

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P50520PC00-3712044-07639	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/US2023/060013	International filing date (<i>day/month/year</i>) 03.01.2023	Priority date (<i>day/month/year</i>) 31.12.2021
International Patent Classification (IPC) or national classification and IPC INV. A61M5/145		
Applicant Baxter International Inc.		
1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36. 2. This REPORT consists of a total of <u>7</u> sheets, including this cover sheet. 3. This report is also accompanied by ANNEXES, comprising: a. ☒ a total of <u>7</u> sheets, as follows: ☒ sheets of the description, claims and/or drawings which have been amended and/or sheets containing rectifications authorized by this Authority, unless those sheets were superseded or cancelled, and any accompanying letters (see Rules 46.5, 66.8, 70.16, 91.2, and Section 607 of the Administrative Instructions). ☐ sheets containing rectifications, where the decision was made by this Authority not to take them into account because they were not authorized by or notified to this Authority at the time when this Authority began to draw up this report, and any accompanying letters (Rules 66.4bis, 70.2(e), 70.16 and 91.2). ☐ superseded sheets and any accompanying letters, where this Authority either considers that the superseding sheets contain an amendment that goes beyond the disclosure in the international application as filed, or the superseding sheets were not accompanied by a letter indicating the basis for the amendments in the application as filed, as indicated in item 4 of Box No. I and the Supplemental Box (see Rule 70.16(b)). b. ☐ a separate electronic file containing a sequence listing (<i>sent to the International Bureau only</i>)		
4. This report contains indications relating to the following items: ☒ Box No. I Basis of the report ☐ 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 Article 35(2) with regard to novelty, inventive step or 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		
Date of submission of the demand 17.10.2023	Date of completion of this report 18.03.2024	
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Fax: +49 89 2399 - 4465	Authorized officer Benes, Václav Telephone No. +49 89 2399-1159 	

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/US2023/060013

Box No. I Basis of the report

1. With regard to the **language**, this report is based on
- ☒ 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 (under Rules 12.3(a) and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4(a))
 - ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a) and (b))
2. With regard to the **elements*** of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

Description, Pages

1-16 as originally filed

Claims, Numbers

1, 3-11, 13-20 filed with the letter of 17-10-2023

Drawings, Sheets

1/14-14/14 as originally filed

- ☐ a sequence listing - see Supplemental Box Relating to Sequence Listing.
3. ☒ The amendments have resulted in the cancellation of:
- ☐ the description, pages
 - ☒ the claims, Nos. 2, 12
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since either they are considered to go beyond the disclosure as filed, or they were not accompanied by a letter indicating the basis for the amendments in the application as filed, as indicated in the Supplemental Box (Rules 70.2(c) and (c-bis)):
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
5. ☐ This report has been established:
- ☐ taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rules 66.1(d-bis) and 70.2(e)).
 - ☐ without taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91(Rules 66.4bis and 70.2(e)).

**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/US2023/060013

6. ☒ With regard to top-up searches (Rules 66.1 *ter* and 70.2(f)):
- ☒ A top-up search was carried out by this Authority on 16.11.2023 (all discovered documents are listed in the Supplemental Box Relating to Top-up Search).
 - ☐ Additional relevant documents have been discovered during the top-up search.
 - ☐ No top-up search was carried out by this Authority because it would serve no useful purpose.
7. ☐ Supplementary international search report(s) from Authority(ies) has/have been received and taken into account in establishing this report (Rule 45bis.8(b) and (c)).

* If item 4 applies, some or all of those sheets may be marked "superseded".

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	<u>1, 3-11, 13-20</u>
	No: Claims	
Inventive step (IS)	Yes: Claims	
	No: Claims	<u>1, 3-11, 13-20</u>
Industrial applicability (IA)	Yes: Claims	<u>1, 3-11, 13-20</u>
	No: Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

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:

see separate sheet

Re Item VIII

Certain observations on the international application

- 1 The application does not meet the requirements of Article 6 PCT, because claims 2-18 (respectively 2-20) are not clear.
 - 1.1 According to Rule 6.1(b) PCT claims should be numbered consecutively, which is not the case of the current application due to deletion of claims 2 and 12.
 - 1.2 The claims should have been re-numbered such as claim 3 should have become claim 2, etc.
 - 1.3 **For the sake of good orientation in the application as currently filed, the claims are referred to by their actual number in the communication dated 17-10-2023.**
- 2 The application does not meet the requirements of Article 6 PCT, because claim 1 is not clear.
 - 2.1 The wording of claim 1 mentions feature of a "swivel door assembly", without any further definition of this feature. The term swivel door assembly is generic, and it is not clear what functioning this feature has. According to the description in par.[0053] - the swivel door assembly comprises multiple features and serves for covering of the plunger lever and therefore preventing access to the plunger lever.

