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APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/866,078	04/20/2021	10980926	130670-08005	8985

86738 7590 03/31/2021  
MCCARTER & ENGLISH, LLP BOSTON  
265 Franklin Street  
Boston, MA 02110

## ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

### **Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)** (application filed on or after May 29, 2000)

The Patent Term Adjustment is 0 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Data Management (ODM) at (571)-272-4200.

APPLICANT(s) (Please see PAIR WEB site <http://pair.uspto.gov> for additional applicants):

Michael Ragusa, Hingham, MA;  
Haemonetics Corporation, Boston, MA;

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NOTICE OF ALLOWANCE AND FEE(S) DUE

86738 7590 02/05/2021
MCCARTER & ENGLISH, LLP BOSTON
265 Franklin Street
Boston, MA 02110

EXAMINER

DEAK, LESLIE R

ART UNIT PAPER NUMBER

3799

DATE MAILED: 02/05/2021

Table with 5 columns: APPLICATION NO., FILING DATE, FIRST NAMED INVENTOR, ATTORNEY DOCKET NO., CONFIRMATION NO. Values: 16/866,078, 05/04/2020, Michael Ragusa, 130670-08005, 8985

TITLE OF INVENTION: SYSTEM AND METHOD FOR COLLECTING PLASMA

Table with 7 columns: APPLN. TYPE, ENTITY STATUS, ISSUE FEE DUE, PUBLICATION FEE DUE, PREV. PAID ISSUE FEE, TOTAL FEE(S) DUE, DATE DUE. Values: nonprovisional, UNDISCOUNTED, \$1200, \$0.00, \$0.00, \$1200, 05/05/2021

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Maintenance fees are due in utility patents issuing on applications filed on or after Dec. 12, 1980. It is patentee's responsibility to ensure timely payment of maintenance fees when due. More information is available at www.uspto.gov/PatentMaintenanceFees.

**PART B - FEE(S) TRANSMITTAL**

Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web.

By mail, send to: Mail Stop ISSUE FEE  
 Commissioner for Patents  
 P.O. Box 1450  
 Alexandria, Virginia 22313-1450

By fax, send to: (571)-273-2885

**INSTRUCTIONS:** This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

86738 7590 02/05/2021  
**MCCARTER & ENGLISH, LLP BOSTON**  
 265 Franklin Street  
 Boston, MA 02110

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

**Certificate of Mailing or Transmission**

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being transmitted to the USPTO via EFS-Web or by facsimile to (571) 273-2885, on the date below.

_____ (Typed or printed name)
_____ (Signature)
_____ (Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/866,078	05/04/2020	Michael Ragusa	130670-08005	8985

TITLE OF INVENTION: SYSTEM AND METHOD FOR COLLECTING PLASMA

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	\$1200	\$0.00	\$0.00	\$1200	05/05/2021

EXAMINER	ART UNIT	CLASS-SUBCLASS
DEAK, LESLIE R	3799	604-006040

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

- Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-09 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

- (1) The names of up to 3 registered patent attorneys or agents OR, alternatively, 1 \_\_\_\_\_
- (2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 2 \_\_\_\_\_
- 3 \_\_\_\_\_

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE \_\_\_\_\_ (B) RESIDENCE: (CITY and STATE OR COUNTRY) \_\_\_\_\_

Please check the appropriate assignee category or categories (will not be printed on the patent):  Individual  Corporation or other private group entity  Government

4a. Fees submitted:  Issue Fee  Publication Fee (if required)  Advance Order - # of Copies \_\_\_\_\_

4b. Method of Payment: (Please first reapply any previously paid fee shown above)

Electronic Payment via EFS-Web  Enclosed check  Non-electronic payment by credit card (Attach form PTO-2038)

The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. \_\_\_\_\_

5. Change in Entity Status (from status indicated above)

- Applicant certifying micro entity status. See 37 CFR 1.29
- Applicant asserting small entity status. See 37 CFR 1.27
- Applicant changing to regular undiscounted fee status.

**NOTE:** Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.  
**NOTE:** If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.  
**NOTE:** Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

**NOTE:** This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature \_\_\_\_\_ Date \_\_\_\_\_

Typed or printed name \_\_\_\_\_ Registration No. \_\_\_\_\_



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Table with 5 columns: APPLICATION NO., FILING DATE, FIRST NAMED INVENTOR, ATTORNEY DOCKET NO., CONFIRMATION NO. Includes application details for Michael Ragusa and attorney MCCARTER & ENGLISH, LLP BOSTON.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702.

## OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

### Privacy Act Statement

**The Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

<b>Notice of Allowability</b>	<b>Application No.</b> 16/866,078	<b>Applicant(s)</b> Ragusa, Michael	
	<b>Examiner</b> LESLIE R DEAK	<b>Art Unit</b> 3799	<b>AIA (FITF) Status</b> Yes

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

- 1.  This communication is responsive to arguments and TD filed 8 January 2021.
  - A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on \_\_\_\_\_.
- 2.  An election was made by the applicant in response to a restriction requirement set forth during the interview on \_\_\_\_\_; the restriction requirement and election have been incorporated into this action.
- 3.  The allowed claim(s) is/are 1-30. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see [http://www.uspto.gov/patents/init\\_events/pph/index.jsp](http://www.uspto.gov/patents/init_events/pph/index.jsp) or send an inquiry to [PPHfeedback@uspto.gov](mailto:PPHfeedback@uspto.gov).
- 4.  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

**Certified copies:**

- a)  All      b)  Some      \*c)  None of the:
  - 1.  Certified copies of the priority documents have been received.
  - 2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3.  Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

- 5.  CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
  - including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

**Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
- 6.  DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- 1.  Notice of References Cited (PTO-892)
- 2.  Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date \_\_\_\_\_.
- 3.  Examiner's Comment Regarding Requirement for Deposit of Biological Material \_\_\_\_\_.
- 4.  Interview Summary (PTO-413), Paper No./Mail Date \_\_\_\_\_.
- 5.  Examiner's Amendment/Comment
- 6.  Examiner's Statement of Reasons for Allowance
- 7.  Other \_\_\_\_\_.

