

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To: BRYANT E. WADE HARNESSE, DICKEY & PIERCE, P.L.C. 5445 CORPORATE DRIVE, SUITE 200 TROY, MI 48098 UNITED STATES OF AMERICA		PCT WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)
Applicant's or agent's file reference 18955-000224-WO-POA		Date of mailing (day/month/year) 08 August 2024 (08.08.2024)
International application No. PCT/US2024/026191		FOR FURTHER ACTION See paragraph 2 below
International filing date (day/month/year) 25 April 2024 (25.04.2024)	Priority date (day/month/year) 28 April 2023 (28.04.2023)	
International Patent Classification (IPC) or both national classification and IPC IPC: A61M 1/38 (2024.01); A61B 5/145 (2024.01); A61M 1/02 (2024.01) CPC: A61M 1/385; A61M 1/3609; A61M 1/0272; A61B 5/14535		
Applicant TERUMO BCT, 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 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/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, VA 22313-1450	Date of completion of this opinion 22 July 2024 (22.07.2024)	Authorized officer MATOS, Taina
Facsimile No. 571-273-8300		Telephone No. 571-272-4300

Form PCT/ISA/237 (cover sheet) (July 2022)

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US2024/026191

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(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 13ter.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:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US2024/026191

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)	<table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 15%; padding: 2px 5px;">Claims</td> <td style="width: 55%; padding: 2px 5px;">1-17</td> <td style="width: 30%; padding: 2px 5px; text-align: right;">YES</td> </tr> <tr> <td style="padding: 2px 5px;">Claims</td> <td style="padding: 2px 5px;">None</td> <td style="padding: 2px 5px; text-align: right;">NO</td> </tr> </table>	Claims	1-17	YES	Claims	None	NO	
Claims	1-17	YES							
Claims	None	NO							
		<table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 15%; padding: 2px 5px;">Claims</td> <td style="width: 55%; padding: 2px 5px;">1-17</td> <td style="width: 30%; padding: 2px 5px; text-align: right;">YES</td> </tr> <tr> <td style="padding: 2px 5px;">Claims</td> <td style="padding: 2px 5px;">None</td> <td style="padding: 2px 5px; text-align: right;">NO</td> </tr> </table>	Claims	1-17	YES	Claims	None	NO	
Claims	1-17	YES							
Claims	None	NO							
	Industrial applicability (IA)	<table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 15%; padding: 2px 5px;">Claims</td> <td style="width: 55%; padding: 2px 5px;">1-17</td> <td style="width: 30%; padding: 2px 5px; text-align: right;">YES</td> </tr> <tr> <td style="padding: 2px 5px;">Claims</td> <td style="padding: 2px 5px;">None</td> <td style="padding: 2px 5px; text-align: right;">NO</td> </tr> </table>	Claims	1-17	YES	Claims	None	NO	
Claims	1-17	YES							
Claims	None	NO							
2. Citations and explanations:	----- EXPLANATION ----- Claims 1-17 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest: Regarding claim 1 [as best understood], the prior art of record, individually or in combination, does not teach or fairly suggest a method for collection of a blood component using a medical system, the method comprising: receiving, by the medical system, data associated with an individual subject, the data associated with the individual subject including a subject's initial hematocrit; identifying, by the medical system, a subject-specific pure component amount to be collected by the medical system, the subject-specific pure component amount to be collected by the medical system determined using the subject's initial hematocrit, an initial total blood volume for the subject, and a targeted change in hematocrit; and performing, using the medical system, a component donation process to collect the identified subject-specific pure component amount to be collected. The following prior art is made of record to support and further define the reasons that claim 1 meets the criteria set out in PCT Article 33(2)-(3): US 2022/0168486 to Fenwal, Inc. (hereafter "Fenwal") discloses a method (method; para. [0012]) for collection of a blood component using a medical system (operating a plasmapheresis system to collect a plasma product volume; para. [0012]; para. [0017]), the method comprising: receiving, by the medical system (plasmapheresis system; para. [0012]; para. [0017]), data associated with an individual subject (determining a total whole blood volume for the donor; para. [0017]), the data associated with the individual subject including a subject's initial hematocrit (a value for the hematocrit of the donor is determined prior to the start of each draw phase; para. [0017]-[0018]; para. [0067]); identifying, by the medical system (plasmapheresis system; para. [0012]; para. [0017]), a subject-specific pure component amount to be collected by the medical system (determining a target volume of plasma product to be collected; para. [0017]-[0018]), the subject-specific pure component amount to be collected by the medical system determined using the subject's initial hematocrit, and an initial total blood volume for the subject (the target volume of plasma product to be collected is based on the donor's hematocrit and the total whole blood volume for the donor; para. [0014]; para. [0016]-[0018]; para. [0067]); and performing, using the medical system (plasmapheresis system; para. [0012]; para. [0017]), a component donation process to collect the identified subject-specific pure component amount to be collected (performing an apheresis procedure to collect the target volume of plasma product; para. [0017]). However, Fenwal fails to disclose the elements of the subject-specific pure component amount to be collected by the medical system determined using the subject's initial hematocrit, an initial total blood volume for the subject, and a targeted change in hematocrit. US 2002/0033370 to Bainbridge et al. (hereafter "Bainbridge") discloses a method (method; para. [0014]) for collection of a blood component (collection of both or either plasma and red blood cells; para. [0014]) using a medical system (Fig. 1, apheresis system 2), the method comprising: receiving, by the medical system (Fig. 1, apheresis system 2), data associated with an individual subject (donor characteristics are								

