

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
5 February 2009 (05.02.2009)

PCT

(10) International Publication Number
WO 2009/017716 A3

(51) International Patent Classification:

A61K 9/00 (2006.01) A61K 9/48 (2006.01)
A61K 9/50 (2006.01)

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(21) International Application Number:

PCT/US2008/009139

(22) International Filing Date: 25 July 2008 (25.07.2008)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

60/952,501 27 July 2007 (27.07.2007) US
60/967,717 5 September 2007 (05.09.2007) 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, 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).

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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:
30 July 2009

(54) Title: PULSATILE GASTRIC RETENTIVE DOSAGE FORMS

(57) Abstract: Dosage forms for delayed and pulsed release of therapeutic agents into the stomach are described. The dosage forms are gastric retentive dosage forms that achieve release of the therapeutic agent into the stomach and upper gastrointestinal tract subsequent to administration of the dosage form. The dosage forms find particular use in administration of acid-labile active agents such as proton pump inhibitors, and in treating gastric acid secretion such as gastroesophageal reflux disease (GERD) and nocturnal acid breakthrough (NAB).



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INTERNATIONAL SEARCH REPORT

International application No
PCT/US2008/009139

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61K9/00 A61K9/50 A61K9/48

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 practical, search terms used)

EPO-Internal, WPI Data, CHEM ABS Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4 764 380 A (J. URQUHART ET AL.) 16 August 1988 (1988-08-16) figures claims column 3, line 66 - line 68 column 6, line 39 - line 40 column 6, line 65 - line 68 column 7, line 4 - line 5 column 8, line 5 - line 28	1-4, 9-30
X	WO 2005/079384 A (STATE OF OREGON) 1 September 2005 (2005-09-01) claims page 16, line 15 - line 24 examples 5-7, 20	1-4, 9-40

☒ 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 document but published on or after the international filing date
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- *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

17 June 2009

Date of mailing of the international search report

23/06/2009

Name and mailing address of the ISA/

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INTERNATIONAL SEARCH REPORT

International application No
PCT/US2008/009139

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 669 129 A (BAYER) 30 August 1995 (1995-08-30) claims figures page 5, line 1 - line 24	1-4,9-30
X	WO 98/11879 A (DEPOMED) 26 March 1998 (1998-03-26) claims examples 3,6,7	1-4,9-40
X	WO 03/035041 A (DEPOMED) 1 May 2003 (2003-05-01) claims page 4, line 15 - line 26 page 7, line 34 - line 36 page 19, line 24 page 29, line 28 - line 34 page 30, line 4 - line 7 page 31, line 1 - line 3 example 1	1-4,9-40
A	WO 99/07342 A (ALZA) 18 February 1999 (1999-02-18) figures 5,6 page 20, line 3 - page 21, line 9	5-8
A	WO 99/33446 A (ALZA) 8 July 1999 (1999-07-08) figures 1,3	5-8
A	WO 88/01160 A (R.J. HUGHES) 25 February 1988 (1988-02-25) figures 6-11	5-8
A	WO 2007/083309 A (INTEC PHARMA) 26 July 2007 (2007-07-26) figure 4	5-8
A	US 4 487 327 A (R.E. GRAYSON) 11 December 1984 (1984-12-11) figures	5-8

INTERNATIONAL SEARCH REPORT

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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.:
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: 1-4, 9-40 (all partially)

Dosage forms able to administer - in addition to a first immediate release (dose or pulse of) drug - a second delayed (dose or pulse of) drug, said drug(s) being preferably a proton-pump inhibitor PPI like omeprazole and/or a NSAID, or being preferably exclusively the same drug, i.e. a PPI like omeprazole for the treatment of diseases known as GERD or NAB, said second delayed (dose or pulse of) drug being contained in a gastric retentive delivery vehicle GRDV comprising a hydrophilic erodible swellable polymer and an optional further protective (enteric or basic) component, said dosage forms being characterized by the fact that SAID VEHICLE HAS PREFERABLY THE FORM OF MULTILAYERED (DISCRETE NON-MICROSCOPIC) BEADS DISPERSED IN A TABLET CORE MATRIX, OR THE FORM OF MACROSCOPIC LAYERED BEADS, OR THE FORM OF CORE/SHELL TABLETS, OR THE FORM OF LAYERED TABLET-IN-TABLET (with specific reference to Figs. 1,2,3A,3B,5A,5B);

2. claims: 1-4, 9-40 (all partially), 5-8

Dosage forms for the same uses and made of the same components as in the above-defined First Invention, characterized by the fact that SAID VEHICLE HAS THE FORM OF MULTIPLE POLYMERIC ERODIBLE INSERTS IN A CONGRUENT OR NESTING ARRANGEMENT WITHIN A CAPSULE, SAID INSERTS COMPRISING CAVITIES THAT CONTAIN SAID FIRST IMMEDIATE RELEASE (DOSE OR PULSE OF) DRUG AND SECOND DELAYED (DOSE OR PULSE OF) DRUG, WHEREIN SAID SECOND DELAYED (DOSE OR PULSE OF) DRUG IS PRESENT IN THE FORM OF MULTILAYERED BEADS OR COMPRESSED PELLETS OR SPHEROIDS (with specific reference to Figs. 4D and 4E).

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2008/009139

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