/LESLIE R DEAK/  
Primary Examiner, Art Unit 3799

Docket No.: 130670-08005  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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In re Utility Application of:  
Haemonetics Corporation

Application No.: 16/866,078

Confirmation No.: 8985

Filed: May 4, 2020

Art Unit: 3799

For: SYSTEM AND METHOD FOR COLLECTING  
PLASMA

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Examiner: L. R. Deak

**AMENDMENT IN RESPONSE TO NON-FINAL OFFICE ACTION UNDER 37 C.F.R. § 1.111**

MS Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

**INTRODUCTORY COMMENTS**

In response to the Office Action dated November 12, 2020, please amend the above-identified U.S. patent application as follows:

**Amendments to the Claims** are reflected in the listing of claims which begins on page 2 of this paper.

**Remarks/Arguments** begin on page 8 of this paper.

### **AMENDMENTS TO THE CLAIMS**

The following **Listing of Claims** will replace all prior versions, and listing, of claims in the application.

#### **Listing of Claims**

1. (Original) A method for collecting plasma comprising:
  - (a) determining a weight of a donor;
  - (b) determining a hematocrit of the donor;
  - (c) calculating a volume of anticoagulant to be collected with a plasma component in a plasma collection container, the volume of anticoagulant to be collected with the plasma component based, at least in part on the hematocrit of the donor;
  - (d) calculating a target volume of pure plasma to collect in the plasma collection container based, at least in part, on the weight of the donor;
  - (e) determining a target collection volume based, at least in part, on the calculated volume of anticoagulant and the calculated volume of pure plasma;
  - (f) withdrawing whole blood from the donor through a venous-access device and a draw line, the draw line connected to a blood component separation device;
  - (g) introducing anticoagulant into the withdrawn whole blood through an anticoagulant line at a predetermined ratio of anticoagulant to whole blood;
  - (h) separating the withdrawn whole blood into the plasma component and at least a second blood component using the blood component separation device;
  - (i) collecting the plasma component from the blood component separation device and into a plasma collection container;
  - (j) continuing steps (f) through (i) until the target collection volume is reached in the plasma collection container.
  
2. (Original) A method according to claim 1, wherein the target collection volume is the calculated volume of pure plasma.

3. (Original) A method according to claim 1, wherein the target collection volume is the calculated volume of pure plasma plus the calculated volume of anticoagulant.
4. (Original) A method according to claim 1, wherein the calculated volume of anticoagulant is further based, in least in part, on the predetermined ratio of anticoagulant.
5. (Original) A method according to claim 1, wherein the calculated volume of anticoagulant includes at least a portion of the anticoagulant to be introduced into the withdrawn blood and at least a portion of a volume of anticoagulant to be added during a priming step.
6. (Original) A method according to claim 1, wherein calculating the volume of anticoagulant includes calculating the volume of anticoagulant before withdrawing whole blood.
7. (Original) A method according to claim 1, wherein calculating the target volume of pure plasma includes calculating the target volume of pure plasma before withdrawing whole blood from the donor.
8. (Currently Amended) A system for collecting plasma comprising:
  - a venous-access device for drawing whole blood from a ~~subject~~ donor and returning blood components to the ~~subject~~ donor;
  - a blood component separation device for separating the drawn blood into a plasma component and a second blood component, the blood component separation device having an outlet and being configured to send the plasma component to a plasma container;
  - a blood draw line fluidly connected to the venous-access device and configured to transport drawn whole blood to the blood component separation device, the flow through the blood draw line being controlled by a blood draw pump;
  - an anticoagulant line connected to an anticoagulant source, the anticoagulant line configured to introduce anticoagulant into the drawn whole blood; and
  - a controller configured to control the operation of the blood component separation device, the controller configured to calculate (1) a volume of anticoagulant to be collected with plasma component in ~~[[a]] the plasma collection~~ container, the volume of anticoagulant to be collected with

the plasma component based, at least in part on the hematocrit of the donor, (2) a target volume of pure plasma to collect in the plasma ~~collection~~ container based, at least in part, on the weight of the donor, and (3) a target collection volume based, at least in part, on the calculated volume of anticoagulant and the calculated volume of pure plasma, the system configured to stop the blood draw pump when the target collection volume is collected within the plasma container.

9. (Original) A system according to claim 8, wherein the target collection volume is the calculated volume of pure plasma.

10. (Currently Amended) A system according to claim 8, wherein the target collection volume is the calculated volume of pure plasma plus the calculated volume of anticoagulant to be collected in the plasma ~~collection~~ container.

11. (Currently Amended) A system according to claim 8, wherein the volume of anticoagulant to be collected within the plasma ~~collection~~ container is further based, in least in part, on the predetermined ratio of anticoagulant.

12. (Original) A system according to claim 8, wherein the volume of anticoagulant to be collected in the collected plasma component includes at least a portion of the anticoagulant to be introduced into the withdrawn blood and at least a portion of a volume of anticoagulant to be added during a priming step.

13. (Original) A system according to claim 8, wherein the controller is configured to calculate the volume of anticoagulant before withdrawing whole blood from the donor.

14. (Original) A system according to claim 8, wherein the controller is configured to calculate the target volume of pure plasma before withdrawing whole blood from the donor.

15. (Currently Amended) A method for programming a blood component processing device:

- (a) receiving, in a control system, a weight of a donor;
- (b) receiving, in the control system, a hematocrit of the donor;

(c) calculating, using the control system, a volume of anticoagulant to be collected with a plasma component in a plasma collection container of the blood component processing ~~system~~ device, the control system calculating the volume of anticoagulant to be collected with the plasma component based, at least in part on the hematocrit of the donor;

(d) calculating, using the control system, a target volume of pure plasma to collect in the plasma collection container, the control system calculating the target volume of pure plasma based, at least in part, on the weight of the donor;

(e) determining a target collection volume based, at least in part, on the calculated volume of anticoagulant and the calculated volume of pure plasma; and

(f) programming a controller of [[a]] the blood component processing device with a blood processing end point, the blood processing end point being based, at least in part on the target collection volume.

16. (Original) A method according to claim 15, wherein the target collection volume is the calculated volume of pure plasma.

17. (Original) A method according to claim 15, wherein the target collection volume is the calculated volume of pure plasma plus the calculated volume of anticoagulant to be collected in the plasma collection container.

18. (Original) A method according to claim 15, wherein the volume of anticoagulant to be collected within the plasma collection container is further based, in least in part, on a predetermined ratio of anticoagulant.

19. (Original) A method according to claim 15, wherein the volume of anticoagulant to be collected in the collected plasma component includes at least a portion of the anticoagulant to be introduced into the withdrawn blood and at least a portion of a volume of anticoagulant to be added during a priming step.

