

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
14 April 2005 (14.04.2005)

PCT

(10) International Publication Number
WO 2005/032555 A3

- (51) International Patent Classification⁷: **A61K 31/485**, 9/00, 9/22
- (21) International Application Number: PCT/US2004/029521
- (22) International Filing Date: 9 September 2004 (09.09.2004)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data: 60/506,222 25 September 2003 (25.09.2003) US
- (71) Applicant (for all designated States except US): **EURO-CELTIQUE S.A.** [LU/LU]; 122, Boulevard de la Petrusse, L-2330 Luxembourg (LU).
- (72) Inventors; and
- (75) Inventors/Applicants (for US only): **OSHLACK, Benjamin** [AU/US]; 351 E. 84th Street, New York, NY 10028 (US). **WRIGHT, Curtis** [US/US]; 1 Jarvis Street, Norwalk, CT 06851 (US). **BREDER, Chris** [US/US]; 5 An-njim Drive, Greenwich, CT 06830 (US).
- (74) Agents: **DAVIDSON, DAVIDSON & KAPPEL, LLC** et al.; 485 Seventh Avenue, 14th Floor, New York, NY 10018 (US).
- (81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, 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, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, 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, IT, LU, MC, 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).
- 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: 12 May 2005
- 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.*



WO 2005/032555 A3

(54) Title: PHARMACEUTICAL COMBINATIONS OF HYDROCODONE AND NALTREXONE

(57) Abstract: Disclosed is a pharmaceutical composition comprising from about 5 to about 20 mg of hydrocodone or a pharmaceutically acceptable salt thereof and from 0.055 to about 0.56 mg naltrexone or pharmaceutically acceptable salt thereof

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US04/29521

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61K 31/485, 9/00, 9/22
 US CL : 424/468; 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)
 U.S. : 424/468; 514/282

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)
 PALM, EAST, PubMed: naltrexone and hydrocodone

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2003/0031712 A1 (KAIKO et al) 13 February 2003 (13.02.2003), [0032], [0072], [0094], [0095], claim 1	1-14, 17, 22
Y	US 6,375,957 B1 (KAIKO et al) 23 April 2002 (23.04.2002) col. 5, lines 3-47; col. 20, line 63-col. 21, line 42; claims 1, 6, 9	1-14, 17, 22
Y	US 6,228,863 B1 (PALERMO et al.) 08 May 2001 (08.05.2001) col. 4, line 47-25; col. 14, line 33-col. 15, line 12	1-14, 17, 22

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	"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
"E" earlier application or patent published on or after the international filing date	"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
"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)	"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
"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	"&"	document member of the same patent family

Date of the actual completion of the international search

18 February 2005 (18.02.2005)

Date of mailing of the international search report

16 MAR 2005

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. (703) 305-3230

Authorized officer

Gregory W. Mitchell

Telephone No. 571-272-0600

INTERNATIONAL SEARCH REPORT

International application NO.

PCT/US04/29521

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.: 15, 16, 18-21 and 23-26
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.
 No protest accompanied the payment of additional search fees.