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[Continued on next page]

(54) Title: INGESTIBLE EVENT MARKER SYSTEMS

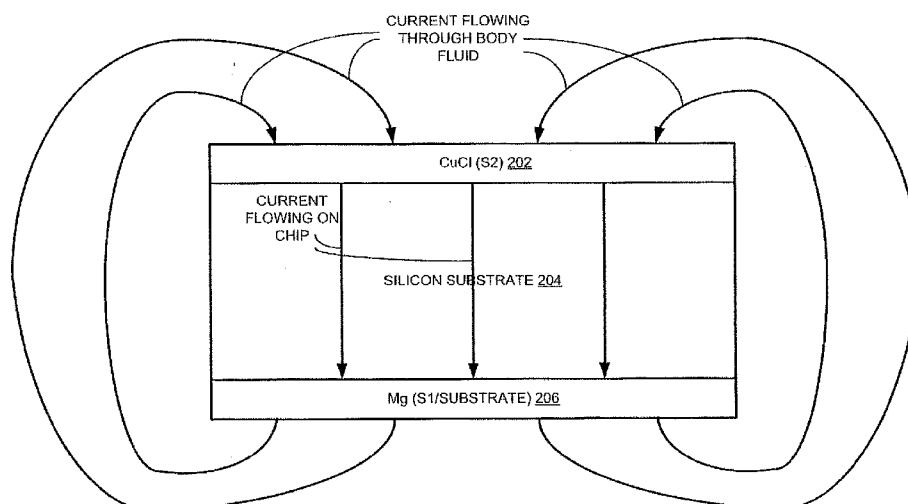


FIG. 3

(57) Abstract: Ingestible event marker systems that include an ingestible event marker (i.e., an IEM) and a personal signal receiver are provided. Embodiments of the IEM include an identifier, which may or may not be present in a physiologically acceptable carrier. The identifier is characterized by being activated upon contact with a target internal physiological site of a body, such as digestive tract internal target site. The personal signal receiver is configured to be associated with a physiological location, e.g., inside of or on the body, and to receive a signal the IEM. During use, the IEM broadcasts a signal which is received by the personal signal receiver.

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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.

NO, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG,  
CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

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## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 08/52845

<b>A. CLASSIFICATION OF SUBJECT MATTER</b> IPC(8) - A61B 5/05 (2008.04) USPC - 600/423 According to International Patent Classification (IPC) or to both national classification and IPC		
<b>B. FIELDS SEARCHED</b> Minimum documentation searched (classification system followed by classification symbols) USPC - 600/423  Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched USPC: 600/300, 309, 407, 414, 426, 423  Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) Electronic databases searched: PubWEST (DB=PGPB,USOC,EPAB,JPAB; PLUR=YES; OP=ADJ), Google. Search terms used: see supplemental sheet		
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X ----- Y	US 2001/0051766 A1 (GAZDZINSKI) 13 December 2001 (13.12.2001), particularly abstract, 520, 522, 524, 528, 540, 700, 712, 714, 716, 800, 802, 904, 906, 908, 910, 912, 916, 1602, 1604, 1610, 1612, 1614, 1616, 3202, paragraphs [0003], [0023], [0039]-[0045], [0050], [0053], [0067]-[0070], [0116], [0155], [0160]-[0188], [0191]-[0223], [0234], [0415]-[0419], Figs. 8-12, 15, 29-30	1, 2, 5-24, 44-66, 71-73 ----- 3, 4, 25-43, 67-70
Y	US 3679480 A, (BROWN, et al.) 25 July 1972 (25.07.1972) particularly Col. 4 lines 4-19	3, 4, 25, and 26
Y	US 2006/0078765 A1, (YANG, et al.) 13 April 2006 (13.04.2006), particularly 10, 12, 14, 21, 22, 23, 24, paragraphs [0022]-[0028], Figs. 1-3	27-33
Y	US 2004/0115507 A1 (POTTER, et al.) 17 June 2004 (17.06.2004) particularly abstract, 205, 215, 210, 615, 620, 625, 630, 645, paragraphs [0037], [0059]-[0063], [0205]-[0208], Figs. 2, 9-13	34-43
Y	US 2003/0135128 A1, (SUFFIN, et al.) 17 July 2003 (17.07.2003), particularly paragraphs [0097], [0105], [0157], [0179], [0187], [0192]-[0194], [0202], Fig. 10	67-70
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/>		
* 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 "&" document member of the same patent family		
Date of the actual completion of the international search 26 September 2008 (26.09.2008)		Date of mailing of the international search report  <b>06 OCT 2008</b>
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201		Authorized officer: Lee W. Young  PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

# INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 08/52845

## Box 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:

1. ☐ Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
  
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 No. 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:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I: claims 1-43 and 61-73 directed to a ingestible event marker that emits a signal upon contact with a physiological site and a signal receiver.

Group II: claims 44-60: directed to signal receiver configured to receive an identifier of a pharmaceutical composition.

----- Continued on Extra Sheet -----

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 additional fees, this Authority did not invite payment of additional fees.
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 and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☒ No protest accompanied the payment of additional search fees.

-- continuation of Box No. III (Unity of Invention) --

The inventions listed as Groups I - II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Group I does not include the inventive concept of an identifier of a pharmaceutical composition as required by Group II.

Group II does not include an ingestible event marker that emits a signal upon contact with a physiological site.

Groups I and II share the technical feature of a receiver associated with a living subject. However, this shared technical feature does not represent a contribution over the prior art of US 5,485,841 A to Watkin et al. (23 Jan 1996), which teaches a three source/receivers 20 are illustrated, but it will be understood that a single such source/receiver 20, or some other plurality, may be employed in the evaluation of the state of the lung of a subject (col 2, ln 64-69). As the above connector position assurance device was known at the time, as evidenced by the teaching of Watkin et al, this cannot be considered a special technical feature that would otherwise unify the groups.

Groups I and II therefore lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.

-- continuation of "B. Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)" ---

Search terms used: ingest, swallow, eat, signal, receiver, clock, generate, power, battery, voltaic, electrode, sensor, data storage, memory, buffer, integrated circuit, IC, microprocessor, interface, fluid port, permeable, planar processing, transmit, broadcast, wireless, short, resistant, series, battery