20. (Currently Amended) A method according to claim 15, wherein the volume of anticoagulant to be collected with the plasma component in the plasma collection container is also based, at least in part, on a volume of anticoagulant to be added to the drawn whole blood.

21. (Currently Amended) A method according to claim 15, wherein the blood processing end point is when the target collection volume has been collected within the plasma collection container.

22. (Original) A method according to claim 15, wherein the control system includes the controller.

23. (Currently Amended) A system for collecting plasma comprising:

a blood processing device including:

a venous-access device for drawing whole blood from a subject donor and returning blood components to the subject donor,

a blood component separation device for separating the drawn blood into a plasma component and a second blood component, the blood component separation device having an outlet and being configured to send the plasma component to a plasma container,

a blood draw line fluidly connected to the venous-access device and configured to transport drawn whole blood to the blood component separation device, the flow through the blood draw line being controlled by a blood draw pump, and

an anticoagulant line connected to an anticoagulant source, the anticoagulant line configured to introduce anticoagulant into the drawn whole blood; and

a controller configured to (1) calculate a volume of anticoagulant to be collected with plasma component in ~~[[a]] the plasma collection container~~, the volume of anticoagulant to be collected with the plasma component based, at least in part on a hematocrit of the donor, (2) calculate a target volume of pure plasma to collect in the plasma ~~collection~~ container based, at least in part, on a weight of the donor, and (3) calculate a target collection volume based, at least in part, on the calculated volume of anticoagulant and the calculated volume of pure plasma.

24. (Original) The system according to claim 23, wherein the blood processing device is configured to stop the blood draw pump when the target collection volume is collected within the plasma container.

25. (Original) The system according to claim 23, wherein the controller is part of the blood processing device.
26. (Currently Amended) The system according to 23, wherein the controller is further configured to program the ~~blood component separation device~~ blood processing device with an end point based, at least in part, on the target collection volume.
27. (Currently Amended) A system according to claim 23, wherein the target collection volume is the calculated volume of pure plasma and/or the calculated volume of pure plasma plus the calculated volume of anticoagulant to be collected in the plasma ~~collection~~ container.
28. (Currently Amended) A system according to claim 23, wherein the volume of anticoagulant to be collected within the plasma ~~collection~~ container is further based, in least in part, on a predetermined ratio of anticoagulant.
29. (Original) A system according to claim 23, wherein the volume of anticoagulant to be collected in the collected plasma component includes at least a portion of the anticoagulant to be introduced into the withdrawn blood and at least a portion of a volume of anticoagulant to be added during a priming step.
30. (Currently Amended) A system according to claim ~~23~~ 26, wherein the ~~blood processing~~ end point is when the target collection volume has been collected within the plasma container.

### **REMARKS**

Applicants would like to thank the examiner for the review of the present application. Applicants request reconsideration of the pending claims in view of the following remarks. Applicant has amended claims 8, 10-11, 15, 20-21, 23, 26-28 and 30 to address some formality-type issues. Claims 1-30 are currently pending in the application.

#### **Examiner Interview Summary**

Applicant would like to thank Examiner Deak for the telephone interview on December 11, 2020. During the interview, Examiner Deak, and Applicant's counsel discussed the present application and the related pending application U.S. 16/931,333 (Attorney Docket No. 130670-80103). With respect to this application, Examiner Deak and Applicant's counsel discussed the pending claims, the Office Action dated November 12, 2020 and the cited prior art (e.g., U.S. Application No. 2003/012881 to Ryan, hereinafter "Ryan"). In particular, Applicant's counsel explained, among other things, why the pending claims calculate the amount of anticoagulant that is collected in the plasma bag and why the present claims look at/calculate the target volume of "pure plasma." Applicant's counsel also explained (1) that Ryan doesn't teach this, (2) that Ryan only takes a mL/pound approach, and (3) that, because Ryan doesn't look at the donor's hematocrit to calculate how much AC is collected in the bag, they will ultimately collect a different amount of pure plasma even for two donors that weigh the same if their hematocrits are different. To illustrate the point, Applicant's counsel gave an example of two 130 pound donors – one with a low hematocrit and one with a high hematocrit – and explained that even if the total collection volume (e.g., plasma + AC) is the same, the actual volume of pure plasma collected, would be different. Examiner Deak acknowledged the differences between Ryan and the present claims, asked that Applicant explain the above in the response, and indicated that doing so should result in an allowance.

### **Double Patenting**

The office action rejects claims 1-3, 8-17 and 23-30 on the grounds of nonstatutory double patenting as being unpatentable over claims 1 and 8 of U.S. Patent No. 10,758,652. To expedite prosecution, Applicant files herewith a terminal disclaimer with respect to U.S. Patent No. 10,758,652. Accordingly, Applicant believes that this rejection is now moot.

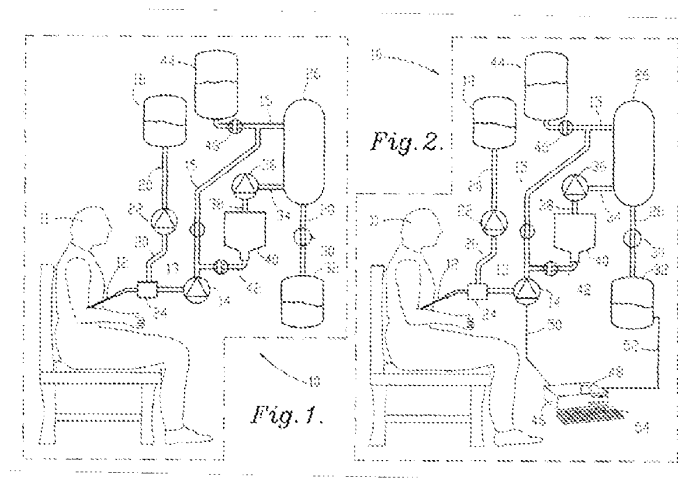
### **35 USC § 102**

Claims 8-14 and 23-30 are rejected under 35 U.S.C. 102(a)(1) and (a)(2) as being anticipated by U.S. 2003/0125881 to Ryan.