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

- 3 Reference is made to the following documents:
 - D1 US 2017/258985 A1 (ADAMS GRANT A [US] ET AL) 14 September 2017 (2017-09-14)
 - D2 US 2017/072133 A1 (GILLESPIE JOHN [US] ET AL) 16 March 2017 (2017-03-16)
 - D3 WO 2021/056265 A1 (SHENZHEN MINDRAY SCIENT CO LTD [CN]) 1 April 2021 (2021-04-01)

D4 US 2020/268963 A1 (DUPREZ REMI [FR] ET AL) 27 August 2020
(2020-08-27)

4 The present application does not meet the criteria of Article 33(3) PCT, because the subject-matter of claim 1 does not involve an inventive step.

4.1 Document D1 may be regarded as being the prior art closest to the subject-matter of claim 1, and discloses:

A patient-controlled analgesia pump (Fig.3 - infusion pump 300) comprising:
an actuator (Fig.1 - pusher rod 128);
a syringe holder (Fig.2 - syringe receptacle 106);
a display screen (see Fig.3 - display screen in upper half of the infusion pump 300);
a security door assembly (Fig.3 - receptacle flap 314);
a security frame assembly (Fig.3 - housing 304);
a swivel door assembly (Fig.2 - pusher head 130);
a plurality of sensors, including at least one occlusion sensor and at least one downstream inline pressure sensor (par.[0066]);
a syringe flange (see Fig.2 - syringe 102 with flange);
a syringe push button (see Fig.2 - thumb press 120);
a syringe barrel clamp (see Fig.2 - clamp grid 110);
a syringe pump lever (Fig.3 - lever inside the pusher head 130);
a processor (par.[0067]); and
a memory storing instructions (par.[0067]), which when executed by the processor, cause the processor to generate a syringe mis-loaded alarm when a syringe is mis-loaded into the PCA pump (par.[0066]); generate a syringe load error alarm when there is a syringe load error in the PCA pump (par.[0066]); ~~generate a door unlocked alarm when the security door assembly is unlocked from the security frame assembly~~; and generate a downstream occlusion alarm when there is a downstream occlusion in the PCA pump, wherein the alarm is an auditory, graphical, visual, and/or tactile notification, or a combination thereof (par.[0066]), wherein user-inputted authentication commands allow the user to silence and/or stop the alarm or alarms (virtually any kind of a device that can trigger an alarm provides a mechanism how to disable it), and wherein the syringe mis-loaded alarm is triggered when the security door assembly is closed and confirmed locked by the user (par.[0071] and [0087]), the pump is in a delivery mode, and any of the following conditions are true, except when the syringe mis-loaded alarm is active: the syringe flange is removed; the syringe

push button is not in contact with the occlusion sensor; the syringe barrel clamp is opened; the syringe pump lever is activated; and/or the syringe push button detects high pressure reading (par.[0066]).

- 4.2 The subject-matter of claim 1 therefore differs from this known from document D1 that the pump is able to generate a door unlocked alarm when the security door assembly is unlocked from the security frame assembly.
- 4.3 Technical effect of the distinguishing feature is detecting the door lock position.
- 4.4 The objective technical problem to be solved by the present invention may therefore be regarded as how to avoid tampering of the pump mechanism.
- 4.5 The solution proposed in claim 1 of the present application cannot be considered as involving an inventive step (Article 33(3) PCT) for the following reasons:

The person skilled in the art would readily use a sensor to detect the door lock position when posed with a problem how to avoid tampering of the pump mechanism. The person skilled in the art would readily use technique disclosed in document D4 - which discloses an infusion pump with control device and a locking sensor monitoring a lock state of the lock, see Fig.1 and 4 with par. [0050], [0065] and [0066]

- 5 The features of dependent claims 2-18 are known from the cited document and/or obvious for the skilled person as set on in the following.
- 5.1 Document D1 discloses the features of the dependent claims according to the following:

Claim 2: (Cancelled)

Claim 3: see par.[0066]

Claim 4: see par.[0066]

Claim 5: The person skilled in the art would readily provide sensors and alert mechanism for sensing different parameters as it is a technique well known and established in the art, see e.g. D4 par.[0028] and [0066]

Claim 6: par.[0066]

Claim 7 and 8: see Fig.3 - syringe pump with door and body fitted together

Claim 9: see Fig.3 - shape of the door 314

Claim 10 and 11: see par.[0053]

Claim 12: (Cancelled)

Claim 13: The specific design of a cover door is a mere design choice for the person skilled in the art, see e.g. D2 - Fig.1 door 36 or D4 - Fig.1 cover element 2

Claim 14: see Fig.2 - lockable clutch release lever 138 of pusher head 130

Claim 15 and 16: see Fig.2 - lockable clutch release lever 138 of pusher head 130

Claim 17 - 20: The specific design of a cover door is a mere design choice for the person skilled in the art, see e.g. D2 - Fig.1 door 36 or D4 - Fig.1 cover element 2

- 5.2 The subject-matter of dependent claims 2-18 does not involve an inventive step in the sense of Article 33(3) PCT over combination of D1 with D4 and the skilled person's knowledge.

Re Item VII

Certain defects in the international application

- 6 Documents D1 - D4 should have been mentioned in the description according to Rule 5 (a - ii) PCT.
- 7 Furthermore, to meet requirements of Rule 6.3 (b - ii) PCT, any independent claim should have been written in a two part form, with the features known from the prior art being placed in the preamble.
- 8 To meet requirements of Rule 6.2 (b), reference signs should have been used in the claims for increasing their intelligibility.

**IN THE EUROPEAN PATENT OFFICE
INTERNATIONAL SEARCHING AUTHORITY**

In the application of: **BAXTER INTERNATIONAL INC. et al.**
For: **INFUSION PUMP SECURITY SYSTEM**
International Application No.: **PCT/US2023/060013**
International Filing Date: **03 January 2023**
Attorney Docket No.: **P50520PC00 (3712044.07639)**

European Patent Office
International Searching Authority of the PCT
P.B. 5818 Patentlaan 2
NL-2280 HV Rijswijk
via Online Filing

**DEMAND FOR CHAPTER II PRELIMINARY EXAMINATION, RESPONSE
TO WRITTEN OPINION, AND AMENDMENTS UNDER PCT ARTICLE 34**

Dear Sir or Madam:

Responsive to the Notification of Transmittal of the International Search Report and the Written Opinion ("Opinion") of the International Searching Authority mailed March 24, 2023 and prior to the expiration of 22 months from the priority date, Applicants submit herewith a Demand for Chapter II Preliminary Examination, Response to Written Opinion, and Amendments under PCT Article 34.

If any fees are owed in connection with this matter, please charge Deposit Account no. 28-300341.

Respectfully submitted,
K&L GATES LLP

/Dennis A. Majewski/
Dennis A. Majewski
Reg. No. 65,578
K&L GATES LLP
P.O. Box 1135
Chicago, Illinois 60690-1135

Dated: October 17, 2023
Enclosures

**RESPONSE TO WRITTEN OPINION OF THE INTERNATIONAL
SEARCHING AUTHORITY**

The Opinion rejects Claims 12, 15, and 16 under PCT Article 33(2) for lacking novelty in view of U.S. Publication No. US 2017/258985 to Adams et al. (“*D1*”). Additionally, the Opinion rejects Claims 1, and 4 to 20 under PCT Article 33(3) as lacking inventive step in view of *D1* and the state of the art, as taught in U.S. Publication No. US 2017/072133 to Gillespie et al. (“*D2*”), WIPO Publication No. WO 2021/056265 to Shenzhen Mindray Scient Co Ltd. (“*D3*”), and U.S. Publication No. US 2020/268963 to Duprez et al. (“*D4*”). For at least the reasons below, present Claims 1, 3 to 11, and 13 to 20 are patentable.

Re: Item V –Novelty and Inventive Step Rejections

The Opinion rejects independent Claim 12 under PCT Article 33(2) as lacking novelty in view of *D1*. Additionally, the Opinion rejects independent Claims 1 and 12 under PCT Article 33(3) as lacking inventive step in view of the state of the art. Moreover, the Opinion finds dependent Claims 2 and 3 to be novel and include an inventive step.

To advance prosecution, Applicants have amended independent Claim 1 to include the subject matter from dependent Claim 2. Applicants respectfully submit that amended independent Claim 1 is novel and includes an inventive step. Applicants have also cancelled independent Claim 12 and amended Claims 13 to 20 to depend directly or indirectly on independent Claim 1.

Applicants respectfully submit that dependent Claims 3 to 11 and 13 to 20 are novel and include an inventive step by virtue of their dependence on amended independent Claim 1.

Re: Item VII –Defects in the International Application

The Opinion indicates that *D1-D4* should be identified in the specification as background prior art. Additionally, the Opinion indicates that independent Claims 1 and 12 should be drafted in the two-part format and that the claims should include reference numbers. Applicants will attend to these alleged defects at the national stage if requested by the national patent office.

Re: Item VIII – Certain Observations on the International Application

The Opinion indicates that since the security door assembly interlockable with the security frame is implicitly provided also in independent Claim 1, as an only logical outcome, independent Claim 1 comprises all the features of independent Claim 12. As such, the Opinion asserts that Claim 12 is a dependent claim in accordance with the definition of R. 6.4(a) PCT. Applicants have cancelled independent Claim 12.

CLAIMS

1. A patient-controlled analgesia pump comprising:
 - an actuator;
 - a syringe holder;
 - a display screen;
 - a security door assembly;
 - a security frame assembly;
 - a swivel door assembly;
 - a plurality of sensors, including at least one occlusion sensor and at least one downstream inline pressure sensor;
 - a syringe flange;
 - a syringe push button;
 - a syringe barrel clamp;
 - a syringe pump lever;
 - a processor; and
 - a memory storing instructions, which when executed by the processor, cause the processor to
 - generate a syringe mis-loaded alarm when a syringe is mis-loaded into the PCA pump;
 - generate a syringe load error alarm when there is a syringe load error in the PCA pump;
 - generate a door unlocked alarm when the security door assembly is unlocked from the security frame assembly; and
 - generate a downstream occlusion alarm when there is a downstream occlusion in the PCA pump,
 - wherein the alarm is an auditory, graphical, visual, and/or tactile notification, or a combination thereof,
 - wherein user-inputted authentication commands allow the user to silence and/or stop the alarm or alarms, and
 - wherein the syringe mis-loaded alarm is triggered when the security door assembly is closed and confirmed locked by the user, the pump is in a delivery mode, and any of the following conditions are true, except when the syringe mis-loaded alarm is active: the syringe flange is removed; the syringe push button is not in contact with

the occlusion sensor; the syringe barrel clamp is opened; the syringe pump lever is activated; and/or the syringe push button detects high pressure reading.

2. (Cancelled)
3. The pump of Claim 1, wherein the syringe mis-loaded alarm is triggered and the pump stops the delivery mode, when the pump is in delivery mode and any of the following conditions are true: the syringe flange is removed; the syringe push button is not in contact with the occlusion sensor; the syringe barrel clamp is opened; and/or syringe pump lever is activated.
4. The pump of Claim 1, wherein the syringe load error alarm is triggered when the security door assembly is closed and confirmed locked by the user, the pump is not in a delivery mode, or is in a stopped state, the syringe push button detects a high pressure reading, and a syringe load point gets actuated.
5. The pump of Claim 1, wherein the door unlocked alarm is triggered when the security door assembly is opened and the pump is in delivery mode.
6. The pump of Claim 1, wherein the downstream occlusion alarm is triggered when the downstream in-line sensor detects pressure outside a user-inputted pressure range at about 1.0 meter downstream.
7. The pump of Claim 1, wherein the security door assembly further comprises mating portions and the security frame assembly further comprises mating portions.
8. The pump of Claim 7, wherein the mating portions on the security door assembly selectively engage the mating portions on the security frame assembly to selectively couple the security door assembly and the security frame assembly.
9. The pump of Claim 1, wherein the security door assembly further comprises ribs, grooves and/or contours on the internal surface of the security door assembly.

10. The pump of Claim 1, wherein the security door assembly further comprises a receiver and the security frame assembly further comprises a lock assembly.
11. The pump of Claim 10, wherein the lock assembly selectively mates with the receiver.
12. (Cancelled).
13. The pump of Claim 1, wherein the swivel door assembly further comprises a main assembly body that includes side walls, a side wall plate coupled to the main assembly body so as to fully cover the syringe pump lever, a lever stopper, a pull knob stopper, and a swivel door that pivotably attaches to the main assembly body.
14. The pump of Claim 13, wherein the swivel door has an internal curvature that interlocks with the plunge lever and redirects force applied on the syringe pump lever, such that the plunge lever cannot be depressed when the swivel door is in a closed configuration relative to the main assembly body.
15. The pump of Claim 13, wherein the lever stopper is pivotably attached to the main assembly body and interlocks with the syringe pump lever to retain it in an upright orientation, and wherein the pull knob stopper includes a locking pin that mates with the lever stopper at a locking receptacle to selectively lock it when it interlocks with the syringe pump lever.
16. The pump of Claim 15, wherein the pull knob lever includes a mechanism to orient the locking pin to engage with the locking receptacle, and wherein the user can selectively inactivate the mechanism, so as to selectively disengage the locking pin and locking receptacle.
17. The pump of Claim 1, wherein when the security door assembly and security frame assembly interlock and are in a closed configuration, the syringe holder is inaccessible.

18. The pump of Claim 1, wherein when the security door assembly and security frame assembly interlock and are in a closed configuration, the display screen is accessible.
19. The pump of Claim 1, wherein when the security door assembly and the security frame assembly interlock and are in a closed configuration, the swivel door assembly is inaccessible.
20. The pump of Claim 1, wherein when the security door assembly and security frame assembly interlock and are in a closed configuration, the actuator is inaccessible.