PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

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PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	18 FEB 2020

Applicant's or agent's file reference	FOR FURTHER ACTION
H-IK-00015-WO	See paragraph 2 below

International application No.	International filing date *(day month year)*	Priority date *(day/month/year)*
PCT/US19/64278	03 December 2019 (03.12.2019)	03 December 2018 (03.12.2018)

International Patent Classification (IPC) or both national classification and IPC

IPC - A61M 16/10, 16/12; G01N 1/22 (2020.01)

CPC - A61M 16/10, 16/12; G01N 1/22

Applicant

MALLINCKRODT HOSPITAL PRODUCTS IP LIMITED

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 43*bis*.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 66.1*bis*(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/US	Date of completion of this opinion	Authorized officer
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	23 January 2020 (23.01.2020)	Shane Thomas PCT Help Desk 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:

☐ in the form of an Annex C/ST.25 text file.

☐ on paper or in the form of an image file.

b. ☐ furnished together with the international application under PCT Rule 13*ter*.1(a) for the purposes of international search only in the form of an Annex C/ST.25 text file.

c. ☐ furnished subsequent to the international filing date for the purposes of international search only:

☐ in the form of an Annex C/ST.25 text file (Rule 13*ter*.1(a)).

☐ on paper or in the form of an image file (Rule 13*ter*.1(b) and Administrative Instructions, Section 713).

4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that forming part of the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

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

1. Statement

Novelty (N)	Claims	***PLEASE SEE BELOW****	YES
	Claims	***PLEASE SEE BELOW****	NO
Inventive step (IS)	Claims	***PLEASE SEE BELOW****	YES
	Claims	***PLEASE SEE BELOW****	NO
Industrial applicability (IA)	Claims	***PLEASE SEE BELOW****	YES
	Claims	NONE	NO

2. Citations and explanations:

Novelty YES 2-3, 6, 8, 11, 14-15, 16/2-3, 16/6, 16/8, 16/11, 16/14-15, 17/16/2-3, 17/16/6, 17/16/8, 17/16/11, 17/16/14-15, 18/16/2-3, 18/16/6, 18/16/8, 18/16/11, 18/16/14-15, 19/16/2-3, 19/16/6, 19/16/8, 19/16/11, 19/16/14-15, 20/1-15, 21/20/1-15, 22/20/1-15, 23/20/1-15, 24/20/1-15
Novelty NO 1, 4-5, 7, 9-10, 12-13, 16/1, 16/4-5, 16/7, 16/9-10, 16/12-13, 17/16/1, 17/16/4-5, 17/16/7, 17/16/9-10, 17/16/12-13, 18/16/1, 18/16/4-5, 18/16/7, 18/16/9-10, 18/16/12-13

Inventive Step YES 20/1-15, 21/20/1-15, 22/20/1-15, 23/20/1-15, 24/20/1-15

Inventive Step NO 1-15, 16/1-15, 17/16/1-15, 18/16/1-15. 19/16/1-15

Industrial applicability YES 1-15, 16/1-15, 17/16/1-15, 18/16/1-15. 19/16/1-15, 20/1-15, 21/20/1-15, 22/20/1-15, 23/20/1-15, 24/20/1-15

Claims 1, 4-5, 7, 9-10, 12-13, 16/1, 16/4-5, 16/7, 16/9-10, 16/12-13, 17/16/1, 17/16/4-5, 17/16/7, 17/16/9-10, 17/16/12-13, 18/16/1, 18/16/4-5, 18/16/7, 18/16/9-10, and 18/16/12-13 lack novelty under PCT Article 33(2) as being anticipated by WO 2016/207838 A1 to Fisher and Paykel Healthcare Limited (hereafter 'Fisher').

