

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

TERUMO BCT INC.,

Petitioner

v.

HAEMONETICS CORP.,

Patent Owner

PGR2026-00009
U.S. Patent No. 12,324,873

**PETITION FOR POST GRANT REVIEW
OF U.S. PATENT NO. 12,324,873**

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Patent Trial and Appeal Board
U.S. Patent & Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

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9. Claim 11: A method according to claim 10, wherein the target volume of pure plasma and/or the target volume of plasma component is based, at least in part, on a weight of the donor. 39
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 - i. 13[preamble] A system for collecting plasma comprising: 41
 - ii. 13[a] a venous-access device for drawing whole blood from a subject and returning blood components to the subject; 41
 - iii. 13[b] a blood component separation device for separating the withdrawn blood into a plasma component and a second blood component, the blood component separation device having an outlet and being configured to convey the plasma component to a plasma collection container; 42
 - iv. 13[c] a blood draw line fluidly coupled to the venous-access device and configured to transport withdrawn whole blood to the blood component separation device, the flow through the blood draw line being controlled by a blood draw pump; 42
 - v. 13[d] an anticoagulant line fluidly coupled to an anticoagulant source, the anticoagulant line configured to introduce anticoagulant into the withdrawn whole blood; and.....42
 - vi. 13[e] a controller configured to control the operation of the blood component separation device and the blood draw pump, ...42

- vii. 13[f] the controller configured to calculate a volume of pure plasma collected within the plasma collection container based, at least in part, on a volume of plasma component collected within the plasma collection container, a ratio of anticoagulant added to the withdrawn whole blood, and a hematocrit of the subject. 43
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 - iii. 24[b] a blood component separation device for separating the withdrawn blood into a plasma component and a second blood component, the blood component separation device having an outlet and being configured to convey the plasma component to a plasma collection container; 52
 - iv. 24[c] a blood draw line fluidly coupled to the venous-access device and configured to transport withdrawn whole blood to the blood component separation device, the flow through the blood draw line being controlled by a blood draw pump; 52
 - v. 24[d] an anticoagulant line fluidly coupled to an anticoagulant source, the anticoagulant line configured to introduce anticoagulant into the withdrawn whole blood; and.....52
 - vi. 24[e] a controller configured to control the operation of the blood component separation device and the blood draw pump, ...52
 - vii. 24[f] the controller configured to calculate a volume of pure plasma to be collected within the plasma collection container based, at least in part, on a volume of plasma component to be collected within the plasma collection container, a ratio of anticoagulant to be added to the withdrawn whole blood, and a hematocrit of the subject. 53
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Statutes

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Other Authorities

37 C.F.R. 42.104(b)(4)-(5)	22, 23
37 C.F.R. § 42.100(b)	22

EXHIBIT LIST

Exhibit	Reference
1001	U.S. Patent No. 12,324,873 (“’873 patent”)
1002	File History of the ’873 patent
1003	Declaration of Dr. Gary D. Fletcher in Support of Petition
1004	U.S. Patent No. 7,072,769 (“Fletcher-Haynes”)
1005	U.S. Patent No. 4,898,675 (“Lavender”)
1006	U.S. Patent No. 8,075,468 (“Min”)
1007	U.S. Patent Publication No. 2003/0125881 (“Ryan”)
1008	U.S. Patent No. 9,370,324 (“Barrett”)
1009	U.S. Patent No. 6,296,602 (“Headley”)
1010	“Membrane versus centrifuge-based therapeutic plasma exchange: a randomized prospective crossover study,” Carsten Hafer et al., Int. Urol. Nephrol (2016) 48:133-138; Springer Science+Business Media Dordrecht 2015.
1011	U.S. Patent Publication No. 2017/0029762 (“Turgut”)
1012	“Volume Limits – Automated Collection of Source Plasma,” November 4, 1992, Memorandum issued by the FDA Center for Biologics Evaluation and Research, Docket Number FDA-2013-S-0613.
1013	Bruce C. McLeod, MD, et al., “Apheresis: Principles and Practice,” 3rd Edition, AABB Press 2010.
1014	Sergent SR, Ashurst JV. Plasmapheresis. [Updated 2023 Jul 10]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK560566/?report=printable
1015	Curriculum Vitae (“CV”) of Dr. Gary D. Fletcher
1016	U.S. Patent Publication No. 2012/0175313 (“Barry”)
1017	Japanese Patent Publication No. JP 2002-282352 A and certified Japanese to English translation (“Takagi”)

Terumo BCT (“Petitioner”) requests Post Grant Review (“PGR”) of claims 1-30 of U.S. Patent No. 12,324,873 (the “’873 patent”) (EX1001).

I. Mandatory Notices

A. Real Parties-In-Interest

Petitioner identifies itself as the real party-in-interest (“RPI”).

B. Related Matters

The ’873 patent is currently asserted against Petitioner by Patent Owner in *Haemonetics Corp. v. Terumo BCT, Inc.*, No. 1:25-cv-1409 (D. Colo. Filed May 5, 2025)¹. Additionally, *Terumo BCT Inc. v. Haemonetics Corp.*, IPR2025-01374 (PTAB Aug. 4, 2025) challenges U.S. Patent No. 11,738,124; *Terumo BCT Inc. v. Haemonetics Corp.*, IPR2025-01391 (PTAB Aug. 11, 2025) challenges U.S. Patent No. 10,758,652; *Terumo BCT Inc. v. Haemonetics Corp.*, PGR2025-00077 (PTAB Sept. 2, 2025) challenges U.S. Patent No. 12,186,474; *Terumo BCT Inc. v. Haemonetics Corp.*, PGR2025-00078 (PTAB Sept. 5, 2025) challenges U.S. Patent No. 12,171,916; *Terumo BCT Inc. v. Haemonetics Corp.*, IPR2026-00046 (PTAB Oct. 17, 2025) challenges U.S. Patent No. 10,980,926; *Terumo BCT Inc. v. Haemonetics Corp.*, IPR2026-00045 (PTAB Oct. 24, 2025) challenges U.S. Patent

¹ Petitioner filed a Motion to Dismiss this lawsuit in the District of Colorado for lack of subject matter eligibility under 35 U.S.C. §101. The issues discussed in this Petition are separate and distinct from the issues discussed in the Motion to Dismiss.

No. 10,980,934; *Terumo BCT Inc. v. Haemonetics Corp.*, IPR2025-01420 (PTAB Oct. 9, 2025) challenges U.S. Patent No. 10,792,416; *Terumo BCT Inc. v. Haemonetics Corp.*, IPR2026-00006 (PTAB Oct. 21, 2025) challenges U.S. Patent No. 12,377,204; which are in the same patent family as the '873 patent. Petitioner notes the '873 patent recently issued on June 10, 2025, with multiple pending applications remaining within its patent application family.

C. Counsel

Petitioner is filing a Power of Attorney appointing the practitioners associated with Customer Number 53,065. Petitioner designates the following lead and back-up counsel:

Lead Counsel	Back-up Counsel
John M. Caracappa (Reg. No. 43,532) Steptoe LLP 1330 Connecticut Ave NW Washington, DC 20036 Telephone: (202) 429-3000 Email: jcaracappa@steptoe.com	Katherine D. Cappaert (Reg. No. 71,639) Matthew Y. Sim (Reg. No. 77,422) Daniel Scott Chappell (Reg. No. 76,333) Steptoe LLP 1330 Connecticut Ave NW Washington, DC 20036 Telephone: (202) 429-3000 Email: kcappaert@steptoe.com msim@steptoe.com schappell@steptoe.com

D. Service Information

Post and hand delivery: Steptoe LLP
1330 Connecticut Ave NW
Washington, DC 20036
Telephone: (202) 429-3000
Email: terumo_bct@steptoe.com

Please address all correspondence to counsel identified above. Petitioner consents to electronic service by email at the above-identified email addresses and:

terumo_bct@steptoe.com.

II. Fees

Petitioner is concurrently electronically submitting the required fees for this Petition. The Board is authorized to charge Steptoe LLP's deposit account, No. 53065, for any fee deficiency.

III. Certification of Grounds of Good Standing

Petitioner certifies that the '873 patent is available for PGR and that Petitioner is not estopped or barred from requesting this PGR.

IV. Identification Of Challenge And Relief Requested

A. Identification of Prior Art

The following references are pertinent to the grounds of unpatentability explained below:

- U.S. Patent No. 7,072,769, issued July 4, 2006 ("Fletcher-Haynes"), prior art under at least 35 U.S.C. §102(a)(1)2.
- U.S. Patent No. 4,898,675, issued February 6, 1990 ("Lavender"), prior art under at least 35 U.S.C. §102(a)(1).

² References to 35 U.S.C. §§ 102 and 103 are to the post-AIA statutory framework.

- U.S. Patent No. 8,075,468, issued December 13, 2011 (“Min”), prior art under at least 35 U.S.C. §102(a)(1).
- U.S. Patent No. 9,370,324, issued June 21, 2016 (“Barrett”), prior art under at least 35 U.S.C. §102(a)(1).
- U.S. Patent No. 6,296,602, issued October 2, 2001 (“Headley”), prior art under at least 35 U.S.C. §102(a)(1).
- U.S. Patent Publication No. 2017/0029762, published February 2, 2017 (“Turgut”), prior art under at least 35 U.S.C. §102(a)(1).

B. Statutory Grounds of Unpatentability

Petitioner requests cancellation of claims 1-30 of the '873 patent under 35 U.S.C. §§ 101, 102, 103, and 112 based on the following Grounds:

Ground	35 U.S.C.	Claims	References
I	§§102/103	1-5, 7, 8, 10-17, and 19-23	Lavender anticipates and/or renders obvious
II	§103	1 and 24-30	Lavender in view of Fletcher-Haynes
III	§103	6 and 18	Lavender in view of Fletcher-Haynes and Min
IV	§103	9 and 18	Lavender in view of Fletcher-Haynes, Headley, and Barrett
V	§103	4 and 15	Lavender in view of Fletcher-Haynes, Min, and Turgut
VI	§101	1-30	Patent Ineligible Subject Matter

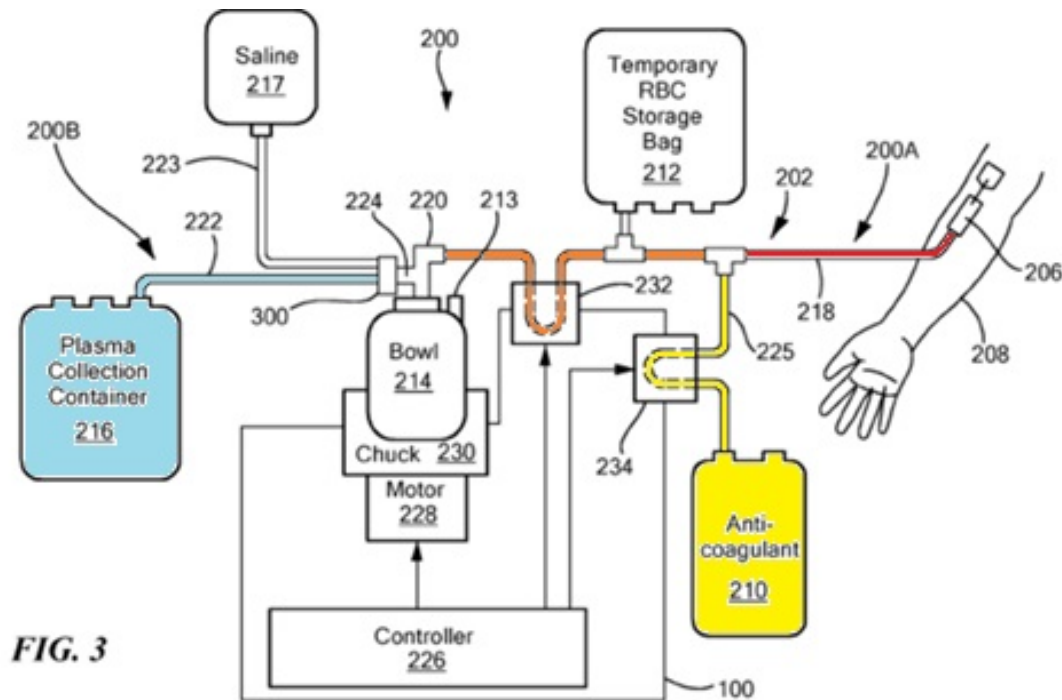
VII	§112	10, 11, 12, 22, 23, and 25	Lack of Written Description
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This Petition demonstrates that there is a reasonable likelihood that Petitioner will prevail with respect to at least one of the challenged claims. *See* 35 U.S.C. § 314(a).

V. '873 Patent Overview

A. The '873 Patent is Directed to Plasma Apheresis

The '873 patent, which issued on June 10, 2025, relates to a “system and method for collecting plasma” in blood apheresis systems where “individual blood components,” *e.g.*, plasma and red blood cells, “can be separated and collected from whole blood.” EX1001, 1:25-27; 1:31-37. The '873 patent relates to plasma apheresis, which is plasma collection. EX1001, Abstract; 1:25-28.'873 patent Figure 3 shows one embodiment of a plasma apheresis system. EX1003, ¶45.



EX1001, Fig. 3.

Plasma apheresis involves withdrawing whole blood from a donor's arm using venous access device 206. EX1001, 5:28-33. Pump 232 "causes the whole blood to be drawn from the donor" through an inlet line 218 (red) and pump 234 adds a fixed amount of anticoagulant "into the whole blood" through "[a]n anticoagulant line" 225 (yellow) into inlet line 218. EX1001, 4:46-47; 5:39-42; 6:26-33. Anticoagulant is introduced in fixed proportions to the drawn whole blood drawn to prevent blood clotting in the draw line. *See* EX1012. "[T]he anticoagulant mixes with the plasma component" because "the osmolarity of the red blood cells prevents the anticoagulant . . . from entering/remaining with the red blood cells." EX1001, 7:58-63; EX1003, ¶46.

Then, the mixture (orange) of anticoagulant and “withdrawn whole blood ... enters a blood component separation device,” *e.g.*, centrifuge bowl 214, which “separates the whole blood into its constituent components,” *e.g.*, “plasma, platelets, red blood cells (“RBCs”) . . . [and] white blood cells.” EX1001, 4:52-61, 4:66-5:5; 6:56-60. The donor’s plasma, *i.e.*, pure plasma, along with anticoagulant introduced during the collection process, exits the blood component separation device and is collected and stored in a collection container (*e.g.*, a bag, shown in blue above). EX1001, 7:33-39. The anticoagulant and pure plasma combination is called anticoagulated plasma or plasma product. EX1001, 1:26-28; 10:3-6; EX1003, ¶47.

The FDA established guidelines regarding how much plasma any individual donor can donate. *See* EX1012. These guidelines consider donor parameters, like weight, hematocrit, and sex. *See* EX1012; EX1003, ¶48.

B. The ’873 Patent’s Purported Invention

The ’873 patent purports to solve problems associated with “determin[ing] the total volume of plasma that has been collected” from a donor after the withdrawn whole blood is mixed with anticoagulant by considering a donor’s hematocrit level and the amount of anticoagulant added into the system. EX1001, 1:56-62; 1:66-3:66; 4:23-33; EX1003, ¶49.

Each donor’s hematocrit level is different, which affects the amount of plasma in the donor’s whole blood. EX1001, 8:3-4. The differing hematocrit levels also

affect the volume of anticoagulant in a plasma collection bag (“anticoagulant volume”). EX1001, 8:7-13. Given this variability, the ’873 patent discloses that controller 226 may use the % AC equation below, which includes a predetermined ratio of anticoagulant to anticoagulated whole-blood and the donor’s hematocrit to calculate the percentage of anticoagulant in the plasma container. EX1001, 8:3-9:25. Specifically, in % AC below, “AC” is the inverse of the predetermined ratio of anticoagulant per unit of anticoagulated whole blood (e.g., “AC” would be 16 if the ratio of anticoagulant to anticoagulated whole blood was 1:16) and Hct_D is the donor’s hematocrit. EX1001, 8:3-61. Anticoagulated whole blood is extracted blood mixed with anticoagulant. EX1003, ¶50.

$$\% AC = \frac{1}{1 + (AC - 1)(1 - Hct_D)}$$

Controller 226 uses a weight sensor to monitor the collection container’s weight and uses the weight to determine the total volume of liquid in the collection container. EX1001, 7:28-39; 7:65-8:2. The controller uses the total volume of liquid in the collection container to calculate the anticoagulant and pure plasma volumes in the collection container. EX1001, 8:3-9:55. The ’873 patent first calculates the anticoagulant volume. EX1001, 8:17-61. It then calculates the volume of pure plasma in the collection container by subtracting the anticoagulant volume from the total volume of liquid in the collection container. EX1001, 8:63-9:12. These

calculations occur in real time. EX1001, claim 1; EX1003, ¶51.

The '873 patent also discloses two alternative methods of determining the amount of anticoagulant in the collection bag that do not consider a donor's hematocrit. These determine the anticoagulant in the collection bag by: (i) monitoring the volume of anticoagulant added to the system based on the number of rotations of the anticoagulant pump,³ and (ii) measuring the change in weight of the anticoagulant container. EX1001, 8:16-9:25. In both methods, the added anticoagulant volume is used to calculate the volume of pure plasma collected in the plasma collection container by subtracting the added anticoagulant volume from the total volume in the collection container. EX1001, 8:16-9:25; EX1003, ¶52.

Of these three methods, only the first, which is based on the predetermined ratio of anticoagulant to anticoagulated whole blood, considers the donor's hematocrit. That method does not, however, use an amount of anticoagulant

³ Because red blood cells' osmolarity "prevents the anticoagulant from mixing with it, essentially all of the anticoagulant exits the bowl 214 and is collected within the plasma collection container 216 along with the plasma." EX1001 at 8:34-38. Thus, subtracting the anticoagulant volume added to the system from the total volume in the collection container estimates the pure plasma volume within the collection container. EX1001 at 8:16-9:25; EX1003, ¶52.

collected within the plasma collection container, or supplied to the system, to determine a percentage of anticoagulant within the collected plasma. EX1001 at 8:16-9:25; 10:16-26; EX1003, ¶53.

The '873 patent repeats each method to determine the pure plasma volume “until a target volume of pure plasma is collected in the plasma collection container,” *e.g.*, the volume set by FDA regulation. EX1001, 8:17-22. When the system reaches a target volume of pure plasma, the controller “stops the draw of whole blood from the subject and reverses the direction of the blood ... to draw the RBCs (and other components)” from the blood component separation device back to the donor. EX1001, 9:17-23; EX1003, ¶54.

C. Prosecution History

Application No. 18/955,269, which resulted in the '873 patent, was filed on November 21, 2024. EX1001, Cover.

On February 6, 2025, the Examiner rejected pending claims 1, 4-8, 10, 11, 13, 14, 16, and 19 as unpatentable over U.S. Patent No. 10,758,652 to Ragusa, concluding that Applicant’s recitations drawn to variables used in calculations recited mathematical calculations, which are not patent eligible subject matter, and do not patentably distinguish over the prior art of record. EX1002, 139-142; EX1007; EX1003, ¶56.

In response, Applicant submitted a Terminal Disclaimer over U.S. Patent No. 10,758,652.

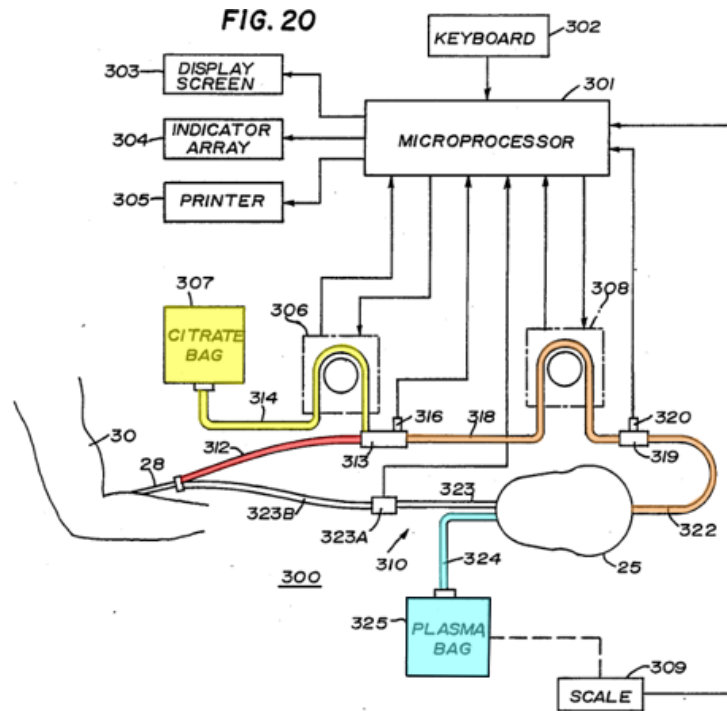
On March 26, 2025, the Examiner issued a Notice of Allowance. EX1002, Notice of Allowance. The '873 patent issued on June 10, 2025. EX1001, Cover.

VI. Prior Art Overview

A. Overview of Lavender

Lavender discloses “a system, method and device for continuously fractionating blood in situ.” EX1003, ¶54. Like the '652 patent, Lavender recognized the need to track the volume of anticoagulant collected during a plasma collection procedure to, among other things, “accurately, safely and economically collect[] plasma from a source of blood.” EX1005, 3:26-28; EX1003, ¶59.

Figure 20 illustrates Lavender’s automatic system 300 for fractionating blood. EX1005, 16:34-53. EX1003, ¶60.



EX1005, Fig. 20 (annotated).

In Lavender's system 300, a needle or catheter 28 is draws whole blood from a donor, which is then mixed with citrate (a blood anticoagulant) pumped from citrate bag 307. EX1005, 16:45-47, 16:60-17:2. System 300 then pumps the whole blood and anticoagulant mixture to blood fractionator 25, which separates the anticoagulated whole blood into plasma and other blood fractions. EX1005, 5:42-52. The plasma and anticoagulant mixture exits the blood separation device through the plasma line and is collected in plasma bag 325. EX1005, 17:14-16; EX1003, ¶61.

Lavender's system performs several real-time calculations during collection. These calculations account for donor parameters, like hematocrit, and a fixed anticoagulant to plasma ratio, which, in turn, relates to a fixed anticoagulant to

anticoagulated whole blood ratio. See EX1005, 22:35-39, cols. 41, 42. Lavender's Plasma Dilution Factor (*PDF*) defines how anticoagulant added to the withdrawn whole blood is added at a rate sufficient to dilute incoming plasma to 68% of the initial concentration. Thus, *PDF*=.68 because, after adding anticoagulant to the withdrawn whole blood at this rate, the amount of collected plasma and anticoagulant mixture is 68% plasma and 32% anticoagulant, and thus *PDF* defines a ratio of anticoagulant added to the withdrawn whole blood relative to incoming plasma from the donor's blood. The weight of the collected plasma and anticoagulant solution is measured during the collection process and *PDF* is used to determine a volume of anticoagulant and volume of pure plasma in the collection container. EX1005, 20:55-68; EX1003, ¶62.

The table below shows several variables used and/or calculated in Lavender's system:

Variable	Description
<i>CF</i> (conversion factor) ⁴	Predetermined ratio (or percentage) of anticoagulant to incoming plasma

⁴ Petitioner notes that Table VI has two different "*CF*" terms, (i) conversion factor (*CF*) and (ii) the rate citrate is filtered from the donor's whole blood in system 300, or citrate filtered in ml/min (*CF*). This appears to be a typographical error and a

<i>PDF</i>	Plasma dilution factor
<i>C1</i>	ml plasma collected/pound of <i>BW</i>
<i>C2</i>	ml dilute plasma collected/pound of <i>BW</i>
<i>C3</i>	ml citrate to be filtered/pound of <i>BW</i>
<i>QB</i>	Blood flow from donor
<i>TQB</i>	Total blood flow
<i>HCTD</i>	Donor's hematocrit
<i>BW</i>	Donor's body weight
<i>QP</i>	Plasma flow
<i>TQP</i>	Total plasma flow
<i>QC</i>	Citrate flow
<i>QCP</i>	Citrate pump rate
<i>TQC</i>	Total citrate (anticoagulant) flow
<i>TDPF</i>	Total dilute plasma (total fluid) in the collection container
<i>TPF</i>	Total plasma filtered (pure plasma) volume in the collection container
<i>TCF</i>	Total citrate (anticoagulant) volume in the collection container
<i>MAXPF</i>	Total plasma filtered (pure plasma) volume to collect

POSITA would understand that “*CF*” used in the total citrate filtered (*TCF*) equation is conversion factor (*CF*). EX1003, ¶63.

<i>MAXCF</i>	Total citrate (i.e. anticoagulant) volume to collect
<i>MAXDPF</i>	Total dilute plasma (pure plasma plus anticoagulant) volume to collect

These variables are used during collection to monitor the amount of plasma collected. For example, plasma flow (QP) is calculated based on the donor's blood flow (QB) and hematocrit ($HCTD$). EX1005, 41:4-44:42. QP is then used to calculate the citrate pump rate (QCP) by multiplying it by the conversion factor (CF). QCP is used to calculate the total citrate flow (TQC). See EX1005, 41:4-44:42. The total plasma volume in the collection container is calculated in real time based on the total volume of fluid in the collection container, determined by the weight of the container, and the plasma dilution factor (PDF). The total citrate volume in the collection container (TCF) is then calculated in real time based on the total plasma volume in the collection container (TPF) and the conversion factor (CF). EX1003, ¶¶63-64.

Lavender's microprocessor repeatedly performs weight measurements and run-time calculations in its algorithm and displays updated values approximately every two seconds. EX1005, 20:55-68. Lavender's system determines the relationship (or ratio) between the pure plasma volume and the anticoagulant volume in the collection container. The relationship is used to determine the pure plasma

volume. Accordingly, Lavender discloses determining pure plasma volume based on the volume of anticoagulant. If any additional conversion or calculation is required, a POSITA would readily understand how to convert between the two volumes using the same relationship. EX1003, ¶65.

Lavender executes a main loop of the algorithm until the total plasma filtered (*TPF*) in plasma bag 325 is equal to or greater than a determined maximum total plasma volume to collect (*MAXPF*), as determined using a donor's weight. EX1005, 43-44, claim 33. EX1003, ¶66.

B. Overview of Fletcher-Haynes

Fletcher-Haynes discloses a blood collection system. EX1005, Abstract. Fletcher-Haynes recognized the need to determine “the maximum amount of plasma which should be collected considering the medical and physical characteristics of the donor.” EX1005, 48:29-31. For example, Fletcher-Haynes' prediction algorithms include donor's gender, height, weight, hematocrit, and platelet pre-count parameters. EX1005, 27:30-35; 49:19-52:36; EX1003, ¶67.

Figure 7A illustrates Fletcher-Haynes' collection assembly 10' for separating blood into components. EX1005, 45:14-16. Donor's blood is pumped through inlet line 22 (red), and anticoagulant is pumped from AC container 30 (yellow) into inlet line 22. EX1005, 45:22-37. The blood is mixed with anticoagulant and separated into components flowing into platelet collect bags 38 and plasma collect bag 54

(blue). EX1005, 45:22-37. The remaining blood is returned to the donor. EX1005, 45:22-37; EX1003, ¶68.

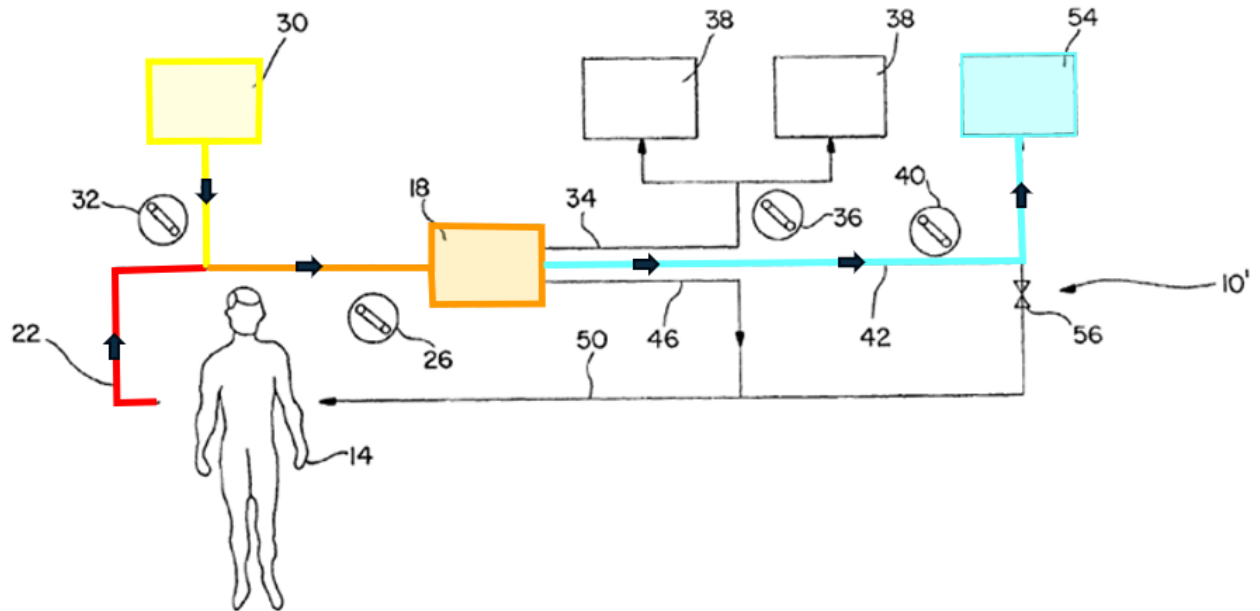


Figure 7A

EX1005, Fig. 7A (annotated).

Assembly 10' operates according to a collection procedure derived from procedure goal(s) and may include maximizing “at least one process control parameter.” EX1005, 7:38-43; 9:35-44. This maximization is determined by inputting donor-provided data, like height, weight, and blood processing machine type in optimization and prediction models. EX1005, 49:19-26; EX1003, ¶69.

Fletcher-Haynes' prediction model uses an initial parameter configuration that accounts for these factors (*i.e.*, height, weight, total blood volume, hematocrit,

and platelet pre-count) to generate several target parameters, including: “. . . ; (2) inlet flow rate; **(3) AC ratio**; (4) procedure time; . . . ; **(7) source plasma volume**; **(8) AC in the platelet and plasma collect bags 38, 54**; . . . ; (10) AC infusion rate; and (11) output approval.” EX1005, 49:22-26. When executed during a blood separation procedure, the prediction model determines any of parameters (1)-(11) in real-time. EX1005, 34:8-24; 48:66-49:19-25; EX1003, ¶70

Fletcher-Haynes’ prediction algorithms may be integrated with its optimization algorithms, and Fletcher-Haynes specifically recites “the optimizer model 172 may interface with the prediction model or actually integrally incorporate the prediction model” and refers to Eqs. 1-22. EX1005, 58:63-67. Stated differently, Fletcher-Haynes discloses 22 equations that can be incorporated into a prediction model to predict a particular blood component’s yield. EX1005, 58:63-67. One is an equation for calculating total blood volume using a donor’s height and weight, another is an equation for calculating anticoagulant (AC) ratio using a donor’s hematocrit, and another is an equation for calculating source plasma volume or a target pure plasma volume collected or to collect. EX1005, 49:40-52:17. Specifically, Equation 10 defines the total blood volume of a donor (V_B) using a donor’s height and weight; Equation 9 determines the AC Ratio (R) using a donor’s hematocrit; and Equation 22 defines the predicted total volume in the source plasma

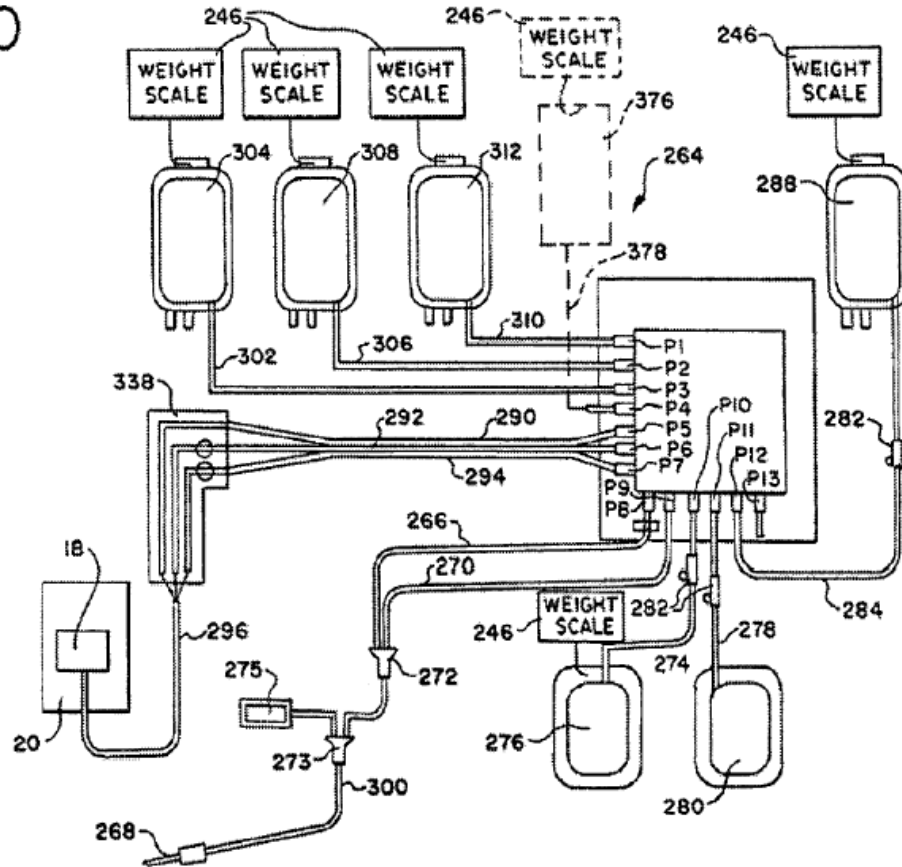
bag (V_{SPB}). EX1005, 49:40-52:17. These equations can be integrated with Fletcher-Haynes' optimization algorithms. EX1005, 58:63-67; EX1003, ¶71.

Fletcher-Haynes explains that it is preferable during procedures “to have computer/database system 140 exert control over apheresis machine functions, including process control manipulation and optimization.” EX1005, 34:8-24, 49:40-52:17; EX1003, ¶72.

C. Overview of Min

Min discloses blood processing systems for separating plasma from whole blood. EX1006, 7:4-8:5. Min teaches plasma collection procedures that include a collection cycle, and pre- and post-collection cycles, which include priming the system's tubing by “convey[ing] a predetermined volume of anticoagulant . . . into the in-process container” during the pre-collection cycle. EX1006, 22:41-43; 32:16-18; EX.1003, ¶73. Figure 10 of Min shows Min's system for performing blood processing procedures, like plasma collection. EX1003, ¶73.

FIG. 10



In Min, weigh sensors 246 track weight changes and derive fluid processing volumes, including volume changes in anticoagulant container 276 and plasma collection container 304. EX1006, 11:52-55, 17:17-22. EX.1003, ¶74.

D. Overview of Barrett

Barrett discloses a hemodialysis patient data acquisition and management system for monitoring blood separation procedures, like hemodialysis. EX1007, 4:14-67. Barrett describes several techniques to monitor hematocrit, including ones used for real-time monitoring during hemodialysis. EX1007, 2:23-57. Barrett specifically discloses determining a patient's hematocrit by dividing a blood

sample's calculated total red blood cell volume by a total volume of the blood sample. EX1007, 2:45-49. EX1003, ¶75.

E. Overview of Headley

Headley discloses systems and methods for collecting, from whole blood, platelets suspended in plasma, among other blood components. EX1008, Abstract. Headley's blood separation systems use a centrifuge to separate blood into components and use of an array of optical sensors with a control unit to determine red blood cell volume in a blood separation system. EX1008, 4:48-64; EX1003, ¶76.

A. Overview of Turgut

U.S. Patent Publication No. 2017/0029762 A1 ("Turgut") discloses separation systems that effectively separate biological material, like blood components, with the help of centrifugal force. EX1009, Abstract. Turgut's blood separation systems use a centrifuge to separate blood into components and use a volume detector to determine a total volume of fluid within, for example, the centrifuge's separation chamber. EX1009, ¶73; EX1003, ¶77.

VII. Level Of Ordinary Skill

A person having ordinary skill in the art ("POSITA") would have had, as of the earliest claimed filing date of May 30, 2017, a bachelor's degree in biomedical engineering, or a related field, such as physical sciences, physics, computer engineering, electrical engineering, or the like, and a minimum of two to three years of experience related to blood separation devices or blood processing devices. A

higher level of education or specific skill might make up for less experience, and vice versa. EX.1003, ¶38.

VIII. Claim Construction

Claims should be construed “in accordance with the ordinary and customary meaning of such claims as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent.” 37 C.F.R. § 42.100(b); *see also Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (*en banc*). Petitioner is unaware of any “prior claim construction determination” related to the ’873 patent. *See* 37 C.F.R. § 42.100(b).

Moreover, the Board “need only construe terms ‘that are in controversy, and only to the extent necessary to resolve the controversy.’” *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor, Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)). Petitioner believes the Challenged Claims need no construction to demonstrate they are unpatentable.

IX. Detailed Grounds Explanation

The sections below, as supported by Dr. Gary D. Fletcher’s Declaration, demonstrate how the claims are unpatentable. 37 C.F.R. 42.104(b)(4)-(5).

A. Ground 1: Claims 1-5, 7, 8, 10-17, and 19-23 are anticipated and/or rendered obvious by Lavender

1. Claim 1

i. 1[preamble] A method for collecting plasma comprising:

To the extent the preamble is limiting, Lavender discloses “[a] system, method and device for continuously fractionating blood in situ.” EX1004, Abstract. Lavender fractions blood “to **collect blood substances, such as plasma.**”⁵ EX1004, 1:12-13; *see also id.* at claim 1 (“A method of collecting plasma....”), 5:42-49, 1:48-56; EX1003, ¶79.

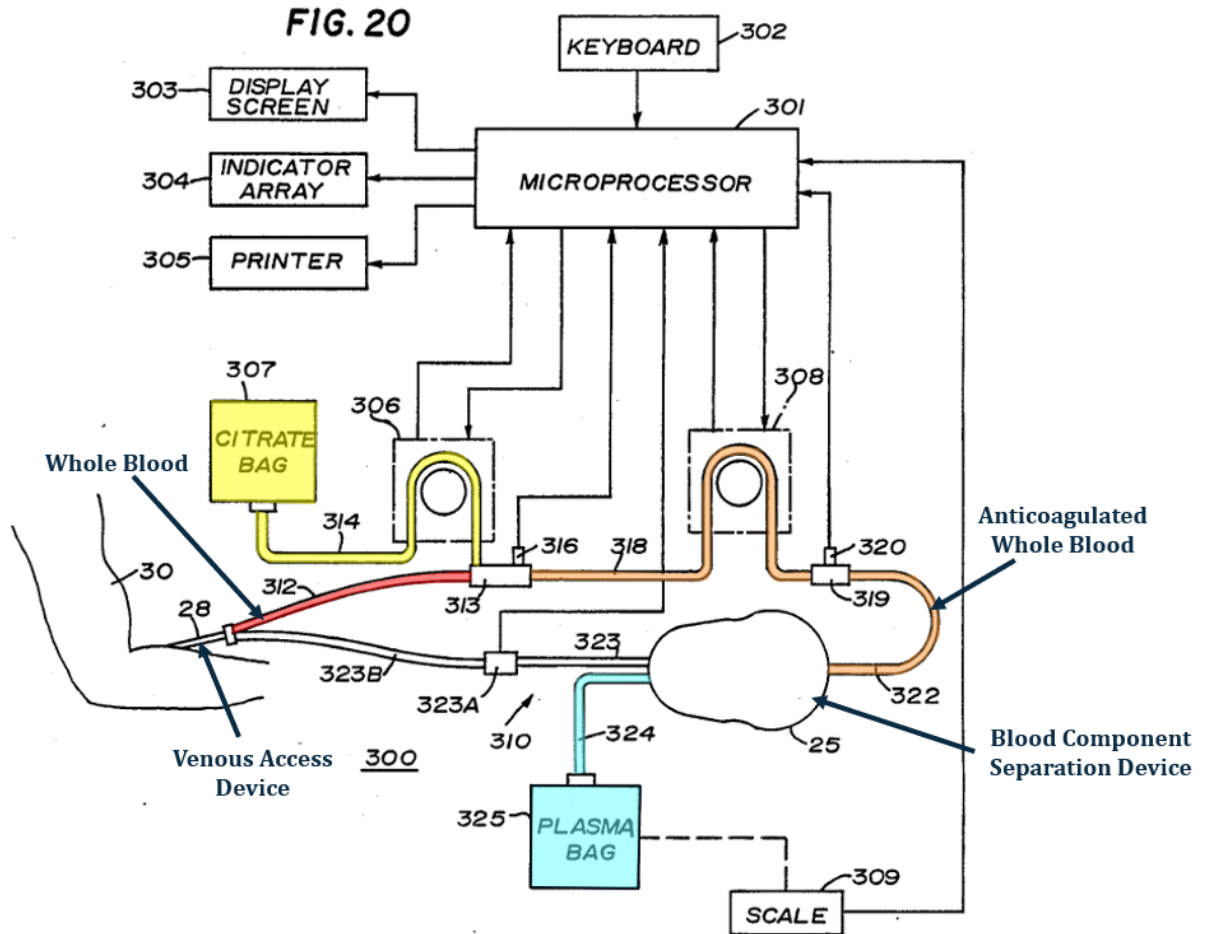
ii. 1[a] inserting a venous-access device into a donor;

Lavender’s blood fractionator uses a catheter, needle, or double lumen needle inserted into an appropriate vein or artery of the donor to draw blood from the donor for processing, allowing blood to flow from the catheter or needle through a blood tube and into an inlet of the blood fractionator. EX1004, 5:13-22, Figs. 1 and 20; EX1003, ¶80.

iii. 1[b] withdrawing whole blood from the donor through the venous-access device and a draw line, the draw line fluidly coupled to a blood component separation device;

Lavender withdraws whole blood through the venous-access device. A pump “pump[s] blood from the donor” through the needle 28, through the tubes 312, 318, 322 and into the fractionator 25, shown below in FIG. 20. EX1004, 5:18-22, Fig. 20.

⁵ All emphasis is added unless otherwise noted.



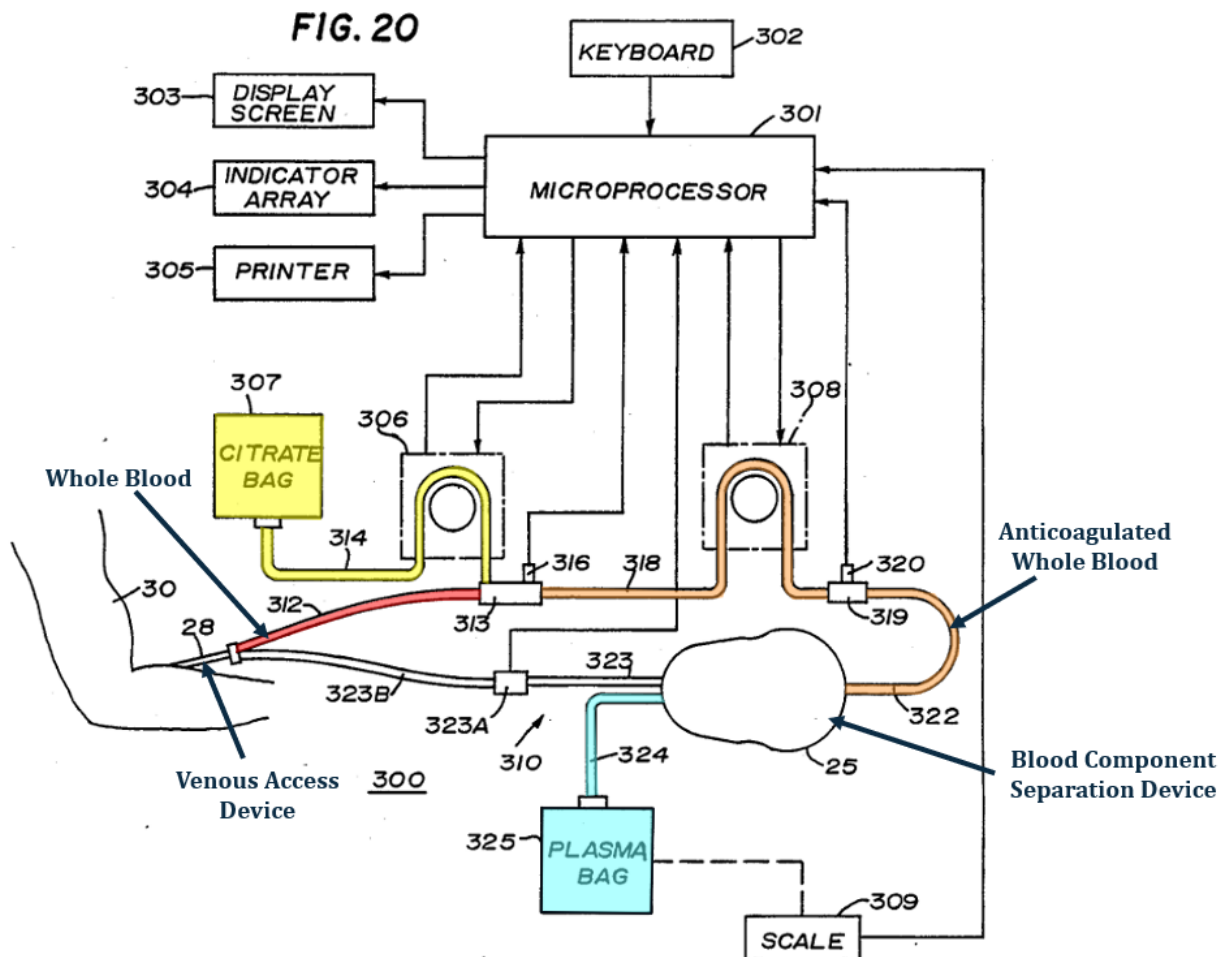
The drawn blood is whole blood because it is a mixture of “a variety of blood fractions.” EX1004, 5:45. EX1003, ¶81.

The draw line is connected to the fractionator 25, as “[t]he blood fractionator has an inlet ..., the inlet being connected to the donor by a blood tube.” EX1004, 5:13-16, Figs. 1 & 20. EX1003, ¶82.

The fractionator is a blood component separation device because “it produces a variety of blood fractions” from whole blood, “plasma [being] one of the most important blood fractions.” EX1004, 5:42-45. EX1003, ¶83.

iv. **1[c] introducing anticoagulant into the withdrawn whole blood through an anticoagulant line;**

In Lavender's blood component separation system, "[a] supply of anticoagulant 35 is connected to the tube 27" supplying withdrawn whole blood from the donor. EX1004, 5:22-28, Figs. 1 and 20. "[A] second pump 31A ...provide[s] a predetermined flow rate ... of anticoagulant with the blood flowing from the donor 30 to the fractionator" via an anticoagulant line 314. EX1004, 5:22-28 and Figs. 1 and 20 (tube 314). EX1003, ¶84.



- v. **1[d] separating the withdrawn whole blood into a plasma component and at least a second blood component using the blood component separation device;**

After harvesting a donor's blood, the blood flows into Lavender's fractionator, which separates the whole blood into blood fractions (components), including a plasma component and a component containing red and white blood cells and platelets. EX1004, 1:21-25, 5:42-52, 10:58-11:6, Figs. 1 and 20; EX1003, ¶85.

- vi. **1[e] collecting the plasma component from the blood component separation device and into a plasma collection container; and**

Lavender discloses that after separating the blood components, “a plasma outlet port ... allows **plasma** to flow to a plasma collection bag” via tubing (*e.g.*, tubing 324 in Fig. 20). EX1004, 10:58-11:6; Figs. 1, 4, 15, 17, and 20. EX1003, ¶86.

- vii. **1[f] calculating a volume of pure plasma collected within the plasma collection container based, at least in part, on a volume of plasma component collected within the plasma collection container, a ratio of anticoagulant added to the withdrawn whole blood, and a hematocrit of the donor.**

Lavender anticipates element 1[f] under the plain and ordinary meaning of the term “based, at least in part, on.” EX1003, ¶87. The claim language itself suggests that the calculation may rely on one or more methods, and the patent does not expressly limit or disavow reasonable interpretations of “based, at least in part, on.” As explained below, Lavender discloses this limitation under its plain and ordinary

meaning. Alternatively, as discussed below, a POSITA would have understood that Lavender renders this limitation obvious. EX1003, ¶87.

In Lavender's system 300, whole blood is drawn from a donor and mixed at mixer 313 with anticoagulant pumped from citrate bag 307. EX1004, 16:54-17:2; Fig. 20. The mixed whole blood and anticoagulant is then pumped to fractionator 25, which separates the blood into components, and a plasma and anticoagulant mixture is collected in plasma bag 325. EX1004, 16:50-53; 17:14-16; EX1003, ¶88.

Lavender uses the volume of plasma component collected within the plasma collection container, a ratio of anticoagulant added to the withdrawn whole blood, and the donor's hematocrit to calculate the total pure plasma volume collected. EX1004, 20:55-68; 41:1-44:33. As blood is being drawn from the donor, Lavender calculates **total plasma filtered (TPF)**, representing the total amount of pure plasma in the plasma collection bag. EX1004, 20:55-68; 41:1-44:33. *TPF* is determined by multiplying the total amount of dilute plasma filtered (*TDPF*) by a plasma dilution factor (*PDF*) ($TPF = TDPF * PDF$). EX1004, 20:55-68; 41:1-44:33. *TDPF* equals the "volume of plasma component collected within the plasma collection container" in claim 1. The plasma dilution factor (*PDF*) is determined using the predefined ratio of citrate (anticoagulant) added per milliliter of plasma to dilute incoming plasma to 68% of the initial concentration. EX1004, 22:35-46. Thus, 32 ml of citrate is added to the incoming whole blood for every 68 ml of plasma to dilute the incoming plasma

to 68% of its initial concentration; and *PDF* is defined at .68. EX1004, 20: 35-46; 41:1-44:33; EX1003, ¶89. Because *PDF* defines the amount of anticoagulant (citrate) added to the incoming whole blood to dilute the incoming plasma to 68% of the initial concentration, a POSITA would understand it is a ratio of “anticoagulant added to the withdrawn whole blood” relative to incoming plasma. EX1003, ¶89.

A POSITA would understand that *PDF* would be expressed as $PDF = \frac{V_P}{V_P + V_{AC}}$ where V_P is the volume of pure plasma and V_{AC} is the volume of anticoagulant. EX1003, ¶90.

This equation, when inserted into the *TPF* equation shows that Lavender determines the volume of pure plasma in the collected plasma component, as follows:

$$TPF = TDPF * PDF = TDPF * \left(\frac{V_P}{V_P + V_{AC}} \right)$$

A POSITA would understand that the volume of plasma introduced into the system (V_P) is related to the volume of whole blood introduced (V_B) as $V_P = V_B * (1 - HCTD)$, which is Lavender’s equation for the plasma flow rate ($TQP = TQB * (1 - HCTD)$) converted to a volume equation. EX1003, ¶91.

Lavender therefore determines the volume of pure plasma in the collection container from $TPF = TDPF * \frac{V_B * (1 - HCTD)}{[V_B * (1 - HCTD) + V_{AC}]}$, showing that Lavender

determines the volume of pure plasma in the collection container (*TPF*) from the volume of plasma component collected within the plasma collection container (*TDPF*), a ratio of anticoagulant added to the withdrawn whole blood relative to incoming plasma through $PDF = \frac{V_P}{V_P + V_{AC}}$, and a hematocrit of the donor (*HCTD*). EX1003, ¶92.

If the Board, however, determines this is not inherent in Lavender, Lavender renders this limitation obvious because a POSITA would (i) recognize the interdependency between the donor's hematocrit and the calculated *TPF*, which is based on *PDF*, which, in turn, is based on the volume of anticoagulant added to the whole blood, and (ii) understand that the plasma volume in the collection bag (*TPF*) is based, at least in part, on the donor's hematocrit (*HCTD*) and the volume of plasma component in the collection bag (*TDPF*). EX1003, ¶93.

2. Claim 2: A method according to claim 1, further comprising calculating a percentage of anticoagulant in the collected plasma component.

Lavender monitors a volume of anticoagulant (*e.g.*, *TCF*) collected within the plasma collection container and monitors a total volume of collected fluid (*e.g.* dilute plasma) in the plasma collection container (*e.g.*, *TDPF*). EX1004, 43:27-28. Lavender updates *TDPF* as the system withdraws blood. EX1003, ¶94. A POSITA would readily understand how to calculate a percentage of anticoagulant in the collected plasma component by dividing *TCF* by *TDPF* (*i.e.*, percentage of

anticoagulant in the collected plasma component = $\left(\frac{TCF}{TDPF}\right) * 100$). As the Federal Circuit has established, ratios and percentages may be treated interchangeably, particularly in the context of evaluating whether a patent claim is anticipated by prior art. *See In re Taylor*, No. 2021-1613, 2022 U.S. App. LEXIS 15170 (Fed. Cir. 2022) (non-precedential) (reasoning that expressing the amount of essential components as weight percentages rather than a ratio was a distinction without a difference”). EX1003, ¶94.

Furthermore, Lavender utilizes a predetermined plasma dilution factor (**PDF** = **0.68**) that represents the percentage of pure plasma in the collected plasma component (**TDPF**), which is derived from the predefined ratio of citrate added per milliliter of plasma to dilute incoming plasma to 68% of the initial concentration. EX1004, 22:35-46; EX1003, ¶95. *PDF* is a fraction of 1, and a POSITA would readily understand that 0.68 represents the 68% dilution of incoming plasma and could easily convert such a decimal representation of 0.68 to 68%. EX1003, ¶95. A POSITA would readily understand that only plasma and anticoagulant are collected within the collected plasma component, and the percentage of anticoagulant in the collected plasma component may be calculated by subtracting **PDF** from 1, i.e., a percentage of anticoagulant in the collected plasma component equals $(1 - PDF)$ where the percentage is represented as a fraction of 1, or $(1 - PDF) * 100$ to determine a percentage represented out of 100. EX1003, ¶95.

3. **Claim 3: A method according to claim 2, wherein the calculated percentage of anticoagulant in the collected plasma component is based, at least in part, on the ratio of anticoagulant added to the withdrawn whole blood, and the hematocrit of the donor.**

As discussed above, Lavender calculates the volume of pure plasma collected in the plasma collection bag (**TPF**) based, at least in part, on the ratio of anticoagulant added to the withdrawn whole blood (**PDF**), and the donor's hematocrit (**HCTD**). See §IX.A.1.g.; EX1003, ¶96. Lavender's calculation of the volume of anticoagulant (*e.g.*, **TCF** total citrate filtered) collected within the plasma collection container is based directly on **TPF** (i.e., $TCF = TPF * CF$). EX1004, 41:4-44:42. EX1003, ¶96. Thus, **TCF** is also calculated based, at least in part, on the ratio of anticoagulant added to the withdrawn whole blood (**PDF**), and the donor's hematocrit (**HCTD**). EX1003, ¶96. As discussed above in §IX.A.2., a POSITA would readily understand how to calculate a percentage of anticoagulant in the collected plasma component by dividing **TCF** by **TDPF** (i.e., percentage of anticoagulant in the collected plasma component = $\left(\frac{TCF}{TDPF}\right) * 100$). EX1003, ¶96.

4. **Claim 4: A method according to claim 2, wherein the calculated volume of pure plasma collected within the plasma collection container is based, at least in part, on the calculated percentage of anticoagulant in the collected plasma component.**

In Lavender's Main Loop algorithm of Table VI, the total plasma in the collected plasma component (**TPF**) is calculated based on the total volume of

anticoagulant and plasma solution in the collection container (total dilute plasma filtered (*TDPF*)), which is determined by the weight of the collection container. As discussed above, $TPF = TDPF * PDF$. EX1004, 41:10-44:57. Plasma dilution factor (*PDF*) represents the factor by which a volume of incoming plasma is diluted with a volume of anticoagulant. EX1004, 22:37-39; 41:10-44:57. A POSITA would therefore understand, using basic arithmetic, that $PDF = \frac{V_P}{V_P + V_{AC}}$, and thus *PDF* is a decimal representation of a percentage of pure plasma in the collected plasma component. EX1003, ¶97. A POSITA would also understand that the remaining percentage, or $1 - PDF$ is a decimal representation of the percentage of anticoagulant in the collected plasma component. EX1003, ¶97. Thus, a POSITA would understand that the calculation of *TPF* is based, at least in part, on the percentage of anticoagulant in the collected plasma component (e.g. indirectly through *PDF*). EX1003, ¶97.

5. **Claim 5: A method according to claim 1, further comprising: calculating a volume of anticoagulant in the collected plasma component based, at least in part, upon the hematocrit of the donor, the calculated 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.**

Lavender anticipates and/or renders obvious claim 5 under the plain and ordinary meaning of the term “based, at least in part, on.” EX1003, ¶98. The claim language itself—“based, at least in part, on”—suggests that the calculation may rely

on one or more methods and is not limited to a single, exclusive method. Although the '873 patent provides an example where a technician determines the volume of collected pure plasma by calculating the volume of anticoagulant in the plasma component by subtracting the measured volume of anticoagulant in the collection container from the total fluid volume in the container—the patent does not expressly disavow other reasonable interpretations of “based, at least in part, on.” As explained below, Lavender discloses this limitation under its plain and ordinary meaning. Alternatively, as discussed below, a POSITA would have understood that Lavender renders this limitation obvious. EX1003, ¶98.

Even if a narrower interpretation of “based, at least in part, on” is adopted, claim 5 is rendered obvious by Lavender in view of Fletcher-Haynes, as discussed in relation to claim 1 in Ground 2, below. EX1003, ¶99.

i. Lavender discloses calculating a volume of anticoagulant in the collected plasma component based, at least in part, upon the hematocrit of the donor.

In Lavender’s system 300, a donor’s whole blood is drawn and mixed with anticoagulant pumped from citrate bag 307. EX1004, 16:54-17:2; Fig. 20. Fractionator 25 then separates the blood into components and a plasma and anticoagulant mixture is then collected in plasma bag 325. EX1004, 16:50-53; 17:14-16; EX1003, ¶100.

In Lavender’s Main Loop algorithm of Table VI, a volume of anticoagulant

in the collected plasma component (**TCF**) is calculated based on a volume of total plasma in the collected plasma component (**TPF**), via $TCF = TPF * CF$, where **CF** is a conversion factor representing the volume of anticoagulant introduced into the incoming whole blood (V_{AC}) per incoming volume of plasma (V_P), or $CF = \frac{V_{AC}}{V_P}$. EX1004, 41:4-44:42. The total plasma in the collected plasma component (**TPF**) is calculated based on the total **volume of anticoagulant** and plasma solution in the collection container (total dilute plasma filtered (**TDPF**)), which is determined by the weight of the collection container. The equation for **TPF** is $TPF = TDPF * PDF$. The plasma dilution factor (**PDF**) represents the factor by which a volume of incoming plasma is diluted with a volume of anticoagulant. EX1004, 22:37-39; 41:10-44:57. A POSITA would therefore understand that $PDF = \frac{V_P}{V_P + V_{AC}}$. EX1003, ¶101.

Lavender therefore determines the volume of anticoagulant in the collected plasma component, as follows:

$$TCF = TPF * CF = TDPF * PDF * CF = TDPF * \left(\frac{V_{AC}}{V_P}\right) * \left(\frac{V_P}{V_P + V_{AC}}\right) = TDPF * \frac{V_{AC}}{V_P + V_{AC}}$$

EX1003, ¶102.

A POSITA would also understand that the volume of plasma introduced into the system (V_P) is related to the volume of whole blood introduced (V_B) as $V_P = V_B * (1 - HCTD)$, which is Lavender's equation for the plasma flow rate ($TQP =$

$TQB * (1 - HCTD)$) converted to a volume equation. EX1003, ¶¶102-103.

Lavender therefore determines the volume of anticoagulant in the collected plasma from $TCF = TDPF * \frac{V_{AC}}{[V_{AC} + V_B * (1 - HCTD)]}$, showing that Lavender determines the volume of anticoagulant in the collected plasma from the subject's hematocrit. EX1003, ¶104.

ii. Lavender discloses 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.

Lavender uses the amount of anticoagulant (citrate) added to the whole blood to calculate the total pure plasma volume collected. EX1004, 20:55-68; 41:1-44:33. Lavender first calculates **total plasma filtered (TPF)**—the total amount of pure plasma in the plasma collection bag—by multiplying the total amount of dilute plasma filtered ($TDPF$) by a plasma dilution factor (PDF) (i.e., $TPF = TDPF * PDF$). EX1004, 20:55-68; 41:1-44:33. As discussed above, PDF is determined using the predefined ratio of citrate added per milliliter of plasma to dilute incoming plasma to 68% of the initial concentration and is defined as 0.68. EX1004, 20: 35-46; 41:1-44:33; EX1003, ¶105.

Next, Lavender calculates the volume of anticoagulant in the plasma container (i.e. **total citrate filtered (TCF)**). Lavender weighs the collected plasma and anticoagulant solution in plasma bag 325 and transmits the weight information to

microprocessor 301. EX1004, 16:50-53; 17:14-16. Using the plasma bag 325's weight, system 300 calculates the volume of anticoagulant in the plasma bag 325 (i.e. (**TCF**)) by multiplying the total amount of **filtered plasma (TPF)** by conversion factor (**CF**) for milliliters of citrate per milliliter of plasma. EX1004, 41:1-44:33 (Table VI, §5(B)). **CF** is determined using a predefined ratio of citrate added per milliliter of plasma to dilute incoming plasma to 68% of the initial concentration. EX1004, 22:35-46; EX1003, ¶106.

Lavender's microprocessor repeatedly measures the weight change of the plasma bag ("**TDPW**", total dilute plasma filtered in grams) in real time and updates the calculated values using the updated total plasma bag weight. EX1004, 20:55-68; 41:1-44:33. Specifically, Lavender discloses "repeatedly performing the measurements and calculations . . . updating these values each time the program cycles through the main loop, and displaying the values in 'Run'-message (Table V) which is updated approximately every two seconds." EX1004, 20:55-68; 41:1-44:33; EX1003, ¶107.

Lavender thus calculates the anticoagulant volume as the plasma component is being collected in the plasma collection container by repeatedly performing the **TCF** calculation in the main loop of the algorithm in real-time, which continues until the total plasma filtered is equal to or greater than the maximum total plasma filtered. EX1004, cols. 43-44; EX1003, ¶108.

As shown in the annotated excerpt of §5(B) of Table VI below, the volume of pure plasma in the plasma collection bag (**TPF**) and the volume of anticoagulant in the plasma container (**TCF**) share a direct mathematical relationship. EX1003, ¶109.

$$\begin{aligned}\underline{\text{TPF}} &= \text{TDPF} * \text{PDF} && \text{(total plasma filtered, ml)} \\ \text{CF} &= \text{PF} * \text{CF} && \text{(citrate filtered, ml/min)} \\ \text{TCF} &= \underline{\text{TPF}} * \text{CF} && \text{(total citrate filtered, ml/min)}\end{aligned}$$

That is, during the collection procedure, any change in the calculated value of the volume of anticoagulant (**TCF**) requires a corresponding change in the calculated value of the volume of pure plasma (**TPF**), and vice versa. Both **TCF** and **TPF** are based on *PDF*. EX1004, 22:35-46. Accordingly, the volume of pure plasma collected in the plasma collection bag (**TPF**) is calculated in real-time based “at least in part” on the calculated volume of anticoagulant in the collected plasma component (**TCF**) because as one value changes, the other necessarily changes. EX1003, ¶110.

Lavender’s disclosure of the dependency of both **TPF** and **TCF** on the *PDF* inherently discloses calculating a volume of pure plasma collected in the plasma collection bag (**TPF**) based, at least in part, on a calculated volume of anticoagulant in the collected plasma component (**TCF**). EX1003, ¶111. If the Board, however, determines this is not inherent in Lavender, Lavender renders this limitation obvious because a POSITA would (i) recognize the interdependency between the predefined ratio of citrate added per milliliter of plasma, **TPF** and **TCF**, and (ii) understand that

the plasma volume in the collection bag is based, at least in part, on the volume of anticoagulant in the collection bag. EX1003, ¶111. As discussed above in §IX.A.5.a, **TCF** is based on the donor's hematocrit because the anticoagulant added to the system is dependent on the plasma flow, and plasma flow is determined based on the donor's hematocrit. Thus, Lavender discloses calculating a volume of anticoagulant in the collected plasma component based, at least in part, upon the hematocrit of the donor, the calculated 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. EX1003, ¶111.

6. Claim 7: A method according to claim 1, further comprising: monitoring the volume of plasma component collected within the plasma collection container.

Lavender monitors a volume of plasma component (*e.g.*, **TDPF** total dilute plasma filtered) collected within the plasma collection container. EX1004, 43:4-6. As discussed above in §IX.A.1.g., Lavender updates **TDPF** as the system withdraws blood. EX1003, ¶112.

7. Claim 8: 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 based, at least in part, on the monitored weight of collected plasma component.

Lavender monitors a weight of plasma component (*e.g.*, **TDPW** total weight of dilute plasma filtered) collected within the plasma collection container. See Table

VI, §5(B). Lavender discloses that the current total volume of pure plasma in the collection container (***TPF***) is based on the ***TDPF***, or “the monitored volume of collected plasma component,” which is based on the weight of the collected plasma component (***TDPW***). EX1004, 41:1-44:33; EX1003, ¶113.

8. **Claim 10: A method according to claim 1, further comprising: continuing steps (b) through (f) to collect a target volume of pure plasma and/or a target volume of plasma component within the plasma collection container.**

As discussed above, Lavender performs steps (b) – (f). See §§IX.A.1.c-g.

In response to the start of Lavender’s blood separation procedure, the system initializes the system algorithm of Table VI. EX1004, 20:55-68, 41:1-44:33, Figs. 25A-25D. The Main Loop of the algorithm repeats **until a desired amount of plasma has been collected**. EX1004, 21:62-22:2; EX1003, ¶115.

For example, Lavender repeats step (d)-(i) by “introducing anticoagulant to the blood from which the plasma is to be collected ... separating plasma from the extracted blood ... **until a predetermined ... volume of plasma has been collected**.” EX1004, 21:62-22:6; 46:14-22; *see also* claim 1; EX1003, ¶116.

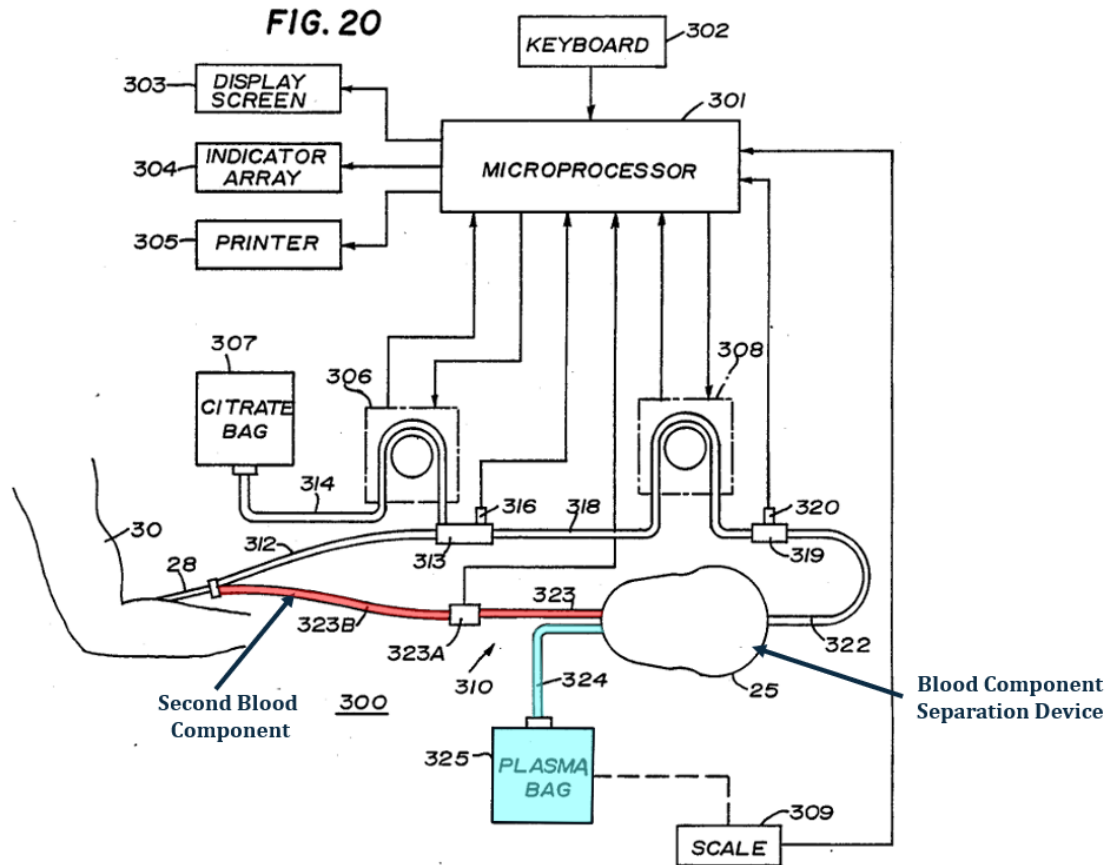
9. **Claim 11: A method according to claim 10, wherein the target volume of pure plasma and/or the target volume of plasma component is based, at least in part, on a weight of the donor.**

Lavender discloses directing “the user in entry and validation of donor data, including ... **donor weight in pounds**.” EX1004, 20:10-14. Then, Lavender

determines a target volume of pure plasma, **MAXPF**, which is based on the donor's bodyweight (**BW**) and a predetermined constant (C1) of milliliters of plasma collected per pound of body weight. EX1004, Table VI, §2(g). EX1003, ¶117.

10. **Claim 12: A method according to claim 10, further comprising: returning, after collecting at least a portion of the target volume of pure plasma and/or the target volume of plasma component, the second blood component to the donor through a return line.**

Lavender collects a first blood component (*e.g.*, plasma) in a “blood fraction collection receptacle or bag.” EX1004, 5:32-33. After collecting at least a portion of the target volume of pure plasma, the second blood component (*e.g.*, RBC), is returned to the donor 30 through the tubing 323. EX1004, 10:58-63; EX1003, ¶118.



EX1004, Fig. 20 (annotated)

11. Claim 13

- i. 13[preamble] A system for collecting plasma comprising:**

Lavender discloses that its methods may be implemented in “a system for harvesting plasma.” EX1004, Abstract, 1:15-17, 1:45-47, Figs. 1 & 20. EX1003, ¶119.

- ii. 13[a] a venous-access device for drawing whole blood from a subject and returning blood components to the subject;**

See §§IX.A.1.iii, *supra*, Ex.1004, 5:13-22 and Figs 1 and 20. EX1003, ¶120.

- iii. **13[b] a blood component separation device for separating the withdrawn blood into a plasma component and a second blood component, the blood component separation device having an outlet and being configured to convey the plasma component to a plasma collection container;**

See §§IX.A.1.vi-vii, *supra*, EX1004, 10:58-11:6; FIGS. 1, 4, 15, 17, 20;

EX1003, ¶121.

- iv. **13[c] a blood draw line fluidly coupled to the venous-access device and configured to transport withdrawn whole blood to the blood component separation device, the flow through the blood draw line being controlled by a blood draw pump;**

See §IX.A.1.c, *supra*, EX1004, 5:13-22 and FIGS 1, 20; EX1003, ¶122.

