

Patent Owner's Preliminary Response  
U.S. Patent No. 12,377,204

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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TERUMO BCT, INC.,

Petitioner

v.

HAEMONETICS CORP.,

Patent Owner

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Case No. PGR2026-00006

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

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**PATENT OWNER'S PRELIMINARY RESPONSE**

**Table of Contents**

I. Introduction ..... 1

II. Overview of the ’204 Patent ..... 4

III. Overview of Primary Prior Art References ..... 5

    A. Fletcher-Haynes..... 5

    B. Lavender ..... 6

        A. Neyrinck ..... 7

IV. Level of Ordinary Skill ..... 7

V. Claim Construction ..... 8

VI. Claims 1-30 Are Not Unpatentable Over Petitioner’s References ..... 8

    A. Ground I: Petitioner Has Failed to Show Fletcher-Haynes Anticipates the Challenged Claims. .... 8

        1. Ground I impermissibly relies on duplicative expert analysis that lacks any rationale or support for Petitioner’s conclusory statements. .... 9

        2. Limitation 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..... 11

        3. Limitation 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 ..... 13

        4. Limitation 8[h]: the target plasma amount to collect tailored to the donor ..... 17

    B. Grounds II-IV: Petitioner Has Failed to Show How Fletcher-Haynes in View of Lavender and/or Neyrinck Renders the Challenged Claims Obvious. .... 19

        1. Petitioner Fails to Articulate a Sufficient Motivation to Combine Fletcher-Haynes and Lavender (Ground II). .... 21

        2. Petitioner Fails to Articulate a Sufficient Motivation to Combine Fletcher-Haynes and Neyrinck (Ground III). .... 25

        3. Petitioner Fails to Articulate a Sufficient Motivation to Combine Fletcher-Haynes with Lavender and Neyrinck (Ground IV)..... 28

C.	Relevant Objective Indicia of Non-Obviousness Refutes Petitioner’s Obviousness Arguments.....	29
1.	A nexus exists between the NexSys Systems and the ’204 Patent Challenged Claims.....	30
2.	The NexSys Systems were commercially successful. ....	31
3.	The NexSys Systems met a long-felt need in the plasma industry. ....	33
4.	The plasma collection industry was skeptical of the NexSys Systems and patented method.....	35
5.	The NexSys Systems have received industry praise.....	36
6.	Patent Owner’s two competitors in the plasma collection industry have copied the NexSys Systems. ....	37
D.	Ground V: The Challenged Claims are Not Invalid Under 35 U.S.C. § 101 .....	39
1.	The Challenged Claims Recite Improvements to Plasma Apheresis Machines .....	40
2.	Claim 8 is Not “Representative” of the Challenged Claims .....	42
3.	<i>Alice</i> Step 1: The Challenged Claims are Directed to Improved Plasma Apheresis Machines, Not Mathematical Calculations.....	44
4.	<i>Alice</i> Step 2: The Challenged Claims Recite an Inventive Concept.....	51
E.	Ground VI: Claims 3, 6, 12, 20-21, and 28-29 Have Adequate Written Description Under 35 U.S.C. § 112(a).....	55
1.	Written Description Support exists for “calculating an optimized, safe target plasma donation volume.” .....	56
2.	Written Description for “anticoagulated plasma target volume” is Satisfied.....	58
F.	Ground VII: Claims 3, 8, 12, 20, 23, and 29 are Not Indefinite Under 35 U.S.C. § 112(b). ....	59
1.	The “optimized” and “safe” plasma collection amount terms are readily ascertainable by a POSITA.....	60
2.	The claim terms requiring the flow through the first line being controlled by a first pump are not indefinite. ....	60
G.	Ground VIII: Claims 3, 12, 20, and 29 are Enabled Under 35 U.S.C. § 112(a).....	62

VII. Conclusion..... 64

**TABLE OF AUTHORITIES**

	<b>Page(s)</b>
<b>CASES</b>	
<i>Aatrix Software, Inc. v. Green Shades Software, Inc.</i> , 882 F.3d 1121 (Fed. Cir. 2018) .....	52, 56
<i>ActiveVideo Networks, Inc. v. Verizon Commc’ns, Inc.</i> , 694 F.3d 1312 (Fed. Cir. 2012) .....	24
<i>Alice Corp. Pty. Ltd. v. CLS Bank Int’l</i> , 573 U.S. 208 (2014).....	passim
<i>Allergan, Inc. v. Sandoz Inc.</i> , 796 F.3d 1293 (Fed. Cir. 2012) .....	64
<i>Amgen Inc. v. Hoechst Marion Roussel, Inc.</i> , 314 F.3d 1313 (Fed. Cir. 2003) .....	57
<i>Ariad Pharms., Inc. v. Eli Lilly &amp; Co.</i> , 598 F.3d 1336 (Fed. Cir. 2010) (en banc) .....	57
<i>BASCOM Glob. Internet Servs., Inc. v. AT&amp;T Mobility, LLC</i> , 827 F.3d 1341 (Fed. Cir. 2016) .....	54, 55
<i>Berkheimer v. HP Inc.</i> , 881 F.3d 1360 (Fed. Cir. 2018) .....	45
<i>CardioNet, LLC v. InfoBionic, Inc.</i> , 955 F.3d 1358 (Fed. Cir. 2020) .....	46, 47, 50
<i>Cephalon, Inc. v. Watson Pharms., Inc.</i> , 707 F.3d 1330 (Fed. Cir. 2013) .....	65
<i>ChargePoint, Inc. v. SemaConnect, Inc.</i> , 920 F.3d 759 (Fed. Cir. 2019) .....	55
<i>Concaten, Inc. v. AmeriTrak Fleet Sols., LLC</i> , 131 F. Supp. 3d 1166 (D. Colo. 2015).....	49

Patent Owner’s Preliminary Response  
U.S. Patent No. 12,377,204

*Content Extraction and Transmission LLC v. Wells Fargo Bank, Nat. Ass’n*,  
776 F.3d 1343 (Fed. Cir. 2014) ..... 44

*Core Wireless Licensing S.A.R.L. v. LG Elecs., Inc.*,  
880 F.3d 1356 (Fed. Cir. 2018) ..... 46

*Diamond v. Diehr*,  
450 U.S. 175 (1981)..... 41, 51, 55

*EcoServices, LLC v. Certified Aviation Serv., LLC*,  
830 Fed. App’x 634 (Fed. Cir. 2020) ..... 46, 47, 48

*Energizer Holdings, Inc. v. Int’l Trade Com’n*,  
435 F.3d 1366 (Fed. Cir. 2006) ..... 62

*Enfish, LLC v. Microsoft Corp.*,  
822 F.3d 1327 (Fed. Cir. 2016) ..... 45, 49

*Haemonetics Corp. v. Terumo BCT, Inc.*,  
No. 1:25-cv-01409 (D. Colo. May 5, 2025) ..... 38, 39

*Haemonetics Corp. v. Terumo BCT, Inc.*,  
No. 1:25-cv-01409-RMR-SBP (D. Colo.) (Aug. 12, 2025), D.I. 48..... ix

*In re Kahn*,  
441 F.3d at 988 ..... 22

*In re Wands*,  
858 F.2d 731 (Fed. Cir. 1988) ..... 63

*InTouch Techs. V. VGO Commc'ns, Inc.*,  
751 F.3d 1327, 1352 (Fed. Cir. 2014) ..... 24

*KSR Int’l Co. v. Teleflex Inc.*,  
550 U.S. 398, 418 (2007)..... 21

*Martin v. Johnson*,  
454 F.2d 746 (CCPA 1972)..... 57

*Mayo Collaborative Servs. v. Prometheus Lab’y, Inc.*,  
566 U.S. 66 71 (2012)..... 55

Patent Owner’s Preliminary Response  
U.S. Patent No. 12,377,204

<i>McRO, Inc. v. Bandai Namco Games Am., Inc.</i> , 837 F.3d 1299 (Fed. Cir. 2016) .....	45, 46, 49, 50
<i>Nautilus, Inc. v. Biosig Instruments, Inc.</i> , 134 S. Ct. 2120 (2014).....	61
<i>Nidec Motor Corp. v. Zhongshan Broad Ocean Motor, Co.</i> , 868 F.3d 1013 (Fed. Cir. 2017) .....	8
<i>OIP Techs., Inc. v. Amazon.com, Inc.</i> , 788 F.3d 1359 (Fed. Cir. 2015) .....	56
<i>Personal Web Techs., LLC v. Apple, Inc.</i> , 848 F.3d 987 (Fed. Cir. 2017) .....	24
<i>Polaris Indus., Inc. v. Artic Cat, Inc.</i> , 882 F.3d 1056 (Fed. Cir. 2018) .....	32
<i>Quanergy Sys., Inc. v. Velodyne Lidar USA, Inc.</i> , 24 F.4th 1406 (Fed. Cir. 2022) .....	30, 32
<i>Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc.</i> , 827 F.3d 1042 (Fed. Cir. 2016) .....	47, 55, 56
<i>Recentive Analytics, Inc. v. Fox Corp.</i> , 134 F.4th 1205 (Fed. Cir. 2025) .....	56
<i>Robert Bosch Tool Corp. v. SD3, LLC</i> , IPR2016-01753, Paper 15 (Mar. 22, 2017) .....	30
<i>Thales Visionix, Inc. v. United States</i> , 850 F.3d 1343 (Fed. Cir. 2017) .....	51, 52
<i>TQ Delta, LLC v. CISCO Sys., Inc.</i> , 942 F.3d 1352 (Fed. Cir. 2019) .....	21
<i>Trinity Info Media, LLC v. Covalent, Inc.</i> , 72 F.4th 1355 (Fed. Cir. 2023) .....	51, 56
<i>Ultramercial, Inc. v. Hulu, LLC</i> , 722 F.3d 1335 (Fed. Cir. 2013), <i>vacated on other grounds</i> , 573 U.S. 942 (2014).....	43

Patent Owner’s Preliminary Response  
U.S. Patent No. 12,377,204

*Verdegaal Bros. v. Union Oil Co. of Cal.*,  
814 F.2d 628 (Fed. Cir. 1987) ..... 9

*Visual Memory LLC v. NVIDIA Corp.*,  
867 F.3d 1253 (Fed. Cir. 2017) ..... 49

*Xerox Corp. v. Bytemark, Inc.*,  
IPR2022-00624, Paper 12 (Feb. 10, 2023) ..... 10, 11, 21

*XY, LLC v. Trans Ova Genetics, LC*,  
968 F.3d 1323, 1331 (Fed. Cir. 2020) ..... 51

**STATUTES**

35 U.S.C. § 101 ..... passim

35 U.S.C. § 102 ..... 1

35 U.S.C. § 103 ..... 1

35 U.S.C. § 112 ..... 1, 3, 65

35 U.S.C. § 112(a) ..... 57, 63

35 U.S.C. § 112(b) ..... 61

35 U.S.C. § 323 ..... 1

35 U.S.C. § 324(a) ..... 2, 20, 28, 66

**OTHER AUTHORITIES**

37 C.F.R. § 42.207 ..... 1

37 C.F.R. § 42.208(c) ..... 2

37 C.F.R. § 42.220 ..... 1

MPEP § 2173.05(e) ..... 62

**List of Exhibits**

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<b>2008</b>	Second Amended Complaint, <i>Haemonetics Corp. v. Terumo BCT, Inc.</i> , No. 1:25-cv-01409-RMR-SBP (D. Colo.) (Aug. 12, 2025), D.I. 48
<b>2009</b>	“ADMA Biologics Advances Expansion Plans and Opens New Plasma Collection Center in Conyers, GA; ADMA Implements Haemonetics’ Persona Technology for NexSys Plasma Collection System,” ADMA Biologics, Inc. (Aug. 10, 2021), available at <a href="https://www.globenewswire.com/news-release/2021/08/10/2278386/33130/en/ADMA-Biologics-Advances-Expansion-Plans-and-Opens-New-Plasma-Collection-Center-in-Conyers-GA-ADMA-Implements-Haemonetics-Persona-Technology-for-NexSys-Plasma-Collection-System.html">https://www.globenewswire.com/news-release/2021/08/10/2278386/33130/en/ADMA-Biologics-Advances-Expansion-Plans-and-Opens-New-Plasma-Collection-Center-in-Conyers-GA-ADMA-Implements-Haemonetics-Persona-Technology-for-NexSys-Plasma-Collection-System.html</a>
<b>2010</b>	“Peer-Reviewed Results of Haemonetics’ Improving Plasma Collection (IMPACT) Trial Published in the Journal Transfusion,” Haemonetics Press Release (Apr. 29, 2021), available at <a href="https://haemonetics.gcs-web.com/news-releases/news-release-details/peer-reviewed-results-haemonetics-improving-plasma-collection/">https://haemonetics.gcs-web.com/news-releases/news-release-details/peer-reviewed-results-haemonetics-improving-plasma-collection/</a>
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<b>2012</b>	U.S. FDA Clears Terumo Blood and Cell Technologies’ New Plasma Collection Technology, Terumo Global (Mar. 10, 2022) <i>available at</i> <a href="https://www.terumo.com/newsrelease/detail/20220310/683">https://www.terumo.com/newsrelease/detail/20220310/683</a>
<b>2013</b>	510(k) Summary, Rika Plasma Donation System, Terumo Blood and Cell Technologies (2021), <i>available at</i> <a href="https://www.fda.gov/vaccines-blood-biologics/substantially-equivalent-510k-device-">https://www.fda.gov/vaccines-blood-biologics/substantially-equivalent-510k-device-</a>

Patent Owner’s Preliminary Response  
U.S. Patent No. 12,377,204

Exhibit No.	Description of Document
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2015	“Q&A Session at the Financial Results Briefing for the FY22,” Terumo Corporation (May 17, 2023), <i>available at</i> <a href="https://www.terumo.com/system/files/document/2023-05/Presentation_23Q4_E_qa.pdf">https://www.terumo.com/system/files/document/2023-05/Presentation_23Q4_E_qa.pdf</a>
2016	“Fresenius Kabi Received FDA 510(k) Clearance for Adaptive Nomogram, Enhancing Plasma Collection Efficiency with the Aurora Xi Plasmapheresis System,” Fresenius Kabi (Jan. 28, 2025), <i>available at</i> <a href="https://www.fresenius-kabi.com/us/news-and-events/receives-fda-510k-clearance-adaptive-nomogram-enhancing-plasma-collection-efficiency-aurora-xi-plasmapheresis-system">https://www.fresenius-kabi.com/us/news-and-events/receives-fda-510k-clearance-adaptive-nomogram-enhancing-plasma-collection-efficiency-aurora-xi-plasmapheresis-system</a>

Patent Owner's Preliminary Response  
U.S. Patent No. 12,377,204

Pursuant to 37 C.F.R. § 42.207 and 35 U.S.C. § 323, Patent Owner Haemonetics Corporation (“Patent Owner”) files this Preliminary Response to the Petition for post-grant review (“Petition”), regarding claims 1-30 of U.S. Patent No. 12,377,204 (the “’204 Patent”), requested by Petitioner Terumo BCT, Inc. (“Petitioner”). Institution should be denied.<sup>1</sup>

**I. INTRODUCTION**

Petitioner filed this Petition challenging the patentability of all claims of the ’204 Patent. The Petition presents eight grounds of unpatentability under 35 U.S.C. §§ 102, 103, 101, and 112. Grounds I-IV relate to 35 U.S.C. §§ 102 and 103 and rely on U.S. Patent No. 7,072,769 to Fletcher-Haynes (“Fletcher-Haynes”) alone or in combination with U.S. Patent No. 4,898,675 to Lavender (“Lavender”) and/or “Calculations in Apheresis” by Neyrinck (“Neyrinck”). Ground V relates to 35 U.S.C. § 101. Grounds VI-VIII relate to 35 U.S.C. § 112 concerning written description, indefiniteness, and enablement. Each Ground fails to establish it is more likely than not that any challenged claims are unpatentable.

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<sup>1</sup> In submitting this Preliminary Response, Patent Owner does not waive any arguments regarding the Petition and the challenged claims. Patent Owner has the right to file a complete response if the Board institutes post-grant review. 37 C.F.R. § 42.220.

Petitioner bears the burden to establish the invalidity of the '204 Patent based on the asserted references and legal theories. The Petition must demonstrate “that it is more likely than not that at least 1 of the claims challenged in the petition is unpatentable” for institution to be authorized, although institution is never required.<sup>2</sup> 35 U.S.C. § 324(a); 37 C.F.R. § 42.208(c). Because Petitioner has failed to meet its burden, institution should be denied.

The Petition itself is not an independent analysis—it is a cut-and-paste job. The alleged expert declaration by Dr. Gary D. Fletcher (“Fletcher”) mirrors the Petition (or vice versa), almost entirely verbatim, typos and all. The Petition offers no independent technical analysis or explanation of what a POSITA would have understood at the time of the invention.

Petitioner's motivations to combine references in Grounds II-IV are inadequate. Like the remainder of the Petition, Petitioner repeatedly cites Fletcher's duplicative analysis in support of combining references. Neither Petitioner nor Fletcher provide sufficient analysis or rationale as to *why* a POSITA would have been motivated to combine Fletcher-Haynes with Lavender and/or Neyrinck nor *why* a POSITA would have reasonably expected success. That does not meet the

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<sup>2</sup> Patent Owner requested discretionary denial of institution of the Petition (Paper 8).

standard. Petitions supported by conclusory and repetitive expert testimony, such as this, should be denied.

Compounding these deficiencies, Patent Owner has extensive secondary indicia of non-obviousness based on its commercialized product practicing the '204 Patent, which Petitioner ignores. Patent Owner's systems embodying the claimed invention transformed the plasma apheresis industry. They achieved significant commercial success, met a long-felt, unresolved need in the industry, overcame industry skepticism, received widespread praise once launched, and have been copied by the only two competitors in this industry—including Petitioner. The success and praise of Patent Owner's system is due to the claimed invention and confirms non-obviousness.

Petitioner's arguments pursuant to 35 U.S.C. §§ 101 and 112 are similarly unavailing. Petitioner ignores most of the claim elements to mischaracterize the claims as directed to mathematical equations. The claims are directed to improved plasma apheresis devices and must be read as an ordered combination to identify their inventive concept. Moreover, each claim term contains ample support and enablement within '204 Patent specification. None of the challenged terms are indefinite.

In short, Petitioner offers nothing more than hindsight speculation, conclusory repetition, flawed legal conclusions, and copied text masquerading as expert analysis. The Board should decline to institute review.

## II. OVERVIEW OF THE '204 PATENT

The '204 Patent is directed to plasmapheresis methods and systems utilizing a donor's characteristics to identify a pure plasma amount to be collected. EX1001, 1:39-41; 2:20-3:18. The disclosed system tailors the plasma collection amount to each donor because "the volume of plasma that is collected from the donor varies from donor to donor (e.g., because it is based on the donor's height, weight, hematocrit, and blood volume). *Id.*, 16:8-11.

This was an improvement over prior art systems. EX1001, 1:64-2:17, 12:64-13:22; 17:4-49. Prior art systems that targeted total collection volume did not consider a donor's individual characteristics, such as height, weight, hematocrit, and blood volume. *Id.*, 13:2-9, 16:8-11. As the patent explains:

[A]s noted above, prior art systems that follow the current FDA nomogram for plasma collection collect a volume of plasma product (e.g., anticoagulant and plasma mixed together) based solely on the weight of the donor—the same volume is collected from every donor at the same weight.

*Id.*, 17:4-8. But, different donors have different heights, hematocrits, and total blood volumes. The '204 Patent, therefore, teaches determining a "target volume" of pure plasma tailored to each donor's characteristics and stopping the collection when

that target is reached. *Id.*, 13:9-12; cls. 1, 8, 15, 23. Thus, the '204 Patent optimizes plasma yields on a donor-by-donor basis by collecting the appropriate amount of plasma from each donor.

### **III. OVERVIEW OF PRIMARY PRIOR ART REFERENCES**

#### **A. Fletcher-Haynes**

Fletcher-Haynes is directed to a platelet collection system that also collects additional blood components. EX1005, 2:56-59, 51:15-16 (the “primary equation” to be solved by the invention is platelet yield). Fletcher-Haynes purports to simultaneously manage “a large number of variables” to “meet the blood bank collection goals” when collecting different types of blood components, “including platelets, red blood cells, white blood cells, stem cells and plasma.” *Id.*, 1:24-26; 2:32-35. The reference explains:

An important purpose of the present system is to address various challenges in the area of blood donation management including increasing productivity, better donor qualification/utilization and improved product quality control and disposition.

*Id.*, 3:50-54. These objectives are achieved by Fletcher-Haynes' invention through centralized management of the machine, blood center customization of collections, donor recruitment, and optimizing collections by targeting the highest need (e.g., the blood component that is most in demand at a particular center). *Id.*, 3:55-4:48.

Fletcher-Haynes also teaches the use of “prediction algorithms” that “predetermine donor eligibility for specific product collections”. *Id.*, 5:28-35.

## **B. Lavender**

Unlike the '204 Patent which determines a target pure plasma volume to be collected, Lavender is directed to a plasmapheresis system that tries to avoid “rapid degradation in plasma production with time” by utilizing specific structural designs and distribution of blood within the machine. EX1004, 11:30-32, 13:23-46. This includes uniform distribution of blood across Lavender's disclosed plates, which have shallow grooves to facilitate blood flow and reduce resistance. *Id.*, 13:23-46. According to Lavender, these structural improvements allow for a higher blood flow velocity rate which helps to avoid rapid degradation. *Id.*, 11:30-44, 13:51-14:5.

An additional purpose of Lavender's invention is to add an appropriate amount of anticoagulant to the donor blood at an appropriate rate to prevent blood clots. *See* EX1004, 13:49-50, 22:35-46. As the reference explains:

Because the plasma volume of whole blood varies with hematocrit, basing anticoagulant volume on the whole blood volume is, of necessity, inaccurate. Blood from donors with low hematocrits may receive too little anticoagulant and blood from donors with high hematocrits may receive too much.

*Id.*, 3:2-7. Accordingly, Lavender teaches pumping anticoagulant (citrate) based on donor hematocrit “at a rate sufficient to dilute incoming plasma to 68% of the initial concentration.” *Id.*, 22:37-39.

**A. Neyrinck**

Neyrinck is an article narrowly focused on different methods of apheresis calculations, including calculations for total blood volume (TBV), extra corporeal volume, and total plasma volume (TPV). EX1006, 38-41. For example, Neyrinck discloses using “Nadler’s formula to calculate the TBV of a human being based on gender, height, and weight,” (EX1006, 39, 41) which was cited in the ’204 Patent (EX1001, Cover p.3).

Neyrinck also describes calculating TPV of a donor utilizing hematocrit and TBV. EX1006, 39-40. Neyrinck focuses on hematocrit because it affects plasma collection procedure duration. *Id.* (hematocrit “is really influencing the duration of a plasma exchange procedure”); (“the Hct is influencing the procedure, especially the procedure time”); (“there will be a longer procedure in patients with a lower Hct”). Neyrinck does not focus on the volume of pure plasma collected in these procedures; rather, only references plasma collection volume, which includes pure plasma and anticoagulant. *See id.*

**IV. LEVEL OF ORDINARY SKILL**

For the purposes of this Preliminary Response, Patent Owner has applied the same skill level proposed by Petitioner pertaining to a POSITA. Pet. at 18.

**V. CLAIM CONSTRUCTION**

Petitioner asserts “the Challenged Claims need no construction.” Pet. at 23. Patent Owner agrees claim construction is not necessary to decide institution. *See also Nidec Motor Corp. v. Zhongshan Broad Ocean Motor, Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (constructions are only needed when “necessary to resolve the controversy”). Thus, for the purpose of this Preliminary Response, Patent Owner does not urge any construction of any claim terms but reserves the right to do so should the Board institute trial and further clarification become necessary.

**VI. CLAIMS 1-30 ARE NOT UNPATENTABLE OVER PETITIONER'S REFERENCES**

**A. Ground I: Petitioner Has Failed to Show Fletcher-Haynes Anticipates the Challenged Claims.**

In Ground I, Petitioner avers claims 8, 11-15, 17-20, 23-24, and 27-29 are anticipated by Fletcher-Haynes. Pet. at 19. Petitioner has not met its burden to demonstrate the unpatentability of the challenged claims.

To establish anticipation, Petitioner must show it is more likely than not that “each and every element as set forth in the [challenged] claim is found, either expressly or inherently described, in” Fletcher-Haynes. *Verdegaal Bros. v. Union Oil Co. of Cal.*, 814 F.2d 628, 631 (Fed. Cir. 1987). Petitioner has failed to do so.

**1. Ground I impermissibly relies on duplicative expert analysis that lacks any rationale or support for Petitioner's conclusory statements.**

Petitioner has not met its burden of establishing it is more likely than not that it will prevail with respect to any challenged claim in Ground I. The Petition does not sufficiently demonstrate that Fletcher-Haynes discloses—expressly or inherently—any challenged claim. The Petition relies almost exclusively on the expert declaration of Fletcher (EX1003) to support what is described in Fletcher-Haynes and what a POSITA would have found obvious based on its teachings. Fletcher's declaration, however, is nearly identical to the Petition and repeats the analysis provided in the Petition, adding no independent reasoning or technical insight.

Such conclusory repetition cannot substitute for substantive analysis and should be given no weight. Indeed, nearly the *entirety* of Ground 1 is *identical* to the Petition. *Compare* Pet. at 19-40 *with* EX1003 ¶¶71-123. In fact, the Petition and Fletcher's declaration are word-for-word duplicates and even reproduce the same quotation emphases, annotated images, and typographical errors. *E.g., compare* Pet. at 20, 31 *with* EX1003 ¶¶71, 97 (same emphases); Pet. at 21 *with* EX1003 ¶74 (same annotated figure without notation of annotation); Pet. at 20 *with* EX1003 ¶72 (extra quotation marks); Pet. at 26 *with* EX1003 ¶ 80 (mistaken period instead of comma);

Pet. at 33 *with* EX1003 ¶¶100, 101 (extra section symbol). The *only* difference between the Petition and Fletcher's declaration in Ground I are the footnotes.

Despite the facially apparent overlap, Petitioner repeatedly cites Fletcher's declaration for what a POSITA would have understood based on the teachings of Fletcher-Haynes. Pet. at 19-40 ("The sections below, as supported by Fletcher's Declaration, demonstrate how the claims are unpatentable"). Because Fletcher's declaration adds nothing beyond the Petition, Petitioner has failed to demonstrate how a POSITA would have understood the teachings of Fletcher-Haynes nor why a POSITA would have found Fletcher-Haynes anticipatory. As the Board has held, denial of institution is appropriate where, as here, the expert's declaration "is an exact restatement of the Petition's arguments without any additional supporting evidence or reasoning." *Xerox Corp. v. Bytemark, Inc.*, IPR2022-00624, Paper 12 at 4 (Feb. 10, 2023) (affirming denial of institution and designating that decision precedential).

Given these deficiencies, the Petition offers nothing more than conclusory, repetitive assertions masquerading as expert analysis. Based on this reason alone, Petitioner has failed to carry its burden of demonstrating that Fletcher-Haynes

anticipates the challenged claims.<sup>3</sup> *Xerox*, IPR2022-00624, Paper 12 at 5 (“the Board was correct in giving little weight to Petitioner’s expert because the expert declaration merely offered conclusory assertions without underlying factual support and repeated, *verbatim*, Petitioner’s conclusory arguments”) (emphasis in original).

Petitioner has not made the requisite showing it is more likely than not Petitioner will prevail with regard to at least one claim where the Petition and Fletcher’s declaration together amount to little more than a single, unsupported narrative. Institution should be denied.

2. **Limitation 8[c]<sup>4</sup>: 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<sup>5</sup>**

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<sup>3</sup> This repetition permeates the entirety of the Petition and, as such, denial of institution is warranted.

<sup>4</sup> Limitation 23[c] is identical and Petitioner merely points back to its analysis regarding limitation 8[c] for that limitation. Pet. at 37. As such, Petitioner has failed to establish a likelihood of invalidating claim 23.

<sup>5</sup> Petitioner challenges this claim term as being indefinite. Part VI.F.2 addresses why claim 8 is not indefinite.

Petitioner asserts Fletcher-Haynes anticipates this limitation, based on its disclosure of inlet pump 26, which allegedly “‘maintain[s] [the] flow’ of whole blood from the donor to the blood component separation device through the first line.” Pet. at 24. But Petitioner’s analysis stops there.

Critically, Petitioner fails to explain how inlet pump 26 of Fletcher-Haynes controls the flow through the first line as claimed, i.e., the flow associated with both transporting whole blood to the separation device and returning fluid from the separation device back to the donor. Claim 8 expressly recites a single “first line” performing both functions, and Petitioner bears the burden to show the cited pump controls flow through that line as configured.

The Petition identifies inlet pump 26 only in the context of maintaining draw flow. It does not allege—let alone explain—how inlet pump 26 controls flow during the return phase, when fluid is returned from the separation device to the donor. Nor does Petitioner point to any disclosure in Fletcher-Haynes establishing that inlet pump 26, as opposed to other system components, controls flow through the donor line during both operational states.

At minimum, Petitioner’s anticipation theory leaves a material gap in its mapping of limitation 8[c]. Where, as here, the Petition fails to articulate how a cited reference satisfies an express claim requirement, Petitioner has not met its burden on institution.

**3. Limitation 8[f]<sup>6</sup>: 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**

Petitioner's argument concerning limitation 8[f] consists almost entirely of reproducing equations from Fletcher-Haynes, with little to no analysis of what those equations mean, the variables included therein, how they interrelate, or how a POSITA would have interpreted them—just conclusory assertions that those equations disclose a “target plasma amount.” *See* Pet. at 27-28. Petitioner does not even cite Fletcher-Haynes in support of these equations, instead relying exclusively on Fletcher's declaration, which itself is a verbatim recitation of the Petition, without citation to Fletcher-Haynes. *Id.*; EX1003 ¶¶82-86.

Petitioner rests its argument regarding plasma volume on two equations: (1) an alleged “target volume for pure plasma ( $V_{SP}$ ),” and; (2) an alleged “target volume for plasma product ( $V_{SPB}$ ).” Pet. at 26. Regarding the volume of plasma product, Petitioner reproduced an equation from Fletcher-Haynes:  $V_{SPB} = V_{SP}(1+f_{ACP})$

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<sup>6</sup> Limitations 1[b], 15[c], and 23[g] are substantively similar to limitation 8[f] and Petitioner merely points back to its analysis regarding limitation 8[f] for those limitations. Pet. at 32-33, 38, 43-44. As such, Petitioner has failed to establish a likelihood of invalidating the other independent claims (claims 1, 15, and 23).

without explaining how this equation relates to the claimed requirement that the target volume be based on “the donor’s total blood volume and a hematocrit of the donor.” Pet. at 28. This equation does not facially support that Fletcher-Haynes teaches determining the volume of plasma product is based, in any part, on the donor’s total blood volume and donor hematocrit. Indeed, after reproducing this equation, Petitioner merely observes “ $V_{SPB}$  is a sum of volume of pure plasma ( $V_{SP}$ ) and volume of added anticoagulant ( $V_{SP} * f_{ACP}$ ).” *Id.* That does not establish that the calculation is based, in any part, on donor total blood volume or hematocrit as required by limitation 8[f].

Notably Petitioner cites no portion of Fletcher-Haynes itself explaining that  $V_{SPB}$  represents a target value for plasma collection, nor that it is derived from donor total blood volume and hematocrit. Instead, Petitioner relies exclusively on Fletcher’s declaration, which, as with the rest of the Petition, repeats the same equations and assertions without further analysis or reasoning. *Id.*; EX1003 ¶86. Such repetition does not cure the Petition’s failure to connect the cited math to the claim language.

Regarding the target volume for pure plasma, Petitioner argues: “Fletcher-Haynes calculates a target volume of pure plasma ( $V_{SP}$ ) using the total blood volume.” Pet. at 27 (citing EX1003 ¶85 (repeating this statement verbatim)). But this assertion suffers from multiple independent defects.

First, Petitioner fails to explain how the purported  $V_{SP}$  calculation is based, even in part, on donor hematocrit, as limitation 8[f] requires. The referenced equations do not utilize hematocrit as a variable, and the Petition does not identify where or how hematocrit meaningfully enters the determination of a target plasma amount. Pet. at 27-28.

Second, Fletcher-Haynes discloses “four choices” for calculating what it calls “source plasma volume,” only one of which includes total blood volume as a variable. EX1005, 50:55-62. Each of these choices calculates source plasma volume based on source platelet volume ( $V_C$ ), underscoring that plasma volume in Fletcher-Haynes is derivative of platelet-focused calculations and not an independently selected plasma collection target.

Neither Petitioner nor Fletcher explain when any choice in Fletcher-Haynes is used, why the total blood volume-based option would be selected, or why a POSITA would understand these calculations to define a target plasma collection amount.

Petitioner's ultimate rationale, that the disclosed plasma volumes are “target values because Fletcher-Haynes can run the prediction model before the collection procedure is actually initiated” rests on a fundamental misreading of Fletcher-Haynes. Pet. at 28 (citing EX1005, 53:36-38); EX1003 ¶ 87.

Fletcher-Haynes distinguishes between a prediction model that estimates expected component yields before a collection procedure begins, and an optimization model, which determines optimized process parameters for achieving a desired collection goal. *Id.* at 48:1-3; 9:20-27; Figs. 9B-9C. The equations on which Petitioner rely come from the prediction model, including source plasma volume. *Id.*, 49:19-26. These equations are used to estimate anticipated yields, not to define target plasma collection amounts as the claim requires.

Fletcher-Haynes' optimization model applies to platelet yield, not plasma yield, and plasma calculations are merely derivative of platelet-centric prediction models. Neither the Petition nor Fletcher explains why an estimated plasma volume produced as part of a platelet-focused prediction model should be understood by a POSITA as a target volume for plasma as the claim requires.

Because Petitioner fails to show that Fletcher-Haynes determines a target plasma volume based on donor total blood volume and hematocrit, it has not carried its burden to establish that Fletcher-Haynes anticipates limitation 8[f].

**4. Limitation 8[h]<sup>7</sup>: the target plasma amount to collect tailored to the donor**

Petitioner's analysis regarding this limitation is conclusory and unsubstantiated. Petitioner points to a passage in Fletcher-Haynes which explains that donors have "differing physiologies" and baselessly concludes that Fletcher-Haynes, therefore, "calculate[es] 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." Pet. at 29. This unsupported leap is repeated verbatim by Fletcher without additional analysis and is insufficient to demonstrate that Fletcher-Haynes anticipates this limitation.

The fact that donors differ physiologically does not, by itself, establish that Fletcher-Haynes determines a *target plasma amount to collect* that is tailored to the

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<sup>7</sup> Limitations 1[b], 15[c], and 23[g] are substantively similar to limitation 8[h] and Petitioner merely points back to its analysis regarding claim 8 for those limitations. Pet. at 32-33, 38, 43-44. In fact, Petitioner fails to even tie limitations 1[b], 15[c], and 23[g] to limitation 8[h] and, instead, only references limitation 8[f] which does not include that the target plasma amount is tailored to a donor. Thus, Petitioner has failed to establish a likelihood of invalidating the other independent claims (claims 1, 15, and 23).

donor, as claim 8 requires. The question is not whether donor characteristics are known or input into a system, but whether the plasma collection amount itself is individualized, i.e., selected or adjusted based on donor-specific parameters.

Petitioner never explains how Fletcher-Haynes performs such tailoring. In particular, Petitioner fails to meaningfully analyze the specific plasma-related equations on which it relies— $V_{SP}$  or  $V_{SPB}$ —or explain how those equations (i.e., EX1005, Eq. 17, Eq. 2) result in a donor-tailored plasma collection target. Pet. at 29.

As set forth regarding limitation 8[f], Fletcher-Haynes' plasma volume calculations are derivative of platelet-focused modeling. The relevant equations calculate estimated plasma volumes as a function of platelet collection parameters ( $V_C$ ), not as independently tailored plasma targets based on donor characteristics. These equations do not facially support that either  $V_{SP}$  or  $V_{SPB}$  tailors a target amount of plasma to collect to the donor using any of height, weight, gender, or hematocrit. Nothing in Fletcher-Haynes indicates that these calculated plasma volumes represent individualized decisions about how much plasma should be collected from a donor.

Nor does Petitioner identify any disclosure in Fletcher-Haynes describing the selection, adjustment, or optimization of a plasma collection amount based on donor-specific criteria such as height, weight, gender, or hematocrit. Instead,

Petitioner relies on a generalized statement about donor variability and assumes—without analysis—that this variability translates into donor-tailored plasma collection targets. Fletcher's declaration merely repeats this assumption verbatim, without additional reasoning or citation. EX1003 ¶¶89.

Absent evidence that Fletcher-Haynes determines a plasma collection amount that is tailored to a donor—rather than incidentally estimated as part of a platelet-centric prediction model—Petitioner has not shown that Fletcher-Haynes discloses limitation 8[h]. Accordingly, Petitioner has failed to establish it is more likely than not to prevail on anticipation of claim 8 with respect to this limitation.

**B. Grounds II-IV: Petitioner Has Failed to Show How Fletcher-Haynes in View of Lavender and/or Neyrinck Renders the Challenged Claims Obvious.**

The same deficiencies that doom Ground I permeate Grounds II-IV. In each Ground, Petitioner again relies on substantially identical, cut-and-paste analysis and conclusory expert testimony—this time attempting to combine Fletcher-Haynes with Lavender and/or Neyrinck to fill the gaps in Fletcher-Haynes' disclosure.

Yet Petitioner never adequately explains *why* a POSITA would have been motivated to modify Fletcher-Haynes' system in the manner proposed, *how* the disparate teachings of the references would have been coherently integrated into Fletcher-Haynes' system, or *why* a POSITA would have reasonably expected success in doing so. Instead, Petitioner simply works backward from the challenged

claims, selectively retrofitting isolated teachings from Lavender and Neyrinck into Fletcher-Haynes' disclosed system until the resulting, reconstructed system resembles the claims. This hindsight-driven approach cannot satisfy Petitioner's burden under 35 U.S.C. § 324(a).

As with Ground I, the Petition repeatedly cites Fletcher's declaration which, for Grounds II-IV, remains substantively indistinguishable from the Petition itself. The declaration does not provide independent technical analysis, explain how the proposed combinations would function in practice, or address incompatibilities between the references. Rather, it simply repeats the Petition's assertions verbatim, without additional reasoning or evidentiary support.

That approach is legally insufficient. The Petition offers nothing more than conclusory, repetitive assertions masquerading as expert analysis, which cannot support an obviousness determination. Based on this reason alone, Petitioner has failed to carry its burden of demonstrating that Fletcher-Haynes in view of Lavender and/or Neyrinck renders obvious the challenged claims. *TQ Delta, LLC v. CISCO Sys., Inc.*, 942 F.3d 1352, 1359 (Fed. Cir. 2019) ("This court's opinions have repeatedly recognized that conclusory expert testimony is inadequate to support an obviousness determination[.]"); *Xerox*, IPR2022-00624, Paper 12 at 5 ("the Board was correct in giving little weight to Petitioner's expert because the expert

declaration merely offered conclusory assertions without underlying factual support and repeated, *verbatim*, Petitioner's conclusory arguments") (emphasis in original).

Because Petitioner fails to articulate specific reasoning, grounded in record evidence, to support its proposed combinations, it has not carried its burden to show that Fletcher-Haynes in view of Lavender and/or Neyrinck renders the challenged claims obvious. *TQ Delta*, 942 F.3d at 1359; *see also KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007) ("Rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness."). As such, institution as to Grounds II-IV should be denied.

**1. Petitioner fails to articulate a sufficient motivation to combine Fletcher-Haynes and Lavender (Ground II).**

To establish a motivation to combine two or more references, Petitioner must provide at least "some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn*, 441 F.3d at 988. The Petition and Fletcher's declaration are devoid of fulsome rationale explaining why a POSITA would have been motivated to combine Fletcher-Haynes with Lavender, or why a POSITA would have had a reasonable expectation of success in that combination. When the conclusory language is stripped away, little substance remains for Patent Owner or the Board to address.

The entirety of Petitioner's motivation to combine argument is repeated, *verbatim*, by Fletcher. Pet. at 40-43; EX1003 ¶¶124-131. Fletcher fails to provide any additional, independent, technical explanation, rationale, or reasoning as to what a POSITA would have known from the references, why a POSITA would seek to modify Fletcher-Haynes, or what result would be expected. Nonetheless, Petitioner repeatedly cites Fletcher's declaration as support for what a POSITA would have found obvious and been motivated to do. Pet. at 40-43.

Petitioner's motivation to combine argument is simply a recitation of similarities between the disclosures of Fletcher-Haynes and Lavender. Nowhere does Petitioner offer a reason why a POSITA would want to modify the teachings of Fletcher-Haynes, let alone any suggestion of that modification in Fletcher-Haynes' or Lavender's disclosure. Petitioner also fails to explain the likely outcome of the combination or why a POSITA would have reasonably expected success in combining the disclosed systems.

Moreover, Petitioner's motivation theory is internally inconsistent and is undermined by its own characterization of the prior art. Petitioner asserts that Lavender's "Main Loop" supplies functionality allegedly missing from Fletcher-Haynes, such as calculating a target volume before the procedure, monitoring plasma volume during collection, and stopping the procedure when a plasma limit is reached. Pet. at 41.

In the same breath, Petitioner contends that Fletcher-Haynes already performs these very functions. *Id.* If Fletcher-Haynes already calculates target volumes, monitors collection status, and stops at a plasma volume limit, Petitioner offers no explanation why a POSITA would have sought to modify Fletcher-Haynes by importing Lavender's Main Loop. A proposed modification that adds no new functionality cannot supply a motivation to combine.<sup>8</sup>

This contradiction highlights the hindsight-driven nature of Petitioner's analysis: Lavender is invoked not because a POSITA would have been motivated to combine the references, but because Petitioner needs Lavender to force Fletcher-Haynes to resemble the claimed invention.

