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Declaration under Rule 4.17:

— of inventorship (Rule 4.17(iv)) for US only

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(54) Title: MUCOADHESIVE ERODIBLE DRUG DELIVERY DEVICE FOR CONTROLLED ADMINISTRATION OF PHARMACEUTICALS AND OTHER ACTIVE COMPOUNDS

(57) Abstract: The present invention relates to a layered pharmaceutical delivery device for the administration of pharmaceuticals or other active compounds to mucosal surfaces. The device may also be used by itself without the incorporation of a therapeutic. The device of the present invention consists of a water-soluble adhesive layer, a non-adhesive, bioerodible backing layer and one or more pharmaceuticals if desired in either or both layers. Upon application, the device adheres to the mucosal surface, providing protection to the treatment site and localized drug delivery. The "Residence Time", the length of time the device remains on the mucosal surface before complete erosion, can be easily regulated by modifications of the backing layer.

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 02/26083

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 | WO 99 55312 A (VIROTEX CORP) 4 November 1999 (1999-11-04) page 5, line 5 -page 6, line 2; figures 1,2 page 19, line 12 - line 17 page 7, line 28 - line 31; claims 1-19; examples 1-40; tables 2-4 | 1-56 |
| X | EP 0 781 546 A (SANWA KAGAKU KENKYUSHO CO) 2 July 1997 (1997-07-02) page 3, line 10 - line 27; claims 1-13 | 1-56 |
| X | EP 0 873 750 A (PERMATEC PHARMA AG) 28 October 1998 (1998-10-28) example 1 | 1-56 |
| | --- -/-- | |

Further documents are listed in the continuation of box C.

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
- *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.
- *Z* document member of the same patent family

Date of the actual completion of the international search

8 April 2003

Date of mailing of the international search report

29/04/2003

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INTERNATIONAL SEARCH REPORT

International Application No.

PCT/US 02/26083

| C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT | | |
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| Category ° | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
| X | US 4 713 243 A (SCHIRALDI MICHAEL T ET AL) 15 December 1987 (1987-12-15) cited in the application claims 1-9; examples 1-7 ----- | 1-56 |
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| A | EP 0 275 550 A (TEIKOKU SEIYAKU KK) 27 July 1988 (1988-07-27) cited in the application claim 1; example 4 ----- | 1-56 |
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| A | WO 00 32172 A (TAKADA KANJI) 8 June 2000 (2000-06-08) page 9; claims 1-13 page 11 ----- | 1-56 |
| A | DATABASE WPI Section Ch, Week 200168 Derwent Publications Ltd., London, GB; Class A11, AN 2001-599816 XP002237282 & JP 2001 163745 A (LION CORP), 19 June 2001 (2001-06-19) abstract ----- | 1-56 |

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 02/26083

Box I Observations where certain claims were found unsearchable (Continuation of item 1 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.: 1-56(part)
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:
see FURTHER INFORMATION sheet PCT/ISA/210

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 II Observations where unity of invention is lacking (Continuation of item 2 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.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

Claims Nos.: 1-56(part)

Present claims 1-56 relate to an extremely large number of possible devices. Support within the meaning of Article 6 PCT and/or disclosure within the meaning of Article 5 PCT is to be found, however, for only a very small proportion of the devices claimed. In the present case, the claims so lack support, and the application so lacks disclosure, that a meaningful search over the whole of the claimed scope is impossible. Consequently, the search has been carried out for those parts of the claims which appear to be supported and disclosed, namely those parts relating to devices as defined in claim 1, which comprise a water-soluble adhesive layer as defined in claim 3 and a water-erodible non-adhesive backing layer as defined in claim 4.

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

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