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(71) Applicant (for all designated States except US): APNEX MEDICAL, INC. [US/US]; 2890 Centre Point Drive, St. Paul, Minnesota 55113 (US).

(72) Inventors; and

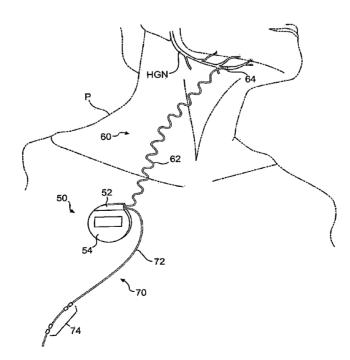
(75) Inventors/Applicants (for US only): BOLEA, Stephen, L. [US/US]; 741 105th Street SE, Watertown, Minnesota 55388 (US). HOEGH, Thomas, B. [US/US]; 4407 Grimes Ave. S., Edina, Minnesota 55424 (US). PERSSON, Bruce, J. [US/US]; 2107 105th Avenue, Dresser, Wisconsin 54009 (US). ATKINSON, Robert, E. [US/US]; 2679 Riviera Drive South, White Bear Lake, Minnesota 55110 (US). HAUSCHILD, Sidney,

F. [US/US]; 294 Spring St., St. Paul, MN 55102 (US). KAPLAN, Paula, M. [US/US]; 2151 Niles Ave., St. Paul, MN 55116 (US). KUHNLEY, Brian, D. [US/US]; 15388 76th Ave. N., Maple Grove, MN 55311 (US). JASPERSON, Keith, E. [US/US]; 13993 Magnolia St., Andover, MN 55304 (US). TESFAYESUS, Wondimeneh [US/US]; 1425 Jessamine Ave. W., #202, St. Paul, MN 55108 (US). THORP, Christopher, K. [US/US]; 1050 Lake Susan Dr., Chanhassen, MN 55317 (US).

- (74) Agent: GARRETT, Arthur S.; Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P., 901 New York Avenue, NW, Washington, District Of Columbia, 20001-4413 (US).
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[Continued on next page]

(54) Title: OBSTRUCTIVE SLEEP APNEA TREATMENT DEVICES, SYSTEMS AND METHODS



(57) Abstract: Devices, systems and methods for nerve stimulation for OSA therapy.

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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, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL, 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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INTERNATIONAL SEARCH REPORT

International application No PCT/US2007/021756

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a. classi INV.	FICATION OF SUBJECT MATTER A61N1/05				
According to	o International Patent Classification (IPC) or to both national classific	ation and IPC	·		
	SEARCHED				
	ocumentation searched (classification system followed by classification	on symbols)			
A61N					
Documental	tion searched other than minimum documentation to the extent that s	uch documents are included in the fields searched	I		
Electronic d	ata base consulted during the international search (name of data base	se and, where practical, search terms used)			
EPO-In	ternal				
C. DOCUM	ENTS CONSIDERED TO BE RELEVANT				
Category*	Citation of document, with indication, where appropriate, of the rel	evant passages	Relevant to claim No.		
Χ	US 2006/004429 A1 (MRVA JOSEPH J AL) 5 January 2006 (2006-01-05)	[US] ET	1-5		
Υ	paragraphs [0040], [0043], [004	4],	6		
	[0116] - [0120], [0130]; figures				
	1,35-37,38a,b,39				
Υ	US 2006/041295 A1 (OSYPKA THOMAS	P (US1)	6		
	23 February 2006 (2006-02-23)		,		
	paragraphs [0021], [0022], [003 [0037], [0045]; figures 3,7	[6],			
X	US 2006/149345 A1 (BOGGS JOSEPH W	TT FUST	1		
^	ET AL) 6 July 2006 (2006-07-06)	11 [03]	1		
,	paragraph [0291]; figures 30,33	·			
					