Thus, Petitioner's suggestion that Fletcher-Haynes and Lavender be combined in this way is insufficient to support a motivation to combine argument, which must explain why a POSITA would be motivated to make this combination. *InTouch Techs. v. VGO Commc'ns, Inc.*, 751 F.3d 1327, 1352 (Fed. Cir. 2014);

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<sup>8</sup> Petitioner's analysis includes over a page of argument that Fletcher-Haynes' and Lavender's equations can be rewritten and broken into the same equations. Pet. at 42-43. This argument has no bearing on the motivation to combine as a POSITA would not be motivated to rewrite and transpose these equations to prove they line up when looking simply to implement Main Loop code from Lavender's system.

*ActiveVideo Networks, Inc. v. Verizon Commc'ns, Inc.*, 694 F.3d 1312, 1327 (Fed. Cir. 2012) (petitioners must explain “why a person of ordinary skill in the art would have combined elements from specific references in the way the claimed invention does”); *Personal Web Techs., LLC v. Apple, Inc.*, 848 F.3d 987, 994 (Fed. Cir. 2017). At base, Petitioner and Fletcher fail to explain: (1) *why* a POSITA would be motivated to combine Lavender's Main Loop with Fletcher-Haynes' teachings; (2) *how* either reference teaches or suggests a reason for this combination; or (3) *how* the proposed combined system would operate consistently with Fletcher-Haynes' design.

Equally important, Petitioner also fails to establish that a POSITA would have had a reasonable expectation of success in combining Fletcher-Haynes and Lavender. While Petitioner repeats the conclusion that a POSITA would have had a reasonable expectation of success in the proposed combination, the Petition is devoid of any analysis, evidence, or explanation as to why the proposed combination would have functioned as intended or produced predictable results. Instead, Petitioner assumes—without support—that the two distinct systems could simply be merged and operate harmoniously. Fletcher likewise provides no discussion of technical compatibility, implementation challenges, or feasibility, as his motivation to combine section simply copies the Petition.

Because Petitioner fails to articulate a non-hindsight motivation to combine Fletcher-Haynes and Lavender, explain how the proposed combination would be implemented, and establish a reasonable expectation of success, it has not established it is more likely than not that the challenged claims in Ground II are obvious over Fletcher-Haynes in view of Lavender. Institution should be denied.

**2. Petitioner fails to articulate a sufficient motivation to combine Fletcher-Haynes and Neyrinck (Ground III).**

Petitioner's purported motivation to combine in Ground III is legally and factually deficient. Here, Petitioner seeks to modify Fletcher-Haynes by substituting its disclosed TBV calculation—based on Nadler's formula—with a TBV calculation utilizing donor body mass index (BMI) drawn from Neyrinck. Pet. at 52-54. Neither the Petition nor Fletcher's declaration explains why a POSITA would have been motivated to make that substitution or why a POSITA would have reasonably expected success in doing so. *Id.*; EX1003 ¶¶155-159.

Petitioner's approach to this combination is pure hindsight and transparently results-driven. Recognizing that Fletcher-Haynes' equations do not utilize BMI as a variable as claimed, Petitioner located a reference that utilizes BMI in one equation and asserts, without support, that a POSITA would simply replace Fletcher-Haynes' TBV equation with Neyrinck's BMI-based approach. Pet. at 52-

54. Petitioner's arguments, however, stop there. Petitioner points to no teachings in Fletcher-Haynes or Neyrinck for this suggested modification, and there are none.

To the contrary, both Fletcher-Haynes and Neyrinck teach calculating donor TBV using Nadler's formula. EX1005, Eq. 10; EX1006, 39; Pet. at 53. As Petitioner notes, Nadler's formula is used by Fletcher-Haynes to "calculate a customized target plasma collection volume." Pet. at 53. Likewise, Neyrinck teaches "various formulas to calculate a more accurate TBV are used," including "[w]ell known Nadler's formula" which is used by "most apheresis equipment." EX1006, 39. Thus, it makes sense that Fletcher-Haynes' disclosures incorporate this well-known formula. *See also* EX1001, Cover, p.3 (disclosing Nadler's formula in the prior art).

Neyrinck further explains that Nadler's formula is useful "to calculate a more accurate TBV" because it "is complicated, taking into account the height, weight, and gender of a person." EX1006, 39. Although Neyrinck later lists alternative methods, including a "last calculation method" including BMI, it does not describe that method as better, more accurate, or preferable to Nadler's formula that utilizes height, weight, and gender.

Despite the references' express reliance on Nadler's formula, Petitioner concludes, without analysis or expert support, that a POSITA would have "been motivated to use a more accurate equation to calculate total blood volume." Pet. at 53. Neyrinck itself never suggests that TBV based on BMI is "more accurate" than

Nadler's formula and, in fact, specifically teaches that Nadler's formula is more complex, utilizes weight and height like a BMI-based calculation, and is more frequently used in apheresis systems. EX1006, 39.

Fletcher provides no further analysis or explanation for why a POSITA would have viewed the BMI-based approach as more accurate, more individualized, or more suitable for Fletcher-Haynes' system. His declaration merely repeats the conclusory and unsupported allegations in the Petition. EX1003 ¶¶155-159. Such conclusory testimony cannot supply the required motivation to combine.

Petitioner likewise fails to establish that a POSITA would have reasonably expected success in substituting Neyrinck's BMI-based TBV calculation into Fletcher-Haynes' system. Petitioner provides no analysis explaining how replacing a core TBV calculation—used to derive downstream plasma-related values—would affect Fletcher-Haynes' prediction and control algorithms, or whether such a substitution would preserve the system's intended operation. The absence of any discussion of compatibility, implementation, or impact on Fletcher-Haynes' disclosed architecture underscores the speculative nature of Petitioner's proposed modification.

Because Petitioner failed to provide a sufficient rationale and motivation to combine Fletcher-Haynes and Neyrinck, and failed to establish a reasonable expectation of success, Petitioner has not met its burden under 35 U.S.C. § 324(a).

**3. Petitioner fails to articulate a sufficient motivation to combine Fletcher-Haynes with Lavender and Neyrinck (Ground IV).**

Petitioner proposes combining Fletcher-Haynes with Lavender and Neyrinck to render obvious claim 2 in Ground IV. Pet. at 56-58. This proposed three-reference combination merely repackages the same unsupported rationales advanced in Grounds II and III and, therefore, fails for the same reasons.

Ground IV relies on the same alleged modifications previously asserted: incorporation of Lavender's Main Loop and substitution of Neyrinck's BMI-based TBV calculation into Fletcher-Haynes' system. *Id.* Petitioner offers no additional motivation to combine these references beyond what was already asserted (and unsupported) in Grounds II and III, nor does it identify any teaching in the references suggesting that these distinct modifications should be implemented in tandem.

Layering two defective motivation-to-combine theories does not cure either deficiency. Where Petitioner fails to establish a motivation to combine Fletcher-Haynes with Lavender, and separately fails to establish a motivation to combine Fletcher-Haynes with Neyrinck, it necessarily fails to establish a motivation to combine all three references together. Ground IV presents no reasoning or evidence that would change that analysis.

Petitioner likewise fails to establish that a POSITA would have had a reasonable expectation of success in implementing both modifications simultaneously. Petitioner provides no explanation of how Lavender's control logic and Neyrinck's BMI-based calculation would be integrated into Fletcher-Haynes' architecture, nor any discussion of compatibility, feasibility, or predictable operation of the resulting system. Again, Fletcher's declaration fails to provide any expert analysis and merely repeats the entirety of Ground IV. EX1003 ¶¶166-170. Institution should be denied.

**C. Relevant Objective Indicia of Non-Obviousness Refutes Petitioner's Obviousness Arguments.**

While the Board need not consider secondary considerations of non-obviousness to deny institution, the objective indicia of non-obviousness surrounding the '204 Patent is compelling and independently confirms that the challenged claims are not obvious. "Evidence of objective indicia of non-obviousness, if present, must always be considered before reaching a determination on the issue of obviousness." *Quanergy Sys., Inc. v. Velodyne Lidar USA, Inc.*, 24 F.4th 1406, 1417 (Fed. Cir. 2022). Patent Owner put Petitioner on notice of evidence of secondary considerations in the parallel district court litigation prior to filing of the Petition. Specifically, in Patent Owner's briefing regarding Petitioner's motion to dismiss filed on September 23, 2025, Patent Owner described its covered

products and the commercial success thereof. Nevertheless, Petitioner failed to address this “known evidence of secondary considerations [which] should be addressed in the Petition.” *Robert Bosch Tool Corp. v. SD3, LLC*, IPR2016-01753, Paper 15 at 28 (Mar. 22, 2017).