As per claim 1, Fisher discloses a removable gas sensor module for a therapeutic gas delivery device (sensor subassembly (module) of a therapy device; abstract; paragraphs [00185], [00397]; figure 19), the gas sensor module comprising: a sample chamber operable to receive a sample gas from the therapeutic gas delivery device (sensor module subassembly 400 has a cover layer 440 and body 442 that align portions 426 and 446 to confine an elongate gas flow portion 448 and 428 (chamber); paragraphs [00397], [00403]; figures 20-21, 22d); and a gas detection unit comprising a plurality of sensors operable to measure at least one property of the sample gas, wherein the plurality of sensors include two or more of a gas detection sensor, a humidity sensor, a temperature sensor, or a combination thereof (the bottom of cover layer 440 comprises a sensing printed circuit board (PCB) 456, temperature sensors, pressure sensors, humidity sensors, and flow rate sensors; paragraph [00407]; figure 21), wherein the gas sensor module is self-contained within the therapeutic gas delivery device and swappable with another gas sensor module (the sensor module is removable and replaceable; paragraph [00413]).

As per claim 4, Fisher discloses the gas sensor module of claim 1, and Fisher further discloses wherein the gas detection sensor is one or more of an NO sensor, an NO2 sensor, an O2 sensor, or combinations thereof (the high flow therapy device delivers oxygen mixed with other gases such as nitric oxide, which are sensed by sensors; paragraphs [00363], [00408]).

As per claim 5, Fisher discloses the gas sensor module of claim 1, and Fisher further discloses wherein the gas detection unit comprises at least two gas detection sensors (the bottom of cover layer 440 comprises a sensing printed circuit board (PCB) 456, temperature sensors, pressure sensors, humidity sensors, and gas flow rate sensors; paragraph [00407]; figure 21).

As per claim 7, Fisher discloses the gas sensor module of claim 1, and Fisher further discloses wherein the gas detection unit comprises two or more different sensors (the bottom of cover layer 440 comprises a sensing printed circuit board (PCB) 456, temperature sensors, pressure sensors, humidity sensors, and flow rate sensors; paragraph [00407]; figure 21).

As per claim 9, Fisher discloses the gas sensor module of claim 1, and Fisher further discloses wherein the at least one property of the sample gas is one or more of a concentration of NO, a concentration of NO2, a concentration of O2, humidity, temperature, or a combination thereof (the bottom of cover layer 440 comprises a sensing printed circuit board (PCB) 456, temperature sensors, humidity sensors, and flow rate sensors; paragraph [00407]; figure 21).

-***-Continued Within the Next Supplemental Box-***-

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Box No. VI Certain documents cited

1. Certain published documents (Rules 43*bis*.1 and 70.10)

Application No. Patent No.	Publication date *(day/month/year)*	Filing date *(day/month/year)*	Priority date (valid claim) *(day/month/year)*
WO 2019/070136 A1	11/04/2019	05/10/2018	06/10/2017

2. Non-written disclosures (Rules 43*bis*.1 and 70.9)

Kind of non-written disclosure	Date of non-written disclosure *(day/month/year)*	Date of written disclosure referring to non-written disclosure *(day/month/year)*

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Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claims 19/16/-15 are objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because the claims are indefinite for the following reason: claims 19/16/-15 include a registered trademark "Nafion" which is indefinite because trademarked goods can change formulation over time while maintaining the same trademark. For purposes of this examination, all instances of the registered trademark Nafion as claim elements are assumed to read as "sulfonated tetrafluoroethylene based fluoropolymer-copolymer".

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-***-Continued from Box V: Citations and Explanations-***-

As per claim 10, Fisher discloses the gas sensor module of claim 1, and Fisher further discloses further comprising a sensing circuit operable to detect and report the at least one property of the sample gas to a gas analyzer controller in the therapeutic gas delivery device (apparatus 10 with transmitter and/or receiver 15 to enable the controller 13 to receive 8 signals from the sensors and to control the various components of the flow therapy apparatus 10 (circuit), including but not limited to the flow generator 11, humidifier 12, and heater wire 16a, or accessories or peripherals associated with the flow therapy apparatus 10 as well as deliver data (report); paragraph [00362]).

