

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
28 May 2009 (28.05.2009)

(10) International Publication Number
WO 2009/067703 A3

(51) International Patent Classification:

A61K 31/135 (2006.01) *A61K 31/197* (2006.01)
A61K 31/137 (2006.01) *A61P 29/00* (2006.01)
A61K 31/192 (2006.01)

(21) International Application Number:

PCT/US2008/084423

(22) International Filing Date:

21 November 2008 (21.11.2008)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

61/004,029 23 November 2007 (23.11.2007) US

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(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, 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, ST, 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, HR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL, NO, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

- with international search report (Art. 21(3))
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))

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

3 September 2009

(54) Title: TAPENTADOL COMPOSITIONS

(57) Abstract: The present invention provides a method of treating pain and pain related conditions by administering to a patient in need thereof, a therapeutically effective amount of a slow release Tapentadol Hydrochloride and therapeutically effective amount of a second analgesic, wherein the second analgesic is tramadol, gamma- aminobutyric acid (GABA) analogue or an NSAID. The present invention further provides a pharmaceutical composition comprising a therapeutically effective amount of a slow release Tapentadol Hydrochloride and a therapeutically effective amount of a second analgesic, wherein the second analgesic is tramadol, gamma-aminobutyric acid (GABA) analogue or an NSAID.



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INTERNATIONAL SEARCH REPORT

International application No
PCT/US2008/084423

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61K31/135 A61K31/137 A61K31/192 A61K31/197 A61P29/00

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)

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, WPI 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 2007/254960 A1 (BLOMS-FUNKE PETRA [DE] ET AL) 1 November 2007 (2007-11-01) paragraphs [0019], [0020], [0049], [0052]	1,4-12, 15,18, 21-23
X	WO 2007/005716 A (CINERGEN LLC [US]; BABUL NAJIB [US]) 11 January 2007 (2007-01-11) claims 1-4	1,4-12, 15,18, 21-23
Y	WO 03/035053 A (GRUENENTHAL GMBH [DE]; BARTHOLOMAEUS JOHANNES [DE]; ZIEGLER IRIS [DE]) 1 May 2003 (2003-05-01) claims	1,4-12, 15,18, 21-23
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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)
- *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

5 February 2009

Date of mailing of the international search report

21/07/2009

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INTERNATIONAL SEARCH REPORT

International application No

PCT/US2008/084423

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	EP 0 534 628 A (MCNEILAB INC [US]) 31 March 1993 (1993-03-31) table 1	1,4-12, 15,18, 21-23
Y	----- WEBB ASHLEY R ET AL: "The addition of a tramadol infusion to morphine patient-controlled analgesia after abdominal surgery: A double-blinded, placebo-controlled randomized trial." ANESTHESIA AND ANALGESIA, vol. 95, no. 6, December 2002 (2002-12), pages 1713-1718, XP002512449 ISSN: 0003-2999 page 1715, column 2	1,4-12, 15,18, 21-23
A	----- TERLINDEN ROLF ET AL: "Absorption, metabolism, and excretion of C-14-labeled Tapentadol HCl in healthy male subjects" EUROPEAN JOURNAL OF DRUG METABOLISM AND PHARMACOKINETICS, vol. 32, no. 3, July 2007 (2007-07), pages 163-169, XP009111333 ISSN: 0378-7966 page 169, column 1	1,4-12, 15,18, 21-23
A	----- RAUSCHKOLB-LOEFFLER C ET AL: "Efficacy and tolerability of tapentadol for relief of moderate-to-severe chronic pain due to osteoarthritis of the knee" ANNALS OF THE RHEUMATIC DISEASES, BRITISH MEDICAL ASSOCIATION, LONDON, vol. 66, no. Suppl. 2, 16 June 2007 (2007-06-16), page 507, XP009101917 ISSN: 0003-4967 the whole document	1,4-12, 15,18, 21-23

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2008/084423

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.: **see annex**
because they relate to subject matter not required to be searched by this Authority, namely:
Although claims 18-21 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:

see additional sheet

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.:

see annex

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: 1,4-12, 15, 18, 21-23 (in part)

a combination comprising tapentadol and tramadol

2. claims: 1, 4-12,15, 18, 21-23 (in part); 3, 13, 16, 20, 25

a combination comprising tapentadol and a GABA analogue

3. claims: 1, 4-12, 15, 18 , 21-23 (in part); 2, 14, 17, 19, 24

A combination comprising tapentadol and a NSAID

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2008/084423

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2007254960	A1	01-11-2007	NONE
WO 2007005716	A	11-01-2007	NONE
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