

(43) International Publication Date
26 May 2011 (26.05.2011)(10) International Publication Number
WO 2011/063150 A3

PCT

(51) International Patent Classification:

A61K 31/4439 (2006.01) A61K 9/14 (2006.01)
A61K 31/44 (2006.01) A61P 3/04 (2006.01)
A61K 9/20 (2006.01) A61P 3/00 (2006.01)

(21) International Application Number:

PCT/US2010/057280

(22) International Filing Date:

18 November 2010 (18.11.2010)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

61/263,274 20 November 2009 (20.11.2009) US

(71) Applicant (for all designated States except US): **HANDA PHARMACEUTICALS, LLC** [US/US]; 39465 Paseo Padre Parkway, Suite 2600, Fremont, CA 94538 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **SHEN, Zhiqun** [CN/CN]; Room 502, Unit 1, Building 21 Shihuiqiao, Xincun, Xihu District, Hangzhou, Zhejiang (CN). **ZHANG, Yu** [CN/CN]; Room 37-1-501, Section 1, Cuiyuan Xihu District, Hangzhou, Zhejiang (CN). **FU, Enjun** [—/CN]; Room 16-3-601, Bazhangjing Xincun, Gongshu District, Hangzhou, Zhejiang (CN). **HE, Min, Michael** [US/US]; 8209 Michaels Rdg, Ellicott City, MD 21043 (US). **LIU, Fang-yu** [US/US]; 30209 Aragon Place, Union City, CA 94587 (US).

(74) Agent: **MALLON, Joseph, J.**; Knobbe Martens Olson & Bear LLP, 2040 Main Street, 14th Floor, Irvine, CA 92614 (US).

(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, CL, 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, PE, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, 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, LR, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

— of inventorship (Rule 4.17(iv))

Published:

— with international search report (Art. 21(3))

[Continued on next page]

(54) Title: ORAL FORMULATION FOR DEXLANSOPRAZOLE

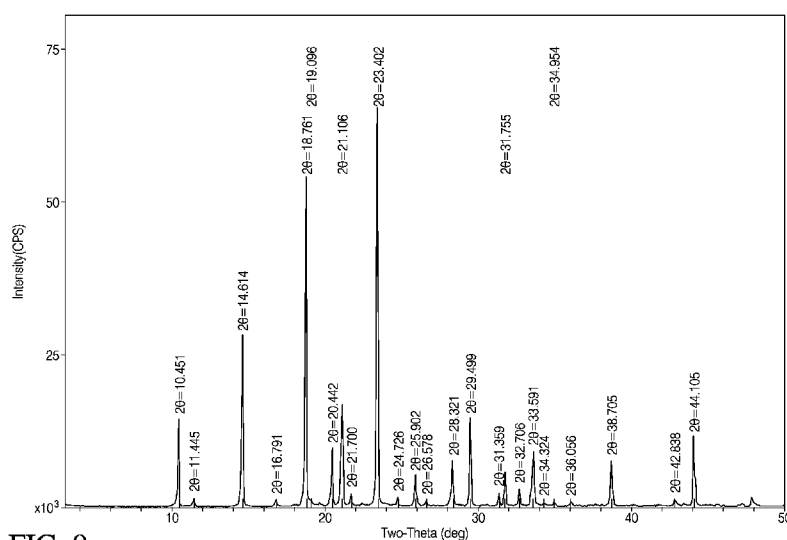


FIG. 9

(57) Abstract: A stable formulation of dexlansoprazole for treating a digestive disorder, and methods of manufacturing the same.



— *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:
15 September 2011

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2010/057280**A. CLASSIFICATION OF SUBJECT MATTER****A61K 31/4439(2006.01)i, A61K 31/44(2006.01)i, A61K 9/20(2006.01)i, A61K 9/14(2006.01)i, A61P 3/04(2006.01)i, A61P 3/00(2006.01)i**

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 31/4439; A61K31/44; A61K 9/20; A61K 9/14; A61P 3/04; A61P 3/00

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 practicable, search terms used)

eKOMPASS (KIPO internal), NCBI (PubMed, MeSH)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2009-0263475 A1 (NAGARAJU MANNE et al.) 22 October 2009 See pp. 1-3 and 7; examples 1 and 13; claims ; abstract	1-3,20-22,25-27,29 ,30
X	US 05433959 A (TADASHI MAKINO et al.) 18 July 1995 See cloumns 1-2 and 10; example 3; experimental example 1n; abstract	1-3,20-22,25-27,29 ,30
A	WO 2009-117489 A1 (DR. REDDY'S LABORATORIES LTD. et al.) 24 September 2009 See the whole document	1-3,20-22,25-27,29 ,30
A	US 2004-0048896 A1 (JEFFREY OWEN PHILLIPS) 11 March 2004 See the whole document	1-3,20-22,25-27,29 ,30
A	US 06132771 A (HELEN DEPUY et al.) 17 October 2000 See the whole document	1-3,20-22,25-27,29 ,30