- v. **13[d] an anticoagulant line fluidly coupled to an anticoagulant source, the anticoagulant line configured to introduce anticoagulant into the withdrawn whole blood; and**

See §IX.A.1.d, *supra*, EX1004, 5:22-28 and FIGS. 1, 20; EX1003, ¶123.

- vi. **13[e] a controller configured to control the operation of the blood component separation device and the blood draw pump,**

See §IX.A.1.f, *supra*, EX1004, 10:58-11:6; and FIGS. 1, 20; EX1003, ¶124.

Lavender recites:

The input and output pressures of the blood pump are sensed and inputted to a microprocessor, into which donor data including weight, sex, and hematocrit is also keyed by the user. The microprocessor operates under program control to calculate, based on the donor data, the amount of plasma to be collected and the amount of anticoagulant to be added. The program controls the operation of the extracorporeal

devices, regulates the operating parameters, and stops the procedure when the predetermined amount of plasma has been obtained.

See EX1004, Abstract. This program control would include blood fractionator 25 and the associated fluid pumps. EX1004, 18:27-64; cls. 28, 29, 33, 35, 36, 38, 40-41. EX1003, ¶124.

- vii. **13[f] the controller configured to calculate a volume of pure plasma collected within the plasma collection container based, at least in part, on a volume of plasma component collected within the plasma collection container, a ratio of anticoagulant added to the withdrawn whole blood, and a hematocrit of the subject.**

See §IX.A.1.g, *supra*. EX1004, 20:55-68; 41:1-44:33; EX1003, ¶125.

- 12. **Claim 14: A system according to claim 13, wherein the controller is further configured to calculate a percentage of anticoagulant in the collected plasma component.**

See §IX.A.2, *supra*. EX1003, ¶126.

- 13. **Claim 15: A system according to claim 14, wherein the calculated percentage of anticoagulant in the collected plasma component is based, at least in part, upon the ratio of anticoagulant added to the withdrawn whole blood, and the hematocrit of the donor.**

See §IX.A.3, *supra*. EX1003, ¶127.

- 14. **Claim 16: A system according to claim 14, wherein the calculated volume of pure plasma collected within the plasma collection container is based, at least in part, on the calculated percentage of anticoagulant in the collected plasma component.**

See §IX.A.4, *supra*. EX1003, ¶128.

15. **Claim 17: A system according to claim 13, wherein the controller is further configured to calculate a volume of anticoagulant in the collected plasma component based, at least in part, upon the hematocrit of the subject, the volume of pure plasma collected within the plasma collection container based, at least in part, upon the volume of anticoagulant in the collected plasma component.**

See §IX.A.5., EX1003, ¶129.

16. **Claim 19: A system according to claim 13, wherein the controller is configured to monitor the operation of an anticoagulant pump to determine a total volume of anticoagulant introduced into the system.**

Lavender uses anticoagulant pump 306 in system 300 “for pumping anticoagulant from an associated source” into “the blood flowing from the donor 30 to the fractionator 25.” EX1004, 5:15:47-53, 16:45-47, 16:54-17:2, 41:27-30; 42:8-44:32, claim 1; Fig. 20. Lavender introduces anticoagulant into the whole blood at “a predetermined flow rate,” which Lavender expresses in its algorithm as QC . EX1004, 5:25-26. Lavender sets the citrate pump flow rate, QCP , to QC via a controller (i.e. microprocessor 301). EX1004, cols. 41 & 42, Fig. 20; EX1003, ¶130. The citrate pump flow rate, QCP , is used to determine TQC in Lavender’s Main Loop algorithm. EX1004, cols. 41 & 42, Fig. 20; EX1003, ¶130. The total volume of anticoagulant introduced into Lavender’s system is monitored by microprocessor 301 in the Main Loop algorithm, specifically tracking TQC or total citrate flow in ml, during a blood separation procedure. EX1004, 5:15:47-53, 16:45-47, 16:54-17:2, 41:27-30; 42:8-44:32; Fig. 20; EX1003, ¶130.

17. **Claim 20: A system according to claim 13, further comprising: a plasma collection container weight sensor configured to monitor the volume of plasma component collected within the plasma collection container.**

Lavender monitors a volume of plasma component (*e.g.*, **TDPF** total dilute plasma filtered) collected within the plasma collection container using a scale 309 monitoring the weight of the plasma collection container (*e.g.* plasma bag 325). EX1004, 16:50-53, Fig. 20. As discussed above in §IX.A.1.g., Lavender updates **TDPF** as the system withdraws blood. EX1003, ¶131.

18. **Claim 21: A system according to claim 13, further comprising: a plasma collection container weight sensor configured to monitor a weight of plasma component collected within the plasma collection container, the calculated volume of pure plasma collected within the plasma collection container based, at least in part, on the monitored weight of collected plasma component.**

See §IX.A.17. As blood is being drawn from the donor, Lavender calculates **total plasma filtered (TPF)**, representing the total amount of pure plasma in the plasma collection bag. EX1004, 20:55-68; 41:1-44:33. **TPF** is determined by multiplying the total amount of dilute plasma filtered (**TDPF**) by a plasma dilution factor (**PDF**) (*i.e.*, $TPF = TDPF * PDF$). EX1004, 20:55-68; 41:1-44:33; EX1003, ¶132.

- 19. Claim 22: A system according to claim 13, wherein the controller is configured control the plasma collection process to collect a target volume of pure plasma and/or a target volume of plasma component within the plasma collection container.**

See §IX.A.8., EX1003, ¶133.

- 20. Claim 23: A system according to claim 22, wherein the target volume of pure plasma and/or the target volume of plasma component is based, at least in part, on a weight of the subject.**

See §IX.A.9., EX1003, ¶134.

B. Ground 2: Claims 1 and 24-30 are obvious over Lavender in view of Fletcher-Haynes

1. Claim 1

i. 1[a]–1[e]

As discussed above, Lavender discloses claim limitations 1[preamble]-1[h].

See §§IX.A.1-IX.A.9; EX1003, ¶135.

- ii. 1[f] calculating a volume of pure plasma collected within the plasma collection container based, at least in part, on a volume of plasma component collected within the plasma collection container, a ratio of anticoagulant added to the withdrawn whole blood, and a hematocrit of the donor.**

Should the Board find that “based, at least in part, on” is narrowly limited to the specific calculation disclosed in the ’873 patent, a POSITA would have found it obvious to implement Fletcher-Haynes’ calculation of the volume of pure plasma in the collection container based, at least in part, on a volume of plasma component

collected within the plasma collection container, a ratio of anticoagulant added to the withdrawn whole blood, and a hematocrit of the donor into Lavender's system. EX1003, ¶136.

A POSITA would be motivated to combine the teachings of Lavender with Fletcher-Haynes to more accurately track and optimize the amount of plasma collected from the donor. EX1003, ¶137. For example, Fletcher-Haynes teaches using a donor's height, weight, and hematocrit to determine the total amount of pure plasma to collect from the donor. EX1005, 20:9-15. By adding the height parameter to Lavender's data collection steps, Lavender's systems would more accurately determine the optimal amount of pure plasma to collect. EX1003, ¶137. A POSITA would readily implement any of Fletcher-Haynes' calculations into Lavender's system to optimize the data tracking and donor parameter monitoring before, during, and after a blood draw procedure. EX1003, ¶137.

A POSITA would have been motivated to combine Lavender's and Fletcher-Haynes' teachings, and would have had a reasonable expectation of success, because each relate to the same well-known technologies, both apply substantially similar techniques to achieve similar results, and Lavender's functionality would not change in the combination as Fletcher-Haynes is used for the same purpose as Lavender's system—using donor parameters to determine the total amount of pure plasma to collect. EX1003, ¶138.

Fletcher-Haynes expressly discloses calculating the volume of pure plasma in the collection container based, at least in part, on (i) a volume of plasma component collected within the plasma collection container, (ii) a ratio of anticoagulant added to the withdrawn whole blood, and (iii) a hematocrit of the donor. EX1005, 22:66-23:3. Specifically, Fletcher-Haynes' Equation 15 recites $f_{ACP} = [(R - 1)(1 - H)]^{-1}$ where f_{ACP} is anticoagulant expressed as a fraction of pure plasma volume, R is the ratio of the collective flow of anticoagulant and blood through the inlet line in relation to the flow of anticoagulant through the inlet line (e.g. a ratio of anticoagulant added to withdrawn whole blood), and H is the donor's hematocrit. EX1004, 48:21-32, 50:16-52:14. Equation 17 defines the target source plasma volume, or maximum volume of pure plasma to collect in the collection container. EX1004, 48:54-62, 50:16-52:14. Equation 22 recites $V_{SPB} = V_{SP}(1 + f_{ACP})$ where V_{SPB} is the total volume in the source plasma bag (including plasma and anticoagulant) and V_{SP} is the volume of pure plasma in the source plasma bag. EX1004, 50:16-52:14. A POSITA would look to Fletcher-Haynes's disclosures related to considering hematocrit when calculating real-time volumes in Lavender's system to better determine the volume of pure plasma. Specifically, a POSITA would look to incorporate Equations 15, 17, and 22 to determine **TPF** based on the donor's hematocrit. EX1003, ¶139.

As discussed hereinabove, **TPF** is the total pure plasma collected in the

plasma collection bag during a procedure. EX1005, Table VI §2.g. Lavender determines **TPF** by using the volume of dilute plasma (**TDPF**) collected: **TPF** = **TDPF** * **PDF**, where **TDPF** is determined using a weight sensor, and **PDF** is a constant derived from a predetermined ratio of plasma to anticoagulant used to dilute incoming plasma to 68%. EX1005, 20:46-54, 41:1-44:33, Table VI: §2.g; EX1003, ¶140. A POSITA would understand that Lavender's **TDPF** could be plugged in as V_{SPB} , the dilute plasma volume in the source bag, into Fletcher-Haynes' Equation 22 to determine V_{SP} , the volume of pure plasma in a plasma collection bag (e.g., **TDPF** = **TPF**(1 + f_{ACP})). When Fletcher-Haynes' f_{ACP} equation is plugged into the V_{SPB} (or **TDPF** in Lavender) equation, a POSITA would readily derive an equation for V_{SP} (or **TPF**) to use in Lavender's system:

$$V_{SPB} = V_{SP}(1 + [(R - 1)(1 - H)]^{-1})$$

$$V_{SP} = \frac{V_{SPB}}{(1 + [(R - 1)(1 - H)]^{-1})}$$

$$TPF = \frac{TDPF}{(1 + [(R - 1)(1 - H)]^{-1})}$$

Lavender's system already tracks **TDPF** using a scale, so a POSITA would simply plug in the derived equation for V_{SP} above from Fletcher-Haynes to determine a real-time pure plasma volume, or **TPF**, in the collection container. R in Fletcher-Haynes is ratio of the collective flow of anticoagulant and blood in relation to the flow of anticoagulant, through the inlet line, and a POSITA would readily

derive this R in Fletcher-Haynes by simply dividing the blood pump rate ($QBP = QB + QC$) by the citrate pump rate ($QCP = QC$), and Lavender is already calculating QBP and QCP prior to and during a procedure (i.e., $R = \frac{QBP}{QCP}$). EX1003, ¶141.

Lavender's system also already receives the donor's hematocrit (H), and thus a POSITA can plug in the derived equation for TPF (or V_{SP}) from Fletcher-Haynes into Lavender's main loop algorithm to determine TPF during a procedure based on parameters the Lavender system is already calculating:

$$TPF = \frac{TDPF}{(1 + [(\frac{QBP}{QCP} - 1)(1 - H)]^{-1})}$$

By utilizing the above TPF equation from Fletcher-Haynes in Lavender's main loop algorithm, Lavender's system calculates a volume of pure plasma collected within the plasma collection container based directly on (i) a volume of plasma component collected within the plasma collection container (e.g. $TDPF$), a ratio of anticoagulant added to the withdrawn whole blood (e.g. $\frac{QBP}{QCP}$), and a hematocrit of the donor (e.g., H). This is reflected in the TPF equation shown immediately above. EX1003, ¶142.

Specifically, Fletcher-Haynes recites "Product Plasma - The volume of plasma product collected during the procedure (total plasma volume less

anticoagulant volume)”⁶, corresponding to the pure plasma collected in claim 1 of the ’873 patent. EX1005, 22:66-23:3. A POSITA would easily utilize this formula in Lavender to determine the collected pure plasma volume by inserting the equation for product plasma from Fletcher-Haynes into Lavender’s Main Loop Algorithm. EX1003, ¶143. Such a combination would have been no more than combining prior art elements according to known methods to yield predictable results. EX1003, ¶143.

A POSITA would understand, after utilizing Fletcher-Haynes’ equations to determine a *new TPF* value based directly on (i) a volume of plasma component collected within the plasma collection container (e.g. *TDPF*), a ratio of anticoagulant added to the withdrawn whole blood (e.g. *QBP/QCP*), and a hematocrit of the donor (e.g., *H*), that the equation for TCF would need be updated to account for this *new TPF* value, i.e. $TCF = TDPF - TPF$. A POSITA would understand that $TCF = TDPF - TPF$, because the volume of fluid in the collection container only includes pure plasma and anticoagulant. EX1003, ¶144.

⁶ Petitioner notes that the equation to determine product plasma by taking the total plasma volume (i.e. total volume of plasma and anticoagulant in the collection bag) less the anticoagulant volume, was well know in the art long before the filing of the ’652 patent. For example, Japanese Patent Publication No. JP 2002-282352A (EX1013) discloses determining a pure plasma volume in a collection container using a volume of anticoagulant in the collection container.

2. Claim 24

- i. 24[preamble] A system for collecting plasma comprising:**

See §IX.A.11.a, EX1003, ¶145

- ii. 24[a] a venous-access device for drawing whole blood from a subject and returning blood components to the subject;**

See §IX.A.11.b, EX1003, ¶146.

- iii. 24[b] a blood component separation device for separating the withdrawn blood into a plasma component and a second blood component, the blood component separation device having an outlet and being configured to convey the plasma component to a plasma collection container;**

See §IX.A.11.c, EX1003, ¶147.

- iv. 24[c] a blood draw line fluidly coupled to the venous-access device and configured to transport withdrawn whole blood to the blood component separation device, the flow through the blood draw line being controlled by a blood draw pump;**

See §IX.A.1.d, EX1003, ¶148.

- v. 24[d] an anticoagulant line fluidly coupled to an anticoagulant source, the anticoagulant line configured to introduce anticoagulant into the withdrawn whole blood; and**

See §IX.A.1.e, EX1003, ¶149.

- vi. 24[e] a controller configured to control the operation of the blood component separation device and the blood draw pump,**

See §IX.A.1.f, EX1003, ¶150.

- vii. **24[f] the controller configured to calculate a volume of pure plasma to be collected within the plasma collection container based, at least in part, on a volume of plasma component to be collected within the plasma collection container, a ratio of anticoagulant to be added to the withdrawn whole blood, and a hematocrit of the subject.**

In Lavender's system the total amount of pure plasma to collect (*MAXPF*) within the plasma collection container is determined by multiplying the donor's bodyweight (*BW*) by a first predetermined constant (*C1*), which is derived from a calculated donor circulating plasma volume of 5% of body weight (*BW*), multiplied by a total pure plasma to collect of 18% of the donor circulating plasma volume, and further multiplied by the conversion between ml of plasma and pound of body weight of 453.6 ml/pound, i.e. $C1 = 0.05 * 0.18 * 453.6 = 4.0824$ ml/pound. EX1005, 22:35-41, 41:4-44:42. Lavender's system also determines a volume of dilute plasma to be collected (*MAXDPF*), or a "volume of plasma component to be collected" in claim 24, by multiplying the donor's bodyweight (*BW*) by a second predetermined constant (*C2*), which is derived from a predetermined ratio of plasma to anticoagulant used to dilute incoming plasma by 68% of its initial concentration, i.e. $C2 = C1 / PDF$. EX1003, ¶151.

A POSITA would be motivated to incorporate Fletcher-Haynes' calculations into Lavender's system as it would result in a more accurate determination of a target volume of pure plasma (*MAXPF*). For example, when a POSITA utilizes Fletcher-

Haynes' calculations in Lavender's system, a target volume of pure plasma may be determined based on a volume of plasma component to be collected within the plasma collection container (*MAXDPF*), a ratio of anticoagulant to be added to the withdrawn whole blood, and a hematocrit of the subject, compared to determining the target volume of pure plasma (*MAXPF*) based only on a donor's weight and a predetermined constant. EX1003, ¶152.

Specifically, a POSITA would look to Fletcher-Haynes to better determine the volume of pure plasma to be collected in Lavender's system. EX1003, ¶153.

Fletcher-Haynes determines a target volume for total plasma component comprising raw plasma and anticoagulant based at least in part on the donor's parameters. Fletcher-Haynes' controller runs a "prediction model for predicting a yield of a particular blood component to be collected before a collection procedure is initiated using a compilation of algorithms" which determine, *e.g.*, calculate, a target volume for plasma component (*e.g.*, V_{SPB} , total volume in source plasma bag) and/or raw plasma (*e.g.*, V_{SP} , volume of pure plasma in the source plasma bag), using entered donor weight, height, and hematocrit. EX1005, 48:1-3; EX1003, ¶154.

Fletcher-Haynes calculates an AC Ratio (R) (low, medium, or high) using the donor's hematocrit (H) in Equation 9. EX1003, ¶155.

$$R = 1 + \frac{2.51}{H} \text{ (low), or } R = 1.33 \left(1 + \frac{2.51}{H} \right) \text{ (medium), or } R =$$

$$1.67 \left(1 + \frac{2.51}{H}\right) (\text{high})$$

Fletcher-Haynes' AC Ratio (R) is the ratio of the collective flow of anticoagulant and whole blood through the inlet line in relation to the flow of anticoagulant through the inlet line. EX1005, 48:23-26; EX1003, ¶156.

