



(51) International Patent Classification:
A61M 5/32 (2006.01)

(21) International Application Number:
PCT/US2014/052400

(22) International Filing Date:
22 August 2014 (22.08.2014)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/869,179 23 August 2013 (23.08.2013) US
61/911,884 4 December 2013 (04.12.2013) US
61/926,793 13 January 2014 (13.01.2014) US
61/931,206 24 January 2014 (24.01.2014) 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, ST, SZ,

[Continued on next page]

(54) Title: APPARATUS AND METHODS USEFUL FOR DISPENSING ONE OR MORE SUBSTANCES FROM A SINGLE CONTAINER

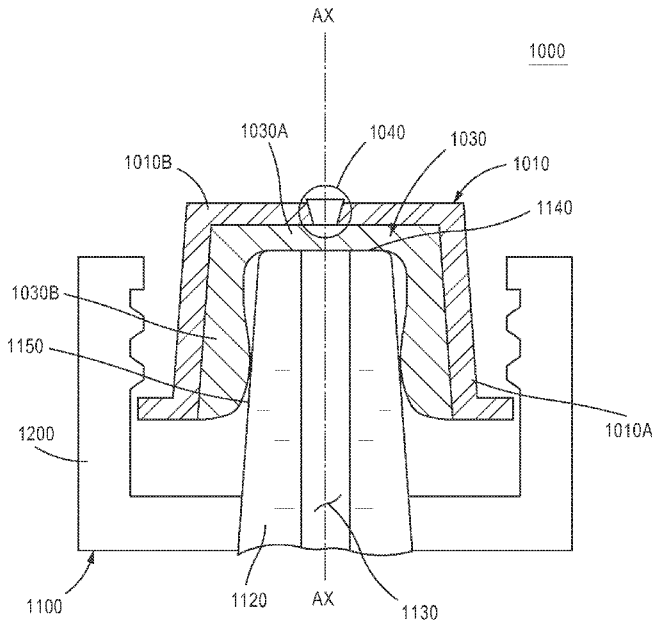


FIG. 1

(57) Abstract: An apparatus includes a housing having a coupling portion and an access portion. The access portion defines a guide opening. The coupling portion is configured to be removably coupled to a syringe (e.g., a prefilled or refillable syringe) such that the guide opening is aligned with an exit lumen defined by a tip of the syringe. The apparatus also includes a septum coupled to the housing. The septum includes a first seal portion and a second seal portion. The first seal portion is substantially planar, and is configured to define a substantially fluid-tight seal with a distal-end surface of the tip of the syringe. The second seal portion is configured to define a substantially fluid-tight seal with a sidewall of the tip.

WO 2015/027219 A3



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).

— *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:
16 April 2015

Published:

