(19) World Intellectual Property Organization

International Bureau





(43) International Publication Date 11 October 2007 (11.10.2007)

(51) International Patent Classification:

A61K 9/16 (2006.01) A61K 9/50 (2006.01)

A61K 31/137 (2006.01)

(21) International Application Number:

PCT/EP2007/053027

(22) International Filing Date: 29 March 2007 (29.03.2007)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

06006979.6 31 March 2006 (31.03.2006)

(71) Applicant (for all designated States except US): Lek Pharmaceuticals d.d. [SI/SI]; Verovskova 57, 1526 Ljubljana (SI).

(72) Inventors; and

(75) Inventors/Applicants (for US only): LEGEN, Igor [SI/SI]; Jakhlova cesta 6, 1290 Grosuplje (SI). KUHAR, Polonca [SI/SI]; Prvomajska 10, 1000 Ljubljana (SI).

(74) Agent: SKULJ, Primoz; Novartis AG, Corporate Intellectual Property, CH-4002 Basel (CH).

(10) International Publication Number WO 2007/113207 A3

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BH, 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, 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, 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, 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, HU, IE, IS, IT, LT, LU, LV, MC, MT, 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

(88) Date of publication of the international search report: 25 September 2008

(54) Title: COATED FORMULATIONS

International application No PCT/EP2007/053027

A. CLASSIFICATION OF SUBJECT MATTER INV. A61K9/16 A61K9/50

A61K31/137

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

 $\begin{tabular}{ll} \begin{tabular}{ll} Minimum documentation searched (classification system followed by classification symbols) \\ A61K \end{tabular}$

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, WPI Data, BIOSIS, EMBASE, FSTA

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Υ.	WO 2004/105735 A (RANBAXY LABORATORIES LIMITED; KUMAR, PRATIK; JAIN, GIRISH KUMAR; RAMPA) 9 December 2004 (2004-12-09) abstract page 3, line 29 - page 4, line 12 page 10; example 3	1-19,22, 23
Υ	US 4 138 475 A (MCAINSH ET AL) 6 February 1979 (1979-02-06) column 1, lines 5-9,50-63 column 2, lines 7-16; example	1-11,13, 14,18-23
Y	US 5 188 841 A (SIMPKIN ET AL) 23 February 1993 (1993-02-23) column 1, lines 34-41 column 2, lines 42-58 column 3; example	1,3-11, 13,14, 16-23

Further documents are listed in the continuation of Box C.	X 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	Date of mailing of the international search report
30 January 2008	04/08/2008
Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Authorized officer van de Wetering, P

International application No
PCT/EP2007/053027

C(Continua	tion). DOCUMENTS CONSIDERED TO BE RELEVANT	rc1/Er200	
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.	
Y	WO 2006/021425 A (KRKA; KRAMER, ANDREJKA; PISEK, ROBERT; RAJER, TADEJA) 2 March 2006 (2006-03-02) page 3, paragraph 2 page 9, paragraph 3 page 11, lines 1-6 page 13; examples 4,5		1-16, 18-23
Α	US 6 911 217 B1 (GREN TORKEL ET AL) 28 June 2005 (2005-06-28) columns 6-7; example 1		1-3,5, 7-13, 15-17, 22,23
Ρ,Χ	"Sustained release pharmaceutical composition of tolterodine" IP.COM JOURNAL, IP.COM INC., WEST HENRIETTA, NY, US, 26 July 2006 (2006-07-26), XP013115218 ISSN: 1533-0001 the whole document		1-4
E	EP 1 810 668 A (LEK PHARMACEUTICALS D D [SI]) 25 July 2007 (2007-07-25)	. :	1-9, 12-14, 16,18-23
	page 5, paragraph 27 examples 2-4 		
i			
		,	
			,

International application No. PCT/EP2007/053027

INTERNATIONAL SEARCH REPORT

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:
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
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 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.:
1–23
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: 1-23

a pharmaceutical composition comprising cores containing only tolterodine and microcrystalline methylcellulose

2. claims: 24-26

a coating comprising ethyl cellulose and hydroxypropyl methylcellulose with EC/HPMC weight ratios of between 8/1 and 10/1

Information on patent family members

International application No
PCT/EP2007/053027

			PC1/EP200//05302/			
	atent document I in search report		Publication date		Patent family member(s)	Publication date
WO	2004105735	Α	09-12-2004	EP	1635795 A1	22-03-2006
US	4138475	А	06-02-1979	AU AU BE CA CH DE DK FR GB	510215 B2 2861477 A 859288 A1 1100040 A1 638399 A5 2740286 A1 244378 A 2392667 A1 1561204 A	12-06-1980 15-03-1979 30-03-1978 28-04-1981 30-09-1983 07-12-1978 02-12-1978 29-12-1978 13-02-1980 27-03-1981
				IE IL JP JP JP KE	45578 B1 52914 A 1148507 C 54059315 A 57040804 B 3120 A	06-10-1982 30-06-1980 26-05-1983 12-05-1979 30-08-1982 10-04-1981
		,		MY NL NO NZ SE ZA	34681 A 7805510 A 773293 A 185101 A 7806446 A 7705370 A	31-12-1981 05-12-1978 04-12-1978 28-03-1979 02-12-1978 31-01-1979
US	5188841	A	23-02-1993	AT CA DE DE DK EP ES JP	109975 T 2019108 A1 69011588 D1 69011588 T2 403383 T3 0403383 A1 2068353 T3 3063220 A	15-09-1994 16-12-1990 22-09-1994 15-12-1994 12-09-1994 19-12-1990 16-04-1995 19-03-1991
WO_	2006021425	A	02-03-2006	EP	1629834 A1	01-03-2006
US	6911217	B1	28-06-2005	AP AR AT CZ DEA ESK ID NO NO WW TW UZA	1323 A 027815 A1 247458 T 1436600 A 2350061 A1 20011627 A3 69910604 D1 5074 B1 2204193 T3 1040917 A1 30039 A 5936 A 25325 A1 20012314 A 511430 A 11673 A 0027364 A1 267385 B 222879 B 72882 C2 200103575 A	05-11-2004 16-04-2003 15-09-2000 18-05-2000 17-10-2001 25-09-2003 28-10-2004 16-04-2004 27-05-2005 01-11-2001 09-05-2001 31-12-2001 09-07-2001 30-05-2003 12-01-2005 18-05-2000 01-12-2006 01-11-2004 15-12-2000 03-05-2002

Information on patent family members

International application No
PCT/EP2007/053027

Patent document cited in search report	Publication date		Patent family member(s)		Publication date
EP 1810668 A	25-07-2007	WO	2007082770	A1	26-07-2007
·				 	
1					: