

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To: DAVID S. RESNICK NIXON PEABODY LLP 53 STATE STREET EXCHANGE PLACE BOSTON, MA 02109		DEC 13 2022	
Applicant's or agent's file reference 002806-190650WOPT		FOR FURTHER ACTION See paragraph 2 below	
International application No. PCT/US2022/042751	International filing date (day/month/year) 07 September 2022	Priority date (day/month/year) 08 September 2021	
International Patent Classification (IPC) or both national classification and IPC IPC(8) - INV. - A61B 10/02 (2022.01) ADD. - G01N 33/00 (2022.01) CPC - INV. - A61B 10/0045; A61B 10/0096; B01L 3/502 (2022.08) ADD. - B01L 2300/0861 (2022.08)			
Applicant PRESIDENT AND FELLOWS OF HARVARD COLLEGE			

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

Name and mailing address of the ISA/ Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, VA 22313-1450 Facsimile No. 571-273-8300	Date of completion of this opinion 09 November 2022	Authorized officer Taina Matos PCT Helpdesk: 571-272-4300 Telephone No. 571-272-4300
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Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:
 - ☒ the international application in the language in which it was filed.
 - ☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).
2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(b)).
3. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing:
 - a. ☐ forming part of the international application as filed.
 - b. ☐ furnished subsequent to the international filing date for the purposes of international search (Rule 13*ter*.1(a)),
☐ accompanied by a statement to the effect that the sequence listing does not go beyond the disclosure in the international application as filed.
4. ☐ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, this opinion has been established to the extent that a meaningful opinion could be formed without a WIPO Standard ST.26 compliant sequence listing.
5. Additional comments:

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 11-34

because:

☐ the said international application, or the said claims Nos. _____ relate to the following subject matter which does not require an international search (*specify*):

☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 11-34 are so unclear that no meaningful opinion could be formed (*specify*):

Claims 11-34 are improper multiple dependent claims not drafted in accordance with the second and third sentences of Rule 6.4(a).

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed (*specify*):

☒ no international search report has been established for said claims Nos. 11-34

☐ a meaningful opinion could not be formed without the sequence listing: the applicant did not, within the prescribed time limit:

☐ furnish a sequence listing complying with WIPO Standard ST.26, and such listing was not available to the International Searching Authority in the form, language and manner acceptable to it.

☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rule 13^{ter}.1(a).

☐ See Supplemental Box for further details.

**WRITTEN OPINION OF THE
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Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-10, 35-39	YES
	Claims	None	NO
Inventive step (IS)	Claims	5-8	YES
	Claims	1-4, 9, 10, 35-39	NO
Industrial applicability (IA)	Claims	1-10, 35-39	YES
	Claims	None	NO

2. Citations and explanations:

Claims 1-4, 9, 10, and 35-39 lack an inventive step under PCT Article 33(3) as being obvious over WO 2016/092333 to Bio Amd Holdings Limited (hereinafter, "Bio Amd") in view of US 2009/0308185 to Wu et al. (hereinafter, "Wu").

Regarding Claim 1, Bio Amd discloses a device for performing an assay (abstract), the device comprising: a housing (body 2, Fig. 1) having a first end (end of body 2 comprising opening 4, Fig. 1) and a second end (end of body 2 opposite opening 4, Fig. 1), the housing defining a first opening at the first end (opening 4, Fig. 1), a first chamber (first chamber 3, Fig. 1), and a second chamber (second chamber 5, Fig. 1), the first chamber being fluidly connected to (i) the second chamber (two chambers 3, 5 are connected by a conduit or capillary 7, Fig. 1), and (ii) an exterior of the housing via the first opening (chamber 3 is connected to the exterior of the exterior of body 2 via opening 4 through first conduit 11, Fig. 1); and a vent (openable vent 8, Fig. 1) configured to aid in controlling flow of a fluid from the first chamber of the housing to the second chamber of the housing (Para [0051]), but fails to explicitly disclose an elongated member configured to be received through the first opening such that the elongated member is least partially disposed within the first chamber.