Patent Owner's NexSys<sup>®</sup> PCS systems with YES<sup>®</sup> and PERSONA<sup>®</sup> technology (“NexSys Systems”) are coextensive with the challenged claims. Additionally, the NexSys Systems: (1) achieved significant commercial success; (2) met a long-felt, unmet need in the plasma collection industry that others failed to solve; (3) overcame skepticism prior to their release; (4) received widespread industry praise post-release; and (5) have been copied by the only two competitors in the industry, including Petitioner.

**1. A nexus exists between the NexSys Systems and the '204 Patent challenged claims.**

The NexSys System is “[a] system for collecting plasma” that performs the claimed method. EX1001, cls. 8, 23. Patent Owner's system includes:

- (a) a venous-access device for drawing whole blood from a donor and returning blood components to the donor;
- (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;

- (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;
- (d) an anticoagulant line connected to an anticoagulant source, the anticoagulant line configured to introduce anticoagulant into the drawn whole blood; and
- (e) 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.

*Id.*, cl. 8; *see* EX2007 (describing the NexSys System); <https://plasma.haemonetics.com/device-solutions>. Indeed, the NexSys System “is essentially the claimed invention.” *Quanergy Sys.*, 24 F.4th at 1417-18.

Accordingly, a nexus between all evidence of non-obviousness and the claimed invention is presumed. *See Polaris Indus., Inc. v. Artic Cat, Inc.*, 882 F.3d 1056, 1072 (Fed. Cir. 2018). “The coextensive requirement does not require a patentee to prove perfect correspondence between the product and a patent claim.” *Quanergy Sys.*, 24 F.4th at 1417-18.

## **2. The NexSys Systems were commercially successful.**

Patent Owner released two versions of its NexSys System, in 2018 and 2020, respectively. EX2008 ¶¶16, 20. The 2018 device included Patent Owner's patented

YES<sup>®</sup> technology and the 2020 system further included Patent Owner's PERSONA<sup>®</sup> technology. *Id.* Both systems have revolutionized the plasma collection industry and Patent Owner remains the industry leader. *Id.* ¶¶13-15.

By utilizing the system components and functionality claimed in the '204 Patent, the NexSys Systems achieve higher plasma collection volumes per donation, on average, and optimize collections by targeting *pure plasma* yield, instead of the preexisting focus on only total collection volume (including plasma and anticoagulant) like prior systems. For example, a study performed in 2020 concluded that the NexSys System increased plasma yield by more than 26 mL per donation. *Id.* ¶21. At commercial scale, the 26 mL plasma yield increase per donation has resulted in hundreds of thousands of liters of additional plasma collected—an extraordinary improvement in both efficiency and output.

The plasma collection industry has overwhelmingly adopted the NexSys Systems, which have been utilized in collection centers across the country. Evidence of commercial success is, therefore, evident based on the widespread adoption of, and demand for, Patent Owner's systems. Moreover, key players in the plasma collection industry have affirmed the success of the NexSys System. *See, e.g.,* EX2009-2011.

**3. The NexSys Systems met a long-felt need in the plasma industry.**

As the '204 Patent indicates, preexisting plasmapheresis systems relied on FDA limits and were “unable to determine the total volume of plasma that has been collected (e.g., because the product collected is a mixture of plasma and anticoagulant) and, therefore collect based on the total collection volume, even if the total volume of plasma that has been collected is below the limit prescribed by the FDA.” EX1001, 1:60-65; EX1007. In accordance with the 1992 FDA Guidance, plasma collection companies followed a simplified nomogram that involved: (1) determining which one of three weight ranges a donor fell into; and (2) collecting the identified “Collection Volume” from that donor (consisting of both pure blood plasma and anticoagulant). EX1007. This “simplified” nomogram is described in the 1992 FDA Guidelines shown below:

To promote rapid implementation of such simplified schema, the Center for Biologics Evaluation and Research is informing all manufacturers that the following limits may be adopted without further notice. The anticoagulant volume is included in the third column below. This volume is based on a 1:16 (0.06) ratio of anticoagulant to anticoagulated-blood.

Donor Weight	Plasma Volume or Weight	Collection Volume
10-149 lbs	625 mL (640 g)	690 mL (705 g)
150-174 lbs	750 mL (770 g)	825 mL (845 g)
175 lbs & up	800 mL (820 g)	880 mL (900 g)

*Id.* For nearly three decades, plasma collections followed this outdated guidance and plasma collection companies targeted the “Collection Volume” (plasma and anticoagulant) because it was easier to measure. While the FDA acknowledged there was a safe amount of plasma-only volume that could be collected, the industry lacked the capability to accurately target and identify the *pure plasma* volume. As a result, donors were grouped into weight categories that were not indicative of the real amount of pure plasma that could be safely and efficiently collected from a donor. The industry long-sought a method to determine plasma collection on a per-donor basis, considering the donor’s individual characteristics, like height, weight, hematocrit, and blood volume.

At the same time, the industry faced mounting pressure to increase plasma yields to meet the growing demand for life-saving medical treatments. Donated plasma is indispensable for treating immune deficiencies, bleeding disorders like hemophilia, and severe burns or trauma. It is also a critical component in therapies for rare chronic diseases where patients rely on plasma-derived therapies for survival and quality of life. Since plasma cannot be manufactured synthetically, consistent donation is the only way to ensure a reliable supply, making plasma collection an essential part of modern medicine and global healthcare systems. Over time, demand for plasma has only continued to rise. In 1990, Petitioner’s reference, Lavender, acknowledged:

In the plasma harvesting art, there has been a long felt need to provide an easier, safer, more economical method of harvesting plasma than that which is commercially available. There has been a significant amount of money both from the private sector and from the government dedicated to finding solutions to the problem, but as of yet there has been no satisfactory solution.

EX1004, 11:23-29. Thirty years later, Petitioner itself reiterated this notion, “[t]here is a huge unmet need for plasma-derived therapies[.]” EX2011. The NexSys System filled this decades-long need that the industry failed to solve by providing a solution that allows for an optimized, safe, and donor-specific higher-yield plasma collection.

**4. The plasma collection industry was skeptical of the NexSys Systems and patented method.**

Prior to releasing the NexSys Systems, Patent Owner had to seek FDA clearance. In doing so, Patent Owner faced widespread skepticism. Those familiar with the plasma collection industry and FDA-approval process did not find it likely that (a) the targeted, individualized nomogram would actually work; or (b) the FDA would ever approve such a narrowly-tailored nomogram (as opposed to the preexisting simplified FDA-approved nomogram).

The skepticism was directed precisely at the claimed invention—targeting *pure plasma* on an individual donor-by-donor basis—that others in the industry found unlikely. These are the very nomograms embodied by the NexSys Systems and covered by the '204 Patent claims. Despite this general skepticism and

regulatory uncertainty, Patent Owner successfully obtained FDA clearance for its NexSys Systems with YES<sup>®</sup> and PERSONA<sup>®</sup> technology and currently employs those systems in plasma collection centers throughout the U.S., demonstrating both the viability and innovation of the claimed invention.

**5. The NexSys Systems have received industry praise.**

Following FDA clearance and release of its NexSys Systems, Patent Owner received widespread praise for its patented technology. For example, in 2021, the President and CEO of ADMA stated: “The implementation of Persona<sup>®</sup> technology and the opening of ADMA’s newest plasma collection center directly advances the Company’s near term and ongoing strategic objectives.” EX2007. He acknowledged that the NexSys Systems provided an “anticipated yield enhancement resulting from Persona<sup>®</sup> implementation.” *Id.*

As another example, in 2021 Patent Owner’s results of its plasma yield trial with this patented technology were peer reviewed and published in the TRANSFUSION journal for medical research. EX2010. “The trial . . . demonstrated a yield increase of +8.2% more plasma per collection on average as compared to the control, based on the donor population in the trial.” *Id.* This per-donor plasma yield increase is crucial given “approximately 750,000 people across Europe and North America rely on plasma for life-saving therapies and it can take hundreds of plasma donations to treat a single patient.” *Id.*

**6. Patent Owner's two competitors in the plasma collection industry have copied the NexSys Systems.**

The plasma industry is small and only three companies provide the vast majority of plasmapheresis systems in the U.S.: (1) Patent Owner; (2) Petitioner; and (3) Fresenius Kabi/Fenwal. Patent Owner was the first to file patents covering its innovative system and the first to release a commercialized version practicing those patents (including the '204 Patent). Both Petitioner and Fresenius Kabi/Fenwal were quick to follow, releasing very similar systems to the NexSys System in recent years.

