

(19) World Intellectual Property Organization  
International Bureau



(43) International Publication Date  
29 November 2007 (29.11.2007)

PCT

(10) International Publication Number  
**WO 2007/136741 A3**

(51) **International Patent Classification:**  
*A61K 31/55 (2006.01) A61P 25/20 (2006.01)*

(21) **International Application Number:**  
PCT/US2007/0 11893

(22) **International Filing Date:** 18 May 2007 (18.05.2007)

(25) **Filing Language:** English

(26) **Publication Language:** English

(30) **Priority Data:**  
60/801,814 19 May 2006 (19.05.2006) US

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(81) **Designated States (unless otherwise indicated, for every kind of national protection available):** AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, 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

(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, 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).

**Declaration under Rule 4.17:**

— *of inventorship (Rule 4.17(iv))*

**Published:**

— *with international search report*

(88) **Date of publication of the international search report:**  
24 January 2008

*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:** N-DESMETHYL-DOXEPIN AND METHODS OF USING THE SAME TO TREAT SLEEP DISORDERS

(57) **Abstract:** The invention relates to desmethyldoxepin, isomers of desmethyldoxepin, and pharmaceutically acceptable salts and prodrugs of desmethyldoxepin; compositions containing the same, and the use of any of the aforementioned for the treatment of sleep disorders.



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**INTERNATIONAL SEARCH REPORT**

International application No  
**PCT/US2007/011893**

**A CLASSIFICATION OF SUBJECT MATTER**  
INV. A61K31/55 A61P25/20

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)  
A61K A61P

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 , BIOSIS, EMBASE, UPI Data

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document with indication, where appropriate of the relevant passages	Relevant to claim No
Y	US 6 211 229 B1 (KAVEY NEIL B [US]) 3 April 2001 (2001-04-03) examples 1-39	1-76
Y	WO 00/50025 A C BIOGLAN LAB LTD [GB]; MCCLEANE GARY JOHN [GB] 31 August 2000 (2000-08-31) page 2, line 19 - line 23 page 3, line 10 - line 13 claim 1	1-76
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Further documents are listed in the continuation of Box C

See patent family 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 in the Rules)
  - "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

29 October 2007

Date of mailing of the international search report

08/11/2007

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**Loher, Florian**

# INTERNATIONAL SEARCH REPORT

International application No  
PCT/US2007/011893

^Continuation), DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>YAN J ET AL: "Stereoselective and simultaneous measurement of cis- and trans-isomers of doxepin and N-desmethyldoxepin in plasma or urine by high-performance liquid chromatography" JOURNAL OF CHROMATOGRAPHY B: BIOMEDICAL SCIENCES &amp; APPLICATIONS, ELSEVIER, AMSTERDAM, NL, vol. 691, no. 1, 28 March 1997 (1997-03-28), pages 131-138, XP004059329 ISSN: 1570-0232 page 132, left-hand column, last paragraph -----</p>	18, 19,21

**FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210**

Continuation of Box II.I

Although claims 1-17, 46-58 and 76 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 composition.

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Continuation of Box II.1

Claims Nos. : -

Rule 39.K iv) PCT - Method for treatment of the human or animal body by therapy

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US2007/011893

## 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:  
see FURTHER INFORMATION sheet PCT/ISA/210
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:

1.  As all required additional search fees were timely paid by the applicant, this international search report covers allsearchable 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 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 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

Information on patent family members

International application No

PCT/US2007/011893

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 6211229	B1	03-04-2001	NONE
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