

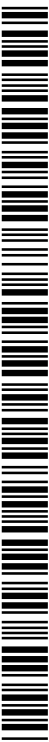
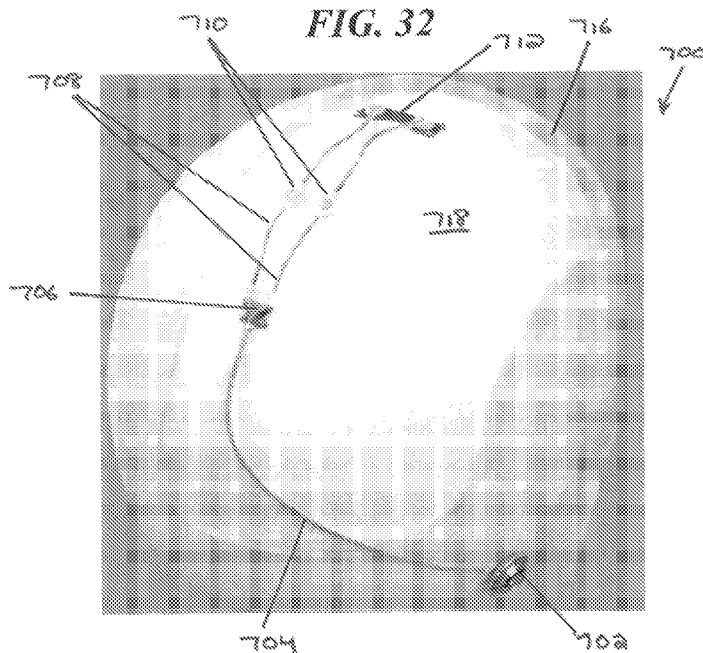


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[Continued on next page]

(54) Title: SYSTEMS AND METHODS FOR DRUG DELIVERY, TREATMENT, AND MONITORING

(57) Abstract: Systems and methods for delivering a drug or other therapy over an extended period of time (e.g., several hours, days, weeks, months, years, and so forth) are disclosed herein, as are systems and methods for monitoring various parameters associated with the treatment of a patient. Systems and methods are also disclosed herein that generally involve CED devices with various features for reducing or preventing backflow.





EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU,
LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK,
SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ,
GW, KM, ML, MR, NE, SN, TD, TG).

— *before the expiration of the time limit for amending the
claims and to be republished in the event of receipt of
amendments (Rule 48.2(h))*

Published:

— *with international search report (Art. 21(3))*

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9 April 2015

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 1-22, directed to an implantable delivery system

Group II: Claims 23-44, directed to a treatment method

-----Please See Continuation 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.:
1-22

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.

A. CLASSIFICATION OF SUBJECT MATTER IPC(8) - A61M 25/02 (2015.01) CPC - A61M 39/0247 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(8): A61M 25/02 (2015.01) CPC: A61M 39/0247 Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched USPC: 604/175, 151, 258, 891.1 CPC: A61M 39/0247, A61B5/14539, A61J1/05 Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) PatBase(Full-text: AU BE BR CA CH CN DE DK EP ES FI FR GB IN JP KR SE TH TW US WO); Google Scholar (Articles and Patents); Search Terms Used: fluid* conduit* channel* catheter* lumen*; resorb* biodegrad*scaffold; skull brain; sens*		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2009/0030373 A1 (Gill) 29 January 2009 (29.01.2009) entire document, especially figs. 1-3 and para [0082]	1-19, 22 1-19, 22 ----
Y -- A	US 2008/0004572 A1 (Morris et al.) 03 January 2008 (03.01.2008) figs. 1-4 and para [0024]	20
Y	US 5,954,687 A (Baudino) 21 September 1999 (21.09.1999) fig. 5, 5A and column 6, lines 1-15	2
Y -- A	WO 2013/019830 A2 (Anand et al.) 07 February 2013 (07.02.2013) figs. 1-4 and para [0122]	5, 8-13, 18, 19, 22 ---- 20, 21
Y	US 2009/0143659 A1 (Li et al.) 04 June 2009 (04.06.2009) figs. 6-8 and para [0786]	12, 14-17
<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 14 January 2015 (14.01.2015)		Date of mailing of the international search report 30 JAN 2015
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

Continuation of Box III - Lack of Unity:

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 1-22, directed to an implantable delivery system

Group II: Claims 23-44, directed to A treatment method

The inventions listed as Groups I and 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:

Groups I and II are related as a device and method of using the device and thus share the technical features of an implantable delivery system, comprising:

a percutaneous access device through which drug-containing fluid can be delivered;
a trunk line having a plurality of independent fluid lumens extending therethrough, the plurality of fluid lumens being in fluid communication with a corresponding plurality of ports formed in the access device;
a manifold configured to route the plurality of fluid lumens in the trunk line into a plurality of branch lines, each branch line including one or more corresponding fluid lumens disposed therein; and
mounting the branch lines to corresponding microfluidic catheters configured to extend into the brain of the patient.

However, these shared technical features are obviated by US 20090030373 A1 to Gill in view of US 20080004572 A1 to Morris et al. (hereinafter Morris).

Gill discloses an implantable delivery system (implantable delivery apparatus part 2, see para [0081]), comprising:
a percutaneous access device (external fluid router 22, see figs. 1-3 and para [0087]) through which drug-containing fluid can be delivered (router 22 attached to external fluid/drug pump device 34, see para [0088]-[0089]);
a trunk line (seven-lumen tube [0082], see figs. 1-3 and para [0082]) having a plurality of independent fluid lumens extending therethrough, the plurality of fluid lumens being in fluid communication with a corresponding plurality of ports formed in the access device (see para [0082]);
a manifold (fluidic router 10, see figs. 1-3 and para [0082]) configured to route the plurality of fluid lumens in the trunk line into a plurality of branch lines (single lumen tubing 14, see figs. 1-3 and para [0082]), each branch line including one or more corresponding fluid lumens (single lumen tubing 14, see figs. 1-3 and para [0082]) disposed therein; and
mounting (see para [0085]) the branch lines (single lumen tubing 14, see figs. 1-3 and para [0082]) to corresponding microfluidic catheters (catheters 12, see figs. 1-3 and para [0082]) configured to extend into the brain of the patient.
Gill fails to specifically disclose the mounting includes a skull anchor configured to be secured to the skull of a patient and being configured to couple branch lines to corresponding microfluidic catheters. Nevertheless, Morris does disclose the mounting includes a skull anchor (anchor 36, see figs. 1-4 and para [0024]) configured to be secured to the skull of a patient (see para [0030]) and being configured to couple branch lines (lines that attached pump 32 to catheters, see figs. 1-4 and para [0024]) to corresponding microfluidic catheters (catheters 34, see figs. 1-4 and para [0024]).

These shared technical features do not represent a contribution over the prior art. Therefore, Groups I and II lack unity under PCT Rule 13.