Fletcher-Haynes then determines the fraction of AC in the collected plasma component f_{ACP} using equation 15's AC ratio and hematocrit. EX1003, ¶157.

$$f_{ACP} = [(R - 1)(1 - H)]^{-1}$$

Fletcher-Haynes calculates a volume of total plasma (V_{SPB}) in equation 22. EX1003, ¶157.

$$V_{SPB} = V_{SP}(1 + f_{ACP})$$

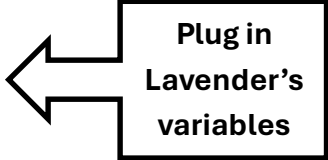
A POSITA would be motivated to incorporate Fletcher-Haynes' f_{ACP} and V_{SPB} calculations into Lavender's system as it would more accurately determine a target volume of pure plasma. For example, using Fletcher-Haynes' calculations in Lavender's system, means a target volume of pure plasma is determined based on a donor's hematocrit and weight, not just weight. EX1003, ¶158.

Specifically, a POSITA would look to Fletcher-Haynes to better determine the volume of pure plasma to be collected using Lavender's system. After using Fletcher-Haynes' calculations to determine f_{ACP} based on **the donor's hematocrit (H)** and **a ratio of anticoagulant to be added to the withdrawn whole blood (R)**,

a POSITA would be motivated to determine a new target volume of pure plasma to collect (*new MAXPF*) by solving Fletcher-Haynes' equation for V_{SPB} using the volume of dilute plasma to be collected (*MAXDPF*) in Lavender. This equation is derived below:

$$V_{SPB} = V_{SP}(1 + f_{ACP})$$
$$\frac{V_{SPB}}{(1 + f_{ACP})} = V_{SP}$$
$$\frac{MAXDPF}{(1 + [(R - 1)(1 - H)]^{-1})} = new\ MAXPF$$

Plug in
Lavender's
variables



See §VIII.A.2.d; EX1005, 22:35-41, 41:4-44:42; EX1003, ¶159.

A POSITA would easily implement the above-derived equation for *new MAXPF* into Lavender's algorithms, and specifically set a new target maximum volume of pure plasma to collect. EX1003, ¶160. A POSITA would also recognize that R in the equation for *new MAXPF* would be determined based on Fletcher-Hayne's equations that use donor hematocrit. EX1005, 48:23-26; EX1003, ¶160. R in Fletcher-Haynes is a ratio of the collective flow of anticoagulant and blood in relation to the flow of anticoagulant through the inlet line, and a POSITA would readily derive R by dividing the blood pump rate ($QBP = QB + QC$) by the citrate pump rate ($QCP = QC$), and Lavender already calculates QBP and QCP prior to and during a procedure (i.e., $R = \frac{QBP}{QCP}$). EX1003, ¶160.

Thus, as illustrated in the above *new MAXPF* equation, a POSITA would

modify Lavender in view of Fletcher-Haynes to configure Lavender's controller to calculate a volume of pure plasma to be collected within the plasma collection container based, at least in part, on a volume of plasma component to be collected within the plasma collection container, a ratio of anticoagulant to be added to the withdrawn whole blood, and a hematocrit of the subject. EX1003, ¶161.

3. **Claim 25: A system according to claim 24, wherein the controller is configured to control the plasma collection process to collect a target volume of pure plasma and/or target volume of plasma component.**

See §IX.A.19., EX1003, ¶162.

4. **Claim 26: A system according to claim 25, wherein the target volume of pure plasma and/or target volume of plasma component is based, at least in part, on a weight of the subject.**

See §IX.A.20., EX1003, ¶163.

5. **Claim 27: A system according to claim 24, wherein the controller is configured to calculate a percentage of anticoagulant to be collected in the plasma component.**

In the Lavender and Fletcher-Haynes system described above, a *new MAXPF* is determined using a volume of plasma component to be collected within the plasma collection container (*MAXDPF*), a ratio of anticoagulant to be added to the withdrawn whole blood (*R*), and a hematocrit of the subject (*H*). See §IX.B.3.g.; EX1003, ¶164. When using Fletcher-Haynes' equation in Lavender's system, a POSITA would recognize the need to recalculate the *MAXCF* by subtracting the

new MAXPF from the calculated *MAXDPF* (e.g., *new MAXCF* = *MAXDPF* – *new MAXPF*). EX1003, ¶164. Accordingly, a POSITA would understand how the controller would calculate a percentage of anticoagulant to be collected in the plasma component by dividing *new MAXCF* by *MAXDPF* (i.e., percentage of anticoagulant to be collected in the plasma component = $\left(\frac{\text{new MAXCF}}{\text{MAXDPF}}\right) * 100$). EX1003, ¶164.

6. **Claim 28: A system according to claim 27, wherein the calculated percentage of anticoagulant to be collected in the plasma component is based, at least in part, upon the ratio of anticoagulant to be added to the withdrawn whole blood and the hematocrit of the donor.**

See §§IX.B.3.g. and IX.B.6. EX1003, ¶165.

7. **Claim 29: A system according to claim 27, wherein the calculated volume of pure plasma to be collected within the plasma collection container is based, at least in part, on the calculated percentage of anticoagulant to be collected in the plasma component.**

In the Lavender-Fletcher-Haynes combination, the total volume of pure plasma to be collected in the plasma collection container (*new MAXPF*) is calculated based on the following equation:

$$\frac{\text{MAXDPF}}{(1 + [(R - 1)(1 - H)]^{-1})} = \text{new MAXPF}$$

As described above, the equation for *new MAXPF* is derived by a POSITA using Fletcher-Haynes' equations, including for f_{ACP} . A POSITA would understand

that f_{ACP} is a representation of the calculated percentage of anticoagulant to be collected in the plasma component and is equivalent to a percentage written in a fraction form. Thus, through the use of f_{ACP} , the calculation of *new MAXPF* is based, at least in part, on the calculated percentage of anticoagulant to be collected in the plasma component. EX1003, ¶¶166-167.

8. **Claim 30: A system according to claim 24, wherein the controller is further configured to calculate a volume of anticoagulant to be collected in the collected plasma component based, at least in part, upon the hematocrit of the subject, the volume of pure plasma to be collected within the plasma collection container based, at least in part, upon the volume of anticoagulant to be collected in the collected plasma component.**

In the Lavender and Fletcher-Haynes system, a *new MAXPF* is determined using a volume of plasma component to be collected within the plasma collection container (*MAXDPF*), a ratio of anticoagulant to be added to the withdrawn whole blood (*R*), and a hematocrit of the subject (*H*). See §IX.B.3.g.; EX1003, ¶168. When using Fletcher-Haynes' equation in Lavender's system, a POSITA would recognize the need to recalculate the *MAXCF* by subtracting the *new MAXPF* from the calculated *MAXDPF* (e.g., $new\ MAXCF = MAXDPF - new\ MAXPF$). EX1003, ¶168. This *new MAXCF* is based, at least in part, on a volume of plasma component to be collected within the plasma collection container (*MAXDPF*), a ratio of anticoagulant to be added to the withdrawn whole blood (*R*), and a hematocrit of the subject (*H*). Due to the direct mathematical relationship between *new MAXCF* and

new MAXPF (i.e., $\text{new MAXCF} = \text{MAXDPF} - \text{new MAXPF}$), a POSITA would readily understand that *new MAXPF* is based, at least in part, on *new MAXCF*. EX1003, ¶168.

Thus, it would be obvious for a POSITA to modify Lavender in view of Fletcher-Haynes to configure Lavender's controller to calculate a volume of anticoagulant to be collected within the plasma collection container based, at least in part, on a hematocrit of the subject; and to calculate a volume of pure plasma to collect based, at least in part, on the calculated volume of anticoagulant to collect. EX1003, ¶169.

C. Ground 3: Claims 6 and 18 are obvious over Lavender in view of Fletcher-Haynes and Min

- 1. Claim 6: A method according to claim 5, 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.**

A POSITA would have been motivated to combine the teachings of Lavender and Fletcher-Haynes with Min, and a POSITA would understand that there is a reasonable expectation of success in making this modification. EX1006, 11:52-55, 17:17-22; EX1003, ¶170.

A POSITA would have found it obvious and would have been motivated to combine the Lavender and Fletcher-Haynes disclosures with Min's teachings of

using weigh sensors 246 to track weight changes and derive fluid processing volumes, including the volume change of anticoagulant container 276. EX1006, 11:52-55, 17:17-22; EX1003, ¶171.

Additionally, a POSITA would have had a reasonable expectation of success in modifying the Lavender-Fletcher-Haynes system in view of Min because each relate to the same well-known technologies, both apply substantially similar techniques to achieve similar results, and Lavender's functionality would not change as Lavender and Min are used for the same purpose—monitoring the weight of an anticoagulant bag in an apheresis procedure to determine a change in volume within the anticoagulant container. EX1006, 11:52-55, 17:17-22. Min's weigh sensors 246 are utilized to track weight changes and derive fluid processing volumes, including the volume change of anticoagulant container 276 and plasma collection container 304. EX1006, 11:52-55, 17:17-22; EX1003, ¶172.

First, Lavender, Fletcher-Haynes, and Min all relate to the well-known technologies of separating blood components. Accordingly, a POSITA would have found it obvious to combine the teachings of Lavender and Fletcher-Haynes with Min because they are in the same field of endeavor with the same well-known technologies, e.g. technologies of separating blood components. That is, combining Lavender, Fletcher-Haynes, and Min entails the mere use of known solutions to improve similar systems and methods in the same way, i.e., to use Min's technique

of monitoring the weight of an anticoagulant bag to determine a volume of anticoagulant provided to whole blood prior to separation of blood components. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007). EX1003, ¶173.

Second, Lavender, Fletcher-Haynes, and Min apply substantially similar techniques to achieve similar results. As discussed above, Lavender discloses fractionating blood “to **collect blood substances, such as plasma.**” EX1004, 1:12-13. Similarly, Min discloses a system for “separating whole blood into plasma and red blood cells.” EX1006, 4:26-29. A POSITA would have been motivated to add Min’s system to monitor the weight (and volume) of an anticoagulant bag into Lavender’s blood fractioning system to provide an additional way to determine the estimated amount of anticoagulant in the plasma collection container, and Min’s disclosed systems for determining the amount of anticoagulant added to a system function substantially similar to Lavender’s technique of adding and monitoring the anticoagulant added to a blood separation system. Indeed, Min’s anticoagulant container and tube arrangement (*See* Fig. 10) is structurally similar to that of Lavender’s (*See* Fig. 20). EX1006, 3:26-29. Therefore, it would have been obvious, and a POSITA would have been motivated, to modify Lavender’s blood fractioning system to incorporate Min’s monitoring of the change in the weight of the anticoagulant container. *See Intel Corp. v. PACT XPP Schweiz AG*, 61 F.4th 1373, 1380-81 (Fed. Cir. 2023) (internal citations omitted). Additionally, it would have

been an obvious design choice to use Min's anticoagulant monitoring scale in Lavender's system to improve the accuracy of the anticoagulant volume added to the system for determining more accurate pure plasma volume based on the anticoagulant volume. EX1003, ¶174.

Finally, the intended functionality of Lavender's blood fractioning system would not change when used for monitoring the anticoagulant weight similarly to Min's apheresis system. That is, a POSITA would have expected Lavender's blood fractioning system to successfully determine the amount of anticoagulant added to the system from the anticoagulant container similarly to Min. *Eli Lilly & Co. v. Teva Pharm. Int'l GmbH*, 8 F.4th 1331, 1345 (Fed. Cir. 2021). Additionally, Lavender discloses converting a change in weight to a change in volume using a specific gravity. EX1003, ¶175. Accordingly, a POSITA would understand that there is a reasonable expectation of success when modifying the algorithms to determine the volume of anticoagulant in the collected plasma component in Lavender's system with the weight scale of Min for monitoring the change in the anticoagulant volume—each relate to the same well-known technologies and both apply substantially similar techniques to achieve similar results. *Par Pharmaceutical, Inc. v. TWI Pharmaceuticals, Inc.*, 773 F.3d 1186, 1198 (Fed. Cir. 2014). EX1003, ¶175.

The combined system of Lavender, Fletcher-Haynes, and Min discloses 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. Specifically, as acknowledged by the '873 patent, a POSITA would understand that substantially all of the anticoagulant added to a centrifuge-based blood fractionating system would end up in the plasma collection container. *See* §V.A.; EX1001 at 7:58-65. If Patent Owner argues that Lavender's fractionator 25, which comprises a series of membranes 75, is not as efficient at separating some blood components and that substantially all of the anticoagulant added to the blood fractionating system of Lavender would not end up in the plasma collection container, it would have been obvious for a POSITA to replace the membrane-based fractionator in Lavender with a centrifuge-based blood component collection device 18, like Fletcher-Haynes'. EX1004, 6:3-12; EX1005, 46:16-43. It was generally known in the art that a centrifuge-based blood separation device provided a comparable treatment quality in a shorter period of time. *See* EX1010, p. 135. A POSITA would have been motivated to combine Lavender's teachings with Fletcher-Haynes' centrifuge-based collection device to more efficiently separate plasma from a donor's blood, and reduce the overall procedure time. EX1003, ¶176.

A POSITA would have been motivated to combine Lavender's and Fletcher-Haynes' teachings, and would have had a reasonable expectation of success, because each relate to the same well-known technologies, both apply substantially similar

techniques to achieve similar results, and Lavender's functionality would not change in the combination as Fletcher-Haynes' centrifuge-based blood component collection device is used for the same purpose as Lavender's system—using donor parameters to determine the total amount of pure plasma to collect and separating a donor's blood to collect pure plasma. EX1003, ¶177.

Therefore, a POSITA would understand that substantially all of the anticoagulant added to the Lavender-Fletcher-Haynes blood fractionating system would end up in the plasma collection container. It would have been obvious to a POSITA to incorporate Min's technique of monitoring the change in volume of the anticoagulant container using a scale into the Lavender-Fletcher-Haynes system to calculate the volume of anticoagulant in the collected plasma component based, at least in part, on the change in volume within the anticoagulant container. By adding this additional technique to determine the volume of anticoagulant in the plasma collection container, the system may reduce potential errors in the determination of the volume of anticoagulant due to errors in the blood and anticoagulant pump rates (e.g., errors in pumps 306, 308 in Lavender). EX1004, Fig.20. IX.C.2; EX1003, ¶178.

2. **Claim 18: A system according to claim 17, further comprising: an anticoagulant source weight sensor configured to measure a weight of the anticoagulant source, the controller further configured to monitor a change in volume within the anticoagulant 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.**

See §IX.C.1, EX1003, ¶179.

D. Ground 4: Claims 9 and 18 are obvious over Lavender in view of Fletcher-Haynes, Headley, and Barrett

1. **Claim 9: A method according to claim 1, further comprising: monitoring a volume of red blood cells collected within the blood component separation device, the hematocrit of the donor being determined 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.**

Lavender teaches determining a volume of whole blood withdrawn from the donor in the Main Loop algorithm, which calculates the total blood flow (**TQB**) in ml while blood is being drawn from the donor. EX1004, 43:7-16. The pump rates for Lavender's blood pump and citrate pump are determined based on the donor's hematocrit. EX1004, 41:21-26; EX1003, ¶180.

Fletcher-Haynes teaches separating red blood cells from incoming whole blood during a blood separation procedure. EX1005, 7:33-35; 9:35-44. Headley relates to systems and methods for separating platelets and other blood components from blood. EX1009, Abstract. Headley teaches the use of an array 97 of optical

sensors within a blood separation system (e.g. a centrifuge), where the optical sensors are used to determine a volume of red blood cells within the blood separation system. EX1009, 1:10-24; 4:48-64. It would have been obvious for a POSITA to include Headley's optical sensor(s) in Lavender's blood separation device to determine the volume of red blood cells collected from the donor and allow the red blood cells to be immediately returned to the donor during the separation procedure. EX1003, ¶181.

Barrett teaches determining a donor's hematocrit by dividing the red blood cell volume of a blood sample over the total volume of the blood sample. EX1008, 2:45-49; EX1003, ¶182.

A POSITA would have been motivated to combine the teachings of Lavender, Fletcher-Haynes, and Headley with Barrett to determine a real-time hematocrit of a donor during a collection procedure. Each of Lavender, Fletcher-Haynes, Headley, and Barrett relate to the well-known technologies of separating blood components. Accordingly, a POSITA would have found it obvious to combine the teachings of Lavender, Fletcher-Haynes, Headley, and Barrett because they are in the same field of endeavor with the same well-known technologies. EX1003, ¶183.

Additionally, Lavender, Fletcher-Haynes, Headley, and Barrett apply substantially similar techniques to achieve similar results. As discussed above, Lavender discloses fractionating blood "to **collect blood substances, such as**

plasma.” EX1004, 1:12-13. Barrett also teaches patient blood data acquisition and management for hemodialysis patients in preparation for blood separation procedures. EX1008, 1:6-19; EX1003, ¶184.

In view of Barrett’s teaching of determining a donor’s hematocrit by dividing the total red blood cell volume of a blood sample over the total volume of a blood sample, a POSITA would want to incorporate this equation from Barrett into Lavender’s Main Loop algorithm to determine the donor’s hematocrit as blood is being drawn from the donor. A POSITA would recognize this would reduce error in the calculated values of Lavender and account for the change in the donor’s hematocrit as blood is being drawn. For example, Lavender’s pump rates, which are determined based on hematocrit of the donor, may be more accurately regulated if the hematocrit is updated in real time during a procedure. EX1004, 41:21-26; EX1003, ¶185.

Thus, a POSITA would use both (i) the monitored volume of red blood cells collected during a blood separation procedure from Headley, and (ii) the volume of whole blood withdrawn from the donor, or total blood flow (***TQB***) in Lavender, to determine a donor’s real-time hematocrit in Lavender’s Main Loop algorithm. This equation could simply be added into the Main Loop algorithm of Lavender and would increase the accuracy of Lavender’s calculated estimates. Also, to more effectively separate the red blood cells in Lavender’s system, a POSITA would be

motivated to replace the membrane-based blood fractionator in Lavender with the centrifuge-based blood component collection device 18 including a centrifuge. §IX.F.1; EX1004, 6:3-12; EX1005, 46:16-43; EX1003, ¶186.

