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APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/608,183	09/01/2020	10758652	130670-08002	7286

86738 7590 08/12/2020
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 539 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, Braintree, MA;

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Docket No.: 130670-08002
(PATENT)

In re Utility Application of:
Haemonetics Corporation

Application No.: 15/608,183

Confirmation No.: 7286

Filed: May 30, 2017

Art Unit: 3799

For: SYSTEM AND METHOD FOR COLLECTING
PLASMA

Examiner: Deak, Leslie R.

REQUEST TO UPDATE THE ADDRESS OF THE APPLICANT AND
REQUEST FOR CORRECTED FILING RECEIPT

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

Dear Sir:

The Applicant hereby requests that the Applicant's address be updated and made of record and a corrected Filing Receipt be issued in the above-identified U.S. Utility Patent Application. The Application Data Sheet filed on May 30, 2017 and the Official Filing Receipt dated June 8, 2017, a copy of which is attached hereto, has an error in the Applicant(s) section.

Please correct the **address of the Applicant, Haemonetics Corporation** to read: **125 Summer Street, Boston, MA 02110** instead of 400 Wood Road, Braintree, MA 02184.

Applicant additionally requests that all pertinent U.S. Patent and Trademark Office records relating to the subject application be changed to reflect this correction.

Concurrent with the filing of this request, the following documents are submitted herewith:

- A Corrected Application Data Sheet (CADS) to correct the address of the Applicant as shown by underlining the correct address and removing the incorrect address as shown by a strikethrough; and

ME1 34017507v.1

- A marked copy of the Official Filing Receipt to correct the city of the Applicant as shown by underlining the correct city and removing the incorrect city as shown by a strikethrough.

The Applicant believes no fee is due with this request. However, if a fee is due, please charge our Deposit Account No. 50-4876, under Order No. 130670-08002 from which the undersigned is authorized to draw.

Dated: August 11, 2010

Respectfully submitted,

Electronic signature: /Jonathan C. Lovely, Reg.

No. 60,821/

Jonathan C. Lovely

Registration No.: 60,821

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Attorney/Agent For Applicant



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United States Patent and Trademark Office
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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY. DOCKET NO.	TOT CLAIMS	IND CLAIMS
15/608,183	05/30/2017	3761	1740	1611/C80 130670-08002	20	2

CONFIRMATION NO. 7286

FILING RECEIPT



CC00000091875350

~~2101~~~~Sunstein Kann Murphy & Timbers LLP~~~~125 SUMMER STREET~~~~BOSTON, MA 02110-1618~~~~86738~~~~MCCARTER & ENGLISH LLP BOSTON~~~~265 Franklin Street~~~~Boston, MA 02110~~

Date Mailed: 06/08/2017

Receipt is acknowledged of this non-provisional patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

Inventor(s)

Michael Ragusa, Hingham, MA;

Applicant(s)

Haemonetics Corporation, ~~Braintree, MA;~~ Boston, MA;Power of Attorney: The patent practitioners associated with Customer Number ~~02101~~ 86738

Domestic Applications for which benefit is claimed - None.

A proper domestic benefit claim must be provided in an Application Data Sheet in order to constitute a claim for domestic benefit. See 37 CFR 1.76 and 1.78.

Foreign Applications for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see <http://www.uspto.gov> for more information.) - None.

Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

Permission to Access Application via Priority Document Exchange: Yes

Permission to Access Search Results: Yes

Applicant may provide or rescind an authorization for access using Form PTO/SB/39 or Form PTO/SB/69 as appropriate.

If Required, Foreign Filing License Granted: 06/06/2017

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 15/608,183**

Projected Publication Date: 12/06/2018

Non-Publication Request: No

Early Publication Request: No
Title

System and Method for Collecting Plasma

Preliminary Class

604

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

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For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, <http://www.stopfakes.gov>. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4258).

LICENSE FOR FOREIGN FILING UNDER
Title 35, United States Code, Section 184
Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

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NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/608,183	05/30/2017	Michael Ragusa	130670-08002	7286
86738	7590	07/28/2020	EXAMINER	
MCCARTER & ENGLISH, LLP BOSTON			DEAK, LESLIE R	
265 Franklin Street			ART UNIT	
Boston, MA 02110			PAPER NUMBER	
			3799	
			NOTIFICATION DATE	DELIVERY MODE
			07/28/2020	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

Response to Rule 312 Communication	Application No. 15/608,183	Applicant(s) Ragusa, Michael	
	Examiner LESLIE R DEAK	Art Unit 3799	AIA (FITF) Status Yes
<p align="center">-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --</p> <p>1. ☒ The amendment filed on <u>15 July 2020</u> under 37 CFR 1.312 has been considered, and has been:</p> <p>a) ☒ entered.</p> <p>b) ☐ entered as directed to matters of form not affecting the scope of the invention.</p> <p>c) ☐ disapproved because the amendment was filed after the payment of the issue fee. Any amendment filed after the date the issue fee is paid must be accompanied by a petition under 37 CFR 1.313(c)(1) and the required fee to withdraw the application from issue.</p> <p>d) ☐ disapproved. See explanation below.</p> <p>e) ☐ entered in part. See explanation below.</p> <p>_____</p>			
/LESLIE R DEAK/ Primary Examiner, Art Unit 3799			

Docket No.: 130670-08002
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Utility Application of:
Haemonetics Corporation

Application No.: 15/608,183

Confirmation No.: 7286

Filed: May 30, 2017

Art Unit: 3799

For: SYSTEM AND METHOD FOR COLLECTING
PLASMA

Examiner: L. R. Deak

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

OK to enter.
/LRD/
22 July 2020

AMENDMENT AFTER ALLOWANCE UNDER 37 C.F.R. § 1.312

Prior to issuance of the patent, Applicant respectfully requests entry of this amendment under 37 C.F.R. § 1.312 for the above-captured patent application.

Amendments to the Claims may be found on page 2.

Remarks may be found on page 7.

Docket No.: 130670-08002
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Utility Application of:
Haemonetics Corporation

Application No.: 15/608,183

Confirmation No.: 7286

Filed: May 30, 2017

Art Unit: 3799

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PLASMA

Examiner: L. R. Deak

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

AMENDMENT AFTER ALLOWANCE UNDER 37 C.F.R. § 1.312

Prior to issuance of the patent, Applicant respectfully requests entry of this amendment under 37 C.F.R. § 1.312 for the above-captured patent application.

Amendments to the Claims may be found on page 2.

Remarks may be found on page 7.

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

3. (Currently Amended) A method according to claim 1, further comprising:
determining a volume of anticoagulant introduced into the whole blood based on a number of rotations of an anticoagulant pump, the calculated volume of anticoagulant in the collected plasma component being based, at least in part, on the number of rotations of the anticoagulant pump.
4. (Currently Amended) A method according to claim 1, further comprising:
determining a volume of anticoagulant within the blood component separation device, the calculated volume of anticoagulant in the collected plasma component being based, at least in part, on the volume of anticoagulant within the blood component separation device.
5. (Currently Amended) A method according to claim 1, further comprising:
monitoring a volume of plasma component collected within the plasma collection container, the calculated volume of pure plasma collected within the plasma collection container ~~device~~ based, at least in part, on the monitored volume of collected plasma component.
6. (Currently Amended) A method according to claim 1, further comprising:
monitoring a weight of plasma component collected within the plasma collection container, the calculated volume of pure plasma collected within the plasma collection container ~~device~~ based, at least in part, on the monitored weight of collected plasma component.
7. (Currently Amended) A method according to claim 1, wherein step (b) includes monitoring a volume of red blood cells collected within the blood component separation device, the determined hematocrit of the donor based, at least in part, on the monitored volume of red blood cells collected within the blood component separation device and a volume of whole blood withdrawn from the donor.
8. (Original) A method according to claim 1, wherein the target volume of pure plasma is based, at least in part, on the weight of the donor.
9. (Previously Presented) A method according to claim 1, wherein the volume of anticoagulant in the collected plasma component includes at least a portion of the anticoagulant introduced into

the withdrawn blood and at least a portion of a volume of anticoagulant added during a priming step.