In 2022, Petitioner was given FDA clearance for its Rika Plasma Donation System with Nomogram A which was first used in a plasma collection center just a few months later. EX2012. Petitioner's newest Rika Plasma System with iNomi Nomogram received FDA clearance in 2024. EX2014. Patent Owner has accused both systems of infringing the '204 Patent in the co-pending district court litigation. *Haemonetics Corp. v. Terumo BCT, Inc.*, No. 1:25-cv-01409 (D. Colo. May 5, 2025). Recognizing the similarities between its systems and the NexSys Systems, Petitioner cites to the NexSys Systems in its 510(k) summaries as the "Reference Device." EX2013; EX2014.

Petitioner informed its investors of the similarities between its Rika System and Patent Owner's NexSys Systems. At the May 15, 2023 financial results

briefing, investors referenced the Patent Owner's patented technology and "hope[d] [Petitioner] will be able to exceed or equal Haemonetics' yield." EX2015. The

President and CEO of Petitioner responded:

We expect to see similar gains compared to Haemonetics. RIKA has generated 30% improvement fundamental technology, and **this Nomogram software change will do the same thing as Persona device**, in terms of locating individual variables, optimize the collection from those individuals.

*Id.* (emphasis added) (also noting that Petitioner's Rika System is "a very similar model" to the NexSys System).

Patent Owner's other competitor, Fresenius Kabi/Fenwal, received FDA clearance for its Aurora Xi System with an "Adaptive Nomogram" on January 28, 2025. EX2016. Just like the NexSys Systems, the Aurora Xi System considers individual donor characteristics to determine the correct total amount of pure plasma to be collected.

The foregoing evidence of secondary considerations is exemplary and, should the Board decide to institute the Petition, Patent Owner reserves the right to put forth additional objective evidence of non-obviousness. Overall, objective evidence of secondary considerations here—including commercial success, long-felt but unmet need, industry skepticism, industry praise, and copying—support the validity of the challenged claims.

**D. Ground V: The Challenged Claims are Not Invalid Under 35 U.S.C. § 101.**

The challenged claims are directed to improved plasmapheresis machines that withdraw blood from a donor, separate plasma from red blood cells, determine a safe and optimized target of plasma to be collected from an individual donor, return red blood cells back to the donor, and continue the collection process until that target is reached. None of these steps, nor the machines themselves, can be considered abstract. The claims are not invalid pursuant to Section 101 and the Petition should not be instituted on that basis.

After decades of development in the plasma apheresis industry, Patent Owner invented an improved plasma collection system that allows for safe, efficient, and higher plasma collection yields on average than preexisting systems. The plasma collection industry was hamstrung by reliance on outdated FDA guidelines focused on total collection volume (plasma and anticoagulant combined) and failed to realize the amount of plasma that could safely be collected could be optimized in a unique way. Accordingly, these preexisting machines were inefficient. Patent Owner's patented invention revolutionized the performance of these machines. The entire plasma collection industry followed.

Petitioner mischaracterizes the patented invention to cast it as conventional. In doing so, Petitioner oversimplifies these machines to support two false premises

under *Alice*: (1) despite being system claims, the challenged claims are only directed to mathematical equations that can be performed by a technician; and (2) all the claimed components and elements were conventional and known in the industry. Both arguments are wrong.

“Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor.” 35 U.S.C. § 101. While laws of nature, natural phenomena, and abstract ideas are not patentable, “[a]t some level, all inventions . . . embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas.” *Alice Corp. Pty. Ltd. v. CLS Bank Int’l*, 573 U.S. 208, 217 (2014). A patented invention is, therefore, not ineligible merely for involving a potentially abstract concept, such as a mathematical formula. *Id.* Courts have recognized that “applications” of abstract ideas “to a new and useful end” are patent eligible. *Id.*

**1. The challenged claims recite improvements to plasmapheresis machines.**

As the specification explains, prior art plasmapheresis devices “follow[ed] the current FDA nomogram for plasma collection [and] collect a volume of plasma product (e.g., anticoagulant and plasma mixed together) based solely on donor weight—the same volume is collected from every donor at the same weight. However, the total blood volume and plasma volume for two donors may vary

greatly.” EX1001, 17:4-10. Additionally, “donors with high hematocrit will have lower plasma volume” and preexisting systems failed to tailor pure plasma collection to specific donor characteristics, such as hematocrit. *Id.*, 17:15-29.

Not only does the specification discuss the specific improvements made to preexisting plasma collection systems, which are embodied in Patent Owner's NexSys Systems, but these exact improvements are recited in the patent claims. For example, independent claims 1, 8, 15, and 23 recite determining a target plasma amount to collect that is tailored to the donor, which is an improvement over the preexisting approach of only targeting total collection volume based on a range of donor weights. The challenged claims rely on individual donor characteristics, including total blood volume and hematocrit, which are used to determine the target plasma volume to be collected from a specific donor. These improvements combine to form an improved plasmapheresis machine. The improved machine is more efficient than preexisting plasmapheresis machines in that it results, on average, in a higher yield of plasma per donation while remaining safe for the donor. EX2008 ¶21; EX1001, 17:5-14.

Petitioner overgeneralizes these improvements and characterizes the individual elements of the challenged claims as basic hardware components and calculations that could be performed by a technician. Pet. at 59-72. The patented system, however, is not so simple. Each claim element cannot be viewed in a

vacuum. While certain parts of, and methods performed by, the patented systems are common to preexisting systems (e.g., withdrawing blood through a venous-access needle, introducing anticoagulant, separating red blood cells, collecting plasma and anticoagulant, and returning red blood cells to the donor), the '204 Patent recites additional elements that work in conjunction with these known components resulting in an improved system. For example, the challenged claims include a controller that monitors changes in volume, calculates donor total blood volume, calculates target plasma collection volumes based on individual donor characteristics like hematocrit, and determines when to stop a collection. EX1001, cls. 1-30. Considered as a whole, the challenged claims cannot be boiled down to a conventional system.

Moreover, Petitioner's focus on the technician's role in using the patented system is misplaced. The claimed functions performed by the controller are not performed by the technician but are determined by the controller in conjunction with the plasmapheresis system hardware.

**2. Claim 8 is not “representative” of the challenged claims.**

Petitioner selected claim 8 as “representative” of the challenged claims. Pet. at 59. However, patent subject matter eligibility is decided on a claim-by-claim basis. *Ultramercial, Inc. v. Hulu, LLC*, 722 F.3d 1335, 1340 (Fed. Cir. 2013), *vacated on other grounds*, 573 U.S. 942 (2014). To establish a claim is

representative, it must be “substantially similar” to the claims it purports to represent. *Content Extraction and Transmission LLC v. Wells Fargo Bank, Nat. Ass'n*, 776 F.3d 1343, 1348 (Fed. Cir. 2014). Petitioner has not met its burden here.

Claim 8 fails to include some limitations found in the other independent claims that recite additional inventive aspects of the '204 Patent. For example, claim 8 does not include certain limitations found within claim 1, including “calculating a donor total blood volume based, at least in part, on a weight and height of a donor” and “collecting the plasma component . . . until the target plasma amount to collect is reached in the plasma collection container.” EX1001, cl. 1.

Claim 8 also fails to include the nuances in the dependent claims. For example, despite Petitioner's assertions that general apheresis hardware includes weigh sensors, claim 8 certainly does not account for “a plasma collection container weight sensor configured to monitor a volume or weight of plasma component collected within the plasma collection container.” *Id.*, cl. 30. Claim 8 similarly does not recite “an optimized safe amount [of plasma] to be collected from the donor.” *E.g., id.*, cl. 3. This “optimized” and “safe” amount of plasma is important to the patented invention.

The nuances in the claims are important where, as here, Petitioner is arguing they rise or fall together. The specific combination of claim elements, including the determinations made and factors considered by the controller, is what allows Patent

Owner's patented invention to yield optimized plasma collection volumes. It is the nuanced combinations of elements—that Petitioner now lumps together as substantially similar—that provide different improvements over preexisting plasma collection systems. *Berkheimer v. HP Inc.*, 881 F.3d 1360, 1365 (Fed. Cir. 2018) (different claims may contain different inventive concepts).

**3. Alice Step 1: the challenged claims are directed to improved plasmapheresis machines, not mathematical calculations.**

The challenged claims are all apparatus claims and, as such, are specifically directed to a “machine” which is patent-eligible