

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

TERUMO BCT INC.,

Petitioner

v.

HAEMONETICS CORP.,

Patent Owner

PGR2026-00006

U.S. Patent No. 12,377,204

**PETITION FOR POST-GRANT REVIEW
OF U.S. PATENT NO. 12,377,204**

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EXHIBIT LIST

Exhibit	Reference
1001	U.S. Patent No. 12,377,204 (“’204 Patent”)
1002	File History of the ’204 Patent
1003	Declaration of Dr. Gary D. Fletcher in Support of Petition
1004	U.S. Patent No. 4,898,675 (“Lavender”)
1005	U.S. Patent No. 7,072,769 (“Fletcher-Haynes”)
1006	“Calculations in Apheresis” (“Neyrinck”)
1007	“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.
1008	Curriculum Vitae (“CV”) of Dr. Gary D. Fletcher
1009	Bruce C. McLeod, MD, et al., “Apheresis: Principles and Practice,” 3rd Edition, AABB Press 2010.
1010	Japanese Patent Publication No. JP 2002-282352 A and certified Japanese to English translation (“Takagi”)
1011	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

Terumo BCT, the “Petitioner,” requests post grant review of claims 1-30 of U.S. Patent No. 12,377,204 (the “’204 Patent”) (EX1001).

I. Mandatory Notices

A. Real Parties-In-Interest

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

B. Related Matters

The ’204 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). Petitioner filed petitions requesting *inter partes* review of U.S. Patent Nos. 11,738,124 (IPR2025-01374), 10,980,926 (IPR2026-00046), 10,792,416 (IPR2025-01246), and 10,758,652 (IPR2025-01391) and post grant review of U.S. Patent Nos. 12,186,474 (PGR2025-00077) and 12,171,916 (PGR2025-00078), which are in the same patent family as the ’204 patent. Petitioner intends to file several other petitions for *inter partes* review and post grant review of patents in the same family as the ’204 patent.

C. Counsel

Petitioner is filing a Power of Attorney appointing the practitioners associated with Customer Number 53065. Petitioner designates the following lead and back-up counsel:

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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. 50-53065, for any fee deficiency.

III. Certification of Grounds of Good Standing

Petitioner certifies that the '204 Patent is available for post grant review ("PGR") and that Petitioner is not estopped or barred from requesting this PGR.

IV. Timing

The '204 patent issued August 5, 2025. Pursuant to 37 C.F.R. §§ 42.201-202, this Petition is being filed within nine months of the issue date of the '204 patent. The earliest possible priority date is May 30, 2017.¹ EX1001, Page 2.

V. Identification Of Challenge And Relief Requested

Petitioner requests post grant review and cancellation of claims 1-30 of the '204 Patent.

A. Identification Of Prior Art

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

¹ The May 30, 2017 earliest possible priority is for matter that was first disclosed in the application that led to U.S. Pat. No. 10,758,652, from which the '204 patent is a continuation-in-part. However, several claims in the '204 patent reference new matter first included in an application, filed Oct. 25, 2017, that later became U.S. Pat. No. 10,792,416. While Petitioner asserts that the '204 patent's claims are not entitled to either priority date because they lack written description support, Petitioner applied the May 30, 2017 priority date in this Petition.

- 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
- 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).
- “Calculations in Apheresis,” published July 17, 2014 (“Neyrinck”), 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 ’204 Patent under 35 U.S.C. §§ 101-103, 112 based on the following Grounds.

Ground	35 U.S.C.	Claims	References
I	§102	8, 11-15, 17-20, 23-24, 27-29	Fletcher-Haynes
II	§103	1, 3-7, 9, 21-22, 25, 30	Fletcher-Haynes in view of Lavender
III	§103	10, 16, 26	Fletcher-Haynes in view of Neyrinck
IV	§103	2	Fletcher-Haynes in view of Lavender and Neyrinck
V	§101	1-30	Patent Ineligible Subject Matter
VI	§112	3, 6, 12, 14, 19-20, 28-29	Lack of Written Description
VII	§112	3, 8, 12, 20, 23, 29	Indefinite
VIII	§112	3, 12, 20, 29	Enablement

² All references to 35 U.S.C. §§102, 103 are to the post-AIA statutory framework.

EX1001, Fig. 3 (annotated); EX1003, ¶45.

Plasma apheresis involves withdrawing whole blood from a donor's arm using venous access device 206. EX1001, 7:60-63. 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) connected "to the inlet line." EX1001, 8:36-37, 9:24-29. Anticoagulant is introduced in fixed proportions to the whole blood drawn from the donor to prevent blood clotting in the draw line. *See* EX1007. "[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, 10:54-58; EX1003, ¶46.

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, 7:63-65, 8:3-6, 9:54-56. The donor's plasma, *i.e.*, pure plasma, along with anticoagulant introduced during collection, exits the separation device and is collected and stored in a collection container (*e.g.*, a bag, shown in blue above). EX1001, 8:31-35. The anticoagulant and pure plasma combination is called anticoagulated plasma or plasma product. EX1001, 17:4-8, 17:34-36; EX1003, ¶47.

The FDA established plasma donation guidelines for individual donors. *See* EX1007. These guidelines consider donor parameters, like weight, hematocrit, and sex. *See* EX1007; EX1003, ¶48.

B. Purported Invention of the '204 Patent

The '204 patent purports to solve problems associated with “determin[ing] the total volume of plasma that has been collected” after a donor’s withdrawn whole blood is mixed with anticoagulant by considering a donor’s hematocrit level and the amount of anticoagulant added into the system. EX1001, 2:4-10, 2:20-23, 7:19-24; EX1003, ¶49. The '204 patent discusses three main volumes—target plasma collection volume, anticoagulant volume, and the total collected plasma volume.

For target plasma collection volume, the technician can calculate the target plasma collection volume “based, at least in part on the weight of the donor.” EX1001, 3:9-10; EX1011; EX1003, ¶50.

Additionally, or alternatively, the technician or system may calculate a donor-specific target pure plasma volume using the donor’s total blood volume. EX1001, 13:41-44. Lemmens’ formula is used to estimate a donor’s total blood volume (TBV) based on their body mass index (BMI). Lemmens’ indexed blood volume (InBV) calculates mL of blood per kilogram using the equation:

$$InBV = \frac{70}{\sqrt{\frac{BMI}{22}}}$$

where 70 (mL/kg) is the assumed blood volume for an individual at ideal body weight (BMI = 22 kg/m²). EX1001, 13:60-65. InBV is multiplied by the donor's body weight in kg to calculate TBV in mL. The donor's plasma volume is then determined from the TBV and the donor's hematocrit. EX1001, 13:65-14:2. The system or technician multiplies this plasma volume by a target percentage—typically between 26.5% and 29.5%—to calculate the target pure plasma collection volume. EX1001, 14:3-20. However, the '204 patent also discloses that “the target percentage may be below 26.5% or above 30%,” “input directly into the system,” or “may be preset from a factory.” EX1001, 14:14-20; EX1003, ¶51.

A technician begins collecting plasma after calculating the target plasma volume. EX1001, 14:21-24. Once the procedure starts, a technician can use an equation to calculate the volume of anticoagulant in a plasma collection bag (“anticoagulant volume”). Specifically, a technician can 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 collection bag. EX1001, 11:20-40. Donors have different hematocrit levels, which affects the amount of plasma in the donor's whole blood and the anticoagulant volume. EX1001, 10:66-11:12; EX1003, ¶52.

In the below equation, “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, 11:20-57. Anticoagulated whole blood is extracted blood mixed with anticoagulant. EX1003, ¶53.

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

Alternatively, the technician can determine, without considering a donor's hematocrit, the amount of anticoagulant added to the system using a "predetermined ratio of anticoagulant per unit anticoagulated whole blood," by monitoring "the number of rotations of the anticoagulant pump"³ introducing anticoagulant into this system, "and/or based on the change in weight of the anticoagulant container 210." EX1001, 11:48-57; EX1003, ¶54.

The '204 patent discloses that the controller uses a weight sensor to monitor the collection container's weight and uses weight to determine the total volume of liquid in the collection container. EX1001, 10:26-28, 10:61-65, 12:33-51. The

³ Because red blood cells' osmolarity prevents anticoagulant from mixing with them, essentially all of the anticoagulant exits bowl 214 and is collected within plasma collection container 216. EX1001, 11:30-34. Thus, subtracting the anticoagulant volume added to the system from the total volume in the collection container estimates the pure plasma volume in the collection container. EX1001, 11:30-34, 11:62-67, 12:33-51; EX1003, ¶52.

controller uses this total volume to calculate the anticoagulant and pure plasma volumes in the collection container. EX1001, 11:12-12:51. The '204 patent first calculates the anticoagulant volume. EX1001, 11:58-62. It then calculates the pure plasma volume by subtracting the anticoagulant volume from the total volume of liquid in the collection container. EX1001, 11:45-12:8; EX1003, ¶55.

The '204 patent repeats any of the above methods 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, 11:67-12:8. When a target volume of pure plasma is collected, 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, 12:9-19; EX1003, ¶56.

C. Prosecution History

Application No. 19/077,384, which resulted in the '204 patent, was filed on March 12, 2025. EX1001, cover. On April 22, 2025, the Examiner rejected all pending claims in the '384 application. EX1002, 151-158.

The Examiner concluded that pending claims 1, 4, 7, 15, 17, 21, and 22 are “designed, configured, and programmed to perform the method” already “claimed by Applicant, thereby anticipating Applicant’s instantly claimed method” in U.S.

Patent Nos. 12,186,474 (the “’474 patent”). EX1002, 155. The Examiner rejected claims 5-6, 8-9, 11, 13-14, 18-19, 23-25, 27-28 under similar reasoning.

The Examiner gave no patentable weight to the “safety” requirements of pending claims 3, 12, 20, and 29 because whether a procedure is “safe” is “a[n] unpatentable mental step ... that occurs as part of a natural phenomenon.” EX1002, 156. However, the Examiner did not reject these claims as unpatentable under Section 101 and instead rejected claims 3, 12, 20, and 29 for non-statutory double patenting because “the safety of the procedure does not patentably distinguish these claims from the cited prior art” and other patented claims in the ’204 patent’s family. EX1002, 154, 156.

The Examiner rejected pending claims 2, 10, 16, and 26 as being unpatentable over claims 15, 16, and 20-25 of Applicant’s U.S. Patent No. 10,792,416 and claims 7, 22 of Applicant’s ’474 patent. The Examiner concluded that “[a] person having ordinary skill at the time of filing would have been motivated to use a donor’s height and weight to calculate a BMI that is then used to calculate a total blood volume.” EX1002, 156.

Lastly, Examiner rejected pending claim 30 as being unpatentable over claims 12, 16, 20-23 of the ’474 patent in view of U.S. Publication No. 2012/0175313 to Barry Jr. The Examiner concluded that “[i]t would [have been] obvious to a person having ordinary skill in the art at the time of filing to add the weight sensors as

disclosed by Barry...in order to determine the volume of fluid collected.” EX1002, 157.

The '204 patent was allowed on June 3, 2025 after Applicant filed a terminal disclaimer to moot the Examiner's non-final double-patenting rejection based on U.S. Patent Nos. 10,792,416 and 12,186,474. EX1002, 17-18, 146, 152-158. The '204 patent issued on August 5, 2025. EX1001, cover.

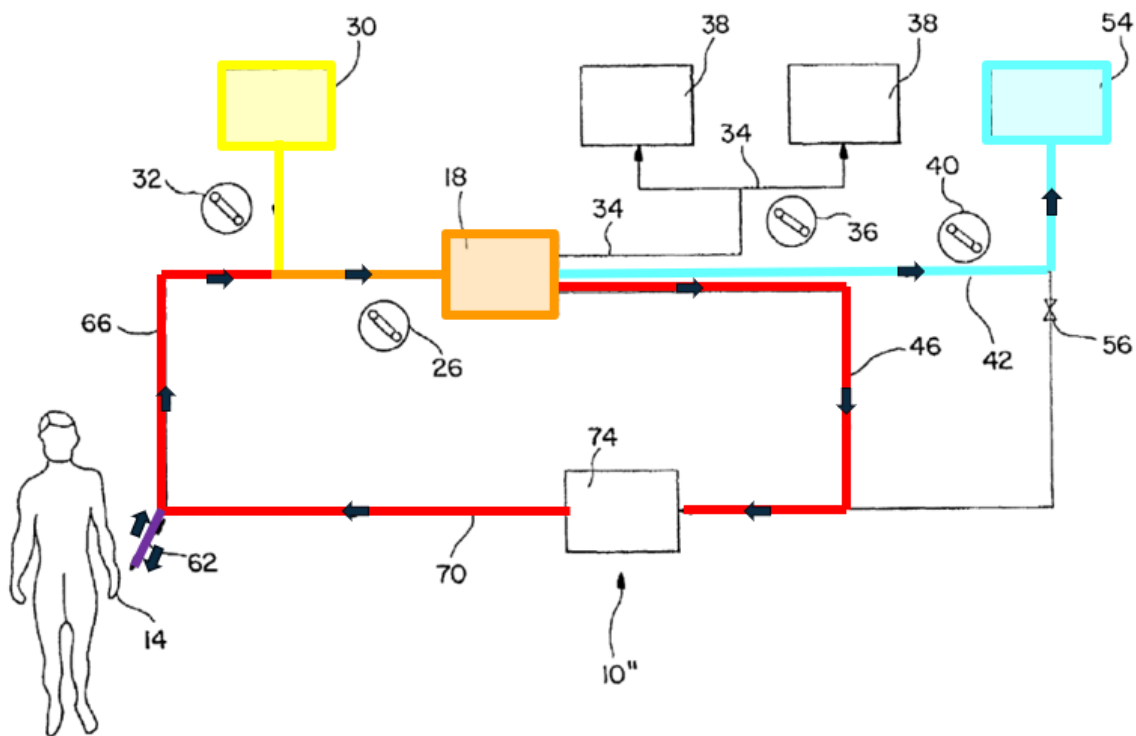
VII. Prior Art Overview

A. Fletcher-Haynes

Fletcher-Haynes discloses a blood collection system that improves blood component yield by maximizing at least one process parameter, based on either a target yield or a fixed procedure time. EX1005, Abstract. Fletcher-Haynes recognized the need to determine a target amount of pure plasma to collect for a donor “considering the medical and physical characteristics of the donor.” EX1005, 48:29-31; 52:13. For example, Fletcher-Haynes' prediction algorithms include a donor's gender, height, weight, hematocrit, and platelet pre-count parameters. EX1005, 27:30-34; 49:19-52:36; EX1003, ¶57.

Figure 7B illustrates Fletcher-Haynes' collection assembly 10” for separating blood into components. EX1005, 45:58-46:15. Donor's blood is pumped through donor access line 62 (purple) and into inlet line 66 (red), and anticoagulant is pumped from AC container 30 (yellow) into to the inlet line 66. EX1005, 45:22-37, 45:58-

63. Blood component separation device 18 separates anticoagulated whole blood into separate components flowing into platelet collect bags 38 and plasma collect bag 54. EX1005,45:63-46:7. The remaining, uncollected blood is pumped back to the donor using return line 70 and the donor line 62. EX1005, 46:10-15; EX1003, ¶58.



EX1005, Fig. 7B (annotated); EX1003, ¶58.

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 and blood processing machine type in optimization and prediction models. EX1005, 49:7-18; EX1003, ¶59.

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, 48:66-49:26; EX1003, ¶60.

Fletcher-Haynes' prediction algorithms may be integrated with its optimization algorithms. Fletcher-Haynes discloses 22 equations that can be incorporated into a prediction model to predict a particular blood component's optimal 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 defines the AC Ratio (R) using a donor's hematocrit; and Equation 22 defines the predicted total

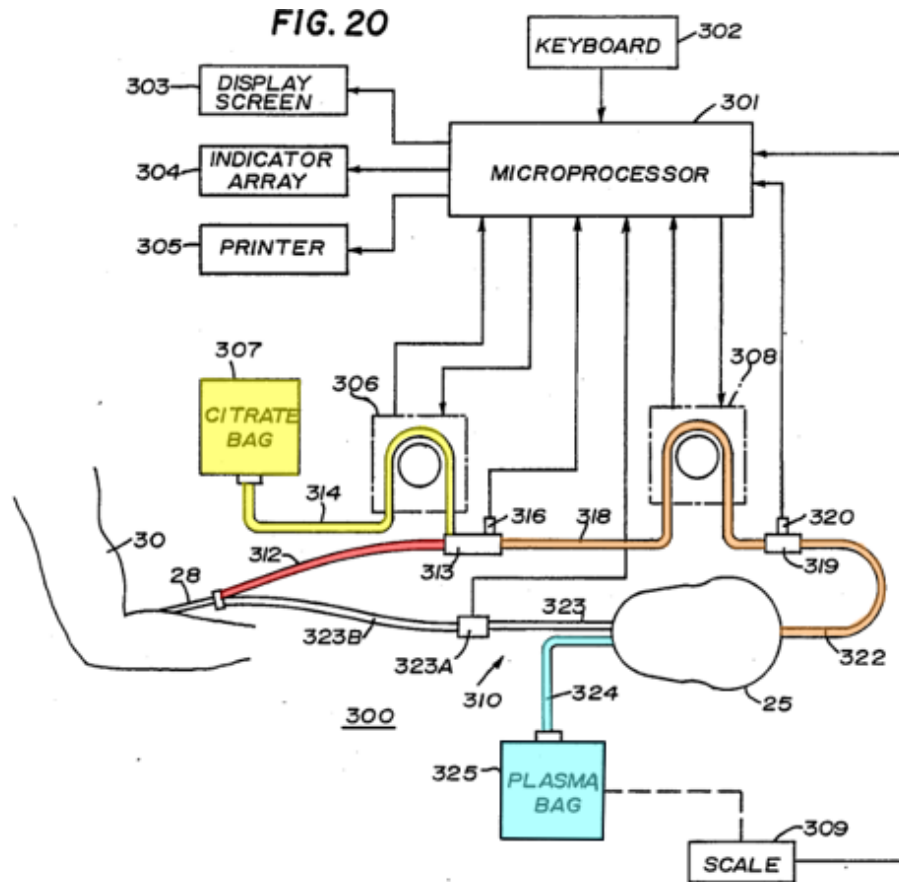
volume in the source plasma bag (V_{SPB}). EX1005, 49:40-52:17. These equations can be integrated with Fletcher-Haynes' optimization algorithms. EX1005, 58:63-67; EX1003, ¶61.

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. Because computer/database system 140 can control apheresis machine functions, including process control manipulation and optimization, a POSITA would understand that optimizer and prediction models, and any of equations 1-22, would be executed during those procedures. EX1005, 34:8-24, 49:40-52:17; EX1003, ¶62.

B. Lavender

Lavender discloses “a system, method and device for continuously fractionating blood in situ.” EX1004, Abstract. Lavender recognized the need to track the volume of anticoagulant in a collected plasma component during a plasma collection procedure, for example to “accurately, safely and economically collect[] plasma from a source of blood.” EX1004, 3:26-28; EX1003, ¶63.

Figure 20 illustrates Lavender's automatic system 300 for fractionating blood. EX1004, 16:34-53.



EX1004, Fig. 20 (annotated). EX1003, ¶64.

In Lavender's system 300, a needle or catheter 28 is used to draw whole blood from a donor, which is then mixed with citrate (a blood anticoagulant) pumped from citrate bag 307. EX1004, 16:60-17:2, 16:45-47. System 300 pumps the whole blood and anticoagulant mixture to blood fractionator 25, which separates it into plasma and other blood fractions. EX1004, 5:42-52. The plasma and anticoagulant mixture exits the blood separation device through the plasma line and is collected in plasma bag 325. EX1004, 17:14-16; EX1003, ¶65.

Lavender's system performs several real time calculations during the collection process. EX1003, ¶68. These calculations account for donor parameters, like hematocrit, as well as a fixed anticoagulant to plasma ratio, which, in turn, relates to a fixed anticoagulant to anticoagulated whole blood ratio. *See* EX1004, 22:35-39, cols. 41, 42. These calculations also account for the weight of the collected plasma and anticoagulant solution during the collection process. These calculations are used to calculate the pure plasma and anticoagulant volumes in the plasma collection bag in real time. EX1004, 20:55-68; EX1003, ¶66.

The microprocessor repeatedly performs weight measurements and run-time calculations set forth in Lavender's algorithm and displays updated values approximately every two seconds. EX1004, 20:55-68. Because Lavender's system determines the relationship (or ratio) between the pure plasma volume and the anticoagulant volume in the collection container, a POSITA would readily understand how to convert between the two volumes. By utilizing this relationship, Lavender's determination of the pure plasma volume is based, at least in part, on the anticoagulant volume. EX1003, ¶67.

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*), which is determined using a donor's weight. EX1004, cols. 43-44, claim 33; EX1003, ¶68.

C. Neyrinck

Neyrinck emphasizes the importance of accurately determining total blood volume (TBV) in apheresis procedures to ensure safety and efficacy. EX1006, 38-39. Because physiological variables impact TBV, Neyrinck discloses multiple methods for calculating TBV using height, weight, sex, age, morphology, and BMI. EX1006, pp.38-39. For example, Nadler's formula, widely used in apheresis machines, calculates TBV based on a person's gender, height, weight, and age. EX1006, p.39. Neyrinck's approaches include models for pediatric patients, based on gender and body type, and using body mass index (BMI) (calculated using weight and height) as the primary variable. EX1006, pp.39-40. These methods assign a blood volume per kilogram of body weight depending on the BMI category. EX1006, 40; EX1003, ¶69.

VIII. 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. EX1003, ¶38.

IX. Claim Construction

The 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 ’204 Patent. *See* 37 C.F.R. § 42.100(b).

Moreover, the Board “need[s] 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. *See* EX1003, ¶19.

X. Detailed Grounds Explanation

The sections below, as supported by Dr. Fletcher’s Declaration, demonstrate how the claims are unpatentable. 37 C.F.R. §42.104(b)(4)-(5). EX1003, ¶¶70-194.

A. Ground I: Fletcher-Haynes anticipates claims 8, 11-15, 17-20, 23-24, and 27-29.

1. Claim 8

- i. [8 pre] A system for collecting plasma comprising:**

To the extent the preamble is limiting, Fletcher-Haynes discloses a system for collecting plasma. Fletcher-Haynes discloses “an extracorporeal blood processing system[]” which utilizes “a method for **collecting** at least one predetermined blood component (“e.g., a collection of platelets or red blood cells or **plasma**”) from a source of whole blood **using a blood component collection system.**” EX1005, 1:10-11, 7:33-38; EX1003, ¶71.

ii. 8[a] a venous-access device for drawing whole blood from a donor and returning blood components to the donor;

Fletcher-Haynes discloses a “single needle assembly... [that] integrates the donor 14 within the blood component separation assembly 10”.” EX1005, 45:58-62. “[B]lood is either being removed from or provided back to the donor 14” using “a needle assembly or other blood access device,” *e.g.*, a venous access device. EX1005, 1:27-31, 46:12-13, Figs. 7B; EX1003, ¶72.

iii. 8[b] a blood component separation device for separating the drawn whole blood into a plasma component and at least a second blood component, the blood component separation device having an outlet and being configured to send the plasma component to a plasma collection container;

Fletcher-Haynes discloses a blood separator (*e.g.*, a blood component collection device 18) which is configured to “separate[] the whole blood ... into three primary constituents” including a plasma product (*e.g.*, “plasma product volume plus anticoagulant volume”) and a second blood component comprising red

blood cells (*e.g.*, “a combination of red and white blood cells”). EX1005, 23:39-41, 45:38-57; EX1003, ¶73.

Fletcher-Haynes’ blood separator contains a plasma output port coupled to a plasma line (*e.g.*, plasma tube 112 that “extend[s] externally of the rotatable device 18”). EX1005, 47:17-34, Figs. 8A & 8B; EX1003, ¶74.

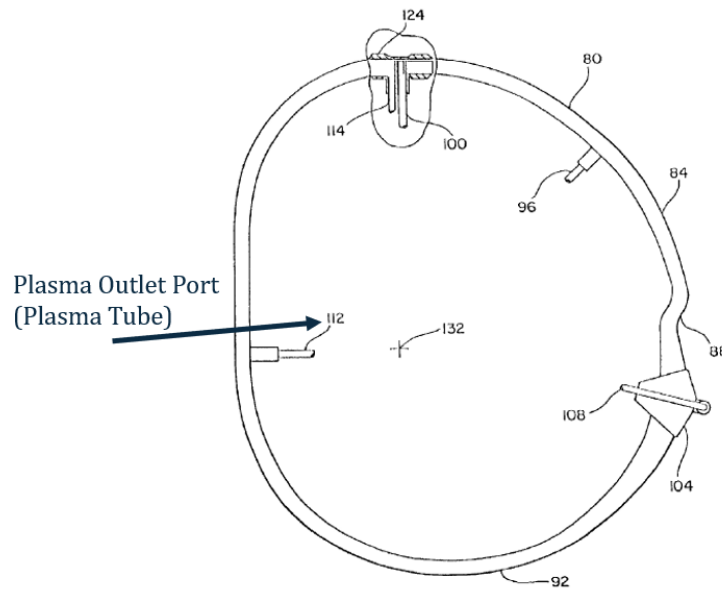
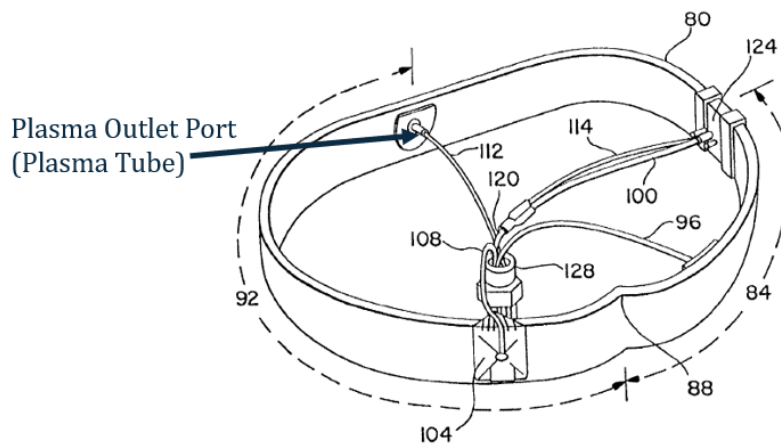


Figure 8B



The blood separator is configured to send the separated plasma through the plasma line to the plasma component collection container, as plasma collect bag 54 “is interconnected with the plasma line 42” and plasma tube 112 to “collect the separated plasma.” EX1005, 45:51-56, 45:58-62; EX1003, ¶75.