However, Wu is in the field of specimen collection devices (abstract) and teaches an elongated member (plunger 9, Fig. 1) configured to be received through the first opening such that the elongated member is least partially disposed within the first chamber (plunger 149 that is movably received in the container 111, Fig. 2).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Bio Amd to include an elongated member configured to be received through the first opening such that the elongated member is least partially disposed within the first chamber as taught by Wu.

The motivation being to improve the efficiency of the sample collection for analysis from the patient.

Regarding Claim 2, modified Bio Amd discloses the device of claim 1, but fails to explicitly disclose an air pressure is generated in the first chamber and the second chamber in response to the elongated member being received through the first opening of the housing.

However, Wu is in the field of analyte detection devices (abstract) and teaches an air pressure is generated in the first chamber and the second chamber in response to the elongated member being received through the first opening of the housing (device has a movable member, which can create an air pressure vacuum in certain chambers of the device when it is moved from a first to a second position; movable member is a plunger 149, Para [0036], Fig. 1).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Bio Amd to include an air pressure is generated in the first chamber and the second chamber in response to the elongated member being received through the first opening of the housing as taught by Wu.

The motivation being to allow the air exchange between the connected chambers thereby causing the fluid to be drawn or expelled from one chamber to another (Para [0036], Wu).

Regarding Claim 3, modified Bio Amd discloses the device of claim 2, wherein in response to the vent being activated, the air pressure generated in the first chamber and the second chamber is released, to thereby cause the fluid to flow from the first chamber to the second chamber (an open position, in which the valve member 14 is raised to provide an open passage through which air can escape from the second chamber 5 and thereby encourage capillary motion of the sample along the flow path from the first chamber 3 to the second chamber 5, Para [0043], Fig. 2).

Regarding Claim 4, modified Bio Amd discloses the device of claim 3, in combination with a base station (actuator 12, Fig. 1), the base station being configured to activate the vent to release the generated air pressure in the first chamber and the second chamber (actuator 12 is operable to move between a closed position such that the vent is closed and air cannot escape through the vent, and an open position, in which the valve member 14 is raised to provide an open passage through which air can escape, Para [0043]).

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

Regarding Claim 9, modified Bio Amd discloses the device of any one of claims 2 to 8, but fails to explicitly disclose the elongated member includes one or more sealing members configured to contact an interior of the housing in response to the elongated member being received by the housing.

However, Wu is in the field of specimen collection devices (abstract) and teaches the elongated member includes one or more sealing members configured to contact an interior of the housing in response to the elongated member being received by the housing (first sealing ring 143 retained around the push bar 147 and a second sealing ring 145 retained around the plunger body 149, Para [0042], Fig. 2).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Bio Amd to include the elongated member includes one or more sealing members configured to contact an interior of the housing in response to the elongated member being received by the housing as taught by Wu.

The motivation being to provide leak-proof connection thereby preventing back flow of the sample fluid.

Regarding Claim 10, modified Bio Amd discloses the device of claim 9, but fails to explicitly disclose the air pressure generated in the first chamber and the second chamber is generated between the one or more sealing members of the elongated member, and the vent.

However, Wu is in the field of specimen collection devices (abstract) and teaches the air pressure generated in the first chamber and the second chamber is generated (Para [0043]) between the one or more sealing members of the elongated member (plunger 311, sealing ring 143, Figs. 5-7), and the vent (vent 165, Figs. 5-7).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Bio Amd to include the air pressure generated in the first chamber and the second chamber is generated between the one or more sealing members of the elongated member, and the vent as taught by Wu.

The motivation being to enable air escape to cause the fluid flow and preventing back flow of the sample fluid.