Claim 8 defines, in relevant part, a system for collecting plasma that includes (1) a venous-access device for drawing whole blood from a donor and returning blood components to the donor, and (2) a blood component separation device for separating the drawn blood into a plasma component and a second blood component. The blood component separation device has an outlet and is configured to send the plasma component to a plasma container. The system also has a blood draw line and an anticoagulant line. The blood draw line is fluidly connected to the venous-access device and transports drawn whole blood to the blood component separation device. The flow through the blood draw line is controlled by a blood draw pump. The anticoagulant line is connected to an anticoagulant source and is configured to introduce anticoagulant into the drawn whole blood. A controller controls the operation of the blood component separation device, and calculates (1) a volume of anticoagulant to be collected with the plasma component in a plasma container based, at least in part on the hematocrit of the donor, (2) a target volume of pure plasma to collect in the plasma container based, at least in part, on the weight of the donor, and (3) a target collection volume based, at least in part, on the calculated volume of anticoagulant and the calculated volume of pure plasma. The system stops the blood draw pump when the target collection volume is collected within the plasma container.

Ryan fails to teach or suggest the claimed system. Rather, Ryan teaches a method and apparatus for collecting a plasma portion and that withdraws donor-weight specific plasma and blood volumes. Ryan's plasmapheresis system 10 includes a controller 46 that is in communicative

control of a whole blood pump 14 as a function of either the volume of blood pumped by pump 14 or the volume of plasma contained in plasma reservoir 32 (e.g., as determined by the weight of the plasma reservoir 32 or by volume using optical sensors). The data from the scale or from the optical sensor is transmitted to the controller 46 and a processor 48 which monitor the amount of plasma collected. During operation, a donor 11 is weighed on a conventional scale, and the donor-specific body weight of the donor is obtained. Ryan then provides the processor 48 with the donor-specific body weight and the processor 48 calculates a particular plasma volume to be extracted from the donor based upon the donor-specific body weight and a selected standard of milliliters of plasma per pound of body weight. Ryan continues processing whole blood and collecting plasma until the calculated plasma volume is collected as determined by the number of revolutions of the pump 14 or the "actual" volume of plasma collected in the plasma reservoir 32 as measured by the weight of the reservoir 32 or the optical sensor.



The office action suggests that Ryan's controller/processor 46/48 constitutes the claimed controller and that Ryan's controller/processor 46/48 calculates (1) a volume of anticoagulant to be collected with the plasma component in the plasma collection container based, at least in part, on the hematocrit of the donor, and (2) a target volume of pure plasma to collect in the plasma collection container based on the weight of the donor. Applicant respectfully disagrees. In particular and as discussed during the examiner interview of December 11, 2020, Ryan does not

calculate (1) a volume of anticoagulant to be collected with the plasma component in the plasma container based, at least in part, on the hematocrit of the donor or (2) a target volume of pure plasma to collect in the plasma collection container, as required by claim 8. Therefore, Ryan also necessarily does not calculate a target collection volume based on the calculated volume of anticoagulant to be collected in the plasma container and the calculated volume of pure plasma. Rather, Ryan merely calculates a total collection volume based on the weight of the donor -- for example, Ryan's collection volume is 5.8 mL X the weight of the donor. This collection volume is the total volume collected within the container and includes the anticoagulant collected and the plasma collected.

By merely taking a mL/pound approach to the collection volume and not taking into account the hematocrit of the donor (e.g., by calculating how much anticoagulant will be collected in the plasma container based on the hematocrit of the donor), the amount of pure plasma collected for each donor will be different, even for those donors with the same weight because the donor's hematocrit impacts how much anticoagulant is collected with the plasma component in the plasma container (e.g., see paragraph [0035] of the present application). For example, as discussed during the examiner interview of December 11, 2020, under Ryan, the total collection volume of two 130 pound donors would be the same (i.e., 130 pounds \* 5.8mL = 754 mL). However, if one has a low hematocrit (e.g., 38%) and one has a high hematocrit (e.g., 54%), the amount of anticoagulant that will be collected in the plasma container will vary between the donors, and therefore, a different amount of pure plasma will be collected from each of the donors, despite them having the same weight. Therefore, because Ryan merely takes a ml/pound approach and does not use hematocrit in the calculation, Ryan cannot calculate the amount anticoagulant that will be collected in the plasma container or a target volume of pure plasma to collect.

Accordingly, claim 8 is allowable over Ryan. Moreover, claims 9-14 which depend from claim 8 are also allowable over Ryan.

In a manner similar to claim 8, claim 23 teaches a system for collecting plasma with a controller that calculates or determines (1) a volume of anticoagulant to be collected with the

plasma component in a plasma container based, at least in part on the hematocrit of the donor, (2) a target volume of pure plasma to collect in the plasma container based, at least in part, on the weight of the donor, and (3) a target collection volume based, at least in part, on the calculated volume of anticoagulant and the calculated volume of pure plasma. Therefore, claim 23 is allowable over Ryan for at least the same reasons as discussed above for claim 8. Moreover, claims 24-30 which depend from claim 23 are allowable over Ryan for at least the same reasons.

**35 USC § 103**

Claims 1-4, 6, 7, 15-18, 21 and 22 are rejected under 35 U.S.C. 103 as being unpatentable over U.S. 2003/0125881 to Ryan.

In a manner similar to claim 8, claim 1 and 15 define, in relevant part, a method for collecting plasma (claim 1) and a method for programming a blood component processing device (claim 15) that calculate or determine (1) a volume of anticoagulant to be collected with the plasma component in a plasma container based, at least in part on the hematocrit of the donor, (2) a target volume of pure plasma to collect in the plasma container based, at least in part, on the weight of the donor, and (3) a target collection volume based, at least in part, on the calculated volume of anticoagulant and the calculated volume of pure plasma. Therefore, claims 1 and 15 are allowable over Ryan for at least the same reasons as discussed above for claim 8. Moreover, claims 2-4, 6, 7, 16-18, 21 and 22 which depend from claims 1 and 15 are allowable over Ryan for at least the same reasons.

Claims 2 and 19 are rejected under 35 U.S.C. 103 as being unpatentable over U.S. 2003/0125881 to Ryan in view of U.S. Patent No. 9,283,316 to Flexman.

As dependent claims of claims 1 and 15, claims 2 and 19 include all of the limitations of the base claim from which they depend. Therefore, claims 2 and 19 are allowable over the cited prior art for at least the reasons discussed above.

**CONCLUSION**

It is believed that the application is now in order for allowance and Applicant respectfully requests that a notice of allowance be issued. Applicant does not believe that any extension of time is required. However, if an extension of time is required, please charge the associated fee and any additional fees required by this paper or credit any overpayment to deposit account number 50-4876. Applicants also request that the examiner contact applicant's attorney, Jonathan C. Lovely, if it will assist in processing this application through issuance.