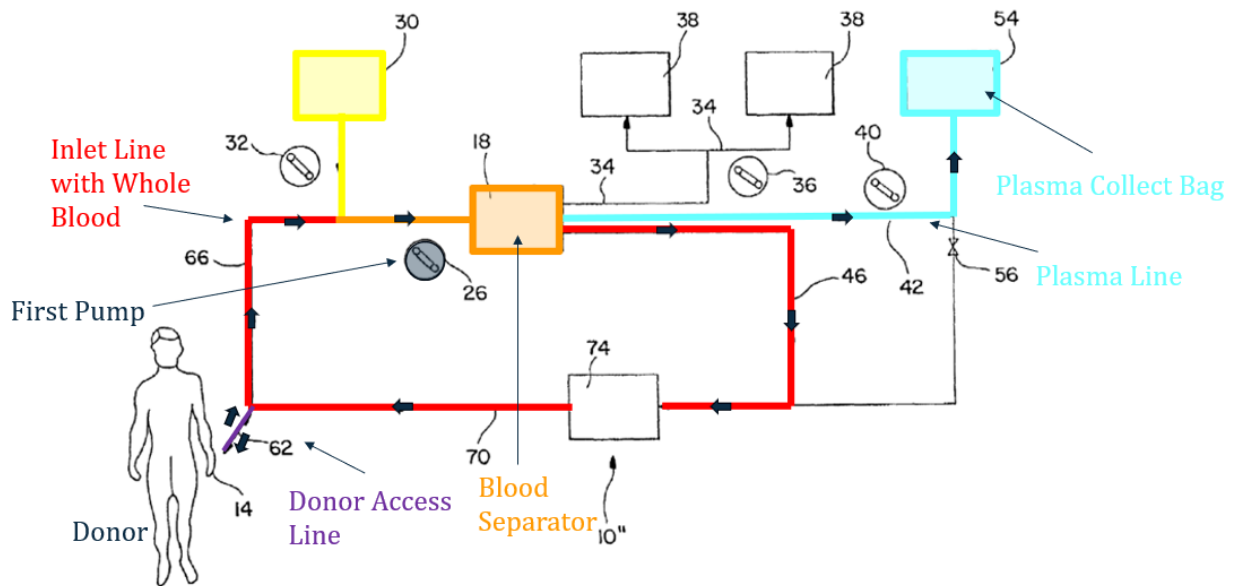


Figure 7B

EX1005, Fig. 7B (annotated); EX1003, ¶75.

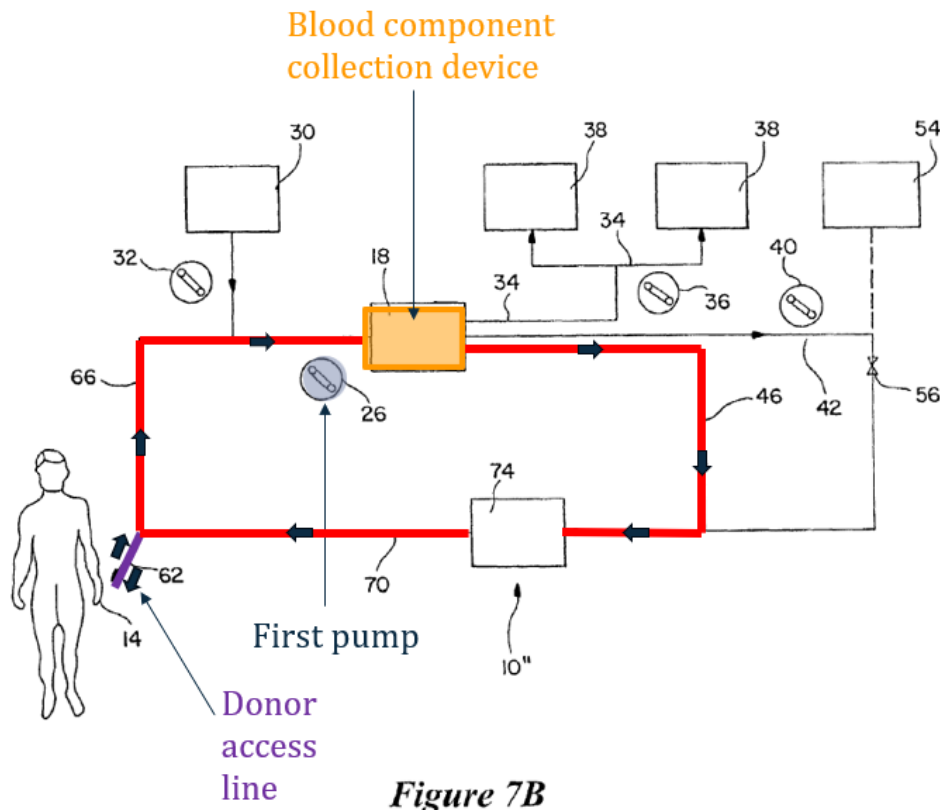
Therefore, Fletcher-Haynes’ blood component separation device has a plasma output port coupled to a plasma line configured to send the plasma product to a plasma product collection container. EX1003, ¶76.

- iv. **8[c] a first line fluidly connected to the venous-access device and configured to transport drawn whole blood to the blood component separation device and return fluid within the blood component separation device to**

the donor, the flow through the first line being controlled by a first pump;⁴

Fletcher-Haynes discloses a first line (*e.g.*, donor access line 62) connected to the venous access device (*e.g.*, the single needle assembly connected to the donor 14) configured to transport drawn whole blood to the blood component separation device (*e.g.*, blood component collection device 18). EX1005, 45:22-29, 45:63-67. Fletcher-Haynes further discloses that fluid from the blood component separation device 18 (*e.g.*, uncollected blood components) is “provided back to the donor 14” using “the donor access line 62.” EX1005, 46:10-15; EX1003, ¶77.

⁴ “[T]he flow through the first line being controlled by a first pump,” lacks and antecedent basis and is indefinite. Any interpretation of this claim limitation in claim 8 is made without waiver of Petitioner’s indefiniteness position.



EX1005, Fig. 7B (annotated); EX1003, ¶77.

Fletcher-Haynes further discloses “an inlet pump 26 (e.g., a peristaltic pump) to maintain [the] flow” of whole blood from the donor to the blood component separation device through the first line. EX1005, 45:24-29; EX1003, ¶78.

- v. **8[d] an anticoagulant line connected to an anticoagulant source, the anticoagulant line configured to introduce anticoagulant into the drawn whole blood; and**

As shown in Fig. 7B, Fletcher-Haynes discloses an anticoagulant line (e.g., the line connecting draw line 66 with AC container 30) coupled to an anticoagulant source (e.g., AC container 30). Fletcher-Haynes further discloses that the

anticoagulant line combines anticoagulant with the whole blood, *e.g.*, by providing “anticoagulant from an anticoagulant (‘AC’) container 30” to the interconnected blood draw line. Whole blood and anticoagulant are combined “[p]rior to the blood of the donor 14 entering the blood component collection device 18.” EX1005, 45:29-37. Fletcher-Haynes “utiliz[es] an AC pump 32,” *e.g.*, a second pump, “to maintain ... flow” of anticoagulant from the anticoagulant source. EX1005, 45:29-37; EX1003, ¶79.

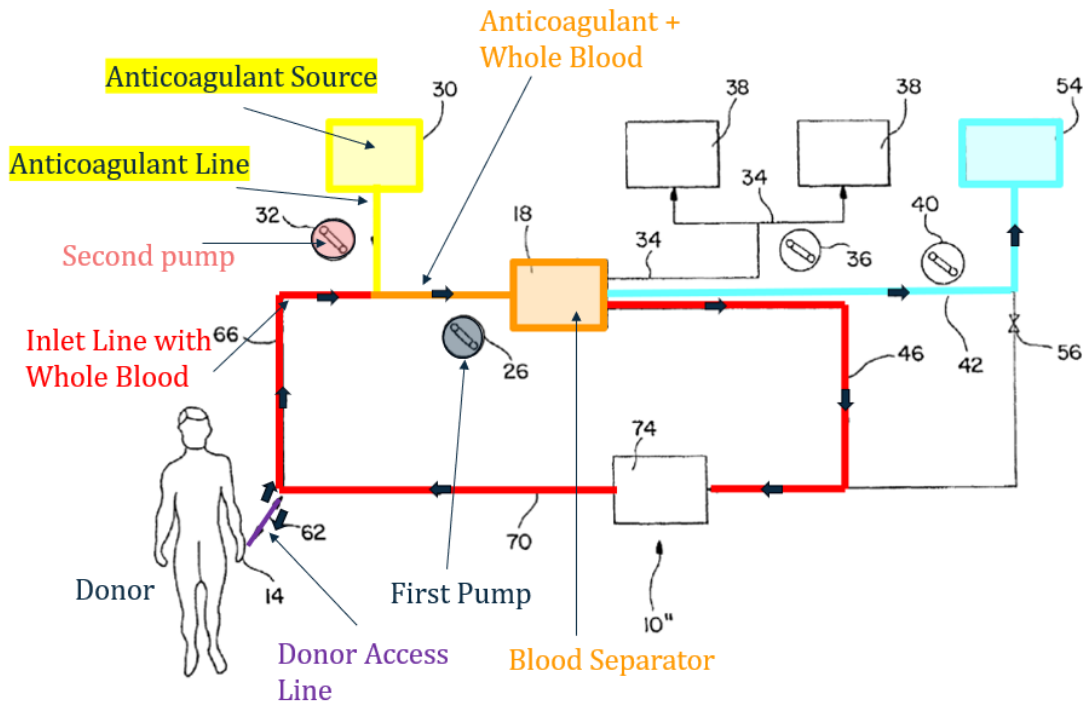


Figure 7B

EX1005, Fig. 7B (annotated); EX1003, ¶79.

- vi. **8[e] a controller configured to control the operation of the blood component separation device and the first pump,**

Fletcher-Haynes discloses a controller (*e.g.*, the internal control of a blood component collection device) that controls the operation of the blood component separation device (*e.g.*, the blood component collection device 18) and the first pump (*e.g.*, inlet pump 26). EX1005, 53:16-20. 45:24-29. The internal control of a blood component collection device 18 maintains “all actual apheresis control during a procedure” and “perform[s] the collection procedure” by controlling the blood component collection device’s hardware. EX1005, 34:12-14, Fig. 9A. For example, the internal control of the blood component separation device controls “the angular velocity of the blood component collection device 18” to “enhance the separation of the various blood components.” EX1005, 48:39-48. Moreover, the internal control of a blood collection device 18 maintains control of inlet pump 26, *e.g.*, the first pump, by “maintain[ing] th[e] flow” of whole blood through first line 62. EX1005, 45:28; EX1003, ¶80.

- vii. **8[f] the controller configured to calculate a target plasma amount to collect based, at least in part, on the donor's total blood volume and a hematocrit of the donor,**

Fletcher-Haynes’ controller calculates both a target volume for plasma product (*e.g.*, V_{SPB} , total volume in source plasma bag), which comprises raw plasma and anticoagulant, and a target volume for pure plasma (*e.g.*, V_{SP} , volume of pure plasma in the source plasma bag), based at least in part on the donor’s total blood

volume and hematocrit. 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 calculates a target volume for plasma product and/or pure plasma. EX1005, 48:1-3; EX1003, ¶81.

First, Fletcher-Haynes calculates a low, medium, or high AC Ratio (R) using the donor's hematocrit (H) in Equation 9. EX1003, ¶82.

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

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

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

Fletcher-Haynes then determines the fraction of AC in the collected plasma component f_{ACP} using the AC ratio and hematocrit in equation 15. EX1003, ¶83.

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

Second, Fletcher-Haynes calculates total blood volume using a donor's weight (W), height (L), and gender in equation 10. EX1003, ¶84.

$$V_B = 604 + 0.006012L^3 + 14.6W \text{ ml (male)}$$

$$= 183 + 0.005835L^3 + 15.0W \text{ ml (female)}$$

Third, in equation 17, Fletcher-Haynes calculates a target volume of pure plasma (V_{SP}) using the total blood volume. EX1003, ¶85.

$$\left\{ \begin{array}{l} V_{SP} = 0 \\ = V_{CON} - V_C \\ = f_{SP}V_B - V_C \\ = \text{specified as modified input} \end{array} \right. \geq 0$$

Finally, Fletcher-Haynes calculates a volume of plasma product (V_{SPB}) in equation 22. EX1003, ¶86.

