

(19) World Intellectual Property Organization  
International Bureau



(43) International Publication Date  
8 November 2007 (08.11.2007)

PCT

(10) International Publication Number  
**WO 2007/125545 A3**

(51) International Patent Classification:

A61K 47/38 (2006.01) A61K 9/70 (2006.01)  
A61K 47/32 (2006.01) A61M 37/00 (2006.01)

New Link Road, Chakala, Andheri (East), Mumbai 400099 (IN).

(21) International Application Number:

PCT/IN2007/000164

(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, 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, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(22) International Filing Date: 25 April 2007 (25.04.2007)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

682/MUM/2006 2 May 2006 (02.05.2006) IN

(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).

(71) Applicant (for all designated States except US): PANACEA BIOTEC LTD [IN/IN]; 201, Samarpan Complex, New Link Road, Chakala, Andheri (East), Mumbai 400099 (IN).

(72) Inventors; and

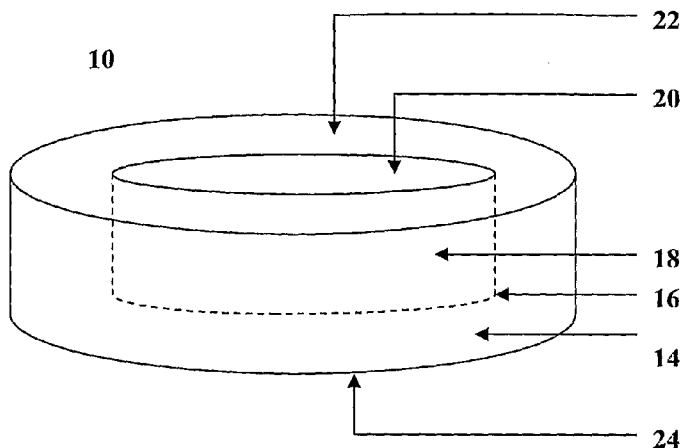
(75) Inventors/Applicants (for US only): SINGH, Amarjit [IN/IN]; 201, Samarpan Complex, New Link Road, Chakala, Andheri (East), Mumbai 400099 (IN). SINGH, Sarabjit [IN/IN]; 201, Samarpan Complex, New Link Road, Chakala, Andheri (East), Mumbai 400099 (IN). PUTHLI, Shivanand [IN/IN]; 201, Samarpan Complex,

Declarations under Rule 4.17:

- as to the identity of the inventor (Rule 4.17(i))
- 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))

[Continued on next page]

(54) Title: TRANSMUCOSAL COMPOSITION



(57) Abstract: The invention provides a composition for delivering active agents through transmucosal administration, more particularly through the buccal mucosa. The composition is a unique transmucosal disk (10) which has two compartments (14) and (18); the compartments consist of at least one active agent and at least one mucoadhesive agent and both the compartments are adapted to be in contact with the mucosal membrane. The invention also provides for transmucosal administration of an active agent and method of treatment of diseases in a subject in need of such treatment.

WO 2007/125545 A3



— *of inventorship (Rule 4.17(iv))*

(88) **Date of publication of the international search report:**  
21 February 2008

**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*

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/IN 2007/000164

## A. CLASSIFICATION OF SUBJECT MATTER

IPC<sup>8</sup>: **A61K 47/38** (2006.01); **A61K 47/32** (2006.01); **A61K 9/70** (2006.01); **A61M 37/00** (2006.01)  
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)  
IPC<sup>8</sup>: 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)  
EPODOC, WPI, TXTE, TXTG, MedLine

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5908637 A (Benes et al.) 1 June 1999 (01.06.1999) <i>Abstract, Fig. 1, Claims</i>	1-3, 6, 7, 9-10, 15, 17-18, 21, 22
	--	
A	US 6242004 B1 (Isabelle Rault) 5 June 2001 (05.06.2001) <i>Abstract, Fig. 3A, Claims</i>	1-3, 6-13, 16-18, 21, 22
	--	
A	DE 44 16 927 C1 (LTS Lohmann Therapie-Systeme GmbH & Co KG) 31 August 1995 (31.08.1995) <i>Abstract, Fig. 5a, 5b, Claims</i>	1-3, 6-13, 16-18, 21, 22
X	<i>Claims 1-4</i>	16
	----	

 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

"&amp;" document member of the same patent family

Date of the actual completion of the international search  
2 November 2007 (02.11.2007)Date of mailing of the international search report  
12 December 2007 (12.12.2007)Name and mailing address of the ISA/ AT  
**Austrian Patent Office**  
Dresdner Straße 87, A-1200 ViennaAuthorized officer  
HUNGER U.

Facsimile No. +43 / 1 / 534 24 / 535

Telephone No. +43 / 1 / 534 24 / 363

**Continuation of first sheet****Continuation 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:

Claims Nos.: 17, 18, 21, 22 because they relate to subject matter not required to be searched by this Authority, namely:

Although claims 17, 18, 21, and 22 refer to a method of treatment of the human/animal body by therapy, a search has been carried out and bases on the alleged effect of the composition.

Claims Nos.: 4, 5, 19, 20 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:

Product claims should be exclusively described by inherent product characteristics. In case of a product claim as in claim 4, describing a procedure for preparing is not allowed. In case of a product claim as in claim 5, a marking feature of the ability for using is not allowed and the term "is adapted..." is too imprecise. Although claims 19 and 20 refer to a method of treatment of the human/animal body by therapy and are normally searched for the alleged effects, no search has been carried out. Use claims should be exclusively described by an application. In case of a use claim as in claim 19, describing a mode of manufacturing is not allowed. In case of a use claim as in claim 20, the marking and distinguishing features of the application and the term "is adapted..." are too imprecise.

---

**Continuation No. IV:****Text of the abstract****(Continuation of item 5 of the first sheet)**

The invention provides a composition for delivering active agents through transmucosal administration, more particularly through the buccal mucosa. The composition is a unique transmucosal disk (10) which has two compartments; the compartments consist of at least one active agent (20) and at least one mucoadhesive agent (22) and both the compartments are adapted to be in contact with the mucosal membrane. The invention also provides a method for transmucosal administration of an active agent and method of treatment of diseases in a subject in need of such treatment.

---

**INTERNATIONAL SEARCH REPORT**  
Information on patent family members

International application No.  
PCT/IN2007/000164

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US A 5908637		US A 5908637	1999-06-01
		WO A1 9534286	1995-12-21
		NZ A 288104	1998-12-23
		JP T 10501816T	1998-02-17
		EP A1 0804154	1997-11-05
		CA A1 2190778	1995-12-21
US A 6242004		JP A 10298063	1998-11-10
		ZA A 9803402	1998-10-27
		NZ A 330250	1999-05-28
		AU A 6352398	1998-10-29
		AU B2 740421B	2001-11-01
		US B1 6242004	2001-06-05
DE A 4416927		GR T3 3035478T	2001-05-31
		US B1 6190689	2001-02-20
		NO A 964799	1996-11-12
		FI A 964534	1996-11-12
		ZA A 9503894	1996-03-07
		SK A3 131196	1997-04-09