

PATENT COOPERATION TREATY

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INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

To:

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Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/US2019/059238

International filing date (day/month/year)
31.10.2019

Priority date (day/month/year)
29.11.2018

International Patent Classification (IPC) or both national classification and IPC
INV. A61M39/24 A61M5/165

Applicant
CAREFUSION 303, INC.

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 usually 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:



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Date of completion of
this opinion

see form
PCT/ISA/210

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Box No. I Basis of the 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 43bis.1(a))
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 13ter.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 13ter.1(a)).
 - on paper or in the form of an image file (Rule 13ter.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:

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

1. Statement

Novelty (N)	Yes: Claims	<u>2-4, 11, 15-17</u>
	No: Claims	<u>1, 5-10, 12-14, 18-20</u>
Inventive step (IS)	Yes: Claims	<u>15</u>
	No: Claims	<u>1-14, 16-20</u>
Industrial applicability (IA)	Yes: Claims	<u>1-20</u>
	No: Claims	

2. Citations and explanations

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

1 **Re Item V**

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

1.1 Reference is made to the following documents:

- D1 KR 101 888 473 B1 (GYVER CO LTD [KR]; KIM KEUN BAE [KR]) 16 August 2018 (2018-08-16)
- D2 WO 2014/107436 A1 (ILLINOIS TOOL WORKS [US]) 10 July 2014 (2014-07-10)
- D3 WO 2010/107597 A1 (ILLINOIS TOOL WORKS [US]; TUMMINARO ROBERT F [US] ET AL.) 23 September 2010 (2010-09-23)
- D4 WO 2017/062110 A1 (ILLINOIS TOOL WORKS [US]) 13 April 2017 (2017-04-13)
- D5 US 3 889 710 A (BROST JULIEN H) 17 June 1975 (1975-06-17)

1.2 **Independent claims 1 and 15**

1.2.1 Notwithstanding the clarity objections raised under section VIII below, the subject-matter of independent claim 1 is so broadly worded that it does not seem to be new in the sense of Article 33(2) PCT as outlined in more detail below, and the criteria of Article 33(1) PCT is therefore not met.

D1 discloses the following features of claim 1 (the reference signs and features in parenthesis referring to the disclosure of D1, see paras. [0017]-[0033], and Figs. 1-4 thereof):

A check valve (22), comprising:
an upper housing (10a) defining an inlet (11) of the check valve;
a lower housing (10b) defining an outlet (12) of the check valve;
a cavity (13) interposed between and defined by the upper and lower housings for fluidly connecting the inlet and the outlet;
a flexible valve member (20, 22) mounted in the cavity to selectively permit fluid flow in a first direction, and prevent fluid backflow in a second direction opposite to the first direction; and
a filter member (30) mounted in the upper housing upstream of the flexible

valve member, the filter member having an elongated portion configured to maximize surface area thereof exposed to the fluid flow and restrict passage of undesirable matter in fluid flowing through the check valve.

Further, since the expression that the filter member has an "elongated portion" is vague as any three-dimensional structure may have an elongated portion, i.e. a portion of a filter that extends into a particular direction with respect to its width, it seems that the disclosure of D2 and D3 are also novelty destroying with respect to the subject-matter of claim 1, see passages cited in the search report.

1.2.2 Similar objections also apply to the subject-matter of independent claim 15, which is therefore also not considered new (Article 33(2) PCT) with respect to the disclosure of documents D1-D3.

1.3 Dependent claims 2-14 and 16-20

Claims 2-4 and 16 to 17 - Article 33(3) PCT - generally relate to the geometry of the filter member and the manner by which it is mounted in the check valve. These features appear to be slight structural changes of said filter member that in view of D1 comes within the scope of the customary practice followed by a person skilled in the art. Moreover, the claimed geometry and type of mounting of the filter member does not appear to provide any surprising technical effect that could form the basis of an allowable invention.

Claim 5 - Article 33(2) PCT - D2 describes that the filter medium may be a woven or non-woven flexible fabric ((D2, para. [0017]). Moreover, porous materials such as plastic and cork are well-known in the art and do not appear to provide any surprising technical effect that could form the basis of an allowable invention.

Claim 6 - Article 33(2) PCT - D1 discloses a seating frame 19 that is in the inner space 13 of the housing 10 and has a central axis aligned with the longitudinal axis of the check valve 22 (D1, para. [0031] and Fig. 2).

Claims 7 to 9 and 20 - Article 33(2) PCT - D2 describes an annular valve seat 86 that is described to contact the elastomeric membrane 80 to essentially block backflow (D2, para. [0051] and Fig. 3).

Claim 10 - Article 33(2) PCT - D3 describes a radially inner shoulder 176 that defines an inwardly projecting ledge 190 for supporting screen 168 (D3, para. [35] and Figs. 1-7).

Claim 11 - Article 33(3) PCT - generally relates to a plurality of ribs that center the valve member within the cavity of the check valve. These ribs are minor structural changes of a check valve that are well-known in the art (e.g. D4, guide ribs 162, para. [0038] and Fig. 4). Hence, a skilled person would not require an inventive step to employ such well-known structures to, for instance, the check valve of D3 in order to ensure its proper alignment.

Claims 12 to 14 and 18 to 19 - Article 33(2) PCT - D1 discloses a filter 30 that has a central hollow channel extending longitudinally through an axial center thereof and that is aligned with the central longitudinal axis of the check valve to, wherein the injection port 11, the hollow channel of said filter 30 and the discharge port 12 are fluidly communicated to define a flow channel through which the fluid flows through the check valve (D1, para. [0017] and Figs. 1-4).

2 **Re Item VII**

Certain defects in the international application

- 2.1 The features of claim 1-20 are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).
- 2.2 Independent claims 1 and 15 are not in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art D1 being placed in the preamble (Rule 6.3(b)(i) PCT) and the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).
- 2.3 Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in D1 is not mentioned in the description, nor is this document identified therein.

3 **Re Item VIII**

Certain observations on the international application

- 3.1 Although claims 1 and 15 have been drafted as separate independent claims, they appear to relate effectively to the same subject-matter and to differ from each other only with regard to the definition of the subject-matter for which protection is sought and/or in respect of the terminology used for the features of that subject-matter. The aforementioned claims therefore lack conciseness and as such do not meet the requirements of Article 6 PCT.

3.2 Claims 1 and 15 are not supported by the description as required by Article 6 PCT, as their scope is broader than justified by the description and drawings. In general, the application as a whole is directed towards check valves used in IV sets (cf. paras. [0002]-[0003] of the present application). However, since claims 1 and 15 only generally refer to check valves, i.e. also include check valves used in the automotive industry, their present scope is broader than justified by the description and drawings.

To overcome this issue, the aforesaid independent claims should be directed to an IV check valve or to a check valve for use in an IV set (cf. paras. [0002]-[0003] of the present application).

3.3 The term "elongated portion" used in claim 1 is vague and unclear as as any three-dimensional structure may have an elongated portion, i.e. a portion of a filter that extends into a particular direction with respect to its width. Hence, this feature leaves the reader in doubt to the meaning of the technical feature to which it refers, thereby rendering the definition of the subject-matter of said claim unclear, Article 6 PCT.