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

Expanding Equation 22 reveals that V_{SPB} is a sum of volume of pure plasma (V_{SP}) and volume of added anticoagulant ($V_{SP} * f_{ACP}$). EX1003, ¶86.

These values are target values because Fletcher-Haynes can run the prediction model “before the collection procedure is actually initiated.” EX1005, 53:36-38. Therefore, Fletcher-Haynes calculates a target volume for plasma product using a donor’s blood volume and hematocrit. EX1003, ¶87.

viii. 8[g] the donor’s total blood volume based, at least in part, on a weight and height of the donor,

The internal control of Fletcher-Haynes’ blood component separation device calculates the “total blood volume of the donor or patient in mL,” V_B , in equation 10:

$$\begin{aligned} V_B &= 604 + 0.006012L^3 + 14.6W \text{ ml (male)} \\ &= 183 + 0.005835L^3 + 15.0W \text{ ml (female)} \end{aligned}$$

using the height (L) and weight (W) of the donor. EX1005, Eq. 10, 47:61-48:3, 51:61, 52:6, 52:15; EX1003, ¶88.

ix. 8[h] the target plasma amount to collect tailored to the donor.

Fletcher-Haynes discloses a method and system that collects plasma that solves the problem of having “a multitude of collection choices [and] a multitude of donors with differing physiologies, each being subject to potential variations in collection procedures.” EX1005, 2:15-19. As such, Fletcher-Haynes “better satisf[ies] the individual needs of patients” by calculating a target plasma amount to collect (*e.g.*, V_{SP} or V_{SPB}) that is tailored to the individual’s characteristics such as height, weight, gender, and hematocrit. EX1005, 2:43; EX1003, ¶89.

2. Claim 11

i. The system according to claim 8, wherein the controller is further configured to calculate the donor’s total blood volume.

See §X.A.1.vii (limitation 8[g]). EX1003, ¶90.

3. Claim 12

i. The system according to claim 8, wherein the calculated target plasma amount to collect is an optimized safe amount to be collected from the donor.⁵

⁵ Petitioner notes that Claim 12, along with similarly worded claims 3, 20, and 29, lack written description and are not enabled. Thus, any anticipation and/or obviousness arguments for claims 3, 12, 20, and 29 are made without waiver of these alternative grounds of invalidity.

Fletcher-Haynes calculates a target plasma collection amount that is an optimized safe amount. Fletcher-Haynes' optimization model "integrally incorporate[s] the prediction model" such that the prediction model "may be used for both product-based and time-based optimizations." EX1005, 58:61-67. The product-based optimization process outputs "optimal values" of target volumes of pure plasma (*e.g.*, V_{SP}) and anticoagulated plasma (*e.g.*, V_{SPB}). EX1005, 1:35-47; EX1003, ¶91.

Fletcher-Haynes' optimized target collection amounts are safe amounts that "satisfy the individual needs of patients." EX1005, 2:43. For example, prior to starting a donation procedure, a technician cannot select a donation procedure "which are not available due to physical (and/or safety) constraints such as the donor not meeting a minimum hematocrit or total blood volume preferred therefor." EX1005, 29:41-43; EX1003, ¶92.

4. Claim 13

- i. **The system according to claim 8, wherein the controller is further configured to: return, after collecting at least a portion of the target plasma amount to collect, the contents of the blood component separation device to the donor through the first line.**

Fletcher-Haynes discloses a blood collection system "wherein blood is removed from a donor, processed in" a centrifuge, "and the uncollected components" from the centrifuge are "thereafter returned to the donor." EX1005, 1:32-36. "[A]ll

actual apheresis control during a procedure,” *e.g.*, when to draw and return blood “remains resident in the apheresis machine 10 itself” *e.g.*, the “internal control of a blood collection device 18.” EX1005, 34:12-14, 52:40-43. Therefore, Fletcher-Haynes’ system contains a controller that returns uncollected blood components after collecting at least a portion of the target plasma collection volume. EX1003, ¶93.

The uncollected blood components are returned to the donor through the first line because in a single-needle configuration, “only a single line is connected to the donor 14, namely the donor access line.” EX1005, 46:10-15; EX1003, ¶94.

5. Claim 14

- i. **The system according to claim 8, wherein the target plasma amount to collect is a target amount of pure plasma to collect or a target amount of anticoagulated plasma to collect.**

Fletcher-Haynes’ prediction algorithm calculates a target plasma amount to collect, V_{SP} , that is a target “volume of pure plasma” to collect “in [the] source plasma bag” in equation 17:

$$\left\{ \begin{array}{l} V_{SP} = 0 \\ = V_{CON} - V_C \\ = f_{SP}V_B - V_C \\ = \text{specified as modified input} \end{array} \right. \geq 0$$

EX1005, Eq. 17, 52:13. EX1003, ¶95.

Fletcher-Haynes’ prediction algorithm also calculates a target plasma amount to collect that is a target amount of anticoagulated plasma to collect, *e.g.*, V_{SPB} , “total

volume in [the] source plasma bag,” in equation 22:
 $V_{SPB} = V_{SP}(1 + f_{ACP})$. EX1005, Eq. 22, 52:14; EX1003, ¶96.

6. Claim 15

i. 15[preamble] A method for collecting plasma comprising:

To the extent the preamble is limiting, Fletcher-Haynes discloses “an extracorporeal blood processing system[.]” which utilizes “a method for **collecting** at least one predetermined blood component (“e.g., a collection of platelets or red blood cells or **plasma**”) from a source of whole blood **using a blood component collection system.**” EX1005, 1:10-11, 7:33-38; EX1003, ¶97.

ii. 15[a] determining individual characteristics of a donor, the individual characteristics of the donor including a weight, a height and a hematocrit of the donor;

Fletcher-Haynes determines, *e.g.*, by having an apheresis system receive an input of donor characteristics on a touchscreen, individual characteristics of a donor which include “height, weight, gender, and platelet pre-count or hematocrit” via the touchscreen. EX1005, 1:48-52; EX1003, ¶98.

iii. 15[b] calculating a donor total blood volume based, at least in part, on the weight and height of the donor;

See §§X.A.1.viii, X.A.2.i (limitation 8[g], claim 11); EX1003, ¶99.

iv. 15[c] calculating a target plasma amount to collect based, at least in part, on the calculated donor total blood volume and the hematocrit of the donor,

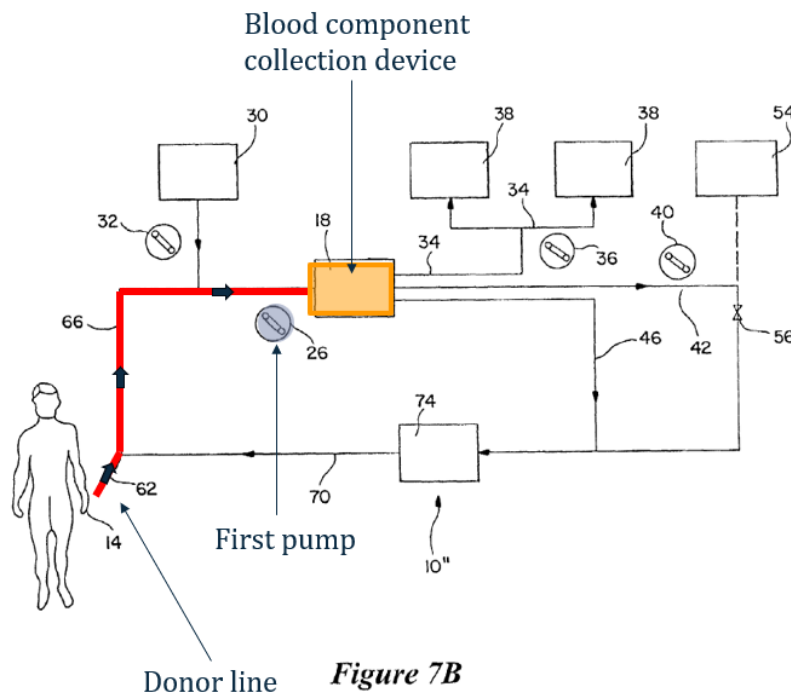
See §§X.A.1.vii (limitation 8[f]); EX1003, ¶100.

- v. **15[d] the target plasma amount to collect being tailored to the individual characteristics of the donor;**

See §§X.A.1.ix (limitation 8[h]); EX1003, ¶101.

- vi. **15[e] withdrawing whole blood from the donor through a venous-access device and a first line, the first line connected to a blood component separation device;**

Fletcher-Haynes withdraws whole blood from donor 14 using “a single needle assembly,” *e.g.*, a venous access device. EX1005, 45:58-63. “Whole blood ... initially flows through a donor access line 62,” *e.g.*, a first line, “which is fluidly connected with the blood component collection device 18,” *e.g.*, the blood component separation device. EX1005, 45:63-67; EX1003, ¶102.



EX1005, Fig. 7B (annotated); EX1003, ¶102.

vii. 15[f] introducing anticoagulant into the withdrawn whole blood through an anticoagulant line;

Fletcher-Haynes introduces anticoagulant to the withdrawn whole blood using an anticoagulant line connected to an anticoagulant source. *See* §X.A.1.v (limitation 8[d]); EX1003, ¶103.

viii. 15[g] separating the withdrawn whole blood into a plasma component and at least a second blood component; and

Fletcher-Haynes discloses a blood separator (*e.g.*, a blood component collection device 18) which is configured to “separate[] the whole blood ... into three primary constituents” including a plasma product (*e.g.*, “plasma product volume plus anticoagulant volume”) and a second blood component comprising red blood cells (*e.g.*, “a combination of red and white blood cells”). EX1005, 23:39-41, 45:38-57; *see also* §X.A.1.iii (limitation 8[b]); EX1003, ¶104.

ix. 15[h] collecting the plasma component from the blood component separation device and into a plasma collection container.

Fletcher-Haynes “collect[s] the separated plasma” *e.g.*, the plasma component, “in ... a plasma collect bag,” *e.g.*, the plasma collection container. EX1005, 45:51-55. The plasma collect bag 54 receives plasma from a “plasma line 42” that is connected to the output of the blood component collection device 18. EX1005, 45:51-55, 47:29-34, Fig. 7B.

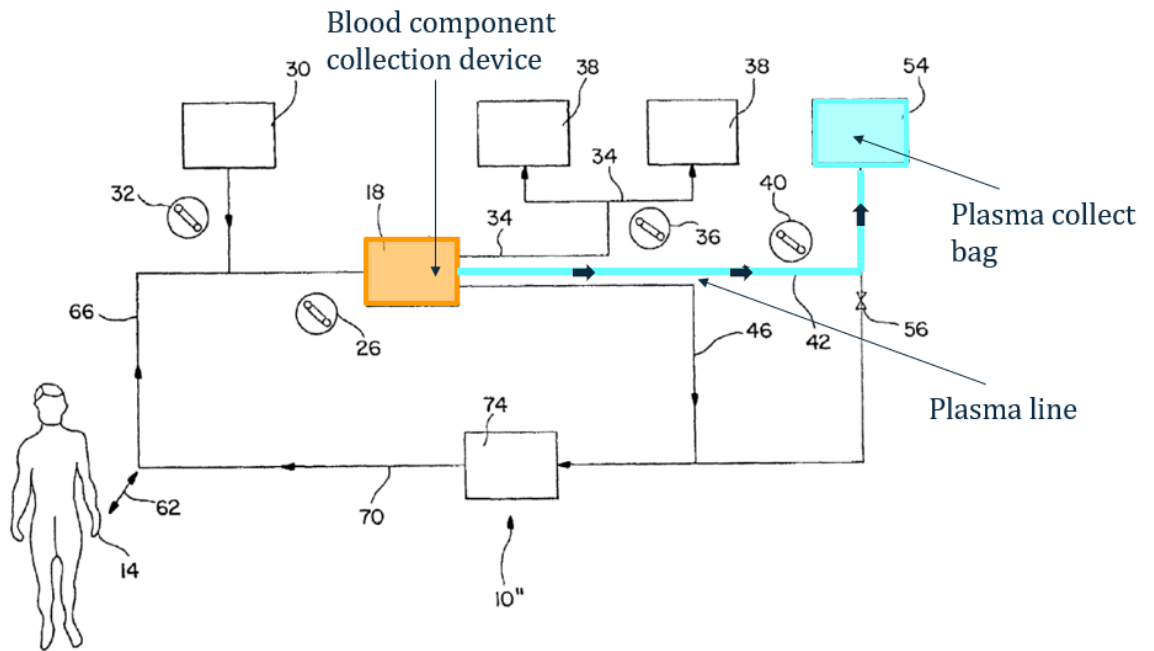


Figure 7B

EX1005, Fig. 7B (annotated); EX1003, ¶105.

7. Claim 17

- i. The method according to claim 15, further comprising: returning, after collecting at least a portion of the target plasma amount to collect, the contents of the blood component separation device to the donor through the first line.**

See §X.A.4.i (claim 13); EX1003, ¶106.