10. (Original) A method according to claim 1, further comprising:
returning, after collecting at least a portion of the target volume of pure plasma, the second blood component to the donor through a return line.

11. (Currently Amended) 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 and the blood draw pump, the controller configured to calculate (1) a volume of anticoagulant in the collected plasma component as the plasma component is being collected in the plasma ~~collection~~ container, and (2) a volume of pure plasma collected within the plasma container based, at least in part, upon the volume of anticoagulant in the collected plasma component, the controller configured to stop the blood draw pump when a target volume of pure plasma is collected within the plasma container.

12. (Previously Presented) A system according to claim 11, wherein the volume of anticoagulant in the collected plasma component is based, at least in part, on a volume of anticoagulant added to the drawn whole blood and the subject's hematocrit.

13. (Currently Amended) A system according to claim 11, further comprising:
an anticoagulant source weight sensor configured to measure the weight of the anticoagulant source, the controller further configured to monitor a change in volume within the anticoagulant ~~container~~ source based on the measured weight of the anticoagulant source, the calculated volume of anticoagulant in the collected plasma component being based, at least in part, on the change in volume within the anticoagulant source.
14. (Currently Amended) A system according to claim 11, wherein the controller is configured to monitor a number of rotations of an anticoagulant pump to determine a volume of anticoagulant introduced into the whole blood, the calculated volume of anticoagulant in the collected plasma component being based, at least in part, on the number of rotations of the anticoagulant pump.
15. (Currently Amended) A system according to claim 11, further comprising:
an optical sensor located on the blood component separation device and configured to monitor the contents of the blood component separation device and determine if a volume of anticoagulant remains within the blood component separation device, the calculated volume of anticoagulant in the collected plasma component being based, at least in part, on the volume of anticoagulant within the blood component separation device.
16. (Currently Amended) A system according to claim 11, further comprising:
a plasma container weight sensor configured to monitor a volume of plasma component collected within the plasma container, the calculated volume of pure plasma collected within the plasma container ~~collection device~~ based, at least in part, on the monitored volume of collected plasma component.
17. (Currently Amended) A system according to claim 11, further comprising:
a plasma container weight sensor configured to monitor a weight of plasma component collected within the plasma container, the calculated volume of pure plasma collected within the plasma container ~~collection device~~ based, at least in part, on the monitored weight of collected plasma component.

18. (Currently Amended) A system according to claim 11, further comprising:
an optical sensor located on the blood component separation device and configured to monitor a volume of red blood cells collected within the blood component separation device, the controller configured to determine the subject's hematocrit based, at least in part, upon on the monitored volume of red blood cells collected within the blood component separation device and a volume of whole blood withdrawn from the ~~donor~~ subject.
19. (Currently Amended) A system according to claim 11, wherein the target volume of pure plasma is based, at least in part, on the weight of the ~~donor~~ subject.
20. (Previously Presented) A system according to claim 11, wherein the volume of anticoagulant in the collected plasma component includes at least a portion of the anticoagulant introduced into the withdrawn blood and at least a portion of a volume of anticoagulant added during a priming step.

REMARKS

Applicant would like to thank the examiner for the Notice of Allowance dated May 8, 2020 and for finding claims 1-20 to be allowable. In the present paper, Applicant requests amendments to claims 2-7, 11 and 13-19 be entered. The amendments to the claims do not include new matter and the claims have not been amended for reasons related to patentability.

Amendments to the Claims

Claims 2-7, 11 and 13-19 have been amended herein for language consistency. In particular, the following amendments have been made:

- Claims 2-4 and 14-15 have been amended such that “collected plasma” now reads “collected plasma component”
- Claim 3 has also been amended to add “to” after “a method according...”
- Claims 5-6 have been amended such that “plasma collection device” now reads “plasma collection container”
- Claim 7 has been amended such that “blood separation device” now reads “blood component separation device”
- Claim 11 has been amended such that “plasma collection container” now reads “plasma container”
- Claim 13 has been amended such that “collected plasma” now reads “collected plasma component” and “anticoagulant container” now reads “anticoagulant source”
- Claims 16 and 17 have been amended such that “plasma collection device” now reads “plasma container”.
- Claim 18 has been amended such that “blood separation device” now reads “blood component separation device” and “donor” now reads “subject”

- Claim 19 has been amended such that “donor” now reads “subject”

Applicant respectfully requests that the Examiner enter the amendments presented herein pursuant to 37 C.F.R. § 1.312. The amendments to the claims merely correct obvious typographical errors and language inconsistency. The amendments do not change the scope of the claims and, therefore, are patentable for at least those reasons given in the Notice of Allowance. Applicant believes that the amended claims do not require additional search or examination. Applicant therefore respectfully requests that the amendments be approved and entered, and the application proceed to issuance.

CONCLUSION

It is believed that the application remains in order for allowance. This amendment is submitted with payment of the issue fee. The director is hereby authorized to charge any additional fees which may be required with respect to this communication or credit any overpayment to deposit account No. 50-4876, under order No. 130670-08002. Applicants also request that the examiner contact applicants’ attorney, Jonathan Lovely, if it will assist in processing this application through issuance.

Dated: July 15, 2020

Respectfully submitted,
Electronic signature: /Jonathan C. Lovely, Reg.
No. 60,821/
Jonathan C. Lovely
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Attorney/Agent For Applicant



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NOTICE OF ALLOWANCE AND FEE(S) DUE

86738 7590 05/08/2020
MCCARTER & ENGLISH, LLP BOSTON
265 Franklin Street
Boston, MA 02110

EXAMINER

DEAK, LESLIE R

ART UNIT

PAPER NUMBER

3799

DATE MAILED: 05/08/2020

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/608,183	05/30/2017	Michael Ragusa	130670-08002	7286

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	\$1000	\$0.00	\$0.00	\$1000	08/10/2020

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 05/08/2020
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.
15/608,183	05/30/2017	Michael Ragusa	130670-08002	7286

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	\$1000	\$0.00	\$0.00	\$1000	08/10/2020

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. _____



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/608,183	05/30/2017	Michael Ragusa	130670-08002	7286
86738	7590	05/08/2020	EXAMINER	
MCCARTER & ENGLISH, LLP BOSTON			DEAK, LESLIE R	
265 Franklin Street			ART UNIT	
Boston, MA 02110			PAPER NUMBER	
			3799	
DATE MAILED: 05/08/2020				

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. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

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 Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

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.

Notice of Allowability	Application No. 15/608,183	Applicant(s) Ragusa, Michael	
	Examiner LESLIE R DEAK	Art Unit 3799	AIA (FITF) Status 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 AFCP filing submitted 1 May 2020.
☐ 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 1-20 . 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 or send an inquiry to 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)	5. ☐ Examiner's Amendment/Comment
2. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____.	6. ☒ Examiner's Statement of Reasons for Allowance
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material _____.	7. ☒ Other <u>AFCP form</u> .
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date. _____.	

/LESLIE R DEAK/ Primary Examiner, Art Unit 3799	
--	--

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.

Allowable Subject Matter

2. Claims 1-20 are allowed.
3. The following is an examiner's statement of reasons for allowance: The prior art fails to disclose or suggest the method and system as claimed by Applicant. In particular, the prior art fails to disclose a method of collecting blood plasma wherein a volume of anticoagulant in the collected plasma component is calculated in real time, as the plasma is being collected (such as by counting anticoagulant pump revolutions), along with the other steps and limitations of the claims. The prior art systems rely on calculations prepared in advance.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

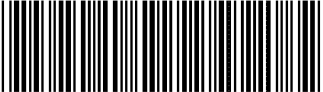
4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LESLIE R DEAK whose telephone number is (571)272-4943. The examiner can normally be reached on Monday-Friday, 9am to 5:30pm.

