(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
12 June 2014 (12.06.2014)

WIPO | PCT

(10) International Publication Number
WO 2014/087247 A3

(51) International Patent Classification:
A61M 5/14 (2006.01) *G01N 33/50* (2006.01)
A61L 2/28 (2006.01) *G01N 31/22* (2006.01)
C12M 1/12 (2006.01) *C12Q 1/18* (2006.01)
A61M 5/00 (2006.01) *A61M 5/142* (2006.01)
C12Q 1/22 (2006.01) *G01N 13/00* (2006.01)

(21) International Application Number:
PCT/IB2013/003163

(22) International Filing Date:
5 December 2013 (05.12.2013)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/733,825 5 December 2012 (05.12.2012) US

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(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, 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).

Published:

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

[Continued on next page]

(54) Title: VALIDATION TECHNIQUES FOR FLUID DELIVERY SYSTEMS

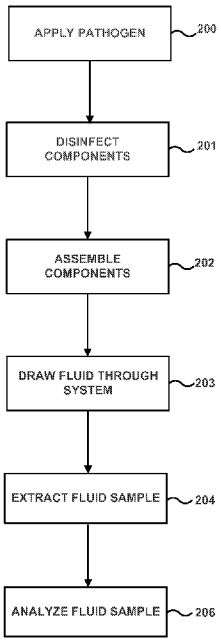


FIG. 5A

(57) Abstract: A fluid delivery system may include a container that houses a medical fluid, a fluid pressurizing unit, and a fluid transfer set that transfers the medical fluid from the container to the fluid pressurizing unit. To validate the integrity and sterility of the fluid delivery system, the system may undergo testing protocols to evaluate the susceptibility of the system to pathogenic ingress, chemical degradation, and/or fluid cross- contamination between patient fluid delivery procedures. The testing protocols may help ensure that delivery system components used during multiple different fluid delivery procedures perform as well as if the components were replaced after each fluid delivery procedure.

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— *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))*

(88) Date of publication of the international search report:
8 January 2015

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2013/003163

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M5/14 A61L2/28 C12M1/12 A61M5/00 C12Q1/22
G01N33/50 G01N31/22 C12Q1/18
ADD. A61M5/142 G01N13/00
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)
A61M A61L C12M C12Q G01N

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 practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2012/179130 A1 (BARNES ERIK [US] ET AL) 12 July 2012 (2012-07-12) figures 1,3	1-54
A	US 2003/072701 A1 (LIN SZU-MIN [US] ET AL) 17 April 2003 (2003-04-17) paragraphs [0003] - [0006]; figure 1	1-18, 25-29, 43-54
A	US 2005/183495 A1 (ICHIKAWA YASUNORI [JP] ET AL) 25 August 2005 (2005-08-25) paragraphs [0062] - [0068]; figures 2A-2E	19-24, 30-42
A	US 5 198 109 A (HANSON WILLIAM A [US] ET AL) 30 March 1993 (1993-03-30) column 1, line 55 - column 2, line 26; figures 1-4	19-24, 30-42

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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"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	Date of mailing of the international search report
20 October 2014	27/10/2014

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, Fax: (+31-70) 340-3016	Diamantouros, S

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB2013/003163

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:

see additional 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 an 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.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

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

1. claims: 1-18, 25-29, 43-54

   Method for the evaluation of the sterility of the connections of a fluid delivery system

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2. claims: 19-24, 30-42

   Method for the evaluation of the sterility of a fluid delivery system under cross-contamination conditions

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/IB2013/003163

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