As per claim 12, Fisher discloses the gas sensor module of claim 1, and Fisher further discloses wherein the sample chamber comprises an inner housing (sensing layer 420 and cover layer 440 assemble to produce the sensing chamber in a sub-assembly housing; paragraph [00398]; figure 20) and an outer housing (sub-assembly housing fits inside recess 250 of lower chassis 202 (outer housing); paragraph [00376]; figures 17a-17b).

As per claim 13, Fisher discloses the gas sensor module of claim 1, and Fisher further discloses wherein the gas detection unit is operable to electronically store or send to the therapeutic gas delivery device serial numbers, calibration data, and/or usage information of the gas sensor module (electronics boards 272 will be in electrical communication or coupled with the sensors to process information received from the sensors and operate the apparatus 10 based on the information received from the sensors, such as gas temperature, oxygen concentration, gas flow rate (usage information); paragraphs [00408], [00478]).

As per claims 16/1, 16/4-5, 16/7, 16/9-10, 16/12-13, Fisher discloses a gas sensor assembly comprising: the gas sensor module of any one of claims 1, 4-5, 7, 9-10, 12-13 (sensor subassembly (module) of a therapy device; abstract; paragraphs [00185], [00397]; figure 19); and Fisher further discloses an assembly inner housing (sub-assembly housing fits inside recess 250 of lower chassis 202 (assembly inner housing); paragraph [00376]; figures 17a-17b) operable to removably receive the gas sensor module (the sensor module is removable and replaceable; paragraph [00413]); and a gas analyzer unit (removable motor and sensor module coupled to controller 13 to receive 8 signals from the sensors; paragraphs [00362], [00397]) comprising: a sample tube fluidly connected to the gas delivery device and the gas sensor module operable to receive the sample gas (a coupling tube could be used to couple the gases outlet 406 with that gases inlet; paragraph [00402]; figure 20); and a pump connected to the gas sensor module through the sample tube, wherein the pump is operable to pump the sample gas through the gas sensor module (motor 402 is a gas blower to pump gas through flow path shown through outlet 406 to sensing layer 420; paragraphs [00400], [00402]; figure 20).

As per claims 17/16/1, 17/16/4-5, 17/16/7, 17/16/9-10, 17/16/12-13, Fisher discloses the gas sensor assembly of claims 16/1, 16/4-5, 16/7, 16/9-10, 16/12-13, and Fisher further discloses wherein the gas analyzer unit further comprises a gas analyzer controller (apparatus 10 with transmitter and/or receiver 15 to enable the controller 13 to receive 8 signals from the sensors and to control the various components of the flow therapy apparatus 10 (circuit), including but not limited to the flow generator 11, humidifier 12, and heater wire 16a, or accessories or peripherals associated with the flow therapy apparatus 10 as well as deliver data (report); paragraph [00362]).

As per claims 18/16/1, 18/16/4-5, 18/16/7, 18/16/9-10, 18/16/12-13, Fisher discloses the gas sensor assembly of claims 16/1, 16/4-5, 16/7, 16/9-10, 16/12-13, and Fisher further discloses wherein the gas analyzer unit further comprises an assembly main housing operable to receive the assembly inner housing (sub-assembly housing fits inside recess 250 of lower chassis 202 (outer housing); paragraph [00376]; figures 17a-17b), wherein the assembly main housing is within the therapeutic gas delivery device (flow therapy apparatus 10 comprises a main housing 100 with upper chassis 102 and a main housing lower chassis 202; paragraph [00367]).

Claims 2-3, 11, 16/2-3, 16/11, 17/16/2-3, 17/16/11, 18/16/2-3, 18/16/11 lack an inventive step under PCT Article 33(3) as being obvious over Fisher in view of US 2015/0351690 A1 to Tricord Holdings, L.L.C. (hereafter 'Tricord').

As per claim 2, Fisher discloses the gas sensor module of claim 1, and Fisher discloses replacement of the gas sensor module (the sensor module is removable and replaceable; paragraph [00413]), but Fisher does not disclose wherein replacement results in less than 5 minutes of down time of the measurement of at least one property of the sample. Tricord discloses a wherein replacement results in less than 5 minutes of down time of the measurement of at least one property of the sample (sensor modules, including humidity and temperature sensors, are hot swappable to maintain a continuous operation (no down time); paragraphs [0042], [0047]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the module of Fisher to provide wherein replacement results in less than 5 minutes of down time of the measurement of at least one property of the sample, as taught by Tricord, in order to provide continuous operation.

As per claim 3, Fisher discloses the gas sensor module of claim 1, and Fisher discloses replacement of the gas sensor module (the sensor module is removable and replaceable; paragraph [00413]) and delivery of therapeutic gas from the therapeutic gas delivery device (delivering a flow of therapy gas to a patient; paragraphs [0006], [00359]-[0360]), but Fisher does not disclose wherein replacement of the sensor module results in no down time of the device. Tricord discloses wherein replacement of the sensor module results in no down time of the device (sensor modules, including humidity and temperature sensors, are hot swappable to maintain a continuous operation (no down time); paragraphs [0042], [0047]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the module of Fisher to provide wherein replacement of the sensor module results in no down time of the device, as taught by Tricord, in order to provide continuous operation.

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Supplemental Box

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As per claim 11, Fisher discloses the gas sensor module of claim 1, and Fisher does not disclose wherein the therapeutic gas delivery device is continuously operable when the gas sensor module is replaced. Tricord discloses wherein a therapeutic gas delivery device is continuously operable when the gas sensor module is replaced (sensor modules, including humidity and temperature sensors, are hot swappable to maintain a continuous operation; paragraphs [0042], [0047]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the module of Fisher to provide wherein the therapeutic gas delivery device is continuously operable when the gas sensor module is replaced, as taught by Tricord, in order to provide continuous operation.

As per claims 16/2-3, 16/11, Fisher and Tricord, in combination, disclose a gas sensor assembly comprising: the gas sensor module of any one of claims 2-3, 11 (sensor subassembly (module) of a therapy device; abstract; paragraphs [00185], [00397]; figure 19); and Fisher further discloses an assembly inner housing (sub-assembly housing fits inside recess 250 of lower chassis 202 (assembly inner housing); paragraph [00376]; figures 17a-17b) operable to removably receive the gas sensor module (the sensor module is removable and replaceable; paragraph [00413]); and a gas analyzer unit (removable motor and sensor module coupled to controller 13 to receive 8 signals from the sensors; paragraphs [00362], [00397]) comprising: a sample tube fluidly connected to the gas delivery device and the gas sensor module operable to receive the sample gas (a coupling tube could be used to couple the gases outlet 406 with that gases inlet; paragraph [00402]; figure 20); and a pump connected to the gas sensor module through the sample tube, wherein the pump is operable to pump the sample gas through the gas sensor module (motor 402 is a gas blower to pump gas through flow path shown through outlet 406 to sensing layer 420; paragraphs [00400], [00402]; figure 20).

As per claims 17/16/2-3, 17/16/11, Fisher and Tricord, in combination, disclose the gas sensor assembly of claims 16/2-3, 16/11, and Fisher further discloses wherein the gas analyzer unit further comprises a gas analyzer controller (apparatus 10 with transmitter and/or receiver 15 to enable the controller 13 to receive 8 signals from the sensors and to control the various components of the flow therapy apparatus 10 (circuit), including but not limited to the flow generator 11, humidifier 12, and heater wire 16a, or accessories or peripherals associated with the flow therapy apparatus 10 as well as deliver data (report); paragraph [00362]).

As per claims 18/16/2-3, 18/16/11, Fisher and Tricord, in combination, disclose the gas sensor assembly of claims 16/2-3, 16/11, and Fisher further discloses wherein the gas analyzer unit further comprises an assembly main housing operable to receive the assembly inner housing (sub-assembly housing fits inside recess 250 of lower chassis 202 (outer housing); paragraph [00376]; figures 17a-17b), wherein the assembly main housing is within the therapeutic gas delivery device (flow therapy apparatus 10 comprises a main housing 100 with upper chassis 102 and a main housing lower chassis 202; paragraph [00367]).

Claims 6, 8, 16/6, 16/8, 17/16/6, 17/16/8, 18/16/6, 18/16/8 lack an inventive step under PCT Article 33(3) as being obvious over Fisher in view of US 2015/0273176 A1 to INO Therapeutics LLC (hereafter 'INO').

As per claim 6, Fisher discloses the gas sensor module of claim 4, and Fisher further discloses wherein the gas detection sensor is one or more of an NO sensor (the high flow therapy device delivers oxygen mixed with other gases such as nitric oxide, which are sensed by sensors; paragraphs [00363], [00408]); but Fisher does not disclose wherein the gas detection unit comprises an NO sensor and an NO2 sensor. INO discloses gas detection unit comprises an NO sensor and an NO2 sensor (sampling system for determining the concentration of target gas including NO, nitrogen dioxide, and oxygen using numerous sensors; paragraphs [0066]-[0067]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the module of Fisher to provide wherein the gas detection unit comprises an NO sensor and an NO2 sensor, as taught by INO, in order to provide an accurate measure of therapeutic gas to a patient (INO: paragraph [0068]).

As per claim 8, Fisher and INO, in combination, disclose the gas sensor module of claim 6, and Fisher further discloses wherein the gas detection unit comprises one or more gas detection sensors and a humidity sensor (the bottom of cover layer 440 comprises a sensing printed circuit board (PCB) 456, temperature sensors, pressure sensors (gas detection), humidity sensors, and flow rate sensors; paragraph [00407]; figure 21).

As per claims 16/6, 16/8, Fisher and INO, in combination, disclose a gas sensor assembly comprising: the gas sensor module of any one of claims 6 and 8 (sensor subassembly (module) of a therapy device; abstract; paragraphs [00185], [00397]; figure 19); and Fisher further discloses an assembly inner housing (sub-assembly housing fits inside recess 250 of lower chassis 202 (assembly inner housing); paragraph [00376]; figures 17a-17b) operable to removably receive the gas sensor module (the sensor module is removable and replaceable; paragraph [00413]); and a gas analyzer unit (removable motor and sensor module coupled to controller 13 to receive 8 signals from the sensors; paragraphs [00362], [00397]) comprising: a sample tube fluidly connected to the gas delivery device and the gas sensor module operable to receive the sample gas (a coupling tube could be used to couple the gases outlet 406 with that gases inlet; paragraph [00402]; figure 20); and a pump connected to the gas sensor module through the sample tube, wherein the pump is operable to pump the sample gas through the gas sensor module (motor 402 is a gas blower to pump gas through flow path shown through outlet 406 to sensing layer 420; paragraphs [00400], [00402]; figure 20).

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As per claims 17/16/6, 17/16/8, Fisher and INO, in combination, disclose the gas sensor assembly of claims 16/6, 16/8, and Fisher further discloses wherein the gas analyzer unit further comprises a gas analyzer controller (apparatus 10 with transmitter and/or receiver 15 to enable the controller 13 to receive 8 signals from the sensors and to control the various components of the flow therapy apparatus 10 (circuit), including but not limited to the flow generator 11, humidifier 12, and heater wire 16a, or accessories or peripherals associated with the flow therapy apparatus 10 as well as deliver data (report); paragraph [00362]).