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
5 May 2020**

Issue Classification 	Application/Control No. 15/608,183	Applicant(s)/Patent Under Reexamination Ragusa, Michael
	Examiner LESLIE R DEAK	Art Unit 3799

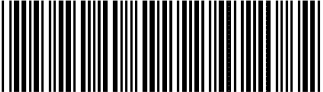
CPC						
Symbol					Type	Version
A61M	/	1	/	024	F	2013-01-01
A61M	/	1	/	029	I	2013-01-01
A61M	/	1	/	3672	I	2013-01-01
A61M	/	1	/	38	I	2013-01-01
G01N	/	15	/	05	A	2013-01-01
G01N	/	2015	/	055	A	2013-01-01
A61M	/	2230	/	207	A	2013-01-01
A61M	/	2202	/	0415	A	2013-01-01
A61M	/	1	/	3693	A	2013-01-01

CPC Combination Sets					
Symbol			Type	Set	Ranking
	/				

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	20	
/LESLIE R DEAK/ Primary Examiner, Art Unit 3799	05 May 2020	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	4

U.S. Patent and Trademark Office

Part of Paper No.: 20200505

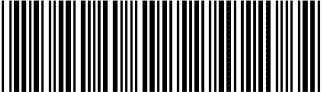
Issue Classification 	Application/Control No. 15/608,183	Applicant(s)/Patent Under Reexamination Ragusa, Michael
	Examiner LESLIE R DEAK	Art Unit 3799

INTERNATIONAL CLASSIFICATION			
CLAIMED			
A61M1/02		1	02
A61M1/36		1	36
A61M1/38		1	38
NON-CLAIMED			
G01N15/05		15	05

US ORIGINAL CLASSIFICATION	
CLASS	SUBCLASS

CROSS REFERENCES(S)						
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)					

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	20	
/LESLIE R DEAK/ Primary Examiner, Art Unit 3799	05 May 2020	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	4

Issue Classification 	Application/Control No. 15/608,183	Applicant(s)/Patent Under Reexamination Ragusa, Michael
	Examiner LESLIE R DEAK	Art Unit 3799

☒ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47															
CLAIMS															
Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original

NONE	Total Claims Allowed:	
(Assistant Examiner)	(Date)	20
/LESLIE R DEAK/ Primary Examiner, Art Unit 3799	05 May 2020	O.G. Print Claim(s)
(Primary Examiner)	(Date)	1
		O.G. Print Figure
		4

AFCP 2.0 Decision

Application No.

15/608,183

Applicant(s)

Ragusa, Michael

Examiner

LESLIE R DEAK

Art Unit

3799

AIA (FITF) Status

Yes

This is in response to the After Final Consideration Pilot request filed 01 May 2020.

1. **Improper Request** – The AFCP 2.0 request is improper for the following reason(s) and the after final amendment submitted with the request will be treated under pre-pilot procedure.

- ☐ An AFCP 2.0 request form PTO/SB/434 (or equivalent document) was not submitted.
- ☐ A non-broadening amendment to at least one independent claim was not submitted.
- ☐ The request is not the first proper AFCP 2.0 request submitted in response to the most recent final rejection.
- ☐ Other: _____

2. Proper Request

- A. After final amendment submitted with the request will not be treated under AFCP 2.0.

The after final amendment cannot be reviewed and a search conducted within the guidelines of the pilot program.

- ☐ The after final amendment will be treated under pre-pilot procedure.

- B. Updated search and/or completed additional consideration.

The examiner performed an updated search and/or completed additional consideration of the after final amendment within the time authorized for the pilot program. The result(s) of the updated search and/or completed additional consideration are:

- ☒ 1. All of the rejections in the most recent final Office action are overcome and a Notice of Allowance is issued herewith.
- ☐ 2. The after final amendment would not overcome all of the rejections in the most recent final Office action. See attached interview summary for further details.
- ☐ 3. The after final amendment was reviewed, and it raises a new issue(s). See attached interview summary for further details.
- ☐ 4. The after final amendment raises new issues, but would overcome all of the rejections in the most recent final Office action. A decision on determining allowability could not be made within the guidelines of the pilot. See attached interview summary for further details, including any newly discovered prior art.
- ☐ 5. Other: _____

Examiner Note: Please attach an interview summary when necessary as described above.

CERTIFICATION AND REQUEST FOR CONSIDERATION UNDER THE AFTER FINAL CONSIDERATION PILOT PROGRAM 2.0		
Practitioner Docket No.: 130670-08002	Application No.: 15/608,183	Filing Date: May 30, 2017
First Named Inventor: Michael Ragusa	Title: SYSTEM AND METHOD FOR COLLECTING PLASMA	
<p>APPLICANT HEREBY CERTIFIES THE FOLLOWING AND REQUESTS CONSIDERATION UNDER THE AFTER FINAL CONSIDERATION PILOT PROGRAM 2.0 (AFCP 2.0) OF THE ACCOMPANYING RESPONSE UNDER 37 CFR 1.116.</p> <ol style="list-style-type: none"> 1. The above-identified application is (i) an original utility, plant, or design nonprovisional application filed under 35 U.S.C. 111(a) [a continuing application (e.g., a continuation or divisional application) is filed under 35 U.S.C. 111(a) and is eligible under (i)], or (ii) an international application that has entered the national stage in compliance with 35 U.S.C. 371(c). 2. The above-identified application contains an outstanding final rejection. 3. Submitted herewith is a response under 37 CFR 1.116 to the outstanding final rejection. The response includes an amendment to at least one independent claim, and the amendment does not broaden the scope of the independent claim in any aspect. 4. This certification and request for consideration under AFCP 2.0 is the only AFCP 2.0 certification and request filed in response to the outstanding final rejection. 5. Applicant is willing and available to participate in any interview requested by the examiner concerning the present response. 6. This certification and request is being filed electronically using the Office's electronic filing system (EFS-Web). 7. Any fees that would be necessary consistent with current practice concerning responses after final rejection under 37 CFR 1.116, e.g., extension of time fees, are being concurrently filed herewith. [There is no additional fee required to request consideration under AFCP 2.0.] 8. By filing this certification and request, applicant acknowledges the following: <ul style="list-style-type: none"> • Reissue applications and reexamination proceedings are not eligible to participate in AFCP 2.0. • The examiner will verify that the AFCP 2.0 submission is compliant, i.e., that the requirements of the program have been met (see items 1 to 7 above). For compliant submissions: <ul style="list-style-type: none"> o The examiner will review the response under 37 CFR 1.116 to determine if additional search and/or consideration (i) is necessitated by the amendment and (ii) could be completed within the time allotted under AFCP 2.0. If additional search and/or consideration is required but cannot be completed within the allotted time, the examiner will process the submission consistent with current practice concerning responses after final rejection under 37 CFR 1.116, e.g., by mailing an advisory action. o If the examiner determines that the amendment does not necessitate additional search and/or consideration, or if the examiner determines that additional search and/or consideration is required and could be completed within the allotted time, then the examiner will consider whether the amendment places the application in condition for allowance (after completing the additional search and/or consideration, if required). If the examiner determines that the amendment does not place the application in condition for allowance, then the examiner will contact the applicant and request an interview. <ul style="list-style-type: none"> ▪ The interview will be conducted by the examiner, and if the examiner does not have negotiation authority, a primary examiner and/or supervisory patent examiner will also participate. ▪ If the applicant declines the interview, or if the interview cannot be scheduled within ten (10) calendar days from the date that the examiner first contacts the applicant, then the examiner will proceed consistent with current practice concerning responses after final rejection under 37 CFR 1.116. 		
Signature	/Jonathan C. Lovely, Reg. No. 60,821/	Date May 1, 2020
Name (Print/Typed)	Jonathan C. Lovely	Practitioner Registration No. 60,821
<p>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, see below*.</p>		
<div style="display: flex; align-items: center;"> <input style="width: 20px; height: 20px; margin-right: 5px;" type="checkbox"/> * Total of <u>1</u> forms are submitted. </div>		

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Utility Application of:
Haemonetics Corporation

Application No.: 15/608,183

Confirmation No.: 7286

Filed: May 30, 2017

Art Unit: 3799

For: SYSTEM AND METHOD FOR COLLECTING
PLASMA

Examiner: L. R. Deak

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

**RESPONSE UNDER 37 CFR 1.116 REQUESTING CONSIDERATION UNDER
THE AFTER FINAL CONSIDERATION PILOT PROGRAM (AFCP 2.0)**

Dear Sir:

INTRODUCTORY COMMENTS

In response to the Final Office Action dated March 3, 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 7 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. (Currently Amended) A method for collecting plasma comprising:
 - (a) determining a weight of a donor;
 - (b) determining a hematocrit of the donor;
 - (c) inserting a venous-access device into the donor;
 - (d) withdrawing whole blood from the donor through the venous-access device and a draw line, the draw line connected to a blood component separation device;
 - (e) introducing anticoagulant into the withdrawn whole blood through an anticoagulant line;
 - (f) separating the withdrawn whole blood into a plasma component and at least a second blood component using the blood component separation device;
 - (g) collecting the plasma component from the blood component separation device and into a plasma collection container;
 - (h) calculating a ~~percentage~~ volume of anticoagulant in the collected plasma component as the plasma component is being collected in the plasma collection container;
 - (i) calculating a volume of pure plasma collected within the plasma collection container based, at least in part, on the calculated ~~percentage~~ volume of anticoagulant in the collected plasma component; and
 - (j) continuing steps (d) through (i) until a target volume of pure plasma is collected within the plasma collection container.
2. (Currently Amended) A method according to claim 1, further comprising:
determining a change in volume within an anticoagulant container, the calculated volume ~~percentage~~ of anticoagulant in the collected plasma being based, at least in part, on the change in volume within the anticoagulant container.