Dated: January 8, 2021

Respectfully submitted,  
Electronic signature: /Jonathan C. Lovely, Reg.  
No. 60,821/  
Jonathan C. Lovely  
Registration No.: 60,821  
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(617) 449-6500  
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Attorney/Agent For Applicant

<b>Doc Code: DIST.E.FILE</b> <b>Document Description: Electronic Terminal Disclaimer - Filed</b>	PTO/SB/26 U.S. Patent and Trademark Office Department of Commerce
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Electronic Petition Request	<b>TERMINAL DISCLAIMER TO OBTAIN A DOUBLE PATENTING REJECTION OVER A "PRIOR" PATENT</b>
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Application Number	16866078
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Filing Date	04-May-2020
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First Named Inventor	Michael Ragusa
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Attorney Docket Number	130670-08005
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Title of Invention	SYSTEM AND METHOD FOR COLLECTING PLASMA
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<input checked="" type="checkbox"/> Filing of terminal disclaimer does not obviate requirement for response under 37 CFR 1.111 to outstanding Office Action
<input checked="" type="checkbox"/> This electronic Terminal Disclaimer is not being used for a Joint Research Agreement.

Owner	Percent Interest
Haemonetics Corporation	100%

The owner(s) with percent interest listed above in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of prior patent number(s)

10758652

as the term of said prior patent is presently shortened by any terminal disclaimer. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the prior patent are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the owner does not disclaim the terminal part of the term of any patent granted on the instant application that would extend to the expiration date of the full statutory term of the prior patent, "as the term of said prior patent is presently shortened by any terminal disclaimer," in the event that said prior patent later:

- expires for failure to pay a maintenance fee;
- is held unenforceable;
- is found invalid by a court of competent jurisdiction;
- is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321;
- has all claims canceled by a reexamination certificate;
- is reissued; or
- is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.

Terminal disclaimer fee under 37 CFR 1.20(d) is included with Electronic Terminal Disclaimer request.

I certify, in accordance with 37 CFR 1.4(d)(4), that the terminal disclaimer fee under 37 CFR 1.20(d) required for this terminal disclaimer has already been paid in the above-identified application.

Applicant claims the following fee status:

- Small Entity
- Micro Entity
- Regular Undiscounted

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

THIS PORTION MUST BE COMPLETED BY THE SIGNATORY OR SIGNATORIES

I certify, in accordance with 37 CFR 1.4(d)(4) that I am:

- An attorney or agent registered to practice before the Patent and Trademark Office who is of record in this application  
  
Registration Number 60821
- A sole inventor
- A joint inventor; I certify that I am authorized to sign this submission on behalf of all of the inventors as evidenced by the power of attorney in the application
- A joint inventor; all of whom are signing this request

Signature	/Jonathan C. Lovely/
Name	Jonathan C. Lovely

\*Statement under 37 CFR 3.73(b) is required if terminal disclaimer is signed by the assignee (owner).  
Form PTO/SB/96 may be used for making this certification. See MPEP § 324.

Doc Code: DISQ.E.FILE

Document Description: Electronic Terminal Disclaimer – Approved

Application No.: 16866078

Filing Date: 04-May-2020

Applicant/Patent under Reexamination: Ragusa

Electronic Terminal Disclaimer filed on January 8, 2021

APPROVED

**This patent is subject to a terminal disclaimer**

DISAPPROVED

Approved/Disapproved by: Electronic Terminal Disclaimer automatically approved by EFS-Web

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/866,078	05/04/2020	Michael Ragusa	130670-08005	8985
86738	7590	12/16/2020	EXAMINER	
MCCARTER & ENGLISH, LLP BOSTON 265 Franklin Street Boston, MA 02110			DEAK, LESLIE R	
			ART UNIT	PAPER NUMBER
			3799	
			NOTIFICATION DATE	DELIVERY MODE
			12/16/2020	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

doCKET@mccarter.com

<b><i>Examiner-Initiated Interview Summary</i></b>	<b>Application No.</b> 16/866,078	<b>Applicant(s)</b> Ragusa, Michael	
	<b>Examiner</b> LESLIE R DEAK	<b>Art Unit</b> 3799	<b>AIA (FITF) Status</b> Yes

All participants (applicant, applicant's representative, PTO personnel):

(1) LESLIE R. DEAK. (3) \_\_\_\_.

(2) Jonathan Lovely, counsel. (4) \_\_\_\_.

Date of Interview: 11 December 2020.

Type:  Telephonic  Video Conference  
 Personal [copy given to:  applicant  applicant's representative]

Exhibit shown or demonstration conducted:  Yes  No.  
If Yes, brief description: \_\_\_\_.

Issues Discussed  101  112  102  103  Others  
(For each of the checked box(es) above, please describe below the issue and detailed description of the discussion)

Claim(s) discussed: 1.

Identification of prior art discussed: US 2003/0125881 to Ryan.

**Substance of Interview**

(For each issue discussed, provide a detailed description and indicate if agreement was reached. Some topics may include: identification or clarification of a reference or a portion thereof, claim interpretation, proposed amendments, arguments of any applied references etc...)

See Continuation Sheet.

**Applicant recordation instructions:** It is not necessary for applicant to provide a separate record of the substance of interview.

**Examiner recordation instructions:** Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

Attachment

/LESLIE R DEAK/  
Primary Examiner, Art Unit 3799

Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Discussed double patenting rejection. Applicant will file a Terminal Disclaimer over this application's parent case, US 10,758,562.

With regard to the prior art rejection, Ryan is using an FDA nomogram to calculate a total amount of fluid in a collection bag, and does not take into account patient's hematocrit when calculating the amount of anticoagulant in the bag. Patient A and Patient B, each with the same weight, but different hematocrit levels will have different amounts of anticoagulant in the collected plasma product due to the nature of the relationship between hematocrit and anticoagulant. As such, Ryan cannot calculate a "pure plasma" collection volume because he does not use hematocrit in the calculations. (See Applicant's step c in claim 1.)

Applicant will submit formal arguments pointing out the above, which Examiner thinks will overcome the Ryan reference.