8. Claim 18

- i. The method according to claim 15, wherein the target plasma amount to collect is a target amount of pure plasma to collect.**

Fletcher-Haynes calculates a target volume of pure plasma to collect, V_{SP} .

See §X.A.5.i (claim 14); EX1003, ¶107.

9. Claim 19

- i. The method according to claim 15, wherein the target plasma amount to collect is a target amount of anticoagulated plasma to collect.**

Fletcher-Haynes calculates a target volume of anticoagulated plasma to collect, V_{SPB} . *See* §X.A.5.i (claim 14); EX1003, ¶108.

10. Claim 20

- i. The method according to claim 15, wherein the target plasma amount to collect is an optimized safe amount to be collected from the donor.**

See §X.A.3.i (claim 12); EX1003, ¶109.

11. Claim 23

- i. 23 [preamble] A system for collecting plasma comprising:**

See §X.A.1.i (limitation 8[pre]); EX1003, ¶110.

- ii. 23[a] a venous-access device for drawing whole blood from a donor and returning blood components to the donor;**

See §X.A.1.ii (limitation 8[a]); EX1003, ¶111.

- iii. 23[b] a blood component separation device for separating the drawn whole blood into a plasma component and at least a second blood component, the blood component separation device having an outlet and being configured to send the plasma component to a plasma collection container;**

See §X.A.1.iii (limitation 8[b]); EX1003, ¶112.

- iv. **23[c] a first line fluidly connected to the venous-access device and configured to transport drawn whole blood to the blood component separation device and return fluid within the blood component separation device to the donor, the flow through the first line being controlled by a first pump;**⁶

See §X.A.1.iv (limitation 8[c]); EX1003, ¶113.

- v. **23[d] an anticoagulant line connected to an anticoagulant source, the anticoagulant line configured to introduce anticoagulant into the drawn whole blood; and**

See §X.A.1.v (limitation 8[d]); EX1003, ¶114.

- vi. **23[e] a controller configured to control the operation of the blood component separation device and the first pump,**

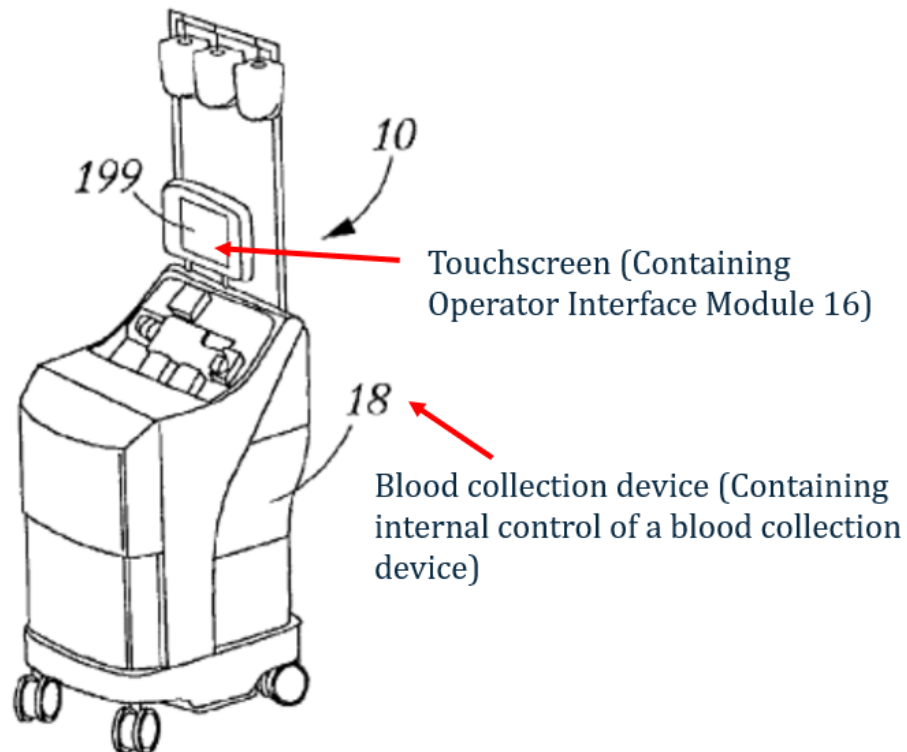
See §X.A.1.vi (limitation 8[e]); EX1003, ¶115.

- vii. **23[f] the controller configured to (1) receive individual characteristics of the donor, the individual characteristics including a weight, height, and hematocrit of the donor, and**

Fletcher-Haynes discloses that “data entry, manipulation and storage may [] be performed at/on each machine using, for example, respective interfaces, which here are ... touchscreen input/output devices.” EX1005, 10:12-15; 53:20-25, 52:43-45, Fig. 1A. Fletcher-Haynes receives an input of a donor’s individual

⁶ “[T]he flow through the first line being controlled by a first pump,” lacks and antecedent basis and is indefinite. Any interpretation of this claim limitation in claim 23 is made without waiver of Petitioner’s indefiniteness position.

characteristics, including “height, weight, gender, and platelet pre-count or hematocrit,” via the touchscreen. EX1005, 1:48-52; EX1003, ¶82. These input values “are downloaded to the internal control of the blood collection device 18,” *e.g.*, the controller. EX1005, 54:8-11. The process of downloading the input values “may include encoding of a computer program of instructions for executing [the] computer process,” meaning that the controller is configured to receive the donor’s weight, height, and hematocrit. EX1005, Fig. 9A, 8:24-34; EX1003, ¶116.



EX1005, Fig. 1A (annotated); EX1003, ¶116.

- viii. 23[g] (2) calculate a target plasma amount to collect based, at least in part, on the donor's total blood volume and a hematocrit of the donor,**

See §§X.A.1.vii, X.A.6.iv (limitation 8[f], 15[c]); EX1003, ¶117.

- ix. 23[h] the donor's total blood volume based, at least in part, on the weight and height of the donor,**

See §§X.A.1.viii, X.A.6.iii, X.A.2.i (limitations 8[g], 15[b] claim 11).

EX1003, ¶118.

- x. 23[i] the target plasma amount to collect being tailored to the individual characteristics of the donor.**

See §§X.A.1.ix, X.A.6.v (limitation 8[h], 15[d]); EX1003, ¶119.

12. Claim 24

- i. The system of claim 23, wherein the controller is further configured to calculate the donor's total blood volume.**

See §§X.A.1.vii, X.A.2.i, X.A.6.iii, X.A.12.ix (limitations 8[g], 15[b], 23[h], claim 11); EX1003, ¶120.

13. Claim 27

- i. The system according to claim 23, wherein the controller is further configured to: return, after collecting at least a portion of the target plasma amount to collect, the contents of the blood component separation device to the donor through the first line.**

See §§X.A.4.i, X.A.7.i (claims 13, 17); EX1003, ¶121.

14. Claim 28

- i. The system according to claim 23, wherein the target plasma amount to collect is a target amount of pure plasma to collect or a target amount of anticoagulated plasma to collect.**

See §§X.A.5.i, X.A.8.i, X.A.9.i (claims 14, 18-19); EX1003, ¶122.

15. Claim 29

- i. The system according to claim 23, wherein the target plasma amount to collect is an optimized safe amount to be collected from the donor.**

See §§X.A.3.i, X.A.12.i (claims 12, 20); EX1003, ¶123.

B. Ground II: Fletcher-Haynes in view of Lavender renders obvious claims 1, 3-7, 9, 21-22, 25, and 30.

- 1. It would have been obvious for a POSITA to combine Fletcher-Haynes and Lavender and would have had a reasonable expectation of success when doing so**

A POSITA would have been motivated to modify Fletcher-Haynes' system in view of Lavender's disclosures, and would have had a reasonable expectation of success in doing so, because 1) each relates to plasma apheresis, 2) each applies substantially similar techniques to achieve similar results, and 3) the functionality of Fletcher-Haynes' system would not change with the further addition of certain of Lavender's disclosures. EX1003, ¶124.

Like Fletcher-Haynes, Lavender "relates to the collection of blood, and, in particular, to the fractioning of blood to collect blood substances, such as plasma" and also uses donor information to improve blood component collection, resulting in "an easier, safer, and more economical method of harvesting plasma." EX1004, 1:11-13, 11:23-26; EX1003, ¶125.

Further, Fletcher-Haynes tracks "the current collection status" for the "blood product ... which may be in the process of being collected as part of a procedure."

EX1005, 35:38-41. Fletcher-Haynes repeatedly runs an optimization procedure to determine a target volume of pure and diluted plasma to collect. EX1005, 54:6-12, Eqs. 21-22. Similarly, Lavender calculates a target volume of pure and diluted plasma to collect before beginning its collection operations, which are executed in its Main Loop. EX1004, Table VI, §2. Thus, a POSITA would have turned to Lavender to supply the requisite computer code related to implementing Fletcher-Haynes' procedure tracking. EX1004, cols. 41-44; EX1003, ¶126.

Additionally, incorporating Lavender's teachings of tracking collection into Fletcher-Haynes' system would have been a routine, minor change to the system that would have yielded predictable results. Lavender's Main Loop contains the same steps as the Fletcher-Haynes procedure. Before beginning a procedure, Lavender and Fletcher-Haynes calculate target volumes of pure plasma. EX1004, Table VI, §2g; EX1005, Eq. 21, 47:60-48:3. During the procedure, Lavender and Fletcher-Haynes monitor the volume of pure plasma collected. EX1004, Table VI, §5B; EX1005, Fig. 5B, 35:36-41. Lastly, Fletcher-Haynes and Lavender stop the collection procedure at the "plasma volume limit," EX1005, 48:27-34, and the code in Lavender's Main Loop shows that the plasma collection procedure is stopped when the volume of pure plasma equals the target volume of pure plasma. EX1004, Table VI, §5C; EX1003, ¶127.

Further, a POSITA would have understood that Fletcher-Haynes' algorithms are essentially the same as Lavender's algorithms. For example, a POSITA would have understood Fletcher-Haynes' anticoagulant volume expressed as a fraction of pure plasma volume (f_{ACP}) is equivalent to Lavender's conversion factor (CF) for ml of citrate per ml of plasma. EX1003, ¶128.

As a second example, Fletcher-Haynes' Equation 15 further defines $f_{ACP} = [(R - 1) * (1 - H)]^{-1}$. R is defined in Equation 3 as $\frac{Q_{IN}}{Q_{AC}}$, which is the ratio of flow of anticoagulated whole blood to flow of anticoagulant. A POSITA would understand that in Lavender $R = \frac{(Q_B + Q_C)}{Q_C} = \frac{Q_B}{Q_C} + 1$, where Q_B is blood flow (mL/min) and Q_C is citrate flow (mL/min), so that $\frac{Q_B}{Q_C} = R - 1$. Lavender's equation TABLE VI, 2.a states that $\frac{Q_P}{Q_B} = 1 - HCTD$. Hence a POSITA would understand from Lavender's equation 2.b., which recites $Q_C = Q_P * CF$, that $CF = \frac{Q_C}{Q_P} = \frac{Q_C}{Q_B} * \frac{Q_B}{Q_P} = \frac{1}{(R-1)} * \frac{1}{(1-HCTD)}$ or $CF = [(R - 1) * (1 - HCTD)]^{-1}$, which is the same equation as Fletcher-Haynes f_{ACP} . EX1003, ¶129.

As a third example, a POSITA would understand that the sum of Lavender's total plasma filtered (TPF) and total citrate filtered (TCF) is equal to Lavender's total dilute plasma filtered; $TDPF = TPF + TCF = TPF + TPF * CF =$

$TPF * (1 + CF)$, or $TDPF = TPF * (1 + CF)$, which is equivalent to Fletcher-Haynes' Eq. 22, which recites $V_{SPB} = V_{SP}(1 + f_{ACP})$. EX1003, ¶130.

Incorporating Lavender's loop code into Fletcher-Haynes' system would have been a known software modification that would have yielded predictable results. That is, incorporating Lavender's Main Loop into Fletcher-Haynes' apheresis system entails the mere use of similar equations to improve similar systems and methods in the same way. "[W]hen a patent 'simply arranges old elements with each performing the same function it had been known to perform' and yields no more than one would expect from such an arrangement, the combination is obvious." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007). EX1003, ¶131.

2. Claim 1

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

See §X.A.6.i (limitation 15 [preamble]); EX1003, ¶132.

- ii. 1[a] calculating a donor total blood volume based, at least in part, on a weight and a height of a donor;**

See §§X.A.1.vii, X.A.2.i, X.A.6.iii, X.A.12.i (limitations 8[g] & 15[b], claims 11 & 24); EX1003, ¶133.

- iii. 1[b] calculating a target plasma amount to collect based, at least in part, on the calculated donor total blood volume and a hematocrit of the donor,**

See §§X.A.1.vii, X.A.6.iv, X.A.11.viii (limitations 8[f], 15[c], 23[g]);

EX1003, ¶134.

- iv. 1[c] the target plasma amount to collect tailored to the donor;**

See §§X.A.1.ix, X.A.6.v, X.A.11.x (limitations 8[h], 15[d], 23[i]); EX1003,

¶135.