3. (Currently Amended) A method according to claim 1, further comprising:
determining a volume of anticoagulant introduced into the whole blood based on a number of rotations of an anticoagulant pump, the calculated volume percentage of anticoagulant in the collected plasma being based, at least in part, on the number of rotations of the anticoagulant pump.
4. (Currently Amended) A method according to claim 1, further comprising:
determining a volume of anticoagulant within the blood component separation device, the calculated volume percentage of anticoagulant in the collected plasma being based, at least in part, on the volume of anticoagulant within the blood component separation device.
5. (Original) A method according to claim 1, further comprising:
monitoring a volume of plasma component collected within the plasma collection container, the calculated volume of pure plasma collected within the plasma collection device based, at least in part, on the monitored volume of collected plasma component.
6. (Original) A method according to claim 1, further comprising:
monitoring a weight of plasma component collected within the plasma collection container, the calculated volume of pure plasma collected within the plasma collection device based, at least in part, on the monitored weight of collected plasma component.
7. (Currently Amended) A method according to claim 1, wherein step (b) includes monitoring a volume of red blood cells ~~collection~~ collected within the blood separation device, the determined hematocrit of the donor based, at least in part, on the monitored volume of red blood cells collected within the blood separation device and a volume of whole blood withdrawn from the donor.
8. (Original) A method according to claim 1, wherein the target volume of pure plasma is based, at least in part, on the weight of the donor.
9. (Currently Amended) A method according to claim 1, wherein the volume percentage of anticoagulant in the collected plasma component includes at least a portion of the anticoagulant introduced into the withdrawn blood and at least a portion of a volume of anticoagulant added during a priming step.

10. (Original) A method according to claim 1, further comprising:
returning, after collecting at least a portion of the target volume of pure plasma, the second blood component to the donor through a return line.
11. (Currently Amended) 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 ~~centrifuge bowl~~ blood component separation device and the blood draw pump, the controller configured to calculate (1) a percentage volume of anticoagulant in the collected plasma component as the plasma component is being collected in the plasma collection container, and (2) a volume of pure plasma collected within the plasma container based, at least in part, upon the percentage volume of anticoagulant in the collected plasma component, the controller configured to stop the blood draw pump when a target volume of pure plasma is collected within the plasma container.
12. (Currently Amended) A system according to claim 11, wherein the percentage volume of anticoagulant in the collected plasma component is based, at least in part, on a volume of anticoagulant added to the drawn whole blood and the subject's hematocrit.
13. (Currently Amended) A system according to claim 11, further comprising:
an anticoagulant source weight sensor configured to measure the weight of the anticoagulant source, the controller further configured to monitor a change in volume within the anticoagulant

container based on the measured weight of the anticoagulant source, the calculated ~~percentage~~ volume of anticoagulant in the collected plasma being based, at least in part, on the change in volume within the anticoagulant source.

14. (Currently Amended) A system according to claim 11, wherein the controller is configured to monitor a number of rotations of an anticoagulant pump to determine a volume of anticoagulant introduced into the whole blood, the calculated ~~percentage~~ volume of anticoagulant in the collected plasma being based, at least in part, on the number of rotations of the anticoagulant pump.

15. (Currently Amended) A system according to claim 11, further comprising:
an optical sensor located on the blood component separation device and configured to monitor the contents of the blood component separation device and determine if a volume of anticoagulant remains within the blood component separation device, the calculated ~~percentage~~ volume of anticoagulant in the collected plasma being based, at least in part, on the volume of anticoagulant within the blood component separation device.

16. (Original) A system according to claim 11, further comprising:
a plasma container weight sensor configured to monitor a volume of plasma component collected within the plasma container, the calculated volume of pure plasma collected within the plasma collection device based, at least in part, on the monitored volume of collected plasma component.

17. (Original) A system according to claim 11, further comprising:
a plasma container weight sensor configured to monitor a weight of plasma component collected within the plasma container, the calculated volume of pure plasma collected within the plasma collection device based, at least in part, on the monitored weight of collected plasma component.

18. (Original) A system according to claim 11, further comprising:
an optical sensor located on the blood component separation device and configured to monitor a volume of red blood cells collected within the blood separation device, the controller

configured to determine the subject's hematocrit based, at least in part, upon on the monitored volume of red blood cells collected within the blood separation device and a volume of whole blood withdrawn from the donor

19. (Original) A system according to claim 11, wherein the target volume of pure plasma is based, at least in part, on the weight of the donor.

20. (Currently Amended) A system according to claim 11, wherein the ~~percentage~~ volume of anticoagulant in the collected plasma component includes at least a portion of the anticoagulant introduced into the withdrawn blood and at least a portion of a volume of anticoagulant added during a priming step.

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 1-4, 7, 9, 11-15 and 20 herewith. Claims 1-20 are currently pending in the application.

Examiner Interview Summary

Applicant would like to thank Examiner Deak for the telephone interview on March 25, 2020. During the interview, Examiner Deak, Applicant's counsel and Michael Ragusa (the inventor) discussed the pending claims, the Office Action dated March 3, 2020 and the cited prior art (e.g., U.S. Application No. 2003/012881 to Ryan, hereinafter "Ryan"). In particular, Applicant's counsel and Mr. Ragusa explained that Ryan does not calculate a volume of pure plasma and calculates the volume of anticoagulant in the plasma component in a different manner. Examiner Deak proposed adding a temporal component to the independent claims to specify when the volume of anticoagulant in the collected plasma component is calculated. To expedite prosecution, Applicant's counsel and Mr. Ragusa suggested the possibility of amending the claims to specify that the anticoagulant in the plasms component is calculated "as the plasma component is being collected in the plasma collection container." Examiner Deak indicated that such an amendment should overcome the cited prior art.

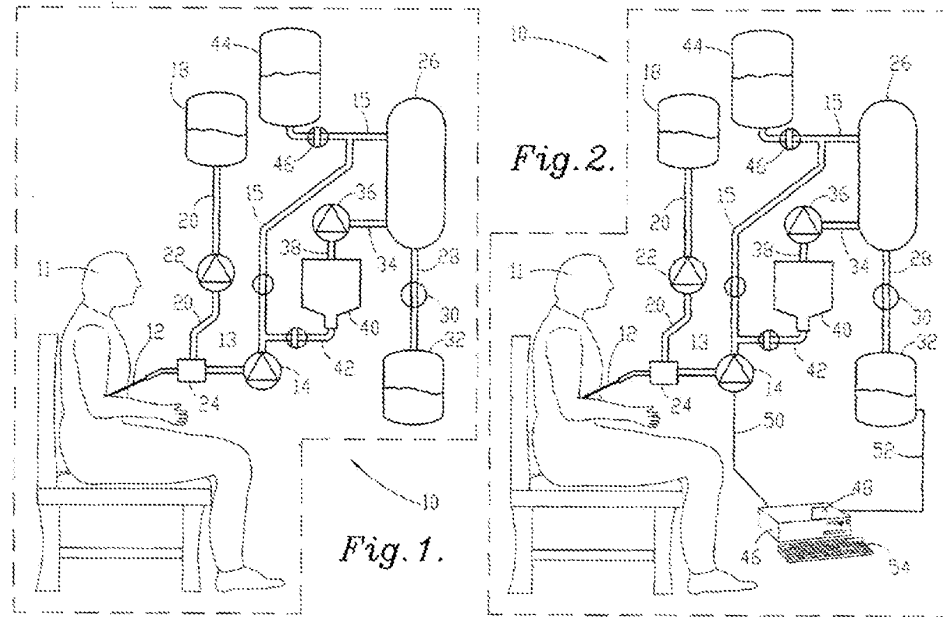
35 USC § 102

Claims 11, 12, 16, 17, 19 and 20 are rejected under 35 U.S.C. 102(a)(1) and (a)(2) as being anticipated by U.S. 2003/0125881 to Ryan.