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/866,078	05/04/2020	Michael Ragusa	130670-08005	8985
86738	7590	11/12/2020	EXAMINER	
MCCARTER & ENGLISH, LLP BOSTON 265 Franklin Street Boston, MA 02110			DEAK, LESLIE R	
			ART UNIT	PAPER NUMBER
			3799	
			NOTIFICATION DATE	DELIVERY MODE
			11/12/2020	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

doCKET@mccarter.com

<b>Office Action Summary</b>	<b>Application No.</b> 16/866,078	<b>Applicant(s)</b> Ragusa, Michael	
	<b>Examiner</b> LESLIE R DEAK	<b>Art Unit</b> 3799	<b>AIA (FITF) Status</b> Yes

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1)  Responsive to communication(s) filed on 4 May 2020.  
 A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on \_\_\_\_.
- 2a)  This action is **FINAL**.                      2b)  This action is non-final.
- 3)  An election was made by the applicant in response to a restriction requirement set forth during the interview on \_\_\_\_; the restriction requirement and election have been incorporated into this action.
- 4)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims\***

- 5)  Claim(s) 1-30 is/are pending in the application.  
5a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 6)  Claim(s) \_\_\_\_ is/are allowed.
- 7)  Claim(s) 1-30 is/are rejected.
- 8)  Claim(s) \_\_\_\_ is/are objected to.
- 9)  Claim(s) \_\_\_\_ are subject to restriction and/or election requirement

\* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see [http://www.uspto.gov/patents/init\\_events/pph/index.jsp](http://www.uspto.gov/patents/init_events/pph/index.jsp) or send an inquiry to [PPHfeedback@uspto.gov](mailto:PPHfeedback@uspto.gov).

**Application Papers**

- 10)  The specification is objected to by the Examiner.
- 11)  The drawing(s) filed on 4 May 2020 is/are: a)  accepted or b)  objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

**Priority under 35 U.S.C. § 119**

- 12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
**Certified copies:**  
a)  All    b)  Some\*\*    c)  None of the:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1)  Notice of References Cited (PTO-892)
- 2)  Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)  
Paper No(s)/Mail Date \_\_\_\_.
- 3)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_.
- 4)  Other: \_\_\_\_.

## DETAILED ACTION

### *Notice of Pre-AIA or AIA Status*

1. The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

### *Double Patenting*

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on nonstatutory double patenting provided the reference application or patent either is shown to be commonly owned with the examined application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See

MPEP § 717.02 for applications subject to examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP § 2146 *et seq.* for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit [www.uspto.gov/patent/patents-forms](http://www.uspto.gov/patent/patents-forms). The filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to [www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp](http://www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp).

3. Claims 1-3, 8-17, 23-30, are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1 and 8 of U.S. Patent No. 10,758,652. Although the claims at issue are not identical, they are not patentably distinct from each other. With regard to claims 1-3, the steps of the patented method are the same as the instantly claimed method, but performed in a different order. It is unclear how the methods differ from one another in a practical or patentable way, other than the order of the steps of the method. With regard to claims 8 and 23, the elements of the apparatus are the same, but are recited in a functionally different manner. With regard to claims 15-17, the programming method claimed by Applicant is realized in the execution of the steps performed in the patented method. That is, if the patented method performs the

steps that are “programmed” into a processing device, the method of programming is already known as a part of the patented method.

With regard to claims 9-14 and 24-30, Applicant is setting forth the intended use of the claimed apparatus, which does not add patentable weight to the structural limitations of the apparatus.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a)(1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention.

(a)(2) the claimed invention was described in a patent issued under section 151, or in an application for patent published or deemed published under section 122(b), in which the patent or application, as the case may be, names another inventor and was effectively filed before the effective filing date of the claimed invention.

5. Claims 8-14 and 23-30 are rejected under 35 U.S.C. 102(a)(1) and (a)(2) as being anticipated by US 2003/0125881 to Ryan.

In the specification and figures, Ryan teaches the apparatus as claimed by Applicant. With regard to claims 8 and 23, Ryan discloses a venous access device 12, a blood component separation device 26, plasma container 32, a blood draw line connected to venous access 12, a blood pump 14, an anticoagulant line 20, and a controller 46/48 that calculates a percentage of anticoagulant in the collected plasma, and a volume of plasma collected, and an appropriate time to stop blood pump 14 (see FIG 2, Table 2, ¶022).

With regard to claims 9-14 and 24-30, Applicant is setting forth the intended use of the claimed apparatus, which does not add patentable weight to the structural limitations of the apparatus.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-4, 6, 7, 15-18, 21, and 22 are rejected under 35 U.S.C. 103 as being unpatentable over US 2003/0125881 to Ryan.

In the specification and figures, Ryan teaches the method substantially as claimed by Applicant. With regard to claims 1-4, 6, and 7, Ryan teaches a method for collecting plasma comprising the steps of using donor weight, donor hematocrit and amount/ratio of anticoagulant used to determine a target amount of plasma that can be collected from a patient (see ¶0014). Once that determination is made, the method includes the steps of drawing blood from a patient, adding anticoagulant, separating the blood, collecting the plasma, and repeating those steps until a target plasma volume is reached (see ¶011, 0012, 0022, 0023). Ryan does not teach that the steps of the method are performed in the same order as set forth by Applicant, but does teach using all of the same variables as those used by Applicant (donor weight, hematocrit, amount

of anticoagulant) to generate the same result (target plasma volume), generally suggesting the claimed method to a person having ordinary skill in the art.

With regard to claims 15-18, 21, and 22, the programming method claimed by Applicant is realized in the execution of the steps performed in the patented method. That is, if the patented method performs the steps that are “programmed” into a processing device, the method of programming is already known as a part of the patented method.

8. Claims 3 and 19 are rejected under 35 U.S.C. 103 as being unpatentable over US 2003/0125881 to Ryan in view of US 9,283,316 to Flexman.

In the specification and figures, Ryan discloses the method substantially as claimed by Applicant (see rejections above). With regard to claims 3 and 19, Ryan does not teach the step of taking priming volume into account when determining an anticoagulant ratio. However, Flexman discloses a blood extraction method that considers the amount of anticoagulant used to prime the system while determining the quantity of blood to extract from a patient in order to accurately generate a desired yield (see column 2, lines 7-30). As such, it would have been obvious to a person having ordinary skill in the art at the time of invention to consider the priming volume of an anticoagulant as disclosed by Flexman in a collection and separation calculation as disclosed by Ryan in order to generate a desired yield, as taught by Flexman.