- v. 1[d] withdrawing whole blood from the donor through a venous-access device and a first line, the first line connected to a blood component separation device of a blood processing system,**

Fletcher-Haynes withdraws whole blood from the donor through a venous-access device and a first line, the first line connected to a blood component separation device. *See* §X.A.6.vi (limitation 15[e]). Fletcher-Haynes' blood component separation device 18 is a part of a "blood component collection and information management system" that is "implemented at a blood bank/center."

EX1005, 9:48-53; EX1003, ¶136.

- vi. 1[e] the blood processing system having a controller configured to stop collecting plasma when the target plasma amount to collect has been collected into a plasma collection container;**

Fletcher-Haynes in view of Lavender renders obvious limitation 1[e].

EX1003, ¶137.

Fletcher-Haynes discloses a controller (*e.g.*, the internal control of a blood component separation device) within a blood component separation device (*e.g.*, blood component collection device) configured to stop collecting the plasma component when the target plasma amount to collect has been collected into the plasma collection container (*e.g.*, plasma bag 54). EX1005, 48:27-31; EX1003, ¶138.

Fletcher-Haynes further discloses that the blood component separation device is part of a blood processing system. For example, Fletcher-Haynes discloses a blood processing “system 2 [that] would typically be implemented at a blood bank/center.” EX1005, 9:52-53. “The system may include a substantially centralized computing/data storage assembly” and a “separation collection assembly 10 [that] preferably includes a blood component separation and collection device as an integral part thereof.” EX1005, 9:53-55, 9:63-66, Fig. 1A; EX1003, ¶139.

Lavender discloses that the controller is configured to stop collecting plasma when the target plasma amount to collect has been collected into a plasma collection container. Lavender runs a main loop that continues to collect plasma until a target volume of raw plasma is collected, *e.g.*, until $TPF = MAXPF$, at which point, Lavender’s controller “stops the pumps.” EX1004, Table VI, §5C, 20:62-68; 21:61-22:2; EX1003, ¶140.

As discussed in §X.B.1, it would have been obvious to incorporate Lavender's main loop into Fletcher-Haynes' plasma collection system, and a POSITA would have had a reasonable expectation of success in doing so. Therefore, Fletcher-Haynes in view of Lavender the blood processing system having a controller configured to stop collecting plasma when the target plasma amount to collect has been collected into a plasma collection container. EX1003, ¶141.

vii. 1[f] introducing anticoagulant into the withdrawn whole blood through an anticoagulant line;

See §X.A.1.v, X.A.6.vii, X.A.11.v (limitations 8[d], 15[f], 23[d]); EX1003, ¶142.

viii. 1[g] separating the withdrawn whole blood into a plasma component and at least a second blood component; and

See §§X.A.1.iii, X.A.6.viii, X.A.11.iii (limitations 8[b], 15[g], 23[b]); EX1003, ¶143.

ix. 1[h] collecting the plasma component from the blood component separation device into the plasma collection container until the target plasma amount to collect is reached in the plasma collection container.

As discussed in §X.A.6.ix (limitation 15[h]), Fletcher-Haynes collects the plasma component from the blood component separation device into the plasma collection container. As discussed in §X.B.2.vi (limitation 1[e]), it would have been obvious for a POSITA to incorporate Lavender's Main Loop into Fletcher-Haynes'

system such that the controller would continue collecting plasma until the target plasma amount to collect is reached in the plasma collection container. EX1003, ¶144.

3. Claim 3

- i. The method according to claim 1, wherein the calculated target plasma amount to collect is an optimized safe amount to be collected from the donor.**

See §§X.A.3.i, X.A.12.i, X.A.15.i (claims 12, 20, 29); EX1003, ¶145.

4. Claim 4

- i. The method according to claim 1, further comprising: returning, after collecting at least a portion of the target plasma amount to collect, the contents of the blood component separation device to the donor through the first line.**

See §§X.A.4.i, X.A.7.i, X.A.13.i (claims 13, 17, 27); EX1003, ¶146.

5. Claim 5

- i. The method according to claim 1, wherein the target plasma amount to collect is a target amount of pure plasma to collect.**

See §§X.A.5.i, X.A.8.i, X.A.14.i (claims 14, 18, 28); EX1003, ¶147.

6. Claim 6

- i. The method according to claim 1, wherein the target plasma amount to collect is a target amount of anticoagulated plasma to collect.**

See §§X.A.5.i, X.A.9.i, X.A.14.i (claim 14, 19, 28); EX1003, ¶148.

7. Claim 7

- i. The method according to claim 1, further comprising: monitoring an amount of plasma component collected within the plasma collection container.**

Fletcher-Haynes performs “real time monitoring of procedures ... to know the status of [the] collection” of plasma. EX1005, 34:25-28. For example, Fletcher-Haynes’ collection tracking “preferably shows the ... current collection status for each of the three blood product types (platelets, plasma, and RBC) which may be in the process of being collected as part of a procedure.” EX1005, 35:36-41; EX1003, ¶149.

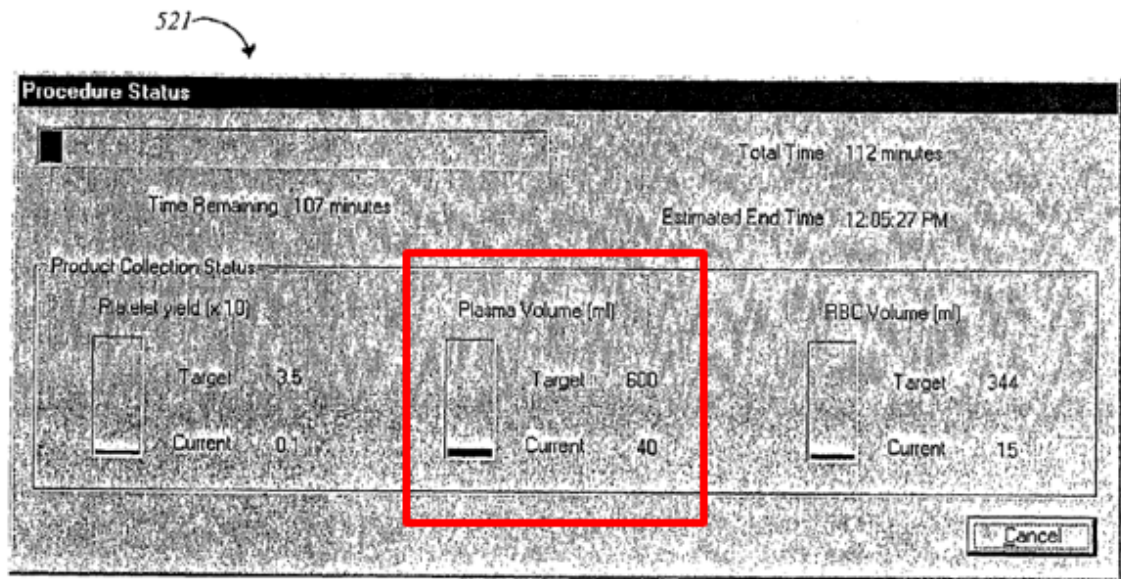


Figure 5B

EX1005, Fig. 5B. The amount of plasma component collected shown in Fig. 5B in Fletcher-Haynes is the amount of plasma component collected within the plasma collection container because Fletcher-Haynes collects plasma in a plasma collect bag, *e.g.*, “plasma collect bag 54.” EX1005, 45:51-55; EX1003, ¶149.

8. Claim 9

- i. The system according to claim 8, wherein the controller is further configured to stop collecting plasma when the target amount of plasma to collect has been collected into the plasma collection container.**

Lavender discloses a controller (*e.g.*, microprocessor 301) that “cycles through the main loop” that repeatedly calculates the amount of plasma collected during a plasma donation procedure. EX1004, 16:40-45, 20:62-68. Lavender’s microcontroller 301 is coupled to “a blood pump 308” for controlling the blood drawing process. EX1004, Fig. 20, 16:45-50. Lavender collects plasma until a target volume of raw plasma is collected, *e.g.*, until $TPF = MAXPF$. EX1004, Table VI, §5C. When “the desired weight of plasma has been collected,” Lavender’s microcontroller “stops the pumps,” thereby stopping plasma collection. EX1004, 21:62-22:6; EX1003, ¶150.

9. Claim 21

- i. The method according to claim 15, further comprising: stopping the collection of the plasma component from the blood component separation device into the plasma collection container when the target plasma amount to collect is reached in the plasma collection container.**

See §X.B.8.i (claim 9); EX1003, ¶151.

10. Claim 22

- i. The method according to claim 15, wherein the blood component separation device is part of a blood processing system, the blood processing system having a controller configured to stop collecting the plasma component when the target plasma amount to collect has been collected into the plasma collection container.**

As discussed in §X.B.2.vi (limitation 1[e]) and §§X.B.9.i, X.B.10.i (claims 9, 21), Fletcher-Haynes in view of Lavender discloses a blood processing system

having a blood component separation device with an internal controller that is configured to stop collecting plasma when the target plasma amount to collect has been collected into a plasma collection container. EX1003, ¶152.

11. Claim 25

- i. The system according to claim 23, wherein the controller is further configured to stop collecting the plasma component when the target amount of plasma to collect has been collected into the plasma collection container.**

See §X.B.8.i, X.B.9.i (claims 9, 21); EX1003, ¶153.

12. Claim 30

- i. The system according to claim 23, further comprising: a plasma collection container weight sensor configured to monitor a volume or weight of plasma component collected within the plasma collection container.**

Lavender discloses “a scale 309 ... for weighing the collected plasma,” *e.g.*, the plasma collection bag 325, “the scale being coupled to the microprocessor 301 for transmitting weight information thereto.” EX1004, 16:50-53. Lavender monitors the weight of the plasma collection container, *e.g.*, the plasma collection bag 325, by “repeatedly performing the [weight] measurements,” converting the weight into a volume, and “updating” the measured volume of the plasma collection container “approximately every two seconds.” EX1004, 20:62-68; EX1003, ¶154.

C. Ground III: Fletcher-Haynes in view of Neyrinck renders obvious claims 10, 16, and 26.

1. It would have been obvious for a POSITA to combine Fletcher-Haynes and Neyrinck

A POSITA would have been motivated to modify Fletcher-Haynes' system with the total blood volume (TBV) calculation in Neyrinck and would have had a reasonable expectation of success in doing so because 1) each relates to plasma apheresis, 2) each applies substantially similar techniques to achieve similar results, and 3) the functionality of Fletcher-Haynes' prediction algorithm would not change after replacing Nadler's formula in Fletcher-Haynes' equation 10 with Neyrinck's formula to calculate total blood volume using BMI. EX1003, ¶155.

First, Fletcher-Haynes and Neyrinck are analogous pieces of art in plasma apheresis. Fletcher-Haynes discloses an "extracorporeal blood processing system[]" which has "optimization capabilities" to collect the maximum amount of plasma "from donors with differing physiologies." EX1005, 1:10-14, 2:15-19. Neyrinck similarly discloses methods for a donation center "to obtain an optimal [plasma] product" that considers the individual physical characteristics of a donor because "not all donors/patients should be addressed in the same way." EX1006, 38; EX1003, ¶156.

Second, both Neyrinck and Fletcher-Haynes apply substantially similar techniques of calculating donor-specific blood volumes to achieve optimal plasma

collection volumes during an apheresis procedure. Fletcher-Haynes's equation 10 calculates a donor's total blood volume using Nadler's formula and uses this to calculate a customized target plasma collection volume. EX1005, Eq. 10. Neyrinck also discloses using Nadler's formula to calculate a donor's total blood volume. EX1006, 39. Neyrinck further discloses a formula that calculates a donor's total blood volume which "take[s] into account the physics of the person" by considering a donor's BMI and/or whether a donor is "obese, thin, normal, or muscular." EX1003, ¶157.

A POSITA designing Fletcher-Haynes' prediction algorithm would have been motivated to use a more accurate equation to calculate total blood volume, *e.g.*, because people of the same weight or height may have different body morphologies or ages that influence their total blood volumes. A POSITA would have turned to Neyrinck for its method of calculating total blood volume using BMI, as Neyrinck discloses calculating total blood volume based on the donor's weight, height, sex, age, morphology, and BMI. EX1003, ¶158.

Third, replacing Nadler's formula with an equation that considers BMI would not change the intended functionality of Fletcher-Haynes' prediction algorithm. Fletcher-Haynes' prediction algorithm using Nadler's formula to calculate total blood volume already uses the same variables (height and weight) used in Neyrinck's method that employs BMI. A POSITA would have had a reasonable expectation of

success in adding the functionality as it only requires simple software modifications to Fletcher-Haynes' total blood volume equation. EX1005, Eq. 10, 9:48-63; EX1003, ¶159.

