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- (74) **Agents: TSIVION, Yoram et al;** Hatochen 2, Casarea, 3148 Casarea (IL).
- (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, 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, 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, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, 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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(54) **Title:** NERVE STIMULATION SYSTEM

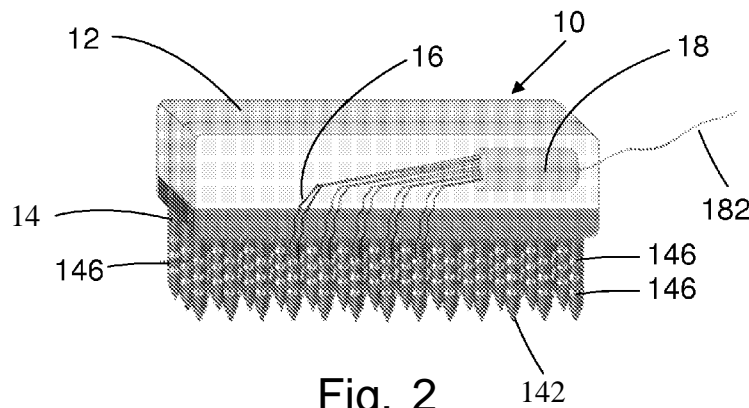


Fig. 2

(57) **Abstract:** A system for stimulating a nerve, comprising: an implantable electrode structure having a base and a plurality of electrodes; an implantable controller having a stimulator, adapted to deliver electrical pulses to the electrodes, a transmitter adapted to transmit signals to other components of the system, a receiver adapted to receive signals from other components of the system, and a processor adapted to process the various activities executed by system; and an implantable power source adapted to provide electrical power to the implantable controller. The implantable electrode structure further comprises a plurality of non-conductive branches extending from the base, and at least one of the electrodes located on the branches, thereby producing a three dimensional array of electrodes.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/IB2012/053676

