



(51) International Patent Classification:

A61K 9/28 (2006.01) *A61K 31/519* (2006.01)
A61K 9/20 (2006.01) *A61K 31/568* (2006.01)

(21) International Application Number:

PCT/NL2012/050336

(22) International Filing Date:

14 May 2012 (14.05.2012)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

11166091.6 13 May 2011 (13.05.2011) EP
11181165.9 13 September 2011 (13.09.2011) EP
11183732.4 3 October 2011 (03.10.2011) EP

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(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, QA, RO, RS, RU, RW, 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, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, 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).

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 April 2013

(54) Title: DRUG DELIVERY SYSTEM

(57) Abstract: The invention relates to a time controlled, immediate release drug delivery system for oral administration of a first active ingredient to a subject in need thereof. The invention additionally relates to a dual drug delivery device, comprising the time controlled, immediate release drug delivery system according to the invention, further comprising a second coating comprising a second active ingredient.



INTERNATIONAL SEARCH REPORT

International application No
PCT/NL2012/050336

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61K9/28 A61K9/20 A61K31/519 A61K31/568
ADD.

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

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)

EP0-Internal, WPI Data, BIOSIS, EMBASE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X A	US 2005/031688 A1 (AYALA WILLIAM J [US]) 10 February 2005 (2005-02-10) paragraphs [0246] - [0261]; claims 4-12; figures 1-5; examples 1-3 ----- -/--	1-22, 24-36 37-39



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 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

11 February 2013

Date of mailing of the international search report

19/02/2013

Name and mailing address of the ISA/

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INTERNATIONAL SEARCH REPORT

International application No

PCT/NL2012/050336

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2009/098697 A1 (DEXXON LTD [IL]; PENHASI ADEL [IL]; GAUCHMAN JANINA [IL]; SHAULI AMAND) 13 August 2009 (2009-08-13)	1-13
Y	page 4, lines 2-6,10,11, 14-24	14-22
A	page 5, lines 8-31	37-39
	page 6, lines 4,5	
	page 8, lines 5-10, 29-31	
	page 9, lines 1-20	
	page 9, line 23 - page 10, line 12	
	page 10, line 10	
	page 10, lines 13-30	
	page 11, lines 3-20	
	page 12, lines 26-30	
	page 16, lines 27-30	
	page 19; table 1A	
	page 23, lines 5-10; examples 2,3	
	page 28 - page 30; claims 1-36; figures 3-11; examples 5,6; tables 8,9	

X	WO 00/74655 A2 (PERIO PROD LTD [IL]; PENHASI ADEL [IL]; FLASHNER MOSHE [IL]; LERNER E) 14 December 2000 (2000-12-14)	1-13, 24-36
Y	page 44, lines 2-12; table 3	14-22
A	page 41, lines 23-28	37-39
	claims 1-34; examples 9-11	
	page 7, lines 6-27	
	page 8, line 7 - page 10, line 9; figures 1-24	

X	WO 98/32425 A1 (POLI IND CHIMICA SPA [IT]; BUSETTI CESARE [IT]; CRIMELLA TIZIANO [IT]) 30 July 1998 (1998-07-30)	1-13
Y	examples 1-3,5,8	14-22
A		37-39

A	WO 93/19741 A1 (BENZON PHARMA AS [DK]; BERTELSEN POUL [DK]; HANSEN NILS GJERLOV [DK];) 14 October 1993 (1993-10-14) the whole document	1-22, 36-39

Y	US 4 596 795 A (PITHA JOSEF [US]) 24 June 1986 (1986-06-24)	24-29
A	column 1, lines 5-16, 52-63, last paragraph; figures 1-5	30-39
	column 4, lines 11-25, paragraph r; examples 1,2; tables 1,2	

Y	US 6 977 083 B1 (HUEBLER DORIS [DE] ET AL) 20 December 2005 (2005-12-20)	24-29
A	column 4, lines 32-52, paragraph r; figures 1-3	30-39
	column 5, line 55, last paragraph - column 10, line 6, paragraph r	

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INTERNATIONAL SEARCH REPORT

International application No
PCT/NL2012/050336

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	STUENKEL C A ET AL: "SUBLINGUAL ADMINISTRATION OF TESTOSTERONE-HYDROXYPROPYL-.BETA.-CYCLODEX TRIN INCLUSION COMPLEX SIMULATES EPISODIC ANDROGEN RELEASE IN HYPOGONADAL MEN", JOURNAL OF CLINICAL ENDOCRINOLOGY AND METABOLISM, THE ENDOCRINE SOCIETY, US, vol. 72, no. 5, 1 January 1991 (1991-01-01), pages 1054-1059, XP008068605, ISSN: 0021-972X	24-29
A	abstract page 1054, right-hand column, paragraph 3 page 1055, right-hand column, last paragraph - page 1056, left-hand column, last paragraph; table 2 -----	30-39

INTERNATIONAL SEARCH REPORT

International application No.
PCT/NL2012/050336

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.:
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

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 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.:
1-22, 24-39
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.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-22(completely); 36-39(partially)

A time controlled, immediate release drug delivery system for oral administration of a first active ingredient to a subject in need thereof, the system comprising a core comprising cellulose, a filler selected from an organic and/or an inorganic salt, and a first active ingredient, and a first coating surrounding the core, said first coating comprising a hydrophobic polymer and a hydrophilic substance.

2. claim: 23

A method for preparing a dual delivery drug device comprising a first and a second coating, wherein a roughness of an outer surface of the first coating differs from a roughness of an outer surface of the second coating.

3. claims: 24-35(completely); 36-39(partially)

A tablet for sublingual administration of an active ingredient said tablet comprising a core, and a coating (outer coating) on the exterior surface of said core and optionally a coating that separates said outer coating from said core (separation coating), wherein said outer coating comprises a mixture of

- an active ingredient in amorphous form in an amount of between about 0.1 -10mg;
- a coating polymer in an amount of between about 0.25 - 25 mg; and
- water in an amount of between about 0.0 - 10% w/w of the outer coating.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/NL2012/050336

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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		DE 60016920 T2	31-08-2006
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