

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
19 February 2004 (19.02.2004)

PCT

(10) International Publication Number
WO 2004/014318 A3

(51) International Patent Classification⁷: **A61K 9/20**, 9/44

(74) Agents: **BUTLER, Gregory, B.** et al.; Edwards & Angell, LLP, P.O. Box 55874, Boston, MA 02205 (US).

(21) International Application Number:

PCT/US2003/025170

(22) International Filing Date: 8 August 2003 (08.08.2003)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

60/402,328	10 August 2002 (10.08.2002)	US
60/402,381	10 August 2002 (10.08.2002)	US
60/403,569	14 August 2002 (14.08.2002)	US
60/403,541	14 August 2002 (14.08.2002)	US
60/403,572	14 August 2002 (14.08.2002)	US
60/403,300	14 August 2002 (14.08.2002)	US

(81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, 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, 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 (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

(71) Applicant (*for all designated States except US*): **KING PHARMACEUTICALS, INC.** [US/US]; 501 Fifth Street, Bristol, TN 37620 (US).

Published:

— with international search report

(72) Inventors; and

(75) Inventors/Applicants (*for US only*): **STRAUSS, Elaine, A.** [US/US]; 9557 135th St. North, Seminole, FL 33776 (US). **FRANZ, G., Andrew** [US/US]; 2220 So. Warson Rd., St. Louis, MO 63124 (US). **DIMENNA, Philip, A.** [US/US]; 6773 32nd Avenue North, St. Petersburg, FL 33710 (US). **GEMMA, Rocco, L.** [US/US]; 4241 Dover-Zoar Road N.E., Dover, OH 44622 (US).

(88) Date of publication of the international search report:
28 October 2004

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.

(54) Title: LEVOTHYROXINE COMPOSITIONS AND METHODS

(57) Abstract: The present invention generally relates to stable pharmaceutical compositions, and methods of making and administering such compositions. In one aspect, the invention features stabilized pharmaceutical compositions that include pharmaceutically active ingredients such as levothyroxine (T4) sodium and liothyronine (T3) sodium (thyroid hormone drugs), preferably in an immediate release solid dosage form. Also provided are methods for making and using such immediate release and stabilized compositions.



WO 2004/014318 A3

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US03/25170

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61K 9/20, 9/44
US CL : 424/464, 465, 467

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. : 424/464, 465, 467

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)
Please See Continuation Sheet

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,225,204 A (CHEN et al) 06 July 1993 (06.07.1993), see entire document.	1-317
Y	US 6,190,696 A (GROENEWOUD) 20 February 2001 (20.02.2001), see entire document.	1-317
Y	US 5,955,105 A (MITRA et al) 21 September 1999 (21.09.1999), see entire document.	1-317
Y	US 5,753,254 A (KHAN et al) 19 May 1998 (19.05.1998), see entire document.	1-317
Y	US 6,290,990 A (GRABOWSKI et al) 18 September 2001 (18.09.2001), see entire document.	1-317

☐ 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	"&" document member of the same patent family
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search 30 November 2003 (30.11.2003)	Date of mailing of the international search report 14 APR 2004
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 <i>Dalena Bell-Hamilton</i> Humera N. Sheikh Telephone No. 571/272-1600

INTERNATIONAL SEARCH REPORT

PCT/US03/25170

Continuation of B. FIELDS SEARCHED Item 3:

WEST

levothyroxine, carrier, tablet, plasma, thyroid, cellulose