<p>A. CLASSIFICATION OF SUBJECT MATTER IPC(8) - A61 N 1/05 (201 3.01) USPC - 607/1 16 According to International Patent Classification (IPC) or to both national classification and IPC</p>																																												
<p>B. FIELDS SEARCHED</p> <p>Minimum documentation searched (classification system followed by classification symbols) IPC(8) - A61N 1/00, 02, 05, 08 (2013.01) USPC - 607/2, 39, 75, 115, 116, 118, 143, 148</p> <p>Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched CPC - A61N 1/00, 02, 025, 04, 05, 0504, 0521, 08</p> <p>Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) PatBase, Google Patents, Google Scholar</p>																																												
<p>C. DOCUMENTS CONSIDERED TO BE RELEVANT</p> <table border="1"> <thead> <tr> <th>Category*</th> <th>Citation of document, with indication, where appropriate, of the relevant passages</th> <th>Relevant to claim No.</th> </tr> </thead> <tbody> <tr> <td>X</td> <td></td> <td>1, 2, 4-8</td> </tr> <tr> <td>---</td> <td></td> <td>-----</td> </tr> <tr> <td>Y</td> <td>US 4,969,468 A (BYERS et al) 13 November 1990 (13.1.1990) entire document</td> <td>3, 9-12, 15, 16, 18</td> </tr> <tr> <td>Y</td> <td>US 2007/0203541 A1 (GOETZ et al) 30 August 2007 (30.08.2007) entire document</td> <td>3</td> </tr> <tr> <td>Y</td> <td>US 201 1/0106229 A1 (ORTMANN) 05 May 201 1 (05.05.201 1) entire document</td> <td>9, 10</td> </tr> <tr> <td>Y</td> <td>WO 2011/046586 A1 (MANN et al) 21 April 201 1 (21.04.201 1) entire document</td> <td>11</td> </tr> <tr> <td>Y</td> <td>US 2010/0160994 A1 (FELDMAN et al) 24 June 2010 (24.06.2010) entire document</td> <td>12</td> </tr> <tr> <td>Y</td> <td>US 2006/0206165 A1 (JAAX et al) 14 September 2006 (14.09.2006) entire document</td> <td>15, 16</td> </tr> <tr> <td>Y</td> <td>US 4,1 18,547 A (WITZKE et al) 03 October 1978 (03.10.1978) entire document</td> <td>15, 16</td> </tr> <tr> <td>Y</td> <td>US 6,306,160 B1 (NIDETZKY) 23 October 2001 (23.10.2001) entire document</td> <td>16</td> </tr> <tr> <td>Y</td> <td>US 3,942,535 A (SCHULMAN) 09 March 1976 (09.03.1976) entire document</td> <td>18</td> </tr> <tr> <td>A</td> <td>US 5,361,760 A (NORMANN et al) 08 November 1994 (08.11.1994) entire document</td> <td>1-12, 15, 16, 18</td> </tr> <tr> <td>A</td> <td>US 2005/0010265 A1 (BARU FASSIO et al) 13 January 2005 (13.01.2005) paragraphs 39-40, 47, 50-51; figures 1A-3</td> <td>1-12, 15, 16, 18</td> </tr> </tbody> </table>			Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.	X		1, 2, 4-8	---		-----	Y	US 4,969,468 A (BYERS et al) 13 November 1990 (13.1.1990) entire document	3, 9-12, 15, 16, 18	Y	US 2007/0203541 A1 (GOETZ et al) 30 August 2007 (30.08.2007) entire document	3	Y	US 201 1/0106229 A1 (ORTMANN) 05 May 201 1 (05.05.201 1) entire document	9, 10	Y	WO 2011/046586 A1 (MANN et al) 21 April 201 1 (21.04.201 1) entire document	11	Y	US 2010/0160994 A1 (FELDMAN et al) 24 June 2010 (24.06.2010) entire document	12	Y	US 2006/0206165 A1 (JAAX et al) 14 September 2006 (14.09.2006) entire document	15, 16	Y	US 4,1 18,547 A (WITZKE et al) 03 October 1978 (03.10.1978) entire document	15, 16	Y	US 6,306,160 B1 (NIDETZKY) 23 October 2001 (23.10.2001) entire document	16	Y	US 3,942,535 A (SCHULMAN) 09 March 1976 (09.03.1976) entire document	18	A	US 5,361,760 A (NORMANN et al) 08 November 1994 (08.11.1994) entire document	1-12, 15, 16, 18	A	US 2005/0010265 A1 (BARU FASSIO et al) 13 January 2005 (13.01.2005) paragraphs 39-40, 47, 50-51; figures 1A-3	1-12, 15, 16, 18
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<p><input type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/></p>																																												
<p>* Special categories of cited documents:</p> <table border="0"> <tr> <td>"A" document defining the general state of the art which is not considered to be of particular relevance</td> <td>"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</td> </tr> <tr> <td>"E" earlier application or patent but published on or after the international filing date</td> <td>"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</td> </tr> <tr> <td>"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)</td> <td>"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</td> </tr> <tr> <td>"O" document referring to an oral disclosure, use, exhibition or other means</td> <td>"&" document member of the same patent family</td> </tr> <tr> <td>"P" document published prior to the international filing date but later than the priority date claimed</td> <td></td> </tr> </table>			"A" document defining the general state of the art which is not considered to be of particular relevance	"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	"E" earlier application or patent but published on or after the international filing date	"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	"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)	"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	"O" document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family	"P" document published prior to the international filing date but later than the priority date claimed																																	
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"P" document published prior to the international filing date but later than the priority date claimed																																												
<p>Date of the actual completion of the international search 15 January 2013</p>		<p>Date of mailing of the international search report 19 MAR 2013</p>																																										
<p>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</p>		<p>Authorized officer: Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774</p>																																										

INTERNATIONAL SEARCH REPORT

International application No.

PCT/IB2012/053676

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:

See 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.:
1-12, 15-16, 18

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.

INTERNATIONALSEARCH REPORT

International application No.

PCT/IB2012/053676

Continuation of Box III.

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 1-12, 15-16, 18, drawn to a nerve stimulation system having an implantable controller having a stimulator, a transmitter, receiver and processor, the implantable electrode has a plurality of non-conductive branches and at least one of the electrodes located on the branches producing a three dimensional array of electrodes.

Group II, claims 13-14, drawn to a system having implantable photo-galvanic cells; an external light source, the external light source adapted to light the area of a patient's body under which the photo-galvanic cells are implanted.

Group III, claim 17, drawn to a system having an implantable transformer and an external magnetic field generator, the external magnetic field generator adapted to produce a changing magnetic field near the area of a patient's body under which the transformer is implanted.

Group IV, claim 19, drawn to a method using a nerve stimulation system for producing an electrical potential in a site in a tissue, while abolishing or reducing the electrical potential in another site by transmitting an electrical signal from a first electrode, and a second electrode, which is in phase 180 degrees opposite to the phase of the signal transmitted from the first electrode.

