

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
4 January 2007 (04.01.2007)

PCT

(10) International Publication Number
WO 2007/000778 A3

(51) International Patent Classification:

A61K 9/20 (2006.01) A61K 31/366 (2006.01)
A61K 9/16 (2006.01)

(21) International Application Number:

PCT/IN2006/000224

(22) International Filing Date: 29 June 2006 (29.06.2006)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

1681/DEL/2005 29 June 2005 (29.06.2005) IN

(71) Applicant (for all designated States except US):
PANACEA BIOTEC LTD. [IN/IN]; B-1 Extn./A-27,
Mohan Co-operative Industrial Estate, Mathura Road,
New Delhi 110 044 (IN).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **JAIN, Rajesh**
[IN/IN]; Panacea Biotec Ltd, B-1 Extn./A-27, Mohan
Co-operative Industrial Estate, Mathura Road, New
Delhi 110 044 (IN). **JINDAL, Kour, Chand** [IN/IN];
Panacea Biotec Ltd, B-1 Extn./A-27, Mohan Co-operative
Industrial Estate, Mathura Road, New Delhi 110 044
(IN). **SINGH, Sukhjeet** [IN/IN]; Panacea Biotec Ltd,
B-1 Extn./A-27, Mohan Co-operative Industrial Estate,
Mathura Road, New Delhi 110 044 (IN). **BOLDHANE,**
Sanjay [IN/IN]; Panacea Biotec Ltd, B-1 Extn./A-27,
Mohan Co-operative Industrial Estate, Mathura Road,
New Delhi 110 044 (IN).

(74) Agent: **GUPTA, Bhartee**; Panacea Biotec Ltd., B-1
Extn./A-27, Mohan Co-operative Industrial Estate,
Mathura Road, New Delhi 110 044 (IN).

(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, HN, HR, HU, ID, IL, IN, IS, JP,
KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT,
LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MZ, NA,
NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC,
SD, SE, SG, SK, SL, SM, 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, 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).

Declarations under Rule 4.17:

- as to applicant's entitlement to apply for and be granted a
patent (Rule 4.17(ii))
- as to the applicant's entitlement to claim the priority of the
earlier application (Rule 4.17(iii))
- of inventorship (Rule 4.17(iv))

Published:

- with international search report

(88) Date of publication of the international search report:
29 March 2007

For two-letter codes and other abbreviations, refer to the "Guid-
ance Notes on Codes and Abbreviations" appearing at the begin-
ning of each regular issue of the PCT Gazette.

(54) Title: MODIFIED RELEASE PHARMACEUTICAL COMPOSITIONS ON THE BASIS OF TWO POLYMERS AND PRO-
CESSES THEREOF

(57) Abstract: Novel modified release pharmaceutical composition comprising at least one active agent(s); a polymer system in an
amount less than about 80% w/w of the composition comprising at least two swellable pH independent polymers wherein at least one
is hydrophilic; optionally other pharmaceutically acceptable excipients is provided. Process for preparation of such compositions
and methods of using them is also provided. The compositions are formulated into suitable dosage forms that provide therapeutic
concentrations of active agent for extended periods of time.

WO 2007/000778 A3

INTERNATIONAL SEARCH REPORT

International application No

PCT/IN2006/000224

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61K9/20 A61K9/16 A61K31/366

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, EMBASE, BIOSIS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 581 676 A2 (MENDELL CO INC EDWARD [US] PENWEST PHARMACEUTICALS CO [US]) 2 February 1994 (1994-02-02) claims 1-21 page 2, line 30 - page 7, line 35 -----	1,2,9-25
X	WO 99/18932 A (MENDELL CO INC EDWARD [US]; BHAGWAT DILEEP [US]; DIEHL DONALD II [US];) 22 April 1999 (1999-04-22) claims 1-18 page 8, line 5 - page 26, line 24 -----	1,2,9-25
X	WO 02/41876 A (LUPIN LAB LTD [IN]) 30 May 2002 (2002-05-30) claims 1-23 page 9, line 1 - page 13, line 24 ----- -/-	1,2,9-25



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

"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 December 2006

Date of mailing of the international search report

28/12/2006

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

Schifferer, Hermann

INTERNATIONAL SEARCH REPORT

International application No

PCT/IN2006/000224

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 093 420 A (BAICHWAL ANAND R [US]) 25 July 2000 (2000-07-25) claims 1-32 tables 1-7 column 7, line 44 - column 8, line 18 -----	1,2,9-25
X	WO 03/086353 A (PENWEST PHARMACEUTICALS CO [US]; BAICHWAL ANAND R [US]; WOODCOCK PAUL) 23 October 2003 (2003-10-23) claims 1-50 -----	1,2,9-25

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IN2006/000224

Box 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:

Although claim 23 is directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.
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 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.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/IN2006/000224

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
EP 0581676	A2	02-02-1994	AT 311861 T	15-12-2005
			AU 4185593 A	03-02-1994
			CA 2101189 A1	31-01-1994
			DE 69333927 T2	29-06-2006
			ES 2252731 T3	16-05-2006
			FI 933393 A	31-01-1994
			HU 67622 A2	28-04-1995
			IL 106253 A	10-03-1998
			JP 6172221 A	21-06-1994
			MX 9304485 A1	29-04-1994
			US 5478574 A	26-12-1995
			US 5472711 A	05-12-1995
WO 9918932	A	22-04-1999	AU 1087799 A	03-05-1999
			CA 2306103 A1	22-04-1999
			EP 1028709 A1	23-08-2000
			JP 2001519377 T	23-10-2001
			US 6537578 B1	25-03-2003
			US 6056977 A	02-05-2000
WO 0241876	A	30-05-2002	AU 2703001 A	03-06-2002
			US 2002103181 A1	01-08-2002
US 6093420	A	25-07-2000	US 6245355 B1	12-06-2001
WO 03086353	A	23-10-2003	AU 2003230805 A1	27-10-2003
			CA 2481091 A1	23-10-2003
			EP 1499295 A1	26-01-2005
			MX PA04009701 A	27-05-2005