Regarding Claim 35, Bio Amd discloses a device for performing an assay (abstract), the device comprising: a housing (body 2, Fig. 1) having a first end (end of body 2 comprising opening 4, Fig. 1) and a second end (end of body 2 opposite opening 4, Fig. 1), the housing defining a first opening at the first end (opening 4, Fig. 1), a first chamber (first chamber 3, Fig. 1), and a second chamber (second chamber 5, Fig. 1), the first chamber being fluidly connected to (i) the second chamber (two chambers 3, 5 are connected by a conduit or capillary 7, Fig. 1), and (ii) an exterior of the housing via the first opening (chamber 3 is connected to the exterior of the exterior of body 2 via opening 4 through first conduit 11, Fig. 1); and a vent (openable vent 8, Fig. 1) configured to aid in controlling flow of a fluid from the first chamber of the housing to the second chamber of the housing (Para [0051]), the vent being configured to be activated to release the air pressure generated in the first chamber and the second chamber, to thereby cause the fluid to flow from the first chamber to the second chamber (an open position, in which the valve member 14 is raised to provide an open passage through which air can escape from the second chamber 5 and thereby encourage capillary motion of the sample along the flow path from the first chamber 3 to the second chamber 5, Para [0043], Fig. 2), but fails to explicitly disclose an elongated member configured to be received through the first opening such that the elongated member is least partially disposed within the first chamber, the elongated member aiding in generating an air pressure in the first chamber and the second chamber.

However, Wu is in the field of analyte detection devices (abstract) and teaches an elongated member configured to be received through the first opening such that the elongated member is least partially disposed within the first chamber (plunger 149 that is movably received in the container 111, Fig. 2), the elongated member aiding in generating an air pressure in the first chamber and the second chamber (device has a movable member, which can create an air pressure vacuum in certain chambers of the device when it is moved from a first to a second position, movable member is a plunger 149, Para [0036], Fig. 1).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Bio Amd to include an elongated member configured to be received through the first opening such that the elongated member is least partially disposed within the first chamber, the elongated member aiding in generating an air pressure in the first chamber and the second chamber as taught by Wu.

The motivation being to allow the air exchange between the connected chambers thereby causing the fluid to be drawn or expelled from one chamber to another (Para [0036], Wu).

Regarding Claim 36, Bio Amd discloses a system for performing an assay (abstract), the system comprising: a device including: a housing (body 2, Fig. 1) having a first end (end of body 2 comprising opening 4, Fig. 1) and a second end (end of body 2 opposite opening 4, Fig. 1), the housing defining a first opening at the first end (opening 4, Fig. 1), a first chamber (first chamber 3, Fig. 1), and a second chamber (second chamber 5, Fig. 1), the first chamber being fluidly connected to (i) the second chamber (two chambers 3, 5 are connected by a conduit or capillary 7, Fig. 1), and (ii) an exterior of the housing via the first opening (chamber 3 is connected to the exterior of the exterior of body 2 via opening 4 through first conduit 11, Fig. 1); and a vent (openable vent 8, Fig. 1) configured to aid in controlling flow of a fluid from the first chamber of the housing to the second chamber of the housing (Para [0051]); and a base station configured to receive the housing of the device therein (actuator 12, Fig. 1), the base station being further configured to activate the vent to cause the fluid to flow from the first chamber to the second chamber (actuator 12 is operable to move between a closed position such that the vent is closed and air cannot escape through the vent, and an open position, in which the valve member 14 is raised to provide an open passage through which air can escape, Para [0043]), but fails to explicitly disclose an elongated member configured to be received through the first opening such that the elongated member is least partially disposed within the first chamber.

However, Wu is in the field of specimen collection devices (abstract) and teaches an elongated member configured to be received through the first opening such that the elongated member is least partially disposed within the first chamber (plunger 149 that is movably received in the container 111, Fig. 2).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Bio Amd to include an elongated member configured to be received through the first opening such that the elongated member is least partially disposed within the first chamber as taught by Wu.

The motivation being to improve the efficiency of the sample collection for analysis from the patient.

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

Regarding Claim 37, modified Bio Amd discloses the system of claim 36, but fails to explicitly disclose an air pressure is generated in the first chamber and the second chamber in response to the elongated member being received through the first opening of the housing. However, Wu is in the field of analyte detection devices (abstract) and teaches an air pressure is generated in the first chamber and the second chamber in response to the elongated member being received through the first opening of the housing (device has a movable member, which can create an air pressure vacuum in certain chambers of the device when it is moved from a first to a second position; movable member is a plunger 149, Para [0036], Fig. 1).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Bio Amd to include an air pressure is generated in the first chamber and the second chamber in response to the elongated member being received through the first opening of the housing.