It would have been an obvious design choice to use Barrett's equation in the Lavender-Fletcher-Haynes-Headley system to determine the real-time hematocrit of the donor during a separation procedure. The intended functionality of the Lavender-Fletcher-Haynes system would not change when including Headley's optical sensor(s) and Barrett's equation for hematocrit. That is, a POSITA would have expected the combined system to successfully determine the hematocrit of a donor using a red blood cell volume determined by Headley's optical sensor(s) and Barrett's hematocrit equation. *Eli Lilly & Co. v. Teva Pharm. Int'l GmbH*, 8 F.4th 1331, 1345 (Fed. Cir. 2021); EX1003, ¶187.

Accordingly, Lavender in view of Fletcher-Haynes, Headley, and Barrett teach monitoring a volume of red blood cells collected within the blood component separation device because Headley teaches monitoring the volume of collected red blood cells. EX1009, 1:10-24; 4:48-64; 17:19-24; EX1008, 2:45-49. 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 is taught by Barrett's equation that determines hematocrit by dividing the red blood cell volume of a blood sample (e.g. the volume

of red blood cells collected) by the total volume of the blood sample (e.g. total blood flow into the system, Lavender's **TQB**). EX1004, 41:8-44:32; EX1006, 12:22-25; 17:19-24; EX1009, 1:10-24; 2:45-49; 4:48-64; EX1003, ¶188.

2. **Claim 18: A system according to claim 11, 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 subject.**

See §IX.D.1. As discussed above, Headley teaches the use of an array 97 of optical sensors within a blood separation system (e.g. a centrifuge) to determine a volume of red blood cells within the blood separation system. EX1009, 1:10-24; 4:48-64. Thus, Headley discloses 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. See §IX.D.1.; EX1009, 1:10-24; 4:48-64; EX1003, ¶189.

Accordingly, Lavender in view of Fletcher-Haynes, Min, Headley, and Barrett teaches 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 using Headley's optical sensor. EX1009, 4:48-64. Using Lavender's Main Loop algorithm and Barrett's equation to determine

hematocrit, Lavender, modified in view of Fletcher-Haynes, Min, Barrett, and Headley teaches a 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 subject. *See* §IX.E.1; EX1003, ¶190; EX1004, 41:8-44:32; EX1006, 12:22-25; 17:19-24; EX1008, 2:45-49.

E. Ground 5: Claims 4 and 15 are obvious over Lavender in view of Fletcher-Haynes, Min, and Turgut

- 1. Claim 4: 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.**

A POSITA would have recognized that determining the total volume of anticoagulant in the collected plasma component based on the change in volume within the anticoagulant container would not account for any remaining anticoagulant within the blood separation device that has not yet flowed into the plasma collection container. *See* §IX.C.1; EX1003, ¶191. A POSITA would have recognized a need to account for the remaining anticoagulant within the blood separation device when determining the volume of anticoagulant in the collection container using the volume of anticoagulant supplied to the blood separation device. *See* EX1003, ¶191. By accounting for this remaining anticoagulant within the blood

separation device, the system would reduce errors and increase the accuracy of the determined anticoagulant volume in the plasma collection container. *See* EX1003, ¶191.

A POSITA would have found it obvious and would have been motivated to combine Lavender, Fletcher-Haynes, and Min with Turgut's teaching of a volume detector to determine a total volume of fluid within a blood separation system, such as a separation chamber of a centrifuge used to separate blood into components. EX1011, [0073]; EX1003, ¶192.

A POSITA would have found it obvious to combine the teachings of Lavender-Fletcher-Haynes-Min with Turgut because they are in the same field of endeavor with the same well-known technologies of separating blood components. *KSR Int'l Co.*, 550 U.S. at 417; EX1003, ¶193.

Turgut's separation system is structurally similar to that of Lavender's (*See* Fig. 20) and is used to separate blood into different components. EX1011, [0052]-[0068], Fig. 1A. Therefore, it would have been obvious, and a POSITA would have been motivated, to modify Lavender's blood fractioning system including Fletcher-Haynes' centrifugal separation device to incorporate Turgut's monitoring of the volume of fluid within the blood separation device. *See Intel Corp. v. PACT XPP Schweiz AG*, 61 F.4th 1373, 1380-81 (Fed. Cir. 2023). Additionally, it would have been an obvious design choice to use Turgut's volume detector in Lavender's system

to improve the accuracy of the calculated volume of anticoagulant within the plasma collection container. EX1003, ¶194.

A POSITA would understand that the volume of plasma plus anticoagulant remaining within the separation device could be determined using Turgut's volume detector to ascertain the total volume remaining in the separation device and subtracting the volume of red blood cells within the separation device, the volume of red blood cells being equal to the total volume of whole blood introduced to the separation device multiplied by the hematocrit (**HCTD**). A POSITA would then determine the volume of anticoagulant remaining within the separation device by multiplying the volume of plasma plus anticoagulant by the conversion factor (*i.e.*, $PDF * CF$). A POSITA would recognize that the determined volume of anticoagulant remaining within the blood component separation device should be subtracted from the amount of anticoagulant supplied to the blood component separation device to more accurately estimate the total amount of anticoagulant within the plasma collection container. EX1003, ¶195.

The combined system discloses 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. EX1003, ¶196.

2. **Claim 15: A system according to claim 11, 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.**

See §IX.F.1. A POSITA would recognize that the volume detector of Turgut may be an optical sensor, like the optical sensor Headley uses to determine a volume of red blood cells within the blood separation system. EX1009, 1:10-24; 4:48-64. It was generally known by a POSITA at the time of the effective filing date of the '873 patent that a volume detector may be an optical sensor. EX1003, ¶197.

F. Ground V: All Claims of the '873 Patent Are Ineligible Under Section 101

Determining whether a patent claim is impermissibly directed to patent ineligible subject matter involves two steps. *Alice Corp. Pty. v. CLS Bank Intern.*, 573 U.S. 208, 217 (2014) (citing *Mayo Collaborative Servs. v. Prometheus Lab'ys, Inc.*, 566 U.S. 66, 75-77 (2012)).

The first step (“*Alice* Step One”) determines whether the claims are directed to an abstract idea or other patent ineligible concept. *Alice*, 573 U.S. at 217. In applying *Alice* Step One, courts recognize that it is useful to “compare claims at issue to those claims already found to be directed to an abstract idea in previous cases.” *Enfish, LLC v. Microsoft Corp.*, 822 F.3d 1327, 1334 (Fed. Cir. 2016).

The second step (“*Alice* Step Two”) requires a search for an inventive concept, such as determining whether there are “additional elements [that] ‘transform the nature of the claim’ into a patent-eligible application.” *Alice*, 573 U.S. at 217. Transformation into a patent-eligible application requires “more than simply stating the abstract idea while adding the words ‘apply it.’” *Id.* at 221 (internal citation omitted). Implementing an abstract idea in a “particular technological environment” and using conventional technology does not make an abstract idea patent eligible. *Atos, LLC v. Allstate Ins. Co.*, No. 20-CV-06224, 2021 WL 6063963, at *5-13 (N.D. Ill. Dec. 22, 2021) (citing *Intell. Ventures I LLC v. Symantec Corp.*, 838 F.3d 1307, 1314, 1319 (Fed. Cir. 2016)); accord *Bilski v. Kappos*, 561 U.S. 593, 610-11 (2010).

1. The Board Should Consider Representative Claim 13 to Assess the Patent Eligibility of the ’873 Patent

Claims can be treated as representative where the other claims do not “differ in any manner that is material to the patent-eligibility inquiry.” *Mortg. Grader, Inc. v. First Choice Loan Servs. Inc.*, 811 F.3d 1314, 1324 n.6 (Fed. Cir. 2016); *Content Extraction & Transmission LLC v. Wells Fargo Bank, Nat. Ass’n*, 776 F.3d 1343, 1348-49 (Fed. Cir. 2014).

Here, claim 13 is representative of all claims, as the claims recite generic computer processors that perform basic plasma collection procedures and automated volume calculations that can be done by a technician using generic computer components. Claim 13 is also representative because it also recites results-oriented

calculations of pure plasma volume that can be performed on a controller as is found in the other challenged claims. Further, claim 13 recites fundamental plasma collection system components found in the challenged claims—a venous-access device, a blood component separation device, a blood draw line, an anticoagulant line, and a controller. These components recited in claim 13 are the basic plasma collection equipment used to perform the fundamental apheresis steps.

Claim 13's limitations, with basic apheresis procedures in green and the abstract idea of automated calculations on a processor in purple, are reproduced below.

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 withdrawn blood into a plasma component and a second blood component, the blood component separation device having an outlet and being configured to convey the plasma component to a plasma collection container;

a blood draw line fluidly coupled to the venous-access device and configured to transport withdrawn 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 fluidly coupled to an anticoagulant source, the anticoagulant line configured to introduce anticoagulant into the withdrawn 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 a volume of pure plasma collected within the plasma collection

container based, at least in part, on a volume of plasma component collected within the plasma collection container, a ratio of anticoagulant added to the withdrawn whole blood, and a hematocrit of the subject.

Claim 13 is representative because it is substantially similar and linked to the same abstract idea as the other claims of the '873 patent. For example, independent claim 1 calculates a volume of pure plasma collected within the plasma collection container based, at least in part, on a volume of plasma component collected within the plasma collection container, a ratio of anticoagulant added to the withdrawn whole blood, and a hematocrit of the subject, the same calculation done by the controller in claim 13. Claims 1 and 24 also contain generic apheresis equipment or processes, such as inserting a venous-access device into a donor and a blood draw line fluidly coupled to the venous-access device, and both calculate a volume of pure plasma based, at least in part, on a volume of plasma component. Therefore, it is unnecessary for the Board to assess the patent eligibility of each claim, and instead, the Board can assess the patent eligibility of just claim 13 when rendering its determination. *See Content Extraction & Transmission*, 776 F.3d at 1348.

2. Alice Step One: The Challenged Patents Are Directed To Abstract Ideas

It is well-established that “methods which can be performed mentally, or which are the equivalent of human mental work,” “are unpatentable abstract ideas.” *See CyberSource Corp. v. Retail Decisions, Inc.*, 654 F.3d 1366, 1371 (Fed. Cir. 2011). That is because “[a] telltale sign of abstraction is when the claimed functions

are mental processes that can be performed in the human mind or using a pencil and paper.” *Trinity Info Media, LLC v. Covalent, Inc.*, 72 F.4th 1355, 1361–62 (Fed. Cir. 2023) (quotation omitted).

Yet, such pen and paper calculations are at the heart of representative claim 13. Specifically, the '873 patent performs a sequence of abstract calculations involving donor and system parameters. For example, claim 13 claims “the controller configured to calculate a volume of pure plasma collected within the plasma collection container based, at least in part, on a volume of plasma component collected within the plasma collection container, a ratio of anticoagulant added to the withdrawn whole blood, and a hematocrit of the subject.”

The '873 patent's specification further supports that the claims are “directed to” these mathematical calculations. For example, the specification explains that the goal of the invention is to determine the total collected volume of plasma. EX1001, 2:5-16. But equipment and steps common to all plasma apheresis procedures are used to gather the information needed to perform this calculation. EX1001, 1:31-48. The system uses well-known equipment to draw blood from the donor, introduce anticoagulant to prevent the drawn blood from clotting, separate the blood into plasma, and collect the anticoagulated plasma in a plasma collection container. EX1001 at Fig. 3.

The '873 patent also explains that a technician can perform these calculations.

Specifically, the '873 patent explains that “the technician . . . may calculate the percentage of anticoagulant within the collected plasma (step 455) (e.g., the plasma product contained within the plasma collection container 216) based on the amount of anticoagulant added/metered into the whole blood and the hematocrit of the donor.” EX1001, 8:24-30. Similarly, the '873 Patent explains that the technician can determine the donor’s weight and use this weight to determine “the volumes of blood components that may be withdrawn/collected (e.g., per the FDA guidelines),” *i.e.*, the target volume of pure plasma to collect. EX1001, 9:2-7. Further, the '873 patent explains that “[o]nce the technician/system 100 has calculated the percentage of anticoagulant within the plasma collection container 216 [based on the donor’s hematocrit and a predetermined ratio of anticoagulant to whole blood], the technician/system 100 may then use this information to calculate the volume of pure plasma within the plasma collection container 216 (Step 465).” EX1001, 8:63-66. The technician can calculate this by subtracting the volume of anticoagulant from “the total volume of fluid within the container 216” and that collection continues until “a target volume of pure plasma is collected within the plasma collection container.” EX1001, 11:66-12:12. In other words, the '873 patent explains how a technician can gather basic donor and system parameters, which are known, to calculate the claimed volumes recited in the '873 patent. *See Trinity Info Media*, 72 F.4th at 1361–62. And while the '873 patent may require the technician to gather

donor and system information used for the calculations, it does not change the fact that representative claim 13 is directed to mathematical calculations, not any improved system, and thus these elements do not make the claim patent eligible.

Additionally, while representative claim 13 recites that a “controller” and not a technician performs these calculations, this does not establish that the claims are not directed to an abstract idea. Simply put, “a claim does not satisfy Section 101’s eligible subject matter requirement by reciting generic computer implementation to ‘optimize’ an already-understood process.” *See, e.g., Concaten*, 131 F. Supp. 3d at 1174; *accord Four Winds Interactive LLC v. 22 Miles, Inc.*, No. 16-cv-00704, 2017 WL 4334074, *6-8 (D. Colo. Mar. 28, 2017). Thus, the ’873 patent cannot be accorded patentability by calculating the recited volumes using a generic computer processor instead of a technician/user. “[Q]uintessential do it on a computer” claims are not patent eligible under *Alice* Step One. *Univ. of Fla. Rsch. Found., Inc. v. Gen. Elec. Co.*, 916 F.3d 1363, 1367 (Fed. Cir. 2019).

While sometimes using a computer to implement traditional pen and paper claims has been found to be patent eligible, those instances are inapposite to this case. Claims previously performed by pen and paper were found to be patent eligible when they encompassed specific sequences of rules that were used and applied to create desired results. *See, e.g., McRO, Inc. v. Bandai Namco Games Am. Inc.*, 837 F.3d 1299, 1315 (Fed. Cir. 2016). In *McRO*, the Federal Circuit concluded that

McRO's claims were directed to creating "a sequence of synchronized, animated characters" by utilizing an objective set of rules that had to be rendered in a specific way, with specific relationships between elements, which prevented broad preemption of all rules-based means of automating lip synchronization. *Id.* at 1304, 1315. In contrast, the '873 patent tries to encompass all known donor variables, as outlined in the FDA's 1992 guidance, that may be considered when collecting any blood product and then claim using a general-purpose processor to perform calculations a technician can do "based on" those variables.

Similarly, while in some situations *Alice* Step One can be satisfied if the claims are directed to improving procedures, that is not the case here. *See CardioNet, LLC v. InfoBionic, Inc.*, 955 F.3d 1358, 1368–69 (Fed. Cir. 2020). In *CardioNet*, the patented method was found to be patent eligible because it improved previous systems for detecting atrial fibrillation. *Id.* at 1366. Here, however, "the claims merely computerize pre-existing techniques" in apheresis, for example, by claiming a blood separator with a generic controller. *Id.* at 1370. Patent Owner may rely upon a single quote in its specification to allege that its patented system is "directed to" technical improvements in plasma collection. *See* EX1001, 1:66-2:24. But nowhere in the '873 patent's specification does Patent Owner "explain[] how [the] particular arrangement of elements" such as its claimed processor, pump, and weight scale are "a technical improvement over prior art." *Amdocs (Israel) Ltd. v. Openet Telecom,*

Inc., 841 F.3d 1288, 1299 (Fed. Cir. 2016). Rather, the generic processor calculating a pure plasma volume supplies the alleged inventive aspect. Thus, the claims at issue here are different than the claims at issue in *CardioNet* because here “the claims merely computerize pre-existing techniques” in apheresis, for example, by claiming a blood separator with a generic controller. *CardioNet*, at 1370.

The generic apheresis equipment in representative claim 13 does not make the claim “directed to” plasma apheresis, either, as generic equipment does not change the abstract nature of claims. For example, Content Extraction unsuccessfully argued that its claims were not “directed to” an abstract idea because they required a scanner in addition to the computer. *Content Extraction*, 776 F.3d at 1347. The Federal Circuit was not convinced because Content Extraction’s claims were directed to basic data recognition and storage. *Id.* The generic claimed scanner was a mere tool to carry out that abstract idea. *See id.* Haemonetics’ claims suffer from the same problem: Haemonetics claims math and any hardware merely supplies information to perform the math.

iLife is similarly instructive. *iLife Techs., Inc. v. Nintendo of Am., Inc.*, No. 3:13-cv-4987, 2020 WL 13281800 (N.D. Tex. Jan. 17, 2020). In *iLife*, the representative claim at issue involved “a system . . . capable of evaluating movement of a body relative to an environment” that included a “sensor . . . that senses dynamic and static accelerative phenomena.” *Id.* at *1. There, the Court found that the claim

was directed to the abstract idea of “collecting, analyzing, and transmitting” information because “the claim does not disclose any improvement in the sensor’s ability to collect information, such as collecting previously unknown information or collecting information more accurately.” *Id.* at *3-4.

Because the ’873 patent is not directed to a novel system of components (see *EcoServices LLC v. Certified Aviation Servs. LLC*, 830 Fed. App’x 634, 643 (Fed. Cir. 2020)), a novel arrangement of known components (see *XY, LLC, v. Trans Ova Generics, LC*, 968 F.3d 1323, 1332 (Fed. Cir. 2020)) and *Thales Visionix, Inc. v. United States*, 850 F.3d 1343, 1349 (Fed. Cir. 2017)), or an unknown plasma collection method (see *CardioNet, LLC v. InfoBionic, Inc.*, 955 F.3d 1358, 1370-71 (Fed. Cir. 2020)), it does not recite patentable subject matter.

3. Alice Step Two: The Challenged Claims Do Not Contain An Inventive Concept

A concept may be patent-eligible despite being directed to an abstract idea only if it recites “an inventive concept sufficient to transform the claimed abstract idea into a patent-eligible application.” *Alice*, 573 U.S. at 221 (quotations and citation omitted). If it does not, it is patent ineligible. Similarly, if the computer functions claimed, individually and in combination, are “well-understood, routine, [and] conventional activities previously known to the industry,” it is ineligible for patenting. See *Coop. Ent., Inc. v. Kollektive Tech., Inc.*, 50 F.4th 127, 130 (Fed. Cir. 2022).

