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- For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: METHODS FOR TREATING LOWER URINARY TRACT DISORDERS AND THE RELATED DISORDERS VULVODYNIA AND VULVAR VESTIBULITIS USING CA_v2.2 SUBUNIT CALCIUM CHANNEL MODULATORS

(57) Abstract: The invention relates to methods of using Cav2.2 subunit calcium channel modulators to treat painful and non-painful lower urinary tract disorders and the related genitourinary tract disorders vulvodynia and vulvar vestibulitis in normal and spinal cord injured patients.

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2004/007175

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61K31/00 A61K38/17 A61P13/00

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 7 A61K

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 practical, search terms used)

EPO-Internal, WPI Data, PAJ, EMBASE, BIOSIS, CHEM ABS Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
E	WO 2004/054560 A (WESTBROOK SIMON LEMPRIERE ; TAYLOR CHARLES PRICE JR (US); WARNER LAMBE) 1 July 2004 (2004-07-01) claims	1-40
X	MAGGI C A ET AL: "Effect of omega conotoxin on reflex responses mediated by activation of capsaicin-sensitive nerves of the rat urinary bladder and peptide release from the rat spinal cord." NEUROSCIENCE. 1990, vol. 34, no. 1, 1990, pages 243-250, XP002292686 ISSN: 0306-4522 abstract page 244, column 1, paragraph 4	1-40

Further documents are listed in the continuation of box C.

Patent family members are listed in 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 document 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.
- *Z* document member of the same patent family

Date of the actual completion of the international search

17 August 2004

Date of mailing of the international search report

31/08/2004

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2004/007175

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>WO 03/018561 A (ASTRAZENECA AB ; D AMICO DERIN (US)) 6 March 2003 (2003-03-06) page 4, line 12 - page 5, line 30 page 7, line 19 - page 8, line 16</p> <p>-----</p>	39,40
Y	<p>PATENT ABSTRACTS OF JAPAN vol. 1999, no. 05, 31 May 1999 (1999-05-31) & JP 11 035483 A (NIPPON KAYAKU CO LTD), 9 February 1999 (1999-02-09) abstract</p> <p>-----</p>	1-38
Y	<p>US 5 698 549 A (TUTTLE JEREMY B ET AL) 16 December 1997 (1997-12-16) claims</p> <p>-----</p>	1-38
Y	<p>WO 00/18402 A (WANG DANIEL Z ; MERCK & CO INC (US); WALDSTREICHER JOANNE (US)) 6 April 2000 (2000-04-06) page 7, line 4 - page 9, line 2; claims 2,9,12</p> <p>-----</p>	1-38
Y	<p>GUIDO MICHAEL III ET AL: "Clinical experience with levetiracetam" EPILEPSIA, vol. 42, no. Supplement 7, 2001, page 180, XP001066203 & ANNUAL MEETING OF THE AMERICAN EPILEPSY SOCIETY; PHILADELPHIA, PA, USA; NOVEMBER 30-DECEMBER 05, 2001 ISSN: 0013-9580 the whole document</p> <p>-----</p>	1-38

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2004/007175

Box 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:

Although claims 1-38 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compounds.
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 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:

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 fee, this Authority did not invite payment of any additional fee.
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.:

Remark on Protest

- The additional search fees were accompanied by the applicant's protest.
- No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US2004/007175

Patent document cited in search report	A	Publication date	Patent family member(s)	Publication date
WO 2004054560	A	01-07-2004	WO 2004054560 A1	01-07-2004
			CA 2451267 A1	13-06-2004
			WO 2004054577 A1	01-07-2004
			WO 2004054559 A1	01-07-2004
			WO 2004054563 A1	01-07-2004
			WO 2004054565 A1	01-07-2004
			WO 2004054564 A1	01-07-2004
			WO 2004054566 A1	01-07-2004
			US 2004138305 A1	15-07-2004
			US 2004132636 A1	08-07-2004
			US 2004143014 A1	22-07-2004
<hr/>				
WO 03018561	A	06-03-2003	EP 1430030 A1	23-06-2004
			WO 03018561 A1	06-03-2003
<hr/>				
JP 11035483	A	09-02-1999	NONE	
<hr/>				
US 5698549	A	16-12-1997	US 5503986 A	02-04-1996
<hr/>				
WO 0018402	A	06-04-2000	AU 6263899 A	17-04-2000
			WO 0018402 A1	06-04-2000
			US 6268377 B1	31-07-2001
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