

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
12 June 2008 (12.06.2008)

PCT

(10) International Publication Number
WO 2008/070795 A3

(51) International Patent Classification:

A61K 31/335 (2006.01) A61K 31/505 (2006.01)
A61P 25/20 (2006.01) A61K 31/4535 (2006.01)
A61K 31/4985 (2006.01) A61K 31/343 (2006.01)
A61K 31/437 (2006.01) A61K 31/4162 (2006.01)

(21) International Application Number:

PCT/US2007/086682

(22) International Filing Date:

6 December 2007 (06.12.2007)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

60/873,056 6 December 2006 (06.12.2006) US
60/910,586 6 April 2007 (06.04.2007) US

(71) Applicant (for all designated States except US): **SO-MAXON PHARMACEUTICALS, INC.** [US/US]; 3721 Valley Centre Drive, Suite 500, San Diego, CA 92130 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **JOCHELSON, Philip** [US/US]; 12626 Intermezzo Way, San Diego, CA 92130 (US). **MANSBACH, Robert** [US/US]; 12615 El Camino Real #E, San Diego, CA 92130 (US). **SKINNER, Michael** [US/US]; 4735 Tarantella Lane, San Diego, CA 92130 (US).

(74) Agent: **MALLON, Joseph, J.**; Knobbe Martens Olson & Bear LLP, 2040 Main Street, Fourteenth Floor, Irvine, CA 92614 (US).

(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, 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.

(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
— before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

(88) Date of publication of the international search report:

9 October 2008

(54) Title: COMBINATION THERAPY USING LOW-DOSE DOXEPIN FOR THE IMPROVEMENT OF SLEEP

(57) Abstract: A composition comprising doxepin, or a pharmaceutically acceptable salt, or prodrug thereof, and a compound that enhances sleep onset, sleep maintenance or reduces early morning awakenings. These compositions are useful for treating multiple manifestations of insomnia.



WO 2008/070795 A3

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2007/086682

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61K31/335 A61P25/20 A61K31/4985 A61K31/437 A61K31/505
A61K31/4535 A61K31/343 A61K31/4162

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, WPI Data, SCISEARCH, 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.
X	US 6 211 229 B1 (KAVEY NEIL B [US]) 3 April 2001 (2001-04-03) claims	1,2,4, 16,21, 25,78, 79,81-86
X	US 5 502 047 A (KAVEY NEIL B [US]) 26 March 1996 (1996-03-26) the whole document	1,2,4, 16,21, 25,78, 79,81-86

☒ 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)
- *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

3 June 2008

Date of mailing of the international search report

29/07/2008

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Venturini, Francesca

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2007/086682

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>HSU T ET AL: "Low-dose doxepin in the treatment of primary insomnia" SLEEP, ALLEN PRESS, LAWRENCE, KS, US, vol. 28, no. suppl, 2005, page A50, XP009094140 ISSN: 0161-8105 abstract</p>	1-136
A	<p>EBERT ET AL: "Treating insomnia: Current and investigational pharmacological approaches" PHARMACOLOGY AND THERAPEUTICS, ELSEVIER, GB, vol. 112, no. 3, 1 December 2006 (2006-12-01), pages 612-629, XP005712410 ISSN: 0163-7258 the whole document</p>	1-136
A	<p>WO 00/10554 A (SEPRACOR INC [US]) 2 March 2000 (2000-03-02) claims</p>	1-136

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2007/086682

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:

Although claims
11-15, 33-38, 46-51, 59-64, 72-77, 85-90, 98-103, 111-117, 124-129, 132-136 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 compound/composition.
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 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.:

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/US2007/086682

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 6211229	B1	03-04-2001	NONE	
US 5502047	A	26-03-1996	US 5643897 A	01-07-1997
WO 0010554	A	02-03-2000	AU 5784499 A	14-03-2000
			CA 2341400 A1	02-03-2000
			EP 1107748 A2	20-06-2001
			JP 2003520189 T	02-07-2003