Here, nothing in the claims of the '873 patent transforms the claimed abstract plasma collection calculations into patent eligible claims. The claims do not use known equations in an unconventional way (see *Diamond v. Deihl*, 450 U.S. 175, 188-89 (1981)) or recite an unconventional arrangement of plasma apheresis equipment (see *BASCOM Global Internet Servs., Inc. v. AT&T Mobility LLC*, 827 F.3d 1341, 1350 (Fed. Cir. 2016)).

First, there is no inventive concept because the '873 patent's claims automate calculations previously performed by a technician using a general-purpose processor. The '873 patent's claimed controller does not provide "specific structural or inventive improvements in computer functionality related to this claimed system." *Customedia Techs., LLC v. Dish Network Corp.*, 951 F.3d 1359, 1366 (Fed. Cir. 2020). Instead, the controller is used to automate mathematical calculations that can be performed by a human using computers in the way that computers were meant to be used. See, e.g., *Affinity Labs of Tex., LLC v. DIRECTV, LLC*, 838 F.3d 1253, 1264 (Fed. Cir. 2016). This does not establish an inventive concept.

Performing math on a generic controller also does not provide an inventive concept because "simply implementing a mathematical principle on a physical machine, namely a computer, [is] not a patentable application of that principle." *Mayo*, 566 U.S. at 84 (citing *Gottschalk v. Benson*, 409 U.S. 63, 71(1972)). "Given the ubiquity of computers, wholly generic computer implementation" of performing

mathematics on a computer “is not generally the sort of additional feature” that makes an abstract idea patentable. *Alice*, 573 U.S. at 223-24.

Moreover, the ’873 patent’s specification, which must be looked at to assess whether an inventive concept exists in the claimed mathematical equations, establishes that there is no inventive concept. See *Arrhythmia Rsch. Tech., Inc. v. Corazonix Corp.*, 958 F.2d 1053, 1058–59 (Fed. Cir. 1992); see also *TecSec, Inc. v. Adobe Inc.*, 978 F.3d 1278, 1292 (Fed. Cir. 2020). The specification reveals that **all** calculations may be performed by a technician. EX1001, at 11:45-12:38. Replacing a technician with a computer does not supply an inventive concept under *Alice* Step Two. See *Trinity Info Media*, 72 F.4th at 1366-67.

Further, even if Patent Owner alleges it invented a new way to calculate a plasma product or anticoagulant volume, which it did not, “the novelty of the mathematical algorithm is not a determining factor” and “is treated as though it were a familiar part of the prior art.” See *Parker v. Flook*, 437 U.S. 584 at 591–92 (1978). That is because “[t]he abstract idea itself,” the mathematical principles behind calculating volumes, “cannot supply [an] inventive concept” no matter how groundbreaking the advance. *ChargePoint*, 920 F.3d at 775.

Patent Owner may allege that the claims supply an inventive concept because of the presence of mechanical components, *i.e.*, a weight sensor. But these are not specialized mechanical components, they are generic sensors. Moreover, their

purpose is merely to provide information for the technician to perform abstract calculations. Use of generic equipment to improve the speed, accuracy, or efficiency of a known process does not provide a patent eligible improvement. *Recentive Analytics, Inc. v. Fox Corp.*, 134 F.4th 1205, 1214 (Fed. Cir. 2025); *OIP Technologies, Inc. v. Amazon.com, Inc.*, 788 F.3d 1359, 1363 (Fed. Cir. 2015). This is true even when “equipment can be ‘vital’ to an advance.” *Yu v. Apple Inc.*, 1 F.4th 1040, 1045 (Fed. Cir. 2021).

Patent Owner may also claim that these tools allow for an increased plasma yield, but Patent Owner would be wrong. The '873 patent's claims merely calculate and collect a target volume of plasma using standard apheresis equipment or track a pure plasma collection volume using generic equipment and stopping at the proscribed target. Thus, any purported increase in plasma yield for certain donors is, at most, a result of math limited by FDA donation limits. EX1001, 11:58-12:8. Such an improvement, regardless of how “[g]roundbreaking, innovative, or even brilliant,” is not enough for patent eligibility. *SAP Am. Inc. v. InvestPic*, 898 F.3d 1161, 1163 (Fed. Cir. 2018). Alternatively, any increase in plasma yield may also be inherent with the use of a computer, which cannot supply an inventive concept. For example, in *Trinity Info Media*, the Court found that the ability to perform faster calculations “merely reflect[ed] the improved speed inherent with applying the abstract idea using a computer” and did not render the claims patentable. *See Trinity*

Info Media, 72 F.4th at 1363-64, 1366. The same applies here. Any alleged improvements are inherent to using standardized equipment with a general processor. If Patent Owner asserts that it has a product that practices these claims, such an argument should be given no weight. A patent owner's product cannot demonstrate an inventive concept because "the § 101 inquiry must focus on the language of the Asserted Claims themselves," not the allegedly patent-practicing product. *ChargePoint*, 920 F.3d at 767.

Simply put, reading the claims as a whole shows that they incorporate well-known plasma collection calculations that incorporate decades-old FDA guidance in an automated plasma collection system using basic plasma collection procedures (drawing, separating, collecting, and returning blood) and equipment (needles, tubing, separation devices, pumps, weight sensors, and collection containers). Such purely "conventional or obvious" plasma collection equipment and/or steps are "not sufficient to transform an unpatentable" idea, like the claimed mathematical calculations, "into a patent-eligible application," especially here where "anyone who wants to make use" of a plasma collection system must perform these claimed on the claimed equipment. *Mayo*, 566 U.S. at 79.

Therefore, taken individually, as a whole, or as an ordered combination, the '873 patent's claims automate known apheresis procedures using well-known plasma collection equipment, and "neither improve the functions of the computer

itself, nor provide specific programming, tailored software, or meaningful guidance for implementing the abstract concept.” *Intell. Ventures I LLC v. Cap. One Fin. Corp.*, 850 F.3d 1332, 1342 (Fed. Cir. 2017). Accordingly, *Alice* Step Two is not satisfied.

G. Ground VI: Claims 10, 11, 12, 22, 23, and 25 Lack an Adequate Written Description Under Section 112⁷

Haemonetics overreached when filing its continuation applications. and the ’873 patent’s claims do not “find support in the original specification.” *TurboCare Div. of Demag Delaval Turbomachinery Corp. v. GE*, 264 F.3d 1111, 1118 (Fed. Cir. 2001).

The ’873 patent is a continuation of the ’652, ’926 patent, and ’916 patents. But many of the ’873 patent’s claims barely resemble the specification it shares with these patents. Thus, Haemonetics’ claims fail to meet the written description requirement of Section 112(a).

⁷ The Examiner never addressed the lack of written description or the support for the new matter. *See* §V.C. The Prosecution History contained only a double patenting rejection, so the Board will address the lack of written description for the first time.

1. Disclosure of the Purported Invention

As discussed above, Haemonetics' purported invention is a blood processing system that continues collecting plasma until reaching a target volume of pure plasma. EX1001, 7:33-36. To do that, Haemonetics purportedly tracks the amount of pure plasma in the container while blood is being drawn and checks whether the amount of pure plasma equals a target volume of pure plasma. See EX1001, Fig. 4. Figure 4 of the '873 patent illustrates the steps allegedly performed by Haemonetics' patented system. EX1003, ¶200.

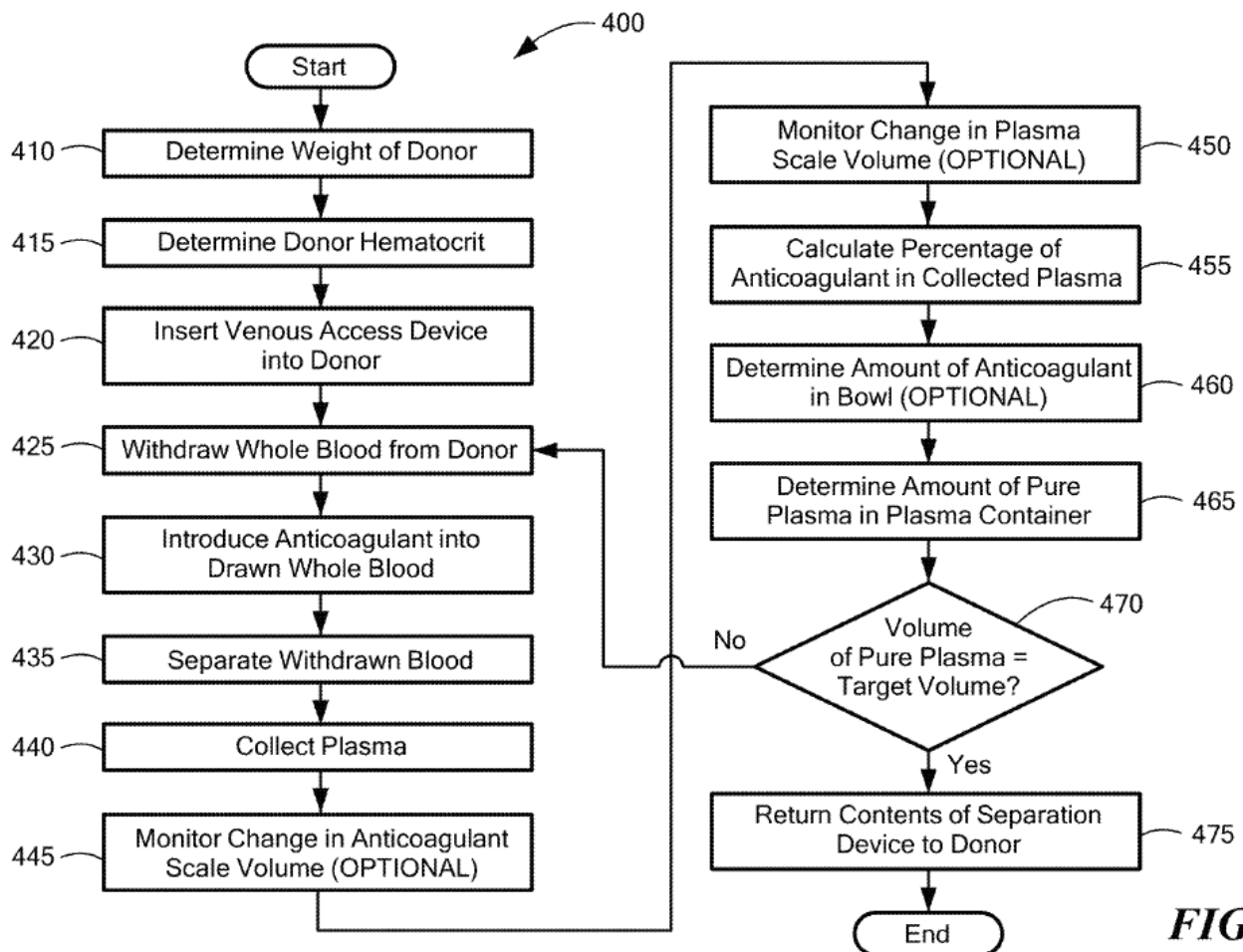


FIG. 4

As shown in Figure 4, the technician or system determines a donor's weight and hematocrit, inserts a venous access device into the donor, and then the method enters a loop (steps 425-470) that continues until "volume of pure plasma = target volume." EX1001, Fig. 4. The technician or the system withdraws whole blood, introduces anticoagulant into withdrawn blood, collects plasma, calculates the percentage of anticoagulant in collected plasma, and determines the amount of pure plasma in the plasma container. EX1001, 6:23-7:39. Once plasma collection is complete, saline is returned to the donor to compensate for lost plasma. EX1001, 9:26-36; EX1003, ¶201.

2. Argument

Claims 10, 11, 12, 22, 23, and 25 recite limitations that lack written description support. For example, these claims, as discussed further below, include claim limitations that recite basic apheresis equipment that allegedly measures/calculates target volumes of **anticoagulated plasma**. This concept lacks sufficient written description support in the '873 patent's specification. EX1003, ¶¶202, 204.

Haemonetics uses the term "plasma component" sparsely in its specification but does not refer to a target volume of plasma component anywhere in the specification except the claims. EX1001, 1:39-41, 17:4-8, 17:34-39. Figure 4, which

shows the purported invention, does not reference plasma component. EX1003, ¶203.

First, Haemonetics' disclosure that the field of the invention is collecting "a plasma product" does not support claim limitations reciting measuring/calculating target or current plasma component volumes. *See Biogen Int'l GMBH v. Mylan Pharms. Inc.*, 18 F.4th 1333, 1342-45 (Fed. Cir. 2021). EX1003, ¶204.

Further, the '873 patent teaches away from collecting a "plasma component" that is not "pure plasma." "[I]llustrative embodiments of" Haemonetics' purported invention include only a system for "collecting a target volume of pure plasma." EX1001, 4:23-25. Haemonetics' claimed system collects plasma until a collected volume reaches a target volume of pure plasma because doing so offers the purported improvement of "collect[ing] a greater volume of plasma as compared to prior art systems that stop based on a plasma/anticoagulant mixture." EX1001, 10:23-26. Thus, the focus of the patent is ***pure plasma*** collection, not plasma component collection. EX1003, ¶205.

Additionally, Haemonetics' claims 11, 23, and 26 broaden the scope of its claims to include calculating a "plasma component" target volume using "and/or" language. EX1001, claim 1. Specifically, each of claims 11, 23, and 26 recite "wherein the target volume of pure plasma and/or target volume of plasma component is based, at least in part, on a weight of the subject." In doing so,

Haemonetics claims what the '873 patent identifies as prior art (calculating a volume of plasma product) in addition to its purported invention (calculating a volume of pure plasma). EX1001, 10:1-6. Haemonetics' disclosure of the prior art calculating a volume of plasma product is insufficient to provide written description support for its claimed invention, which is focused on both calculating pure plasma volumes and calculating plasma component volumes. EX1003, ¶206.

Simply put, Haemonetics' claimed system does not calculate a target volume for plasma component, rendering any claims that calculate a target volume of anticoagulated plasma invalid for a lack of written description. EX1003, ¶207.

Dated: November 3, 2025

Respectfully submitted,
/ John M. Caracappa, Reg. No. 43,532/
John M. Caracappa, Reg. No. 43,532
Katherine D. Cappaert, Reg. No. 71,639
Matthew Y. Sim, Reg. No. 77,422
Scott Chappell, Reg. No. 76,333
Steptoe LLP
1330 Connecticut Ave NW
Washington, DC 20036
Tel: (202) 429-3000
Fax: (202) 429-3902
Email: jcaracappa@steptoe.com
Email: kcappaert@steptoe.com
Email: msim@steptoe.com
Email: schappell@steptoe.com

Counsel for Terumo BCT, Inc

CERTIFICATE OF WORD COUNT UNDER 37 CFR §42.24(d)

Pursuant to 37 C.F.R. §42.24(a), Petitioner hereby certifies that portions of the above-captioned Petition for Post Grant Review of U.S. Patent 12,324,873, in accordance with and reliance on the word count provided by the word-processing system used to prepare this Petition, that the number of words in this paper is 18,675. Pursuant to 37 C.F.R. §42.24(a), this word count is in compliance and excludes the table of contents, table of authorities, mandatory notices under §42.8, certificate of service, certificate of word count, appendix of exhibits, and any claim listing. This word count was prepared using Microsoft Word.

Dated: November 3, 2025

Respectfully submitted,
/ John M. Caracappa, Reg. No. 43,532/
John M. Caracappa, Reg. No. 43,532
Steptoe LLP
1330 Connecticut Ave NW
Washington, DC 20036
Telephone: (202) 429-3000
Fax: (202) 429-3902
Email: jcaracappa@steptoe.com

Counsel for Terumo BCT, Inc

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§ 42.6(e), The undersigned certifies service pursuant to 37 C.F.R. §§ 42.6(e) and 42.105(b) on the Patent Owner on November 3, 2025 by filing a copy of this Petition for IPR of U.S. Patent No. 12,324,873 and supporting materials through the Patent Trial and Appeal Case Tracking System and sending a copy of the same via pre-paid, overnight Federal Express at the correspondence address of record for U.S. Patent No. 12,324,873:

McCarter & English, LLP
c/o Jonathan C. Lovely
265 Franklin Street
Boston, MA 02110

With a courtesy copy to Patent Owner at the purported address according to the assignment records of the United States Patent and Trademark Office and according to Patent Owner's website, <https://www.haemonetics.com/contact-support>:

Haemonetics Corporation
125 Summer Street
Boston, MA 02110

With a courtesy copy to Patent Owner's counsel of record in Haemonetics Corporation v. Terumo BCT, Inc., Case No. 25-cv-1409-RMR-SBP (D. Colo.) by electronic mail:

Carolyn Juarez
NOD Law PC
726 Front St. Suite 220
Louisville, CO 80027-1881
(720) 536-4904
carolyn@nod-law.com

Erik B. Milch
Elizabeth Shrieves
Proskauer Rose LLP
1001 Pennsylvania Ave., NW
Suite 600 South
Washington, DC 20004-2533
(202) 416-6899
emilch@proskauer.com
eshrieves@proskauer.com

Joseph M. Drayton
Connor J. Villar
Proskauer Rose LLP
Eleven Times Square
New York, NY 10036-8299
(212) 969-2900
cvillar@proskauer.com

Alan S. Teran
Proskauer Rose LLP
2255 Glades Road
Suite 421 Atrium
Boca Raton, FL 33431-7360
(561) 995-4723
ateran@proskauer.com

Petition for Post Grant Review of U.S. Patent No. 12,324,873
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Date: November 3, 2025

By: / John M. Caracappa, Reg. No. 43,532/

John M. Caracappa, Reg. No. 43,532

STEPTOE LLP

1330 Connecticut Ave NW

Washington, DC 20036

Telephone: (202) 429-3000

Fax: (202) 429-3902

Email: jcaracappa@steptoe.com

Counsel for Terumo BCT, Inc.