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[Continued on next page]

(54) Title: FLUID DIVERSION MECHANISM FOR BODILY-FLUID SAMPLING

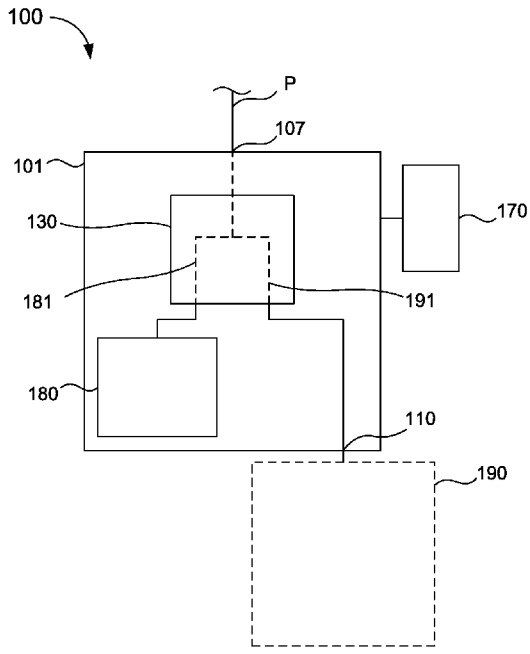


FIG. 1

(57) Abstract: An apparatus includes a housing, a flow control mechanism, and an actuator. At least a portion of the flow control mechanism is movably disposed within the housing. The apparatus further includes an inlet port and an outlet port, and defines a fluid reservoir. The outlet port is fluidically coupled to a second fluid reservoir and is fluidically isolated from the first fluid reservoir. The actuator is configured to move the flow control mechanism between a first configuration, in which the inlet port is placed in fluid communication with the fluid reservoir such that the fluid reservoir receives a first flow of bodily-fluid, and a second configuration, in which the inlet port is placed in fluid communication with the outlet port.

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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))*

— *with information concerning request for restoration of the right of priority in respect of one or more priority claims (Rules 26bis.3 and 48.2(b)(vii))*

(88) Date of publication of the international search report:
23 October 2014

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 13/71491

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61B 5/00; B65D 81/00 (2014.01)
USPC - 600/579
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)
USPC: 600/579

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC: 600/573; 604/246, 249, 256, 30, 33
IPC: A61M 1/00, 5/00, 5/14 (keyword limited; terms below)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PatBase; Google Patents; Google
Search Terms Used: blood, fluid, liquid, collect*, sampl*, donat*, valve$, divert*, vacuum, negative pressure, actuator, housing, manifold, bodily fluid

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2008/0145933 A1 (PATTON) 19 June 2008 (19.06.2008) fig 5, 7A, 7B, para [0040], [0044]-[0046]	1-18
A	US 2008/0108954 A1 (MATHIAS et al) 08 May 2008 (08.05.2008) fig 3-8, para [0059], [0062]-[0066]	1-18

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

* 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	Date of mailing of the international search report
08 July 2014 (08.07.2014)	05 AUG 2014
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

Form PCT/ISA/210 (second sheet) (July 2009)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 13/71491

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 1-18 and 23-30 (exemplified by figs 1-12) directed to a device and methods for parenterally-procuring bodily-fluid samples from a patient.

Group II: Claims 19-22 (exemplified by figs 13-18) directed to a device parenterally-procuring bodily-fluid samples from a patient.

-----Continued on Supplemental Page-----

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.:
1-18

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/US 13/71491

Continuation of Box III: Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

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:

SPECIAL TECHNICAL FEATURES

The invention of Group I includes the special technical feature is a housing having an inlet port configured to be fluidically coupled to the patient and an outlet port configured to be fluidically coupled to a sample reservoir, not required by the claims of Group II.

The invention of Group II includes the special technical feature of a housing including a proximal end portion being substantially open and configured to receive a sample reservoir;
and a needle disposed in the inner volume and having a lumen configured for insertion into the sample reservoir; and a flow control mechanism disposed in the inner volume and fluidically coupled to the needle, the flow control mechanism including an inlet port, not required by the claims of Group I.

COMMON TECHNICAL FEATURES

Groups I-II share the common technical features of a housing; and a flow control mechanism disposed in the housing to selectively control fluid flow. However, this shared technical feature does not represent a contribution over prior art as being anticipated by US 5,097,842 A (BONN). Bonn discloses a housing (12, fig 1); and a flow control mechanism (14A, 14B, 30) disposed in the housing to selectively control fluid flow (fig 1, col 2, ln 24-30).

As the common technical features were known in the art at the time of the invention, these cannot be considered special technical feature that would otherwise unify the groups.

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