**Conclusion**

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LESLIE R DEAK whose telephone number is (571)272-4943. The examiner can normally be reached on Monday-Friday, 9am to 5:30pm.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at <http://www.uspto.gov/interviewpractice>.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tom Sweet can be reached on 571-272-4761. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <https://ppair-my.uspto.gov/pair/PrivatePair>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

**/LESLIE R DEAK/  
Primary Examiner, Art Unit 3799  
6 November 2020**



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/866,078	05/04/2020	Michael Ragusa	130670-08005	8985
86738	7590	05/12/2020	EXAMINER	
MCCARTER & ENGLISH, LLP BOSTON 265 Franklin Street Boston, MA 02110			ART UNIT	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

doCKET@mccarter.com

<b><i>Decision Granting Request for Prioritized Examination (Track I)</i></b>	<b>Application No.</b> 16/866,078	<b>Applicant(s)</b> Ragusa, Michael	
	<b>Examiner</b> CHERYL P GIBSON BAYLOR	<b>Art Unit</b> OPET	<b>AIA (FITF) Status</b> Yes
<p>1. THE REQUEST FILED <u>04 May 2020</u> IS <b>GRANTED</b> .</p> <p>The above-identified application has met the requirements for prioritized examination</p> <p>A. <input checked="" type="checkbox"/> for an original nonprovisional application (Track I).</p> <p>B. <input type="checkbox"/> for an application undergoing continued examination (RCE).</p> <p>2. <b>The above-identified application will undergo prioritized examination.</b> The application will be accorded special status throughout its entire course of prosecution until one of the following occurs:</p> <p>A. filing a <b><u>petition for extension of time</u></b> to extend the time period for filing a reply;</p> <p>B. filing an <b><u>amendment to amend the application to contain more than four independent claims, more than thirty total claims</u></b>, or a multiple dependent claim;</p> <p>C. filing a <b><u>request for continued examination</u></b> ;</p> <p>D. filing a notice of appeal;</p> <p>E. filing a request for suspension of action;</p> <p>F. mailing of a notice of allowance;</p> <p>G. mailing of a final Office action;</p> <p>H. completion of examination as defined in 37 CFR 41.102; or</p> <p>I. abandonment of the application.</p> <p>Telephone inquiries with regard to this decision should be directed to CHERYL GIBSON BAYLOR at (571)272-3213. In his/her absence, calls may be directed to Petition Help Desk at (571) 272-3282.</p>			
/CHERYL GIBSON BAYLOR/ Paralegal Specialist, OPET			

<b>CERTIFICATION AND REQUEST FOR PRIORITIZED EXAMINATION                      UNDER 37 CFR 1.102(e) (Page 1 of 1)</b>			
First Named Inventor:	Michael Ragusa	Nonprovisional Application Number (if known):	Not Yet Assigned
Title of Invention:	SYSTEM AND METHOD FOR COLLECTING PLASMA		
<p><b>APPLICANT HEREBY CERTIFIES THE FOLLOWING AND REQUESTS PRIORITIZED EXAMINATION FOR THE ABOVE-IDENTIFIED APPLICATION.</b></p> <p>1. The processing fee set forth in 37 CFR 1.17(i)(1) and the prioritized examination fee set forth in 37 CFR 1.17(c) have been filed with the request. The publication fee requirement is met because that fee, set forth in 37 CFR 1.18(d), is currently \$0. The basic filing fee, search fee, and examination fee are filed with the request or have been already been paid. I understand that any required excess claims fees or application size fee must be paid for the application.</p> <p>2. I understand that the application may not contain, or be amended to contain, more than four independent claims, more than thirty total claims, or any multiple dependent claims, and that any request for an extension of time will cause an outstanding Track I request to be dismissed.</p> <p>3. The applicable box is checked below:</p> <p>I. <input checked="" type="checkbox"/> <b>Original Application (Track One) - Prioritized Examination under § 1.102(e)(1)</b></p> <p>i. (a) The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a). This certification and request is being filed with the utility application via EFS-Web.                      ---OR---</p> <p>(b) The application is an original nonprovisional plant application filed under 35 U.S.C. 111(a). This certification and request is being filed with the plant application in paper.</p> <p>ii. An executed inventor's oath or declaration under 37 CFR 1.63 or 37 CFR 1.64 for each inventor, <u>or</u> the application data sheet meeting the conditions specified in 37 CFR 1.53(f)(3)(i) is filed with the application.</p> <p>II. <input type="checkbox"/> <b>Request for Continued Examination - Prioritized Examination under § 1.102(e)(2)</b></p> <p>i. A request for continued examination has been filed with, or prior to, this form.</p> <p>ii. If the application is a utility application, this certification and request is being filed via EFS-Web.</p> <p>iii. The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a), or is a national stage entry under 35 U.S.C. 371.</p> <p>iv. This certification and request is being filed prior to the mailing of a first Office action responsive to the request for continued examination.</p> <p>v. No prior request for continued examination has been granted prioritized examination status under 37 CFR 1.102(e)(2).</p>			
Signature	/Jonathan C. Lovely, Reg. No. 60,821/	Date	May 4, 2020
Name (Print/Typed)	Jonathan C. Lovely	Practitioner Registration Number	60,821
<p><i>Note: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. Submit multiple forms if more than one signature is required.*</i></p>			
<p><input type="checkbox"/> *Total of <u>  1  </u> forms are submitted.</p>			

What is claimed is:

1. A method for collecting plasma comprising:
  - (a) determining a weight of a donor;
  - (b) determining a hematocrit of the donor;
  - (c) calculating a volume of anticoagulant to be collected with a plasma component in a plasma collection container, the volume of anticoagulant to be collected with the plasma component based, at least in part on the hematocrit of the donor;
  - (d) calculating a target volume of pure plasma to collect in the plasma collection container based, at least in part, on the weight of the donor;
  - (e) determining a target collection volume based, at least in part, on the calculated volume of anticoagulant and the calculated volume of pure plasma;
  - (f) withdrawing whole blood from the donor through a venous-access device and a draw line, the draw line connected to a blood component separation device;
  - (g) introducing anticoagulant into the withdrawn whole blood through an anticoagulant line at a predetermined ratio of anticoagulant to whole blood;
  - (h) separating the withdrawn whole blood into the plasma component and at least a second blood component using the blood component separation device;
  - (i) collecting the plasma component from the blood component separation device and into a plasma collection container;
  - (j) continuing steps (f) through (i) until the target collection volume is reached in the plasma collection container.
2. A method according to claim 1, wherein the target collection volume is the calculated volume of pure plasma.
3. A method according to claim 1, wherein the target collection volume is the calculated volume of pure plasma plus the calculated volume of anticoagulant.
4. A method according to claim 1, wherein the calculated volume of anticoagulant is further based, in least in part, on the predetermined ratio of anticoagulant.