Amended claim 11 defines, in relevant part, a system for collecting plasma that includes (1) a venous-access device for drawing whole blood from a subject and returning blood components to the subject, 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 may have an outlet and may send the plasma component to a plasma container. A blood draw line fluidly

connected to the venous-access device transports the drawn whole blood to the blood component separation device, and the flow through the blood draw line is controlled by a blood draw pump. An anticoagulant line is connected to an anticoagulant source and introduces anticoagulant into the drawn whole blood. The system also has a controller that controls the operation of the centrifuge bowl and the blood draw pump. The controller may calculate (1) a volume of anticoagulant in the collected plasma component as the plasma component is being collected in the plasma collection container, and (2) a volume of pure plasma collected within the plasma container based, at least in part, upon the volume of anticoagulant in the collected plasma component. The controller may stop the blood draw pump when a target volume of pure plasma 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 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 "actual" volume of plasma is a combination of plasma and anticoagulant.



The office action suggests that Ryan's controller/processor 46/48 constitutes the claimed controller and that Ryan's controller/processor 46/48 calculate a percentage of anticoagulant in the collected plasma, a volume of plasma collected, and an appropriate time to stop the blood pump 14. As noted above, Applicant has amended claim 11 to specify that the controller calculates a volume of anticoagulant in the collected plasma component as the plasma component is being collected in the plasma collection container. Ryan fails to teach or suggest such an anticoagulant calculation. Rather, at best, Ryan calculates a total collection volume (plasma and anticoagulant) prospectively prior to the start of the blood processing. In particular, as discussed within Ryan (e.g., see paragraphs [0024], [0025] and [0032] to [0036]), Ryan determines the donor's body weight and then multiplies the weight by a collection volume per pound (e.g., 5.8 milliliters per pound of donor body weight) to determine a volume of plasma and anticoagulant to collect. Ryan does not calculate the volume of anticoagulant in the collected plasma as the plasma component is collected in the container, as required by amended claim 11.

Furthermore, Ryan does not calculate a volume of pure plasma (plasma only without anticoagulant) collected within the plasma collection container and then stop the processing once a target of pure plasma is collected. Rather, as evidenced by the equation provided in paragraphs [0032] and [0033] of Ryan (e.g., “ $V_{pac}=DW \times CV$ ”) and the comparison in Table 3 of Ryan, Ryan calculates and stops based on a volume that includes both plasma and anticoagulant, not just pure plasma as required by amended claim 11. Additionally, Ryan specifically teaches using a scale to measure the weight of the bag 32 (the plasma collection container) or an optical sensor to measure the volume within the bag 32 and stopping when this measurement reaches the target. However, both the scale and the optical sensor measure the volume of the plasma and anticoagulant collected in the bag. Accordingly, Ryan does not teach or suggest calculating the volume of anticoagulant in the collected plasma component as the plasma component is collected and does not compensate for this volume of anticoagulant obtain/calculate a volume of “pure plasma,” as required by claim 11.

Therefore, claim 11 is allowable over Ryan. Moreover, claims 12, 16, 17, 19 and 20 which depend from claim 11 are also allowable over Ryan

35 USC § 103

Claims 1, 5, 6, 8-10 are rejected under 35 U.S.C. 103 as being unpatentable over U.S. 2003/0125881 to Ryan.

In a manner similar to claim 11, claim 1 defines, in relevant part, a method for collecting plasma that includes (1) determining the weight and hematocrit of a donor, (2) calculating a volume of anticoagulant in the collected plasma component as the plasma component is being collected in the plasma container, (3) calculating a volume of pure plasma collected within the plasma collection container, and (4) collecting plasma until a target volume of pure plasma is collected within the plasma collection container. Accordingly, claim 1 is allowable over Ryan for at least the same reasons as discussed above for claim 11. For example, as discussed above, Ryan fails to teach or suggest calculating the volume of anticoagulant in the collected plasma component as the plasma component is collected and does not compensate for this volume of anticoagulant to obtain/calculate a volume of “pure plasma” – Ryan sets a total volume of plasma and anticoagulant to collect prior

to the start of processing and looks at the volume of plasma and anticoagulant combined. Therefore, amended claim 1 is allowable over Ryan. Moreover, claims 5, 6, and 8-10 are allowable over Ryan for at least the same reasons.

Claims 2-4, 13 and 14 are rejected under 35 U.S.C. 103 as being unpatentable over U.S. 2003/0125881 to Ryan in view of U.S. 2012/0175313 to Barry et al.

As dependent claims of claims 1 and 11, claims 2-4 and 13-14 include all of the limitations of the base claim from which they depend. Therefore, claims 2-4 and 13-14 are allowable over the cited prior art for at least the reasons discussed above for claims 1 and 11.

Comments Regarding Claim Amendments

As discussed above, Applicant has amended the pending claims to specify that the volume of anticoagulant in the plasma component is calculated as the plasma component is being collected in the plasma collection container. Applicant would like to note that these amendments are being made to expedite prosecution and is not meant to be an agreement that the cited prior art teaches the claims as originally filed. Additionally, Applicant would like to note that other embodiments disclosed within the present application may calculate the anticoagulant within the plasma collection container in a different manner. For example, other disclosed embodiments may calculate the percentage of anticoagulant in the container and/or may calculate it at a different time (e.g., before blood processing begins). The amendments made herein are not intended to limit Applicant's ability to pursue such alternative embodiments in the future and are not intended to be a disclaimer of these alternative embodiments or any other subject matter supported by the disclosure of the present application, including the originally filed claims.

CONCLUSION

It is believed that the application is now in order for allowance and Applicants respectfully request that a notice of allowance be issued. Applicant believes no fee is due with this response. Applicants also request that the examiner contact applicants' attorney, Jonathan Lovely, if it will assist in processing this application through issuance.

Dated: May 1, 2020

Respectfully submitted,
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/608,183	05/30/2017	Michael Ragusa	130670-08002	7286
86738	7590	03/30/2020	EXAMINER	
MCCARTER & ENGLISH, LLP BOSTON			DEAK, LESLIE R	
265 Franklin Street				
Boston, MA 02110			ART UNIT	PAPER NUMBER
			3781	
			NOTIFICATION DATE	DELIVERY MODE
			03/30/2020	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

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) 1.133 Interviews

Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiners responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicants correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted, -
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicants record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiners version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, Interview Record OK on the paper recording the substance of the interview along with the date and the examiners initials.

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: Steps h, i, j are the meat here. Prior art systems, when they collect plasma, FDA provides a nomogram based on weight of the patient, sets out how much volume you can pull out of each of the weight groups. Prior art systems collect plasma and AC, and base measurements off of the combined volume. In the instant case, if we tailor calculations to the donor, it's more accurate. Calculate the percentage of AC in the container, and from that, calculate the amount of pure plasma. Ryan doesn't follow FDA nomogram directly, but uses individual weights to figure out how much plasma to pull out. Ryan's calculations of collections are that of plasma and AC. AC percentage calculations done by Ryan are at the beginning of separation, and there's no teaching of how to calculate the AC in the actual collection bag.

How does this invention make the calculation of how much AC is in the collection bag? Fxn of donor hct and AC ratio. Based on weight or pump strokes.

Ryan calculates how much AC is going into the separator. Here, we're seeing how much AC is in the plasma after separation. Ryan lacks any ability to track how much AC is going to the product, and how much is being returned to the donor.