As per claims 18/16/6, 18/16/8, Fisher and INO, in combination, disclose the gas sensor assembly of claims 16/6, 16/8, and Fisher further discloses wherein the gas analyzer unit further comprises an assembly main housing operable to receive the assembly inner housing (sub-assembly housing fits inside recess 250 of lower chassis 202 (outer housing); paragraph [00376]; figures 17a-17b), wherein the assembly main housing is within the therapeutic gas delivery device (flow therapy apparatus 10 comprises a main housing 100 with upper chassis 102 and a main housing lower chassis 202; paragraph [00367]).

Claims 14-15, 16/14-15, 17/16/14-15. 18/16/14-15 lack an inventive step under PCT Article 33(3) as being obvious over Fisher in view of US 2017/0188908 A1 to Abbott Diabetes Care Inc. (hereafter 'Abbott').

As per claim 14, Fisher discloses the gas sensor module of claim 1, and Fisher further discloses the gas sensor module (the sensor module is removable and replaceable; paragraph [00413]), but Fisher does not disclose is wherein the sensor module is pre-calibrated and shelf stable for at least 1 month. Abbott discloses a sensor is pre-calibrated and shelf stable for at least 1 month (factory calibrated sensors with a shelf-life of 6 to 18 months; paragraphs [0060], [0154]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the sensor module of Fisher to provide wherein the sensor module is pre-calibrated and shelf stable for at least 1 month, as taught by Abbott, in order to provide a sensor that doesn't require any reference analyte tests (Abbott: paragraph [0060]).

As per claim 15, Fisher discloses the gas sensor module of claim 13, and Fisher further discloses the gas sensor module (the sensor module is removable and replaceable; paragraph [00413]), but Fisher does not disclose is wherein the sensor module is shelf stable for at least 3 months. Abbott discloses a sensor module is shelf stable for at least 3 months (factory calibrated sensors with a shelf-life of 6 to 18 months; paragraphs [0060], [0154]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the sensor module of Fisher to provide wherein the sensor module is shelf stable for at least 3 months, as taught by Abbott, in order to provide a sensor that is stable up to 18 months (Abbott: paragraph [0060]).

As per claims 16/14-15, Fisher and Abbott, in combination, disclose a gas sensor assembly comprising: the gas sensor module of any one of claims 6 and 8 (sensor subassembly (module) of a therapy device; abstract; paragraphs [00185], [00397]; figure 19); and Fisher further discloses an assembly inner housing (sub-assembly housing fits inside recess 250 of lower chassis 202 (assembly inner housing); paragraph [00376]; figures 17a-17b) operable to removably receive the gas sensor module (the sensor module is removable and replaceable; paragraph [00413]); and a gas analyzer unit (removable motor and sensor module coupled to controller 13 to receive 8 signals from the sensors; paragraphs [00362], [00397]) comprising: a sample tube fluidly connected to the gas delivery device and the gas sensor module operable to receive the sample gas (a coupling tube could be used to couple the gases outlet 406 with that gases inlet; paragraph [00402]; figure 20); and a pump connected to the gas sensor module through the sample tube, wherein the pump is operable to pump the sample gas through the gas sensor module (motor 402 is a gas blower to pump gas through flow path shown through outlet 406 to sensing layer 420; paragraphs [00400], [00402]; figure 20).

As per claims 17/16/14-15, Fisher and Abbott, in combination, disclose the gas sensor assembly of claims 16/14-15, and Fisher further discloses wherein the gas analyzer unit further comprises a gas analyzer controller (apparatus 10 with transmitter and/or receiver 15 to enable the controller 13 to receive 8 signals from the sensors and to control the various components of the flow therapy apparatus 10 (circuit), including but not limited to the flow generator 11, humidifier 12, and heater wire 16a, or accessories or peripherals associated with the flow therapy apparatus 10 as well as deliver data (report); paragraph [00362]).