5. A method according to claim 1, wherein the calculated volume of anticoagulant includes at least a portion of the anticoagulant to be introduced into the withdrawn blood and at least a portion of a volume of anticoagulant to be added during a priming step.
6. A method according to claim 1, wherein calculating the volume of anticoagulant includes calculating the volume of anticoagulant before withdrawing whole blood.
7. A method according to claim 1, wherein calculating the target volume of pure plasma includes calculating the target volume of pure plasma before withdrawing whole blood from the donor.
8. A system for collecting plasma comprising:
  - a venous-access device for drawing whole blood from a subject and returning blood components to the subject;
  - a blood component separation device for separating the drawn blood into a plasma component and a second blood component, the blood component separation device having an outlet and being configured to send the plasma component to a plasma container;
  - a blood draw line fluidly connected to the venous-access device and configured to transport drawn whole blood to the blood component separation device, the flow through the blood draw line being controlled by a blood draw pump;
  - an anticoagulant line connected to an anticoagulant source, the anticoagulant line configured to introduce anticoagulant into the drawn whole blood; and
  - a controller configured to control the operation of the blood component separation device, the controller configured to calculate (1) a volume of anticoagulant to be collected with plasma in a plasma collection container, the volume of anticoagulant to be collected with the plasma based, at least in part on the hematocrit of the donor, (2) a target volume of pure plasma to collect in the plasma collection container based, at least in part, on the weight of the donor, and (3) a target collection volume based, at least in part, on the calculated volume of anticoagulant and the calculated volume of pure plasma, the system configured to stop the blood draw pump when the target collection volume is collected within the plasma container.

9. A system according to claim 8, wherein the target collection volume is the calculated volume of pure plasma.
10. A system according to claim 8, wherein the target collection volume is the calculated volume of pure plasma plus the calculated volume of anticoagulant to be collected in the plasma collection container.
11. A system according to claim 8, wherein the volume of anticoagulant to be collected within the plasma collection container is further based, in least in part, on the predetermined ratio of anticoagulant.
12. A system according to claim 8, wherein the volume of anticoagulant to be collected in the collected plasma component includes at least a portion of the anticoagulant to be introduced into the withdrawn blood and at least a portion of a volume of anticoagulant to be added during a priming step.
13. A system according to claim 8, wherein the controller is configured to calculate the volume of anticoagulant before withdrawing whole blood from the donor.
14. A system according to claim 8, wherein the controller is configured to calculate the target volume of pure plasma before withdrawing whole blood from the donor.
15. A method for programming a blood component processing device:
  - (a) receiving, in a control system, a weight of a donor;
  - (b) receiving, in the control system, a hematocrit of the donor;
  - (c) calculating, using the control system, a volume of anticoagulant to be collected with a plasma component in a plasma collection container of the blood processing system, the control system calculating the volume of anticoagulant to be collected with the plasma component based, at least in part on the hematocrit of the donor;
  - (d) calculating, using the control system, a target volume of pure plasma to collect in the plasma collection container, the control system calculating the target volume of pure plasma based, at least in part, on the weight of the donor;

(e) determining a target collection volume based, at least in part, on the calculated volume of anticoagulant and the calculated volume of pure plasma; and

(f) programming a controller of a blood processing device with a blood processing end point, the blood processing end point being based, at least in part on the target collection volume.

16. A method according to claim 15, wherein the target collection volume is the calculated volume of pure plasma.

17. A method according to claim 15, wherein the target collection volume is the calculated volume of pure plasma plus the calculated volume of anticoagulant to be collected in the plasma collection container.

18. A method according to claim 15, wherein the volume of anticoagulant to be collected within the plasma collection container is further based, in least in part, on a predetermined ratio of anticoagulant.

19. A method according to claim 15, wherein the volume of anticoagulant to be collected in the collected plasma component includes at least a portion of the anticoagulant to be introduced into the withdrawn blood and at least a portion of a volume of anticoagulant to be added during a priming step.

20. A method according to claim 15, wherein the volume of anticoagulant to be collected with plasma component in the plasma collection container is also based, at least in part, on a volume of anticoagulant to be added to the drawn whole blood.

21. A method according to claim 15, wherein the blood processing end point is when the target collection volume has been collected within the plasma container.

22. A method according to claim 15, wherein the control system includes the controller.

23. A system for collecting plasma comprising:  
a blood processing device including:

a venous-access device for drawing whole blood from a subject and returning blood components to the subject,

a blood component separation device for separating the drawn blood into a plasma component and a second blood component, the blood component separation device having an outlet and being configured to send the plasma component to a plasma container,

a blood draw line fluidly connected to the venous-access device and configured to transport drawn whole blood to the blood component separation device, the flow through the blood draw line being controlled by a blood draw pump, and

an anticoagulant line connected to an anticoagulant source, the anticoagulant line configured to introduce anticoagulant into the drawn whole blood; and

a controller configured to (1) calculate a volume of anticoagulant to be collected with plasma in a plasma collection container, the volume of anticoagulant to be collected with the plasma based, at least in part on a hematocrit of the donor, (2) calculate a target volume of pure plasma to collect in the plasma collection container based, at least in part, on a weight of the donor, and (3) calculate a target collection volume based, at least in part, on the calculated volume of anticoagulant and the calculated volume of pure plasma.

24. The system according to claim 23, wherein the blood processing device is configured to stop the blood draw pump when the target collection volume is collected within the plasma container.

25. The system according to claim 23, wherein the controller is part of the blood processing device.

26. The system according to 23, wherein the controller is further configured to program the blood component separation device with an end point based, at least in part, on the target collection volume.

27. A system according to claim 23, wherein the target collection volume is the calculated volume of pure plasma and/or the calculated volume of pure plasma plus the calculated volume of anticoagulant to be collected in the plasma collection container.

28. A system according to claim 23, wherein the volume of anticoagulant to be collected within the plasma collection container is further based, in least in part, on a predetermined ratio of anticoagulant.

29. A system according to claim 23, wherein the volume of anticoagulant to be collected in the collected plasma component includes at least a portion of the anticoagulant to be introduced into the withdrawn blood and at least a portion of a volume of anticoagulant to be added during a priming step.

30. A system according to claim 23, wherein the blood processing end point is when the target collection volume has been collected within the plasma container.