Group V, claims 20-25, drawn to a method using nerve stimulation for determining which electrode is located near a nerve by measuring electrical potential in other electrodes as an electrical signal is transmitted to a first electrode; determining which electrode has a higher electrical potential from measuring; determining that the electrodes having a higher potential are near the nerve that was stimulated by the first electrode; repeating the above cycle with all electrodes and determining which electrodes are located near the same nerve.

Group VI, claims 26-27, drawn to a method for controlling the maximum number of erections per given time period, using a nerve stimulation system implanted near a nerve controlling erection, having the steps of predetermining a maximal number of erections per given time period; counting the number of erections stimulated during the time period; if the number equals the maximal number, disabling an additional erection; when the time period is over, zeroing the counted number and stating over from the counting step; changing the maximal number of erections per time period and starting over from the first step.

Group VII, claims 28-29, drawn to a method for controlling the maximal duration of an erection, by the steps of predetermining a maximal duration of an erection; measuring the duration of an erection stimulated by the nerve stimulation system; if the duration equals the maximal duration, disabling the stimulation; changing the maximal duration and starting over from the predetermining step.

The inventions listed as Groups I, II, III, IV, V, VI and 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: the special technical feature of the Group I invention: an implantable controller having a stimulator, a transmitter, receiver and processor, the implantable electrode has a plurality of non-conductive branches and at least one of the electrodes located on the branches producing a three dimensional array of electrodes as claimed therein is not present in the invention of Groups II, III, IV, V, VI or VII. The special technical feature of the Group II invention: implantable photo-galvanic cells; an external light source, the external light source adapted to light the area of a patient's body under which the photo-galvanic cells are implanted as claimed therein is not present in the invention of Groups I, III, IV, V, VI or VII. The special technical feature of the Group III invention: an implantable transformer and an external magnetic field generator, the external magnetic field generator adapted to produce a changing magnetic field near the area of a patient's body under which the transformer is implanted as claimed therein is not present in the invention of Groups I, II, IV, V, VI or VII. The special technical feature of the Group IV invention: a nerve stimulation system for producing an electrical potential in a site in a tissue, while abolishing or reducing the electrical potential in another site by transmitting an electrical signal from a first electrode, and a second electrode, which is in phase 180 degrees opposite to the phase of the signal transmitted from the first electrode as claimed therein is not present in the invention of Groups I, II, III, V, VI or VII. The special technical feature of the Group V invention: using nerve stimulation for determining which electrode is located near a nerve by measuring electrical potential in other electrodes as an electrical signal is transmitted to a first electrode; determining which electrode has a higher electrical potential from measuring; determining that the electrodes having a higher potential are near the nerve that was stimulated by the first electrode; repeating the above cycle with all electrodes and determining which electrodes are located near the same nerve as claimed therein is not present in the invention of Groups I, II, III, IV, VI or VII. The special technical feature of the Group VI invention: controlling the maximum number of erections per given time period, using a nerve stimulation system implanted near a nerve controlling erection, having the steps of predetermining a maximal number of erections per given time period; counting the number of erections stimulated during the time period; if the number equals the maximal number, disabling an additional erection; when the time period is over, zeroing the counted number and stating over from the counting step; changing the maximal number of erections per time period and starting over from the first step as claimed therein is not present in the invention of Groups I, II, III, IV, V or VII. The special technical feature of the Group VII invention: controlling the maximal duration of an erection, by the steps of predetermining a maximal duration of an erection; measuring the duration of an erection stimulated by the nerve stimulation system; if the duration equals the maximal duration, disabling the stimulation; changing the maximal duration and starting over from the predetermining step as claimed therein is not present in the invention of Groups I, II, III, IV, V or VI.

Groups I, II, III, IV, V, VI and VII lack unity of invention because even though the inventions of these groups require the technical feature of a nerve stimulation system; an implantable electrode; and an implanted rechargeable battery, this technical feature is not a special technical feature as it does not make a contribution over the prior art in view of US 2005/0010265 A1 (BARU FASSIO et al) 13 January 2005 (13.01.2005) paragraphs 39-40, 47, 50-51; figures 1A-3.

Since none of the special technical features of the Group I, II, III, IV, V, VI or VII inventions are found in more than one of the inventions, unity of invention is lacking.