☐ 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 application or patent 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 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

11 JULY 2011 (11.07.2011)

Date of mailing of the international search report

12 JULY 2011 (12.07.2011)

Name and mailing address of the ISA/KR

Korean Intellectual Property Office
Government Complex-Daejeon, 189 Cheongsu-ro,
Seo-gu, Daejeon 302-701, Republic of Korea

Facsimile No. 82-42-472-7140

Authorized officer

SUNG Sun Young

Telephone No. 82-42-481-8405



INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2010/057280**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.: 31
because they relate to subject matter not required to be searched by this Authority, namely:
The claim pertains to a method for treatment of the human body by therapy, and thus relates to a subject matter which this International Searching Authority is not required, under Article 17(2)(a)(I) of the PCT and Rule 39.1(iv) of the Regulations under the PCT, to search.
2. ☒ Claims Nos.: 13, 18
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:
Claims 13 and 18 are unsearchable because they are worded in reference to multiple dependant claims.
3. ☒ Claims Nos.: 4-12, 14-17, 19, 23, 24, 28, 31
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 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 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/US2010/057280

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2009-0263475 A1	22.10.2009	US 2009-263475 A1	22.10.2009
US 05433959 A	18.07.1995	None	
WO 2009-117489 A1	24.09.2009	CA 2717578 A1	24.09.2009
		CN 101977909 A	16.02.2011
		EP 2265605 A1	29.12.2010
		US 2011-0028518 A1	03.02.2011
US 2004-0048896 A1	11.03.2004	AU 2000-19071 A1	22.05.2000
		AU 2001-32767 A1	24.07.2001
		AU 2002-330863 B2	31.05.2007
		AU 2003-212685 A1	02.12.2003
		AU 2003-214858 A1	02.09.2003
		AU 2003-214858 B8	21.02.2008
		CA 2396159 A1	19.07.2001
		CA 2453117 A1	06.02.2003
		CA 2473669 A1	31.07.2003
		CA 2594185 A1	19.07.2001
		CN 1551768 A	01.12.2004
		CN 1666259 A	07.09.2005
		EP 1246622 A1	09.10.2002
		EP 1246622 B1	27.09.2006
		EP 1414452 A1	06.05.2004
		EP 1430895 A1	23.06.2004
		EP 1506544 A1	16.02.2005
		EP 1538908 A2	15.06.2005
		EP 1927354 A1	04.06.2008
		EP 2201952 A1	30.06.2010
		EP 2305259 A1	06.04.2011
		JP 2003-519656 A	24.06.2003
		JP 2004-521955 A	22.07.2004
		JP 2005-519901 A	07.07.2005
		JP 2005-526344 A	02.09.2005
		JP 2007-277271 A	25.10.2007
		KR 10-0679767 B1	07.02.2007
		KR 10-0739671 B1	13.07.2007
		KR 10-2004-0047771 A	05.06.2004
		KR 10-2004-0099265 A	26.11.2004
		TW 221285 A	21.09.2004
		US 05840737A A	24.11.1998
		US 2002-0045646 A1	18.04.2002
		US 2003-0118669 A1	26.06.2003
		US 2003-0144306 A1	31.07.2003
		US 2003-0214900 A1	20.11.2003
		US 2003-191159 A1	09.10.2003
		US 2003-215527 A1	20.11.2003
		US 2004-0058018 A1	25.03.2004
		US 2004-0171646 A1	02.09.2004

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/US2010/057280

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 06132771 A	17. 10. 2000	US 2005-0004171 A1	06. 01. 2005
		US 2005-0042304 A1	24. 02. 2005
		US 2005-0054682 A1	10. 03. 2005
		US 2006-0291337 A1	28. 12. 2006
		US 6489346 B1	03. 12. 2002
		US 6645988 B2	11. 11. 2003
		US 6699885 B2	02. 03. 2004
		US 6780882 B2	24. 08. 2004
		US 7167437 B2	23. 01. 2007
		US 7399772 B2	15. 07. 2008
		US 7782740 B2	24. 08. 2010
		WO 2000-26185 A2	11. 05. 2000
		WO 2001-51050 A1	19. 07. 2001
		WO 2003-009846 A1	06. 02. 2003
		WO 2003-061584 A2	31. 07. 2003
		WO 2003-098608 A1	27. 11. 2003
		AU 1997-13240 B2	11. 11. 1999
		CA 2214033 C	10. 01. 2006
		CN 1142792 C0	24. 03. 2004
		CN 1183049 A0	27. 05. 1998
		EP 0814840 A1	07. 01. 1998
		EP 0814840 B1	20. 11. 2002
		JP 11-501949 A	16. 02. 1999
		KR 10-0486057 B1	08. 09. 2005
		WO 97-25065 A1	17. 07. 1997