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Furti	her documents are listed in the continuation of Box C.	X See patent family annex.			
* Special c	categories of cited documents :	"T" later document published after the international			
	ent defining the general state of the art which is not dered to be of particular relevance	or priority date and not in conflict with the appointed to understand the principle or theory un			
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"L" docume	ent which may throw doubts on priority claim(s) or	cannot be considered novel or cannot be con involve an inventive step when the document			
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O docume other r	ent referring to an oral disclosure, use, exhibition or means	document is combined with one or more othe ments, such combination being obvious to a			
	ent published prior to the international filing date but nan the priority date claimed	in the art. '&' document member of the same patent family			
Date of the	actual completion of the international search	Date of mailing of the international search repo	ort		
1	0 April 2008	13/08/2008			
Name and r	mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2	Authorized officer			
NL - 2280 HV Rijswijk Tet. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016		Schöffmann			

International application No. PCT/US2007/021756.

INTERNATIONAL SEARCH REPORT

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. X Claims Nos.: 13-17, 18-50, 61-63, 70-87, 90, 94-100, 116-152 because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy
 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 additional 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 an 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 reportcovers 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.:
1–6
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.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-6

stimulation lead with anchoring means and a body having portions with differing flexibility

2. claims: 11,12

stimulation lead having a plurality of undulations

3. claim: 64

device for treating apnea comprising lead, stimulator, respiratory sensor and patient controller

4. claims: 65-69

electrode body with a plurality of electrodes, whereby, for a given pulse, one of the electrodes is adapted to deliver a charge density which is different from the other charge densities

5. claims: 88,89,91,92,93

system for treating apnea comprising a lead with electrode for implantation on a nerve and a tether for connection to tissue for relieving stress applied to the nerve and a pulse generator

6. claims: 101,102

nerve electrode with split cylindrical cuff an electrode disposed on an inside surface of the cuff

7. claims: 103,104,105,106,107

nerve electrode comprising a complaint sheet wrap configured to be wrapped about a nerve and comprising a plurality of fenestrations to accomodate nerve swelling

8. claim: 108

nerve electrode with a semi-cylindrical portion carrying electrodes and one or more strips configured to be wrapped around a nerve

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

9. claims: 109,110

electrode with a relatively long semi-cylindrical portion carrying a plurality of anodes, and a relatively short integral semi-cylindrical portion carrying a cathode

10. claim: 111

nerve electrode with a plurality of independent cuff electrodes each with independent leads

11. claim: 112

nerve electrode array with at least three independent cuff electrodes with a middle cuff comprising a cathode and two end cuff electrodes comprising anodes

12. claim: 113

a split cuff nerve electrode with a plurality of spaced electrode contacts to facilitate field steering

13. claim: 114

slit cylinder nerve electrode with longitudinal ends having a tapered thickness to reduce mechanical abrasion

14. claim: 115

nerve electrode with a housing to be connected to a nerve, the housing comprising a receptacle for removably receive a lead with ring electrodes and windows configured to align with the ring electrodes to permit electrical exposure of the ring electrodes to the nerve

15. claims: 7-10

method of manufacturing a sigmoid shaped lead by extruding silicone in a semi cross-linked state

16. claims: 51-60

method of selecting between electrodes for measuring bio-impedance $% \left(1\right) =\left(1\right) \left(1\right) +\left(1\right) \left(1\right) \left(1\right) +\left(1\right) \left(1\right) \left(1\right) \left(1\right) +\left(1\right) \left(1$

INTERNATIONAL SEARCH REPORT International application No

Information on patent family members

PCT/US2007/021756

Patent document cited in search report		Publication date		Patent family member(s)		Publication date	
US 2006004429	A1	05-01-2006	NONE	ν,	:		
US 2006041295	A1	23-02-2006	NONE	- 			
US 2006149345	A1	06-07-2006	AU CA EP US WO	2005331913 A1 2608017 A1 1885438 A1 2006173507 A1 2006124068 A1	·	23-11-2006 23-11-2006 13-02-2008 03-08-2006 23-11-2006	