As per claims 18/16/14-15, Fisher and Abbott, in combination, disclose the gas sensor assembly of claims 16/14-15, and Fisher further discloses wherein the gas analyzer unit further comprises an assembly main housing operable to receive the assembly inner housing (sub-assembly housing fits inside recess 250 of lower chassis 202 (outer housing); paragraph [00376]; figures 17a-17b), wherein the assembly main housing is within the therapeutic gas delivery device (flow therapy apparatus 10 comprises a main housing 100 with upper chassis 102 and a main housing lower chassis 202; paragraph [00367]).

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Claims 19/16/1, 19/16/4-5, 19/16/7, 19/16/9-10, 19/16/12-13 lack an inventive step under PCT Article 33(3) as being obvious over Fisher in view of WO 2018/157172 A1 to Third Pole, Inc. (hereafter 'Third').

As per claims 19/16/1, 19/16/4-5, 19/16/7, 19/16/9-10, 19/16/12-13, Fisher discloses the gas sensor assembly of claims 16/1, 16/4-5, 16/7, 16/9-10, 16/12-13, but Fisher does not disclose wherein at least a portion of the sample tube is a sulfonated tetrafluoroethylene based fluoropolymer-copolymer tube. Third discloses a sample tube is a sulfonated tetrafluoroethylene based fluoropolymer-copolymer tube (gas line handling the sample gases is be made from Nafion (sulfonated tetrafluoroethylene based fluoropolymer-copolymer) to prevent condensation of moisture and protect sensors from gas that is too dry; paragraph [00246]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the assembly of Fisher to provide wherein at least a portion of the sample tube is a sulfonated tetrafluoroethylene based fluoropolymer-copolymer tube, as taught by Third, in order to provide prevent condensation of moisture and protect sensors from gas that is too dry (Third: paragraph [00246]).

Claims 19/16/2-3, 19/16/11 lack an inventive step under PCT Article 33(3) as being obvious over Fisher, in view of Tricord, and in further view of Third.

As per claims 19/16/2-3, 19/16/11, Fisher and Tricord, in combination, disclose the gas sensor assembly of claims 16/2-3, 16/11, but Fisher does not disclose wherein at least a portion of the sample tube is a sulfonated tetrafluoroethylene based fluoropolymer-copolymer tube. Third discloses a sample tube is a sulfonated tetrafluoroethylene based fluoropolymer-copolymer tube (gas line handling the sample gases is be made from Nafion (sulfonated tetrafluoroethylene based fluoropolymer-copolymer) to prevent condensation of moisture and protect sensors from gas that is too dry; paragraph [00246]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the assembly of Fisher to provide wherein at least a portion of the sample tube is a sulfonated tetrafluoroethylene based fluoropolymer-copolymer tube, as taught by Third, in order to provide prevent condensation of moisture and protect sensors from gas that is too dry (Third: paragraph [00246]).

Claims 19/16/6, 19/16/8 lack an inventive step under PCT Article 33(3) as being obvious over Fisher, in view of INO, and in further view of Third.

As per claims 19/16/6, 19/16/8, Fisher and INO, in combination, disclose the gas sensor assembly of claims 16/6, 16/8, but Fisher does not disclose wherein at least a portion of the sample tube is a sulfonated tetrafluoroethylene based fluoropolymer-copolymer tube. Third discloses a sample tube is a sulfonated tetrafluoroethylene based fluoropolymer-copolymer tube (gas line handling the sample gases is be made from Nafion (sulfonated tetrafluoroethylene based fluoropolymer-copolymer) to prevent condensation of moisture and protect sensors from gas that is too dry; paragraph [00246]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the assembly of Fisher to provide wherein at least a portion of the sample tube is a sulfonated tetrafluoroethylene based fluoropolymer-copolymer tube, as taught by Third, in order to provide prevent condensation of moisture and protect sensors from gas that is too dry (Third: paragraph [00246]).

Claims 19/16/14-15 lack an inventive step under PCT Article 33(3) as being obvious over Fisher, in view of Abbott, and in further view of Third.