2. Claim 10

- i. The system according to claim 8, wherein the controller is further configured to: calculate the donor's body mass index based, at least in part on the weight and height of the donor, the target plasma amount to collect calculated based, at least in part, on the donor's body mass index.**

Neyrinck discloses calculations in an apheresis machine (*e.g.*, Fletcher-Haynes' blood component separation device) that “obtain an optimal product without putting [a] donor/patient at risk” by accounting for differences in the “total blood volume (TBV) of the donor/patient.” EX1006, 38. Specifically, Neyrinck calculates a total blood volume in relation to body mass index (BMI). First, Neyrinck calculates the BMI of a patient using height (Ht) and weight (Wt) in the following formula: $BMI = \frac{Wt}{Ht^2}$. EX1006, 40. Next, Neyrinck calculates a blood volume per kg of body weight using the BMI in Table III, reproduced below. EX1006, 40.

	BMI < 18.5	BMI 18.5-24.9	BMI 25-29.9	BMI > 30
Blood volume	80 mL/kg	70 mL/kg	65 mL/kg	55 mL/kg

EX1003, ¶160.

Lastly, “[b]ased on the BMI, the bodyweight of the person needs to be multiplied by” the blood volume per kg of bodyweight “to achieve the TBV.” EX1006, 39-40; EX1003, ¶161.

As discussed in §X.C.1, it would have been obvious to a POSITA to replace Fletcher-Haynes’ equation for TBV with the alternative TBV equation disclosed in Neyrinck, and a POSITA would have had a reasonable expectation of success in making the modification. It would have been obvious to a POSITA to then use Neyrinck’s calculated TBV as V_B in Fletcher-Haynes’ equation 17 to calculate a target volume of pure plasma to collect, *e.g.*, V_{SP} .

$$\left\{ \begin{array}{l} V_{SP} = 0 \\ = V_{CON} - V_C \\ = f_{SP}V_B - V_C \\ = \text{specified as modified input} \end{array} \right. \geq 0$$

EX1005, Eq. 17; EX1003, ¶162.

Therefore, Fletcher-Haynes in view of Neyrinck renders obvious a controller configured to calculate the donor's body mass index based, at least in part on the weight and height of the donor, the target plasma amount to collect calculated based, at least in part, on the donor’s body mass index. EX1003, ¶163.

3. Claim 16

- i. **The method according to claim 15, further comprising: calculating the donor’s body mass index based, at least in part, on the weight and height of the donor, the target plasma amount to collect calculated based, at least in part, on the donor’s body mass index.**

See §X.C.2.i (claim 10); EX1003, ¶164.

4. Claim 26

- i. The system according to claim 23, wherein the controller is further configured to: calculate the donor's body mass index based, at least in part on the weight and height of the donor, the target plasma amount to collect calculated based, at least in part, on the donor's body mass index.**

See §§X.C.2.i, X.C.3.i (claims 10, 16); EX1003, ¶165.

D. Ground IV: Fletcher-Haynes in view of Lavender and in further view of Neyrinck renders obvious claim 2.

- 1. It would have been obvious for a POSITA to further modify the Fletcher-Haynes and Lavender system with Neyrinck**

As discussed in §§X.B.1, X.C.1 (Grounds II-III), a POSITA would have been motivated to combine Fletcher-Haynes with Lavender and Fletcher-Haynes with Neyrinck, respectively, and would have had a reasonable expectation of success in making the proposed combination. A POSITA would have found it obvious and would have been motivated to incorporate the teachings of Neyrinck into the Fletcher-Haynes/Lavender system and would have had a reasonable expectation of success because 1) all references relate to the same well-known technologies, 2) apply substantially similar techniques to achieve similar results, and 3) the intended functionality of Fletcher-Haynes/Lavender system would remain substantially the same in the proposed combination adding Neyrinck. EX1003, ¶166.

First, as discussed above in §§X.B.1, X.C.1 (Grounds II-III), Fletcher-Haynes, Lavender, and Neyrinck relate to plasma apheresis. EX1003, ¶167.

Second, as discussed above in §§X.B.1, X.C.1 (Grounds II-III), Fletcher-Haynes, Lavender, and Neyrinck use substantially similar techniques to achieve similar results. Fletcher-Haynes discloses “processing biological data such as height, weight, gender, and platelet pre-count or hematocrit” to determine a target collection volume for “a multitude of donors with differing physiologies, each being subject to potential variations in collection procedures.” EX1005, 1:48-59, 2:15-19. Neyrinck and Lavender similarly rely on using donor-specific information to determine a safe and effective plasma collection volume. EX1004, 3:26-28; EX1006, p.38. Lavender calculates the donor’s circulating plasma volume as 5% of body weight and collects 18% of that volume. EX1004, 1:12-13, 22:35-46. Neyrinck similarly utilizes the donor’s data such as weight and height to calculate TBV and uses the calculated TBV and hematocrit to calculate total plasma volume. EX1005, p.39-40; EX1003, ¶168.

Lastly, as discussed in §X.B.1, incorporating Fletcher-Haynes’ prediction algorithm into Lavender’s main loop would have been a similarly minor software change for which a POSITA would have had a reasonable expectation of success. As discussed in §X.C.1, replacing Fletcher-Haynes’ calculation of total blood volume with Neyrinck’s calculation based on donor BMI would have been a routine software

change that would not have altered Fletcher-Haynes' functionality. Likewise, replacing Fletcher-Haynes' calculation of total blood volume with Neyrinck's calculation based on donor BMI within a structure like Lavender's Main Loop would have been a similarly minor routine change. EX1003, ¶169.

2. Claim 2

- i. The method according to claim 1, further comprising: calculating the donor's body mass index based, at least in part on the weight and the height of the donor, the target plasma amount to collect calculated based, at least in part, on the donor's body mass index**

Fletcher-Haynes in view of Lavender and Neyrinck renders obvious claim 2. *See* §§X.C.2.i, X.C.3.i, X.C.4.i (claims 10, 16, 26). As discussed in §X.D.1, a POSITA would have been successful incorporating Neyrinck's calculation of total blood volume into Fletcher-Haynes' prediction algorithm and would have had a reasonable expectation of success in doing so in the Fletcher-Haynes/Lavender system. EX1003, ¶170.

XI. §§101/112 GROUNDS

The Examiner never issued a rejection based on Section 101 and never addressed lack of written description, indefiniteness, or enablement issues. See §VI.C. The Prosecution History contained only a double patenting rejection, so the Board will address these issues for the first time.

A. Ground V: All Claims of the '204 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 8 to Assess the Patent Eligibility of the '204 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 8 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 8 is also representative because it also recites results-oriented calculations of anticoagulant and pure plasma volumes that can be performed on a controller as is found in the other challenged claims. Further, claim 8 recites fundamental plasma collection steps found in the challenged claims—drawing blood, introducing anticoagulant, separating blood into components, and collecting plasma. Lastly, like the other claims, representative claim 8 also recites the basic plasma collection equipment used to perform the fundamental apheresis steps.

Claim 8'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 donor and returning blood components to the donor;

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

a first line fluidly connected to the venous-access device and configured to transport drawn whole blood to the blood component separation device and return fluid within the blood component separation device to the donor, the flow through the first line being controlled by a first pump;

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

a controller configured to control the operation of the blood component separation device and the first pump, the controller configured to calculate a target plasma amount to collect based, at least in part, on the donor's total blood volume and a hematocrit of the donor, the donor's total blood volume based, at least in part, on a weight and height of the donor, the target plasma amount to collect tailored to the donor.

Claim 8 is representative because it is substantially similar and linked to the same abstract idea as the other claims of the '204 patent. For example, dependent claim 2 automates a target volume calculation using body mass index. Other claims such as claims 5 and 6 clarify whether the calculated target volume is a volume of

pure plasma or anticoagulated plasma. Claim 8 also contains generic apheresis equipment similarly found dependent claim 30, which claims a weight sensor. 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 8 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 8. Specifically, the '204 patent performs a sequence of abstract calculations involving donor and system parameters. For example, claim 8 of the '204 patent claims “the controller coupled to the touchscreen and programmed to receive at least a donor’s weight, height, sex and hematocrit, to determine a target volume for plasma product

and/or raw plasma based at least in part on the donor's total blood volume and/or the donor's plasma volume.”

The '204 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, 1:45-55. 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 '204 patent also explains that a technician can perform these calculations. Specifically, the '204 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, 11:20-26. Similarly, the '204 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 '204

patent explains that “[o]nce the technician/system 100 has calculated the percentage of anticoagulant within the plasma collection container 216, 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, 11:58-62. 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, 11:62-12:8. In other words, the ’204 patent explains how a technician can gather basic donor and system parameters, which are known, to calculate the claimed volumes recited in the ’204 patent. *See Trinity Info Media*, 72 F.4th at 1361–62. And while the ’204 patent may require the technician to gather donor and system information used for the calculations, it does not change the fact that representative claim 8 is directed to mathematical calculations, not any improved system, and thus these elements do not make the claim patent eligible.

Additionally, while representative claim 8 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 '204 patent cannot be accorded patentability by calculating the recited volumes using a generic computer processor instead of having a technician/user do them. “[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. For example, 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 '204 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, 1:59-2:4. But nowhere throughout the specification of the ’204 patent 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, it is the generic processor that calculates a pure plasma volume that 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 8 does not make the claim “directed to” plasma apheresis, either, as the Federal Circuit has repeatedly

found that 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 the technician or processor with 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 ’204 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)), the '204 patent 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 '204 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 '204 patent's claims automate calculations previously performed by a technician using a general-purpose processor. The '204 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 under *Alice* Step Two 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 '204 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 at all” 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 and equipment. 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 yield in plasma, but Patent Owner would be wrong. The '204 patent's claims merely (1) calculate and collect a target volume of plasma using standard apheresis equipment or (2) track a pure plasma collection volume using generic equipment and stopping at the target proscribed the FDA. Thus, any purported increase in plasma yield for certain donors, at most, a result of math limited by FDA donation limits. EX1001, 11:58-12:8. And 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 claim limitations of the '204 patent 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.

B. Ground VI: Claims 3, 6, 12, 20-21, and 28-29 Lack an Adequate Written Description Under Section 112

Haemonetics overreached when filing its continuation applications. Despite the requirement that “the new claims” in a continuation “must find support in the original specification” the ’204 patent’s claims do not. *TurboCare Div. of Demag Delaval Turbomachinery Corp. v. GE*, 264 F.3d 1111, 1118 (Fed. Cir. 2001).

The ’204 patent is a continuation-in-part of the ’652 patent and a continuation of the ’416 patent. But many of the ’204 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). EX1003, ¶172.

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, 7:17-19. 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. 5. Figure 5 of the ’204 patent illustrates the steps allegedly performed by Haemonetics’ patented system. EX1003, ¶173.

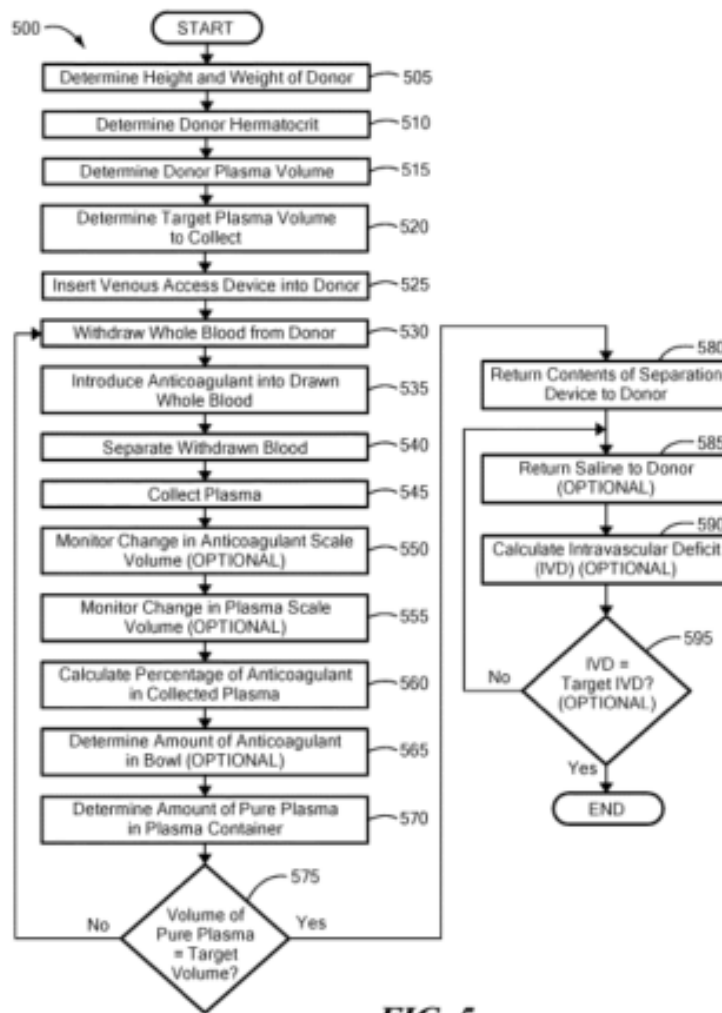


FIG. 5

As shown in Figure 5, the technician or system determines a donor’s weight, height, and hematocrit to calculate a total plasma volume to collect before withdrawing blood. Then, the method enters a loop (steps 530-570) that continues until “volume of pure plasma = target volume.” EX1001, Fig. 5. 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. EX1005, 11:58-12:8.