The motivation being to allow the air exchange between the connected chambers thereby causing the fluid to be drawn or expelled from one chamber to another (Para [0036], Wu).

Regarding Claim 38, modified Bio Amd discloses the system of claim 37, wherein in response to the vent being activated by the base station, the air pressure generated in the first chamber and the second chamber is released, to thereby cause the fluid to flow from the first chamber to the second chamber (an open position, in which the valve member 14 is raised to provide an open passage through which air can escape from the second chamber 5 and thereby encourage capillary motion of the sample along the flow path from the first chamber 3 to the second chamber 5, Para [0043], Fig. 2).

Regarding Claim 39, Bio Amd discloses a system for performing an assay (abstract), the system comprising: a device (strip 1, Fig. 1) including: a housing (body 2, Fig. 1) having a first end (end of body 2 comprising opening 4, Fig. 1) and a second end (end of body 2 opposite opening 4, Fig. 1), the housing defining a first opening at the first end (opening 4, Fig. 1), a first chamber (first chamber 3, Fig. 1), and a second chamber (second chamber 5, Fig. 1), the first chamber being fluidly connected to (i) the second chamber (two chambers 3, 5 are connected by a conduit or capillary 7, Fig. 1), and (ii) an exterior of the housing via the first opening (chamber 3 is connected to the exterior of the exterior of body 2 via opening 4 through first conduit 11, Fig. 1); and a vent (openable vent 8, Fig. 1) configured to aid in controlling flow of a fluid from the first chamber of the housing to the second chamber of the housing (Para [0051]), the vent being configured to be activated to release the air pressure generated in the first chamber and the second chamber, to thereby cause the fluid to flow from the first chamber to the second chamber (an open position, in which the valve member 14 is raised to provide an open passage through which air can escape from the second chamber 5 and thereby encourage capillary motion of the sample along the flow path from the first chamber 3 to the second chamber 5, Para [0043], Fig. 2); and a base station (actuator 12, Fig. 1) configured to receive the housing of the device therein, the base station being further configured to activate the vent to cause the fluid to flow from the first chamber to the second chamber (actuator 12 is operable to move between a closed position such that the vent is closed and air cannot escape through the vent, and an open position, in which the valve member 14 is raised to provide an open passage through which air can escape, Para [0043]), but fails to explicitly disclose an elongated member configured to be received through the first opening such that the elongated member is least partially disposed within the first chamber, the elongated member aiding in generating an air pressure in the first chamber and the second chamber.

However, Wu is in the field of specimen collection devices (abstract) and teaches an elongated member (plunger 9, Fig. 1) configured to be received through the first opening such that the elongated member is least partially disposed within the first chamber (plunger 149 that is movably received in the container 111, Fig. 2), the elongated member aiding in generating an air pressure in the first chamber and the second chamber (device has a movable member, which can create an air pressure vacuum in certain chambers of the device when it is moved from a first to a second position; movable member is a plunger 149, Para [0036], Fig. 1).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Bio Amd to include an elongated member configured to be received through the first opening such that the elongated member is least partially disposed within the first chamber, the elongated member aiding in generating an air pressure in the first chamber and the second chamber as taught by Wu.

The motivation being to allow the air exchange between the connected chambers thereby causing the fluid to be drawn or expelled from one chamber to another (Para [0036], Wu).

Claims 5-8 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest:

Regarding claim 5, the prior art of record, individually or in combination, does not teach or fairly suggest the device of claim 4, wherein the vent includes a second opening defined by the housing at the second end thereof, the second chamber being fluidly connected to the exterior of the housing via the second opening.

The following prior art is made of record to support and further define the reasons that claim 5 meets the criteria set out in PCT Article 33(2)-(3).

Modified Bio Amd discloses the device of claim 4, and Bio Amd further discloses wherein the vent includes a second opening defined by the housing at the second end thereof (openable and closable air holes 17, Fig. 2), but fails to explicitly disclose the second chamber being fluidly connected to the exterior of the housing via the second opening.

Claims 6-8 depend from claim 5, and therefore meet the criteria set out in PCT Article 33(2)-(3) for at least the same reasons as claim 5.

Claims 1-10 and 35-39 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.