As per claims 19/16/1, 19/16/4-5, 19/16/7, 19/16/9-10, 19/16/12-13, Fisher and Abbott, in combination, disclose the gas sensor assembly of claims 16/14-15, but Fisher does not disclose wherein at least a portion of the sample tube is a sulfonated tetrafluoroethylene based fluoropolymer-copolymer tube. Third discloses a sample tube is a sulfonated tetrafluoroethylene based fluoropolymer-copolymer tube (gas line handling the sample gases is be made from Nafion (sulfonated tetrafluoroethylene based fluoropolymer-copolymer) to prevent condensation of moisture and protect sensors from gas that is too dry; paragraph [00246]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the assembly of Fisher to provide wherein at least a portion of the sample tube is a sulfonated tetrafluoroethylene based fluoropolymer-copolymer tube, as taught by Third, in order to provide prevent condensation of moisture and protect sensors from gas that is too dry (Third: paragraph [00246]).

Claims 20/1-15 meets the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest an apparatus comprising: a voltage source; and the gas sensor module of any one of claims 1-15, wherein the voltage source provides an electrical potential across the plurality of sensors in the gas detection unit to maintain calibration of the plurality of sensors when the gas sensor module is in a non-installed configuration.

Fisher discloses a gas sensor assembly comprising: the gas sensor module of any one of claims 1, 4-5, 7, 9-10, 12-13; however Fisher does not disclose a voltage source; and the gas sensor module of any one of claims 1-15, wherein the voltage source provides an electrical potential across the plurality of sensors in the gas detection unit to maintain calibration of the plurality of sensors when the gas sensor module is in a non-installed configuration.

-***-Continued Within the Next Supplemental Box-***-

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US19/64278

Supplemental Box

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

-***-Continued from Previous Supplemental Box-***-

Abbott discloses a sensor with maintained calibration (factory calibrated sensors with a shelf-life of 6 to 18 months; paragraphs [0060], [0154]). However, Abbott does not disclose a voltage source; and a gas sensor module, wherein the voltage source provides an electrical potential across the plurality of sensors in the gas detection unit to maintain calibration of the plurality of sensors when the gas sensor module is in a non-installed configuration.

User Manual for Analog Sensor Developer Kit by SPEC Sensors (hereafter 'SPEC') discloses voltage source for supplying power during storage and shipment of a gas sensor (coin cell power supplying power during storage and shipment; page 1; heading Please review contents of package to confirm that you have received everything); however, SPEC does not disclose a sensor module wherein the voltage source provides an electrical potential across the plurality of sensors in the gas detection unit to maintain calibration of the plurality of sensors when the gas sensor module is in a non-installed configuration.

The paper "Operating principle" by Figaro (hereafter 'Figaro') discloses storing gas sensors (When stored without powering in normal air for a long period, or in an environment contaminated with organic vapors or volatile oils, the sensor may show a reversible drift in resistance according to the environment; page 3, heading Storage conditions), however Figaro does not disclose a sensor module wherein the voltage source provides an electrical potential across the plurality of sensors in the gas detection unit to maintain calibration of the plurality of sensors when the gas sensor module is in a non-installed configuration.

Fisher, Abbott, SPEC, and Figaro, alone or in combination, do not provide any motivation for an apparatus comprising: a voltage source; and the gas sensor module of any one of claims 1-15, wherein the voltage source provides an electrical potential across the plurality of sensors in the gas detection unit to maintain calibration of the plurality of sensors when the gas sensor module is in a non-installed configuration.

Claims 21/20/1-15, 22/20/1-15, 23/20/1-15, 24/20/1-15 meet the criteria set out in PCT Article 33(2)-(3), because they depend from claims 20/1-15.

Claims 1-15, 16/1-15, 17/16/1-15, 18/16/1-15. 19/16/1-15, 20/1-15, 21/20/1-15, 22/20/1-15, 23/20/1-15, and 24/20/1-15 have industrial applicability as defined by PCT Article 33(4) because the subject matter can be made or used in industry.