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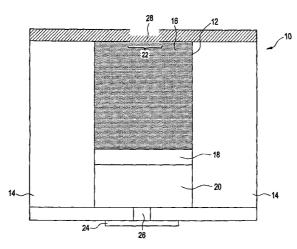
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(54) Title: MICRO-RESERVOIR OSMOTIC RELEASE SYSTEMS AND MICROTUBE ARRAY DEVICE



(57) Abstract: Devices and methods are provided for controlled release of chemical molecules, such as drugs. One device (10) comprises a plurality of reservoirs (12); a rupturable covering, such as a thin metal film (28), enclosing a first end of each reservoir; a release formulation (16) in each reservoir comprising chemical molecules for release; an expanding material layer (20) in each reservoir; and a semi-permeable membrane (26) enclosing a second end of each reservoir distal the release formulation, the semipermeable membrane being operable to permit selected molecules (e.g., water) from outside the reservoir to diffuse to the expanding material layer (20) to expand the expanding material layer and displace the release formulation in an amount effective rupture the rupturable membrane and discharge the release formulation. The device may further comprises a reservoir cap (24) covering semipermeable membrane and means for selectively disintegrating the reservoir cap to initiate diffusion of fluid molecules from outside the reservoir and through the semi-permeable membrane.



Internation Application No PCT/US 03/29924

a. classification of subject matter IPC 7 A61K9/00 A61M37/00 A61M31/00

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 A61M 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

C. DOCUME	NTS CONSIDERED TO BE RELEVANT		
Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.	
Х	WO 01/64344 A (MICROCHIPS INC) 7 September 2001 (2001-09-07)	1,2,6, 8-10	
Y A	page 28, line 14 - page 30, line 9; figures 10-11B	3-5 7,14-19	
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the whole document	
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Further documents are listed in the continuation of box C.	X Patent family members are listed in annex.
<ul> <li>Special categories of cited documents:</li> <li>"A" document defining the general state of the art which is not considered to be of particular relevance</li> <li>"E" earlier document but published on or after the international filing date</li> <li>"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)</li> <li>"O" document referring to an oral disclosure, use, exhibition or other means</li> <li>"P" document published prior to the international filing date but later than the priority date claimed</li> </ul>	"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 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  12 February 2004	Date of mailing of the international search report  0 9. 07. 2004
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  Krassow, H

Internation Application No
PCT/US 03/29924

C (Continue	ntion) DOCUMENTS CONSIDERED TO BE RELEVANT	1 7 1 7 0 0 00	3/29924		
Category °	Citation of document, with indication, where appropriate, of the relevant passages		Relevant to claim No.		
- ,					
A	WO 01/12157 A (MICROCHIPS INC) 22 February 2001 (2001-02-22) figures 10A-C	18-20			
P,A	WO 02/099457 A (MASSACHUSETTS INST TECHNOLOGY) 12 December 2002 (2002-12-12) page 21, line 25 - page 22, line 22				
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International application No. PCT/US 03/29924

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. X Claims Nos.: 30-38 because they relate to subject matter not required to be searched by this Authority, namely:  Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy
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:
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:
see additional sheet
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.:  1-10, 14-29
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.1

Claims Nos.: 30-38

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

#### FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

### 1. claims: 1-10, 14-29

Claims 1-10 and 14-29 essentially define comprising

- 1) a plurality of reservoirs with a rupturable covering at a first end,
- 2) a release formulation comprising the molecules within the reservoir.
- 3) an expanding material layer in each reservoir,
- 4) a semi-permeable membrane enclosing a second end of each reservoir.

#### 2. claims: 11-13

Claims 11-13 essentially define a device for controlled release of fluid drug formulation comprising

1) a first reservoir with a fluid drug formulation,

2) a second reservoir with an inert fluid,

3) the first and second reservoir each having a discharge

outlet controlled by a shared flow switch,

4) an osmotic engine for driving the fluids from the first and second reservoirs.

Internation Application No
PCT/US 03/29924

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