Examiner suggested adding "real-time" measurements of AC volume in steps h and i of the claimed method. Applicant will review the claim language and make formal amendments. Applicant's suggested claim language appears to overcome the Ryan reference.



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/608,183	05/30/2017	Michael Ragusa	130670-08002	7286
86738	7590	03/03/2020	EXAMINER	
MCCARTER & ENGLISH, LLP BOSTON			DEAK, LESLIE R	
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docket@mccarter.com

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.

Response to Arguments

2. Applicant's arguments filed 31 January 2020 have been fully considered but they are not persuasive.

3. Applicant argues that Ryan fails to calculate a volume of "pure plasma" (plasma without anticoagulant) in the plasma container, the value of which is used to control the blood draw pump. Applicant alleges that Ryan calculates only the amount of fluid in the plasma container, which is a combination of pure plasma and anticoagulant. While Ryan focuses on total volume collection in Table 1, the following paragraphs go deeper. Ryan clearly discloses in paragraph 0022 that the apparatus and method can calculate a plasma volume of (such as 625mL) based on a total collection volume of plasma and anticoagulant (such as 690mL), and this information may be used to control the pumping of blood from the donor (see Table 2, ¶0022). As such, Ryan reasonably discloses the calculation of a pure plasma volume as claimed by Applicant.

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 11, 12, 16, 17, 19, and 20 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 claim 11, 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, ¶0022).

With regard to claims 12, 19, 20, Ryan teaches using a patient's weight, hematocrit, and amount of anticoagulant used to determine a target amount of collected plasma with a determined amount of anticoagulant (see ¶0014).

With regard to claims 15-17, Ryan discloses a plasma container weight sensor as well as an optical sensor (see ¶0031).

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, 5, 6, and 8-10 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 as claimed by Applicant. With regard to claims 1, 8, 9, Ryan teaches a method for collecting plasma comprising the steps of using donor weight, donor hematocrit and amount 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 ¶0011, 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 5, 6, Ryan teaches that the volume of plasma collected is monitored throughout the procedure via weight or light transmission (see ¶0031, 0044).

With regard to claim 10, Ryan discloses that a second, cellular blood component may be returned to the patient (see ¶0012).

8. Claims 2-4, 7, 13, 14, and 18 are rejected under 35 U.S.C. 103 as being unpatentable over US 2003/0125881 to Ryan in view of US 2012/0175313 to Barry et al.

In the specification and figures, Ryan discloses the method and apparatus substantially as claimed by Applicant. With regard to claims 2-4, 13, 14, Ryan fails to disclose the step of determining a change in the volume of anticoagulant to determine the amount of anticoagulant in the system. However, Barry discloses monitoring pump strokes and, as a backup, weight of the anticoagulant container to determine the amount of anticoagulant in the extracorporeal system (see ¶0057). The monitoring of the pumps and weight sensor help ensure an accurate metering of anticoagulant within the separation circuit (see ¶0057). It would have been obvious to a person having ordinary skill in the art at the time of filing to add the monitoring system and steps disclosed by Barry to the apparatus and method disclosed by Ryan in order to provide accurate metering of anticoagulant within the separation circuit, as taught by Barry.

With regard to claims 7 and 18, Ryan is silent as to an optical hematocrit sensor. However, Barry discloses an apheresis apparatus and method that uses an optical hematocrit sensor to accurately set and monitor target collection volumes in order to more accurately control the collection procedure (see US 2009/0215602 ¶0327, incorporated by reference in '313. ¶0035, 0058, 0084). It would have been obvious to a person having ordinary skill in the art at the time of filing to add the optical monitoring system and steps disclosed by Barry to the apparatus and method disclosed by Ryan in order to provide accurate setting and monitoring of target collection values within the separation circuit, as taught by Barry.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. 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, Tatyana Zalukaeva can be reached on 571-272-1115. 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 <http://pair-direct.uspto.gov>. 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 3781
27 February 2020**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Utility Application of:
Michael Ragusa

Application No.: 15/608,183

Confirmation No.: 7286

Filed: May 30, 2017

Art Unit: 3781

For: SYSTEM AND METHOD FOR COLLECTING
PLASMA

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 1, 2019, 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 7 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) inserting a venous-access device into the donor;
 - (d) withdrawing whole blood from the donor through the venous-access device and a draw line, the draw line connected to a blood component separation device;
 - (e) introducing anticoagulant into the withdrawn whole blood through an anticoagulant line;
 - (f) separating the withdrawn whole blood into a plasma component and at least a second blood component using the blood component separation device;
 - (g) collecting the plasma component from the blood component separation device and into a plasma collection container;
 - (h) calculating a percentage of anticoagulant in the collected plasma component;
 - (i) calculating a volume of pure plasma collected within the plasma collection container based, at least in part, on the calculated percentage of anticoagulant in the collected plasma component; and
 - (j) continuing steps (d) through (i) until a target volume of pure plasma is collected within the plasma collection container.
2. (Original) A method according to claim 1, further comprising:
 - determining a change in volume within an anticoagulant container, the calculated percentage of anticoagulant in the collected plasma being based, at least in part, on the change in volume within the anticoagulant container.

3. (Original) A method according claim 1, further comprising:
determining a volume of anticoagulant introduced into the whole blood based on a number of rotations of an anticoagulant pump, the calculated percentage of anticoagulant in the collected plasma being based, at least in part, on the number of rotations of the anticoagulant pump.
4. (Original) A method according to claim 1, further comprising:
determining a volume of anticoagulant within the blood component separation device, the calculated percentage of anticoagulant in the collected plasma being based, at least in part, on the volume of anticoagulant within the blood component separation device.
5. (Original) A method according to claim 1, further comprising:
monitoring a volume of plasma component collected within the plasma collection container, the calculated volume of pure plasma collected within the plasma collection device based, at least in part, on the monitored volume of collected plasma component.
6. (Original) A method according to claim 1, further comprising:
monitoring a weight of plasma component collected within the plasma collection container, the calculated volume of pure plasma collected within the plasma collection device based, at least in part, on the monitored weight of collected plasma component.
7. (Original) A method according to claim 1, wherein step (b) includes monitoring a volume of red blood cells collection within the blood separation device, the determined hematocrit of the donor based, at least in part, on the monitored volume of red blood cells collected within the blood separation device and a volume of whole blood withdrawn from the donor.
8. (Original) A method according to claim 1, wherein the target volume of pure plasma is based, at least in part, on the weight of the donor.
9. (Original) A method according to claim 1, wherein the percentage of anticoagulant in the collected plasma component includes at least a portion of the anticoagulant introduced into the withdrawn blood and at least a portion of a volume of anticoagulant added during a priming step.

10. (Original) A method according to claim 1, further comprising:
returning, after collecting at least a portion of the target volume of pure plasma, the second blood component to the donor through a return line.
11. (Original) 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 centrifuge bowl and the blood draw pump, the controller configured to calculate (1) a percentage of anticoagulant in the collected plasma component, and (2) a volume of pure plasma collected within the plasma container based, at least in part, upon the percentage of anticoagulant in the collected plasma component, the controller configured to stop the blood draw pump when a target volume of pure plasma is collected within the plasma container.
12. (Original) A system according to claim 11, wherein the percentage of anticoagulant in the collected plasma component is based, at least in part, on a volume of anticoagulant added to the drawn whole blood and the subject's hematocrit.
13. (Original) A system according to claim 11, further comprising:
an anticoagulant source weight sensor configured to measure the weight of the anticoagulant source, the controller further configured to monitor a change in volume within the anticoagulant container based on the measured weight of the anticoagulant source, the calculated percentage of

anticoagulant in the collected plasma being based, at least in part, on the change in volume within the anticoagulant source.

14. (Original) A system according to claim 11, wherein the controller is configured to monitor a number of rotations of an anticoagulant pump to determine a volume of anticoagulant introduced into the whole blood, the calculated percentage of anticoagulant in the collected plasma being based, at least in part, on the number of rotations of the anticoagulant pump.

15. (Original) A system according to claim 11, further comprising:
an optical sensor located on the blood component separation device and configured to monitor the contents of the blood component separation device and determine if a volume of anticoagulant remains within the blood component separation device, the calculated percentage of anticoagulant in the collected plasma being based, at least in part, on the volume of anticoagulant within the blood component separation device.

