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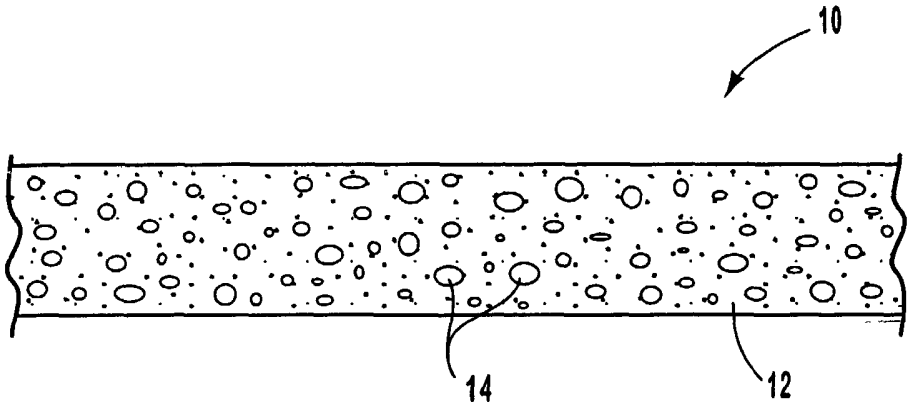
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Published:
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2 June 2005

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

(54) Title: DISSOLVABLE BACKING LAYER FOR USE WITH A TRANSMUCOSAL DELIVERY DEVICE



(57) Abstract: A dissolvable backing layer for use with transmucosal drug delivery devices includes a dissolvable hydrophilic region and a non-hydrophilic region that inhibits or slows migration of water, drugs, other active agents, or other molecules through the backing layer. The non-hydrophilic region can be a disperse phase of gaseous voids, droplets of a hydrophobic liquid, solid particles of a hydrophobic material, or water insoluble particles that are not necessarily hydrophobic. In the alternative, the non-hydrophilic region may comprise a continuous layer or component that is readily dispersible upon dissolving of the hydrophilic region. The backing layers may be used within any transmucosal delivery device used to delivery drugs or other active agents across a mucosal surface.

WO 2004/100925 A3

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2004/014550

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61K9/00 A61K9/70

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 7 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, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 700 478 A (BIEGAJSKI JAMES E ET AL) 23 December 1997 (1997-12-23) figure 4 column 4, line 21 - line 46 column 7, line 48 - line 58 column 17, line 45 - column 18, line 6 ----- -/--	1-11, 13-19, 22-34, 42,43, 46-55, 59,60

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in 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

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"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
21 December 2004	24/01/2005

Name and mailing address of the ISA	Authorized officer
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	Boulois, D

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2004/014550

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 99/55312 A (VIROTEX CORP) 4 November 1999 (1999-11-04) page 5, line 5 - page 6, line 2 figure 2 page 6, line 24 - line 27 page 9, line 1 - line 25 page 12, line 5 - page 15, line 17 page 18, line 18 - line 20; examples	1-9,11, 15-34, 42-60
X	US 6 375 963 B1 (REPKA STACI L ET AL) 23 April 2002 (2002-04-23) column 8, line 34 - line 33 example 12	1-9,14, 17-19, 21-24, 42,43, 46, 49-55, 59,60
X	US 4 307 075 A (MARTIN FREDERICK H) 22 December 1981 (1981-12-22) column 3, line 18 - line 41	1-5,11, 13,14, 17-34, 42,43, 47-55, 58-60
X	WO 02/02085 A (LOHMANN THERAPIE SYST LTS ; KRUMME MARKUS (DE); LAUX WOLFGANG (DE); VO) 10 January 2002 (2002-01-10) page 14; example 1 claim 1	1-12,17, 21-34
X	WO 03/015748 A (ACCESS PHARMA INC ; MORO DANIEL G (US); CALLAHAN HOWARD (US); NOWOTNIK) 27 February 2003 (2003-02-27) page 18, paragraph 15 - page 19	1-11,13, 14,17-34
X	US 5 529 782 A (STAAB ROBERT) 25 June 1996 (1996-06-25) column 7 - column 8; example 15	1-12,17, 21-34
X	US 2002/068151 A1 (KIM MIN J ET AL) 6 June 2002 (2002-06-06) column 6; examples 2-5	1-5,11, 12,17, 21-34
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INTERNATIONAL SEARCH REPORT

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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 2001/006677 A1 (ROBINSON JOSEPH R ET AL) 5 July 2001 (2001-07-05) column 11 - column 12; example 3	1-11, 15-17, 21-34, 42,43

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2004/014550

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. [X] Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

Although claims 52-60 are 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

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