Once plasma collection is complete, saline is returned to the donor to compensate for lost plasma and “reduce any adverse reactions that the donor may experience.” EX1001, 17:41-49. EX1003, ¶174.

2. Argument

Claims 3, 6, 12, 14, 19-20, and 28-29 recite limitations that lack written description support in the '204 patent. For example, these claims, as discussed further below, include claim limitations that recite basic apheresis equipment that allegedly **calculates an optimized, safe target plasma donation volume**, and measures/calculates target volumes of **anticoagulated plasma**. None of these categories have sufficient written description support in the '204 patent's specification. EX1003, ¶175.

i. **There is no written description support for “calculating an optimized, safe target plasma donation volume”**

Claims 3, 12, 20, and 29, which require calculating an optimized, safe target plasma donation volume lack adequate written description support. The only time that the words “optimized,” “safe,” or any variants thereof appear in the '204 patent are in claims 3, 12, 20, and 29. There is no mention of what optimization entails — whether it refers to maximizing plasma yield, minimizing donor risk, or balancing both. That is because the specification provides only general guidance on calculating plasma volumes based on donor characteristics such as weight, height, and

hematocrit, but it does not explain how these calculations result in a plasma volume that is “optimized” or “safe.” EX1003, ¶176.

The '204 patent identifies various side effects that may occur during a plasma donation procedure, including falling, fainting, light-headedness, vasovagal reactions, but the '204 patent does not distinguish whether and when these side effects are *unsafe clinical risks* for the donor. See EX1001, 17:45-49. Further, the '204 patent describes that it is the saline return, not the removal of a specific target volume of pure plasma, that minimizes these adverse side effects. EX1001, 17:45-49. Thus, this disconnect further underscores the lack of written description support for the claimed “optimized, safe” target plasma volume. EX1003, ¶177.

ii. Limitations requiring an anticoagulated plasma target volume are unsupported.

Claims 6, 14, 19, and 23, which require calculating a target volume of anticoagulated plasma, lack adequate written description support. EX1003, ¶178.

Haemonetics uses the term “plasma product” sparsely in its specification: once to describe the technical field, later to distinguish the alleged invention over prior art systems, and finally in discussing saline return in prior art systems. EX1001, 1:39-41, 17:4-8, 17:34-39. Figure 5, which shows the purported invention, does not reference plasma product. EX1003, ¶179.

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 product volumes. *See Biogen Int'l GMBH v. Mylan Pharms. Inc.*, 18 F.4th 1333, 1342-45 (Fed. Cir. 2021). EX1003, ¶180.

Further, the reason for these sparse disclosures is that the '204 patent teaches away from collecting a "plasma product" 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, 7:17:19. 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 pure plasma collected as compared to prior art systems that collect based on the volume of the plasma product." EX1001, 10:29-31; 11:13-18. 17:34-39. Thus, the focus of the patent is *pure plasma* collection, not plasma product collection. EX1003, ¶181.

Additionally, Haemonetics' claim 1 broadens the scope of its claims to include calculating a "plasma product" target volume using "and/or" language. EX1001, claim 1. Specifically, it recites "to determine a target volume for plasma product and/or raw plasma." In doing so, Haemonetics claims what the '204 patent identifies as prior art (calculating a volume of plasma product) in addition to its purported invention (calculating a volume of pure plasma). EX1001, 12:64-13:2. 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 calculating pure plasma volumes, also calculating plasma product volumes. EX1003, ¶182.

Simply put, Haemonetics' claimed system does not calculate a target volume for plasma product, rendering any claims that calculate a target volume of anticoagulated plasma invalid for a lack of written description. EX1003, ¶183.

C. Ground VII: Claims 3, 8, 12, 20, 23, and 29 Are Indefinite Under Section 112(b).

Section 112(b) requires that a patent specification conclude with claims that “particularly point out and distinctly claim the subject matter which the applicant regards as the invention.” A patent claim is indefinite and invalid under Section 112(b) if it fails to inform, with reasonable certainty, those skilled in the art about the scope of the invention when viewed in light of the specification and prosecution history. *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014). Terms of degree, such as “optimized” or “safe” are indefinite if the specification and prosecution history do not provide “some standard for measuring that degree” to ensure that the claim language offers sufficient clarity to a person of ordinary skill in the art. *Bausch & Lomb Inc. v. Alcon Lab'ys, Inc.*, 64 F. Supp. 2d 233, 236 (W.D.N.Y. 1999).

1. Claims that calculate a target plasma amount that is an optimized, safe amount are indefinite.

Claims 3, 12, 20, and 29, which require calculating a target plasma amount that is an optimized, safe amount, are invalid for indefiniteness. As a threshold matter, neither the specification, nor the prosecution history offer any clarity regarding the meaning of an “optimized, safe” target plasma amount. *See* §§VI.C (Prosecution History), XI.B.2.i (Lack of Written Description). Because neither the specification nor the prosecution history offer any guidance on the meaning of the term “optimized safe” amount, it is unclear to a POSITA whether the “optimization” refers to the volume of plasma that is collected from the donation procedure, the donor’s overall safety, or both. EX1003, ¶184.

Assuming that the claimed “optimization” refers to volume, a POSITA would not understand what an optimized plasma collection amount is because the specification gives contradictory guidance on calculating an optimized volume. The beginning of the specification suggests that “[t]he target volume of pure plasma may be based, at least in part, on the weight of the donor” and that a “a target volume of pure plasma is ... a limit prescribed by the FDA or similar governing body” but the end of the specification suggests that the FDA nomogram for plasma collection which is “based solely on the weight of the donor” is not optimized. EX1001, 11:65-12:8, 3:9-10, 17:4-29. The ’204 patent also mentions a range of percentages of

plasma to collect (e.g., 26.5% to 30%) but also acknowledges that these percentages may vary and be “preset from the factory” or “input directly into the system.” EX1001, 14:14-20. Immediately thereafter, the ’204 patent suggests that “the target percentage may be below 26.5% or above 30%, indicating that the range of 26.5% to 30%, or other machine-selected plasma volume, is not optimal. EX1001, 14:19-20. This wide variability in the target volume of plasma to collect from the donor’s total plasma volume undermines the notion of a fixed, optimized amount to collect. If the target percentage can be arbitrarily selected, then the scope of the claimed “optimized safe amount” becomes entirely dependent on technician or manufacturer discretion, which is impermissibly vague.

If the claims refer to optimizing the safety of a target collection volume, then the term “safe” is also indefinite. The specification discusses possible “adverse reactions that the donor may experience (e.g., falling, fainting, light-headedness, vasovagal reactions)” but discusses “tailoring the saline return” and “achieving isovolemia”—as opposed to calculating a target plasma donation amount— that minimizes such adverse reactions. EX1001, 17:34-49. In other words, the only “safe” plasma target donation volume is 0 mL because it is the removal of blood from the patient that reduces donor safety and *all* target donation volumes above 0 mL are unsafe. That is because the side effects of falling, fainting, light-headedness, or vasovagal reactions are ever present when removing plasma from a donor.

Moreover, neither the specification nor the prosecution history clarify which of the side effects listed in the specification—falling, fainting, light-headedness, or vasovagal reactions—are forms of donor discomfort or side effects cross in the realm of clinical unsafety. If a safe plasma donation amount means “FDA approved,” then the specification does not describe how to achieve such FDA clinical approval. EX1003, ¶186.

Lastly, if an “optimized, safe” plasma target donation volume means optimizing both safety and volume together, then the claims are still indefinite. There is no guidance on how much to reduce a target plasma volume to reduce to minimize side effects, *e.g.*, such as fainting or falling. Similarly, the specification does not describe when it is better to further increase the target plasma donation volume at the cost of a greater risk of side effects, *e.g.*, more lightheadedness. EX1003, ¶187.

2. Claims requiring the flow through the first line being controlled by a first pump are indefinite

A POSITA cannot ascertain the scope of the phrase “the flow through the first line being controlled by a first pump,” rendering the claim indefinite under 35 U.S.C. § 112(b). First, the phrase “the flow through the first line being controlled by a first pump” lacks antecedent basis, so it is unclear what flow is being controlled by the pump. Second, the claim fails to clarify whether the “first pump” controls the draw flow (from the donor to the separation device), the return flow (from the separation

device back to the donor), or both. This is particularly problematic given that the claimed “first line” serves both functions. Third, the specification describes multiple components that influence flow, including valves and a controller, raising uncertainty as to whether the claimed pump is the sole or primary means of flow control through the first line. Likewise, “controlled” is a broad and undefined term that could encompass a range of mechanisms—such as regulation of flow rate, initiation or cessation of flow, pressure modulation, or directional control—none of which are clearly specified in the claim language or adequately supported in the specification. Fourth, the claim language recites a function—controlling flow—without providing sufficient structural detail such that a POSITA would understand the specific flow control the claimed pump performs, *e.g.*, whether it is directional, volumetric, or pressure-based, or whether the claimed pump is the primary or sole means of flow control through the first line. Without a clear delineation of the pump’s flow control, a person of ordinary skill in the art would not be able to design the claimed apheresis system with the claimed pump. EX1003, ¶188.

D. Claims 3, 12, 20, and 29 Are Not Enabled Under Section 112(a).

Section 112(a) requires that the specification contain a written description of the invention and the manner of making and using it in “full, clear, concise, and exact terms” to enable a person skilled in the art to make and use the invention. The enablement requirement is satisfied when the specification teaches those skilled in

the art how to make and use the invention without undue experimentation. *In re Wands*, 858 F.2d 731, 736-37 (Fed. Cir. 1988). “Claims are not enabled when, at the effective filing date of the patent, one of ordinary skill in the art could not practice their full scope without undue experimentation.” *Wyeth & Cordis Corp. v. Abbott Lab’ys*, 720 F.3d 1380, 1384 (Fed. Cir. 2013). The *Wands* factors used to assess whether undue experimentation is required include: (1) the quantity of experimentation necessary; (2) the amount of direction or guidance provided; (3) the presence or absence of working examples; (4) the nature of the invention; (5) the state of the prior art; (6) the relative skill of those in the art; (7) the predictability of the art; and (8) the breadth of the claims. *In re Wands*, 858 F.2d at 737. For substantially the same reasons described in §XI.B.2.i and §XI.C, claims 3, 12, 20, and 29 are also not enabled. Finally, “it is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement.” *Auto. Techs. Int’l, Inc. v. BMW of N. Am., Inc.*, 501 F.3d 1274, 1284 (Fed. Cir. 2007). Otherwise, the specification provides “only a starting point, a direction for further research” and does not provide to a POSA how to make or use the invention. *Id.* at 1284. EX1003, ¶189.

As a threshold matter, the breadth of the claims (Factor 8) is substantial: it covers any plasma collection process that results in an “optimized safe amount” tailored to a donor, yet the specification provides no clear definition or boundaries

for what “optimized” or “safe” mean. Similarly, the nature of the invention (Factor 4) involves medical procedures with patient-specific variables, where safety and optimization are governed by clinical standards and regulatory limits. These are complex and context-dependent concepts that require precise guidance, which, as discussed in Section X.B.2.i, the ’204 patent fails to provide. This is true even though POSITAs in the field of plasma apheresis have a relatively higher skill level than those of other fields (Factor 6). EX1003, ¶190.

Since the specification and prosecution history provide no guidance as to the meaning of “optimized” or “safe” target plasma donation volumes (Factor 2)—and optimal donation volume and safety are subjective to each donor—a POSITA would need a high amount of experimentation (Factor 1) to enable claims 3, 12, 20, and 29 of the ’204 patent. Specifically, a POSITA would need to conduct clinical trials or develop their own criteria to determine what plasma volume is both optimized and safe for different donor profiles. EX1003, ¶191.

As discussed in §XI.C, the specification gives contradictory examples of target plasma volumes (Factor 3), suggesting that there is no such optimal volume. The same is true for donor safety, as the patent suggests removing any target volume of plasma may always result in “falling, fainting, light-headedness, vasovagal reactions” unless an amount of saline is returned to the donor to compensate for blood loss. EX1003, ¶192.

Finally, the predictability or unpredictability of the art (Factor 7) weighs heavily against enablement, as human physiology varies widely. What is safe or optimal for one donor may not be for another. Without concrete guidance, the claim invites trial-and-error experimentation. EX1003, ¶193.

Since all *Wands* factors support a finding that claims 3, 12, 20, and 29 require undue experimentation, the Board should find these claims invalid for a lack of enablement. EX1003, ¶194.

Dated: October 21, 2025

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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 Inter Partes Review of U.S. Patent 12,377,204, 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 16,162. 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: October 21, 2025

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CERTIFICATE OF SERVICE

The undersigned certifies service pursuant to 37 C.F.R. §§ 42.6(e) and 42.105(b) on the Patent Owner on October 21, 2025 by filing a copy of this Petition for IPR of U.S. Patent No. 12,377,204 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. 12,377,204:

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. Filed May 5, 2025) by electronic mail:

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Petition for Post Grant Review of U.S. Patent No. 12,377,204
PGR2026-00006

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Respectfully submitted,

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