

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

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
17 September 2009 (17.09.2009)

PCT

(10) International Publication Number
WO 2009/114118 A3

(51) International Patent Classification:
A01N 43/42 (2006.01) *A61K 31/44* (2006.01)

(21) International Application Number:
PCT/US2009/001502

(22) International Filing Date:
9 March 2009 (09.03.2009)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/064,505 8 March 2008 (08.03.2008) US

(71) Applicant (for all designated States except US): **THER-
AQUEST BIOSCIENCES, INC.** [US/US]; 146 Medi-
nah Drive, Blue Bell, PA 19422-3212 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **BABUL, Najib**
[US/US]; 146 Medinah Drive, Blue Bell, PA 19422-3212
(US). **REHNI, Ashish, Kumar** [IN/IN]; 39 Gurmat
Colony, Sular Road, Patiala 147001 (IN).

(74) Common Representative: **BABUL, Najib**; 146 Medinah
Drive, Blue Bell, PA 19422-3212 (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, 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, MK, 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).

Declarations under Rule 4.17:

- as to applicant's entitlement to apply for and be granted
a patent (Rule 4.17(ii))
- as to the applicant's entitlement to claim the priority of
the earlier application (Rule 4.17(iii))
- of inventorship (Rule 4.17(iv))

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:
18 March 2010

(54) Title: ORAL PHARMACEUTICAL COMPOSITIONS OF BUPRENORPHINE AND METHOD OF USE

(57) Abstract: The present invention is directed to oral pharmaceutical compositions of buprenorphine and it pharmaceutically acceptable salts and the use thereof.



WO 2009/114118 A3

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 09/01502

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A01N 43/42; A61K 31/44 (2009.01)

USPC - 514/282

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)

USPC: 514/282

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

USPC: 424/423; 514/649 (see search terms below)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

Electronic Databases Searched: USPTO WEST (PGPUB, EPAB, JPAB, USPT), Google. Search Terms Used: buprenorphine, oral immediate release, norbuprenorphine, controlled release, pain or cough or dyspnea or herps or opioid

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X - Y	US 2008/0026052 A1 (Schoenhard) 31 January 2008 (31.01.2008) para [0006], [0009], [0017], [0021]-[0024], [0046], [0050], [0115], [0122], [0129], [0217]	1-4, 52-54, 63-65, 74-76 and 131-134 55-62, 66-73, 77-85, 135-141 and 167
Y	US 7,270,830 B2 (Reidenberg et al.) 18 September 2007 (18.09.2007) col 2, ln 6-10; col 14, ln 27-33; col 22, ln 55 to col 23, ln 44	55-62, 66-73, 77-85, 135-141 and 167
A	US 2003/0198675 A1 (Reder et al.) 23 October 2003 (23.10.2003) entire document	1-4, 52-85, 131-141 and 167
A	US 2005/0075361 A1 (Wang) 07 April 2005 (07.04.2005) entire document	1-4, 52-85, 131-141 and 167

☐ Further documents are listed in the continuation of Box C.

* 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 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

21 December 2009 (21.12.2009)

Date of mailing of the international search report

11 JAN 2010

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US, Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450

Facsimile No. 571-273-3201

Authorized officer:

Lee W. Young

PCT Helpdesk: 571-272-4300

PCT OSP: 571-272-7774

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 09/01502

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:

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.: 5-51, 86-130, 142-166
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 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.