16. (Original) A system according to claim 11, further comprising:
a plasma container weight sensor configured to monitor a volume of plasma component collected within the plasma container, the calculated volume of pure plasma collected within the plasma collection device based, at least in part, on the monitored volume of collected plasma component.

17. (Original) A system according to claim 11, further comprising:
a plasma container weight sensor configured to monitor a weight of plasma component collected within the plasma container, the calculated volume of pure plasma collected within the plasma collection device based, at least in part, on the monitored weight of collected plasma component.

18. (Original) A system according to claim 11, further comprising:
an optical sensor located on the blood component separation device and configured to monitor a volume of red blood cells collected within the blood separation device, the controller configured to determine the subject's hematocrit based, at least in part, upon on the monitored

volume of red blood cells collected within the blood separation device and a volume of whole blood withdrawn from the donor

19. (Original) A system according to claim 11, wherein the target volume of pure plasma is based, at least in part, on the weight of the donor.

20. (Original) A system according to claim 11, wherein the percentage of anticoagulant in the collected plasma component includes at least a portion of the anticoagulant introduced into the withdrawn blood and at least a portion of a volume of anticoagulant added during a priming step.

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. Claims 1-20 are currently pending in the application.

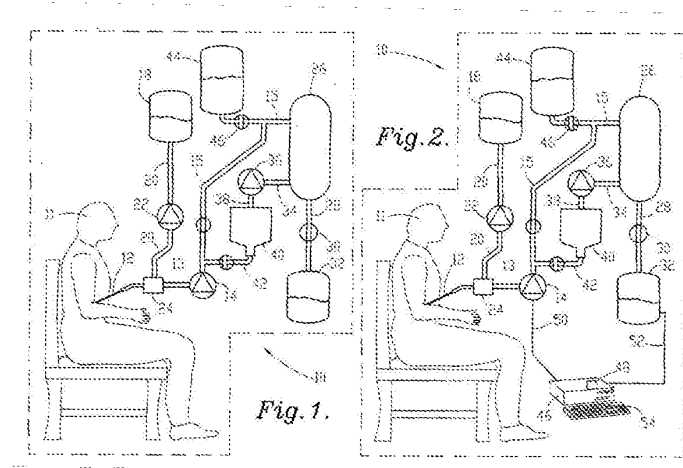
35 USC § 102

Claims 11, 12, 16, 17, 19 and 20 are rejected under 35 U.S.C. 102(a)(1) and (a)(2) as being anticipated by U.S. 2003/0125881 to Ryan.

Claim 11 defines, in relevant part, a system for collecting plasma that includes (1) a venous-access device for drawing whole blood from a subject and returning blood components to the subject, 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 may have an outlet and may send the plasma component to a plasma container. A blood draw line fluidly connected to the venous-access device transports the drawn whole blood to the blood component separation device, and the flow through the blood draw line is controlled by a blood draw pump. An anticoagulant line is connected to an anticoagulant source and introduces anticoagulant into the drawn whole blood. The system also has a controller that controls the operation of the centrifuge bowl and the blood draw pump. The controller may calculate (1) a percentage of anticoagulant in the collected plasma component, and (2) a volume of pure plasma collected within the plasma container based, at least in part, upon the percentage of anticoagulant in the collected plasma component. The controller may stop the blood draw pump when a target volume of pure plasma is collected within the plasma container.

Ryan fails to teach or suggest the claimed system. Rather, Ryan teaches a method and apparatus for collecting the 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 calculate a percentage of anticoagulant in the collected plasma and a volume of plasma collected, and an appropriate time to stop the blood pump 14. Applicant respectfully disagrees and would like to note that nowhere does Ryan teach or suggest calculating and/or collecting a volume of “pure plasma,” as required by claim 11. As discussed within the present application, the volume of “pure plasma” is the volume of plasma only...it is not the volume of the plasma and anticoagulant mixed together (see paragraphs [0018] and [0035] of the present application. Additionally, as also discussed within the present application, the osmolarity

of the red blood cells prevents the added anticoagulant to remain with the red blood cells, and the anticoagulant mixes with the plasma component and is collected within the plasma collection container along with the plasma. Ryan does not calculate the volume of pure plasma collected within the plasma container and then stop when a target volume of pure plasma is collected in the container. Rather, as discussed above, Ryan either stops based on a volume of whole blood drawn from the subject (based on a number of pump rotations; see paragraph [0038] of Ryan) or the total volume of fluid (i.e., both plasma and anticoagulant) collected within the reservoir bag 32. For example, for embodiments that stop based on the fluid volume within the bag 32, Ryan may use a scale to measure the weight of the bag 32 or an optical sensor to measure the volume within the bag. However, both the scale and the optical sensor measure the volume of the plasma and anticoagulant collected in the bag...Ryan does not teach or suggest compensating for the volume of anticoagulant that is mixed with the plasma to obtain/calculate a volume of “pure plasma,” as required by claim 11.

Applicant would also like to note that, although Ryan refers to the volume of plasma measured by the scale and/or optical sensor as the “actual volume of plasma,” as discussed above this volume is actually a mixture of plasma and anticoagulant (e.g., because the added anticoagulant mixes with and is collected with the plasma). This is further evidenced by the equations provided within Ryan. In particular, Ryan provides the equation “ $V_{pac}=DW \times CV$ ” to determine the volume of plasma to collect. However, Ryan also specifically states that V_{pac} , which is the volume of plasma to be collected, is the “plasma and anticoagulant collection volume in milliliters” (emphasis added). Additionally, as shown in Table 3 of Ryan, Ryan is basing the amount of plasma on the FDA guidelines which specifically state that the values are “with anticoagulant.” In other words, Ryan does not calculate a volume of pure plasma and/or stop based on a volume of pure plasma -- Ryan specifically teaches using a volume of plasma and anticoagulant.

Accordingly, claim 11 is allowable over Ryan. Moreover, claims 12, 16, 17, 19 and 20 which depend from claim 11 are also allowable over Ryan

35 USC § 103

Claims 1, 5, 6, 8-10 are rejected under 35 U.S.C. 103 as being unpatentable over U.S. 2003/0125881 to Ryan.

In a manner similar to claim 11, claim 1 defines, in relevant part, a method for collecting plasma that includes (1) determining the weight and hematocrit of a donor, (2) calculating a percentage of anticoagulant in the collected plasma component and a volume of pure plasma collected within the plasma collection container, and (3) collecting plasma until a target volume of pure plasma is collected within the plasma collection container. Accordingly, claim 1 is allowable over Ryan for at least the same reasons as discussed above for claim 11. For example, as discussed above, Ryan fails to teach or suggest calculating a volume of pure plasma and collecting plasma until a target volume of pure plasma is collected – Ryan looks at the volume of plasma and anticoagulant combined. Moreover, claims 5, 6, and 8-10 are allowable over Ryan for at least the same reasons.

Claims 2-4, 13 and 14 are rejected under 35 U.S.C. 103 as being unpatentable over U.S. 2003/0125881 to Ryan in view of U.S. 2012/0175313 to Barry et al.

As dependent claims of claims 1 and 11, claims 2-4 and 13-14 include all of the limitations of the base claim from which they depend. Therefore, claims 2-4 and 13-14 are allowable over the cited prior art for at least the reasons discussed above for claims 1 and 11.

CONCLUSION

It is believed that the application is now in order for allowance and Applicants respectfully request that a notice of allowance be issued. Applicant believes no fee is due with this response. Applicants also request that the examiner contact applicants' attorney, Jonathan Lovely, if it will assist in processing this application through issuance.

Dated: January 31, 2020

Respectfully submitted,
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/608,183	05/30/2017	Michael Ragusa	130670-08002	7286
86738	7590	11/01/2019		
MCCARTER & ENGLISH, LLP BOSTON 265 Franklin Street Boston, MA 02110			EXAMINER DEAK, LESLIE R	
			ART UNIT	PAPER NUMBER
			3781	
			NOTIFICATION DATE	DELIVERY MODE
			11/01/2019	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

Office Action Summary	Application No. 15/608,183	Applicant(s) Ragusa, Michael	
	Examiner LESLIE R DEAK	Art Unit 3781	AIA (FITF) Status 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 30 May 2017.
☐ 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) 1-20 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) 1-20 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 or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

10) ☐ The specification is objected to by the Examiner.

