi et al teaches apparatus 10 for applying stimulus 16 to a patient and that "[t]hese stimuli 16 can be periodic, aperiodic and can also be combinations of each available type of stimulus 16. In the illustrated embodiment of FIG. 1A, the stimulus 16 is controlled responsive to a control signal 18 from a main computer, such as a microcomputer unit 22. The type of stimulus 16 is selected by a user input, such as a keyboard 23. The stimulus 16 can also be provided responsive to a stimulus controller 20 which is a separate microcomputer or is a remote control source" (col 5, ln14-36). As the above stimulator operably coupled to the controller was known at the time, as evidenced by the teaching of Trivedi, this cannot be considered a special technical feature that would otherwise unify the groups.

Groups I-VII therefore lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.