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

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2014/052400

<p>A. CLASSIFICATION OF SUBJECT MATTER IPC(8) - A61M 5/32 (2015.01) CPC - A61M 5/3202 (2015.01) According to International Patent Classification (IPC) or to both national classification and IPC</p>																										
<p>B. FIELDS SEARCHED</p> <p>Minimum documentation searched (classification system followed by classification symbols) IPC(8) - A61M 5/32, 5/34, 2005/3217 (2015.01) CPC - A61M 5/32, 5/3202, 2005/3217, 5/34 (2015.01)</p> <p>Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched USPC - 604/192, 195, 196, 198, 199, 200, 201, 202, 203, 204 (keyword delimited)</p> <p>Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) Orbit, Google Patents, Google Scholar. Search terms used: cap assembly, dispenser, container, syringe, septum, injector pen, seal, closure, cover, flexible, luer lock, sterilant gas, piercing, ophthalmic, medicine, substances</p>																										
<p>C. DOCUMENTS CONSIDERED TO BE RELEVANT</p> <table border="1"> <thead> <tr> <th>Category*</th> <th>Citation of document, with indication, where appropriate, of the relevant passages</th> <th>Relevant to claim No.</th> </tr> </thead> <tbody> <tr> <td>X</td> <td>US 7,762,988 B1 (VITELLO) 27 July 2010 (27.07.2010) entire document</td> <td>1-8</td> </tr> <tr> <td>-----</td> <td></td> <td>-----</td> </tr> <tr> <td>Y</td> <td></td> <td>56</td> </tr> <tr> <td>Y</td> <td>US 2006/0167435 A1 (ADAMIS et al) 27 July 2006 (27.07.2006) entire document</td> <td>56</td> </tr> <tr> <td>A</td> <td>US 2002/0189705 A1 (REIHL et al) 19 December 2002 (19.12.2002) entire document</td> <td>1-16, 56</td> </tr> <tr> <td>A</td> <td>US 2012/0109059 A1 (RANALLETTA et al) 03 May 2012 (03.05.2012) entire document</td> <td>1-16, 56</td> </tr> <tr> <td>A</td> <td>US 2008/0097310 A1 (BUEHLER et al) 24 April 2008 (24.04.2008) entire document</td> <td>1-16, 56</td> </tr> </tbody> </table>			Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.	X	US 7,762,988 B1 (VITELLO) 27 July 2010 (27.07.2010) entire document	1-8	-----		-----	Y		56	Y	US 2006/0167435 A1 (ADAMIS et al) 27 July 2006 (27.07.2006) entire document	56	A	US 2002/0189705 A1 (REIHL et al) 19 December 2002 (19.12.2002) entire document	1-16, 56	A	US 2012/0109059 A1 (RANALLETTA et al) 03 May 2012 (03.05.2012) entire document	1-16, 56	A	US 2008/0097310 A1 (BUEHLER et al) 24 April 2008 (24.04.2008) entire document	1-16, 56
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<p>* Special categories of cited documents:</p> <table border="0"> <tr> <td>“A” document defining the general state of the art which is not considered to be of particular relevance</td> <td>“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</td> </tr> <tr> <td>“E” earlier application or patent but published on or after the international filing date</td> <td>“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</td> </tr> <tr> <td>“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)</td> <td>“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</td> </tr> <tr> <td>“O” document referring to an oral disclosure, use, exhibition or other means</td> <td>“&” document member of the same patent family</td> </tr> <tr> <td>“P” document published prior to the international filing date but later than the priority date claimed</td> <td></td> </tr> </table>			“A” document defining the general state of the art which is not considered to be of particular relevance	“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	“E” earlier application or patent but published on or after the international filing date	“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	“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)	“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	“O” document referring to an oral disclosure, use, exhibition or other means	“&” document member of the same patent family	“P” document published prior to the international filing date but later than the priority date claimed															
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<p>Date of the actual completion of the international search</p> <p>20 January 2015</p>		<p>Date of mailing of the international search report</p> <p>06 FEB 2015</p>																								
<p>Name and mailing address of the ISA/US</p> <p>Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201</p>		<p>Authorized officer:</p> <p>Blaine R. Copenheaver</p> <p>PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774</p>																								

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2014/052400

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 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.:
1-16, 56

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.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2014/052400

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 need to be paid.

Group I, claims 1-16 and 56 (in part) are drawn to an apparatus comprising a housing including a coupling portion and an access portion.

Group II, claims 17-27 and 56 (in part) are drawn to an elastomeric member comprising a transfer portion configured to be moved between a first configuration and a second configuration.

Group III, claims 28-55 and 56 (in part) are drawn to an apparatus having first port, a second port, a first flow pathway and a second flow pathway.

The inventions listed in Groups I-III 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 feature for the following reason:

The special technical features of Group I, an apparatus comprising a coupling portion and an access portion, the access portion defining a guide opening, the coupling portion configured to be movably coupled to a syringe such that the guide opening is aligned with an exit lumen defined by a tip of the syringe and a septum coupled to the housing, the septum including a first seal portion and a second seal portion, are not present in Groups II or III; the special technical features of Group II, an elastomeric member comprising a transfer portion, the transfer portion configured to be moved between a first configuration and a second configuration, the transfer portion configured to be pierced by a needle to facilitate transfer of a substance into the medicament container when the transfer portion is in the first configuration are not present in Groups I or III; and the special technical features of Group III, a first port, a second port, a first flow pathway in fluid communication with the first port, a second fluid flow pathway in fluid communication with the second port, are not present in Groups I or II.

Groups I-III share the technical feature of conveying two or more substances, a first container containing a first substance and a second container containing a second substance, a sealing surface forming a substantially fluid-tight seal and a needle.

However, these shared technical features do not represent a contribution over the prior art. Specifically, US 4,601,704 A to Larkin discloses conveying two or more substances (abstract regarding medicament and diluent), a first container containing a first substance and a second container containing a second substance (abstract regarding medicament in one container with the diluent in the other), a sealing surface forming a substantially fluid-tight seal (abstract regarding sealed by means of a flange) and a needle (abstract regarding piercing element; Fig. 5 needle 77).

Since none of the special technical features of the Groups I-III inventions are found in more than one of the inventions, unity is lacking.