11) ☒ The drawing(s) filed on 24 August 2017 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: ____.

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.

Claim Rejections - 35 USC § 102

2. 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.

3. Claims 11, 12, 16, 17, 19, and 20 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 claim 11, 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 and accompanying test).

With regard to claims 12, 19, 20, Ryan teaches using a patient's weight, hematocrit, and amount of anticoagulant used to determine a target amount of collected plasma with a determined amount of anticoagulant (see ¶0014).

With regard to claims 15-17, Ryan discloses a plasma container weight sensor as well as an optical sensor (see ¶0031).

Claim Rejections - 35 USC § 103

4. 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.

5. Claims 1, 5, 6, 8-10 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 as claimed by Applicant. With regard to claims 1, 8, 9, Ryan teaches a method for collecting plasma comprising the steps of using donor weight, donor hematocrit and amount 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 ¶0011, 0012, 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 5, 6, Ryan teaches that the volume of plasma collected is monitored throughout the procedure via weight or light transmission (see ¶¶0031, 0044).

With regard to claim 10, Ryan discloses that a second, cellular blood component may be returned to the patient (see ¶¶0012).

6. Claims 1, 5, 6, 8-10 are rejected under 35 U.S.C. 103 as being unpatentable over US 2003/0125881 to Ryan in view of US 2012/0175313 to Barry et al.

In the specification and figures, Ryan discloses the method and apparatus substantially as claimed by Applicant. With regard to claims 2-4, 13, 14, Ryan fails to disclose the step of determining a change in the volume of anticoagulant to determine the amount of anticoagulant in the system. However, Barry discloses monitoring pump strokes and, as a backup, weight of the anticoagulant container to determine the amount of anticoagulant in the extracorporeal system (see ¶¶0057). The monitoring of the pumps and weight sensor help ensure an accurate metering of anticoagulant within the separation circuit (see ¶¶0057). It would have been obvious to a person having ordinary skill in the art at the time of filing to add the monitoring system and steps disclosed by Barry to the apparatus and method disclosed by Ryan in order to provide accurate metering of anticoagulant within the separation circuit, as taught by Barry.

With regard to claims 7 and 18, Ryan is silent as to an optical hematocrit sensor. However, Barry discloses an apheresis apparatus and method that uses an optical

hematocrit sensor to accurately set and monitor target collection volumes in order to more accurately control the collection procedure (see US 2009/0215602 ¶0327, incorporated by reference in '313. ¶0035, 0058, 0084). It would have been obvious to a person having ordinary skill in the art at the time of filing to add the optical monitoring system and steps disclosed by Barry to the apparatus and method disclosed by Ryan in order to provide accurate setting and monitoring of target collection values within the separation circuit, as taught by Barry.

Conclusion

7. 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, Tatyana Zalukaeva can be reached on 571-272-1115. 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 <http://pair-direct.uspto.gov>. 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 3781
28 October 2019**

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) inserting a venous-access device into the donor;
 - (d) withdrawing whole blood from the donor through the venous-access device and a draw line, the draw line connected to a blood component separation device;
 - (e) introducing anticoagulant into the withdrawn whole blood through an anticoagulant line;
 - (f) separating the withdrawn whole blood into a plasma component and at least a second blood component using the blood component separation device;
 - (g) collecting the plasma component from the blood component separation device and into a plasma collection container;
 - (h) calculating a percentage of anticoagulant in the collected plasma component;
 - (i) calculating a volume of pure plasma collected within the plasma collection container based, at least in part, on the calculated percentage of anticoagulant in the collected plasma component; and
 - (j) continuing steps (d) through (i) until a target volume of pure plasma is collected within the plasma collection container.
2. A method according to claim 1, further comprising:

determining a change in volume within an anticoagulant container, the calculated percentage of anticoagulant in the collected plasma being based, at least in part, on the change in volume within the anticoagulant container.
3. A method according claim 1, further comprising:

determining a volume of anticoagulant introduced into the whole blood based on a number of rotations of an anticoagulant pump, the calculated percentage of anticoagulant in

the collected plasma being based, at least in part, on the number of rotations of the anticoagulant pump.

4. A method according to claim 1, further comprising:

determining a volume of anticoagulant within the blood component separation device, the calculated percentage of anticoagulant in the collected plasma being based, at least in part, on the volume of anticoagulant within the blood component separation device.

5. A method according to claim 1, further comprising:

monitoring a volume of plasma component collected within the plasma collection container, the calculated volume of pure plasma collected within the plasma collection device based, at least in part, on the monitored volume of collected plasma component.

6. A method according to claim 1, further comprising:

monitoring a weight of plasma component collected within the plasma collection container, the calculated volume of pure plasma collected within the plasma collection device based, at least in part, on the monitored weight of collected plasma component.

7. A method according to claim 1, wherein step (b) includes monitoring a volume of red blood cells collection within the blood separation device, the determined hematocrit of the donor based, at least in part, on the monitored volume of red blood cells collected within the blood separation device and a volume of whole blood withdrawn from the donor.

8. A method according to claim 1, wherein the target volume of pure plasma is based, at least in part, on the weight of the donor.

9. A method according to claim 1, wherein the percentage of anticoagulant in the collected plasma component includes at least a portion of the anticoagulant introduced into the withdrawn blood and at least a portion of a volume of anticoagulant added during a priming step.

10. A method according to claim 1, further comprising:

returning, after collecting at least a portion of the target volume of pure plasma, the second blood component to the donor through a return line.

11. 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 centrifuge bowl and the blood draw pump, the controller configured to calculate (1) a percentage of anticoagulant in the collected plasma component, and (2) a volume of pure plasma collected within the plasma container based, at least in part, upon the percentage of anticoagulant in the collected plasma component, the controller configured to stop the blood draw pump when a target volume of pure plasma is collected within the plasma container.

12. A system according to claim 11, wherein the percentage of anticoagulant in the collected plasma component is based, at least in part, on a volume of anticoagulant added to the drawn whole blood and the subject's hematocrit.

13. A system according to claim 11, further comprising:

an anticoagulant source weight sensor configured to measure the weight of the anticoagulant source, the controller further configured to monitor a change in volume within the anticoagulant container based on the measured weight of the anticoagulant source, the

calculated percentage of anticoagulant in the collected plasma being based, at least in part, on the change in volume within the anticoagulant source.

14. A system according to claim 11, wherein the controller is configured to monitor a number of rotations of an anticoagulant pump to determine a volume of anticoagulant introduced into the whole blood, the calculated percentage of anticoagulant in the collected plasma being based, at least in part, on the number of rotations of the anticoagulant pump.

15. A system according to claim 11, further comprising:

an optical sensor located on the blood component separation device and configured to monitor the contents of the blood component separation device and determine if a volume of anticoagulant remains within the blood component separation device, the calculated percentage of anticoagulant in the collected plasma being based, at least in part, on the volume of anticoagulant within the blood component separation device.

16. A system according to claim 11, further comprising:

a plasma container weight sensor configured to monitor a volume of plasma component collected within the plasma container, the calculated volume of pure plasma collected within the plasma collection device based, at least in part, on the monitored volume of collected plasma component.

17. A system according to claim 11, further comprising:

a plasma container weight sensor configured to monitor a weight of plasma component collected within the plasma container, the calculated volume of pure plasma collected within the plasma collection device based, at least in part, on the monitored weight of collected plasma component.

18. A system according to claim 11, further comprising:

an optical sensor located on the blood component separation device and configured to monitor a volume of red blood cells collected within the blood separation device, the controller configured to determine the subject's hematocrit based, at least in part, upon on the

monitored volume of red blood cells collected within the blood separation device and a volume of whole blood withdrawn from the donor

19. A system according to claim 11, wherein the target volume of pure plasma is based, at least in part, on the weight of the donor.

20. A system according to claim 11, wherein the percentage of anticoagulant in the collected plasma component includes at least a portion of the anticoagulant introduced into the withdrawn blood and at least a portion of a volume of anticoagulant added during a priming step.