Form PCT/ISA/237 (Box No. V) (July 2022)

**WRITTEN OPINION OF THE
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International application No.

PCT/US2024/026191

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

input; para. [0016]), the data associated with the individual subject including a subject's initial hematocrit (donor characteristics include hematocrit; para. [0016]); identifying, by the medical system (Fig. 1, apheresis system 2), a subject-specific pure component amount to be collected by the medical system (the system determines, based on total blood volume and hematocrit, how many and what combinations of products the donor can donate; para. [0016]), the subject-specific pure component amount to be collected by the medical system determined using the subject's initial hematocrit and an initial total blood volume for the subject (the system determines, based on total blood volume and hematocrit, how many and what combinations of products the donor can donate; para. [0016]); and performing, using the medical system (Fig. 1, apheresis system 2), a component donation process to collect the identified subject-specific pure component amount to be collected (Fig. 1, whole blood is withdrawn from a donor/patient 4 and separated for collection of at least one separated blood component types; para. [0016]; para. [0085]). However, Bainbridge fails to disclose the elements of the subject-specific pure component amount to be collected by the medical system determined using the subject's initial hematocrit, an initial total blood volume for the subject, and a targeted change in hematocrit. While Bainbridge describes a target hematocrit, this is the desired hematocrit of the final blood product and not of the donor, nor does Bainbridge disclose a targeted change in hematocrit.

US 2023/0001059 to Haemonetics Corporation (hereafter "Haemonetics") discloses a method (Fig. 4, method; para. [0028]) for collection of a blood component (collecting plasma; para. [0028]) using a medical system (Fig. 1, blood processing device 100), the method comprising: receiving, by the medical system (Fig. 1, blood processing device 100), data associated with an individual subject (Fig. 4, obtain/determine some information regarding the donor, namely, the donor's weight (Step 410) and hematocrit (Step 415); para. [0028]), the data associated with the individual subject including a subject's initial hematocrit (Fig. 4, the information includes hematocrit; para. [0028]); identifying, by the medical system (Fig. 1, blood processing device 100), a subject-specific pure component amount to be collected by the medical system (a target volume of pure plasma is identified; para. [0010]; para. [0028]; para. [0045]), the subject-specific pure component amount to be collected by the medical system (Fig. 1, blood processing device 100) determined using the subject's initial hematocrit (the target volume of pure plasma is based on the donor's weight and hematocrit; para. [0010]; para. [0028]; para. [0045]); and performing, using the medical system (Fig. 1, blood processing device 100), a component donation process to collect the identified subject-specific pure component amount to be collected (Fig. 1, blood processing device 100 performs the plasma collection process until a target volume of pure plasma is collected; para. [0034]). However, Haemonetics fails to disclose the elements of the subject-specific pure component amount to be collected by the medical system determined using the subject's initial hematocrit, an initial total blood volume for the subject, and a targeted change in hematocrit.

None of the cited prior art references taken alone or in combination disclose or suggest the specific elements of the subject-specific pure component amount to be collected by the medical system determined using the subject's initial hematocrit, an initial total blood volume for the subject, and a targeted change in hematocrit as recited above, and none of the cited references cure the deficiencies of Fenwal, Bainbridge, and Haemonetics discussed in this written opinion.

Claims 2-17 ultimately depend from claim 1, and therefore meet the criteria set out in PCT Article 33(2)-(3) for at least the same reasons as claim 1.

Claims 1-17 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.

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International application No.

PCT/US2024/026191

Box No. VII Certain defects in the international application

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

Claim 1 is objected to under PCT Rule 66.2(a)(iii) as containing the following defect in the form or contents thereof:

Claim 1 appears to include a typographical error because claim 1 recites “for collection blood component”. For the purposes of this written opinion, claim 1 is best understood as “for collection of a blood component” to correct this typographical error.

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US2024/026191

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:

Claim 10 is objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because the claim is indefinite for the following reason:

Claim 10 recites “the body mass index”, which appears to lack antecedent basis. For the purposes of this written opinion, claim 10 is best understood as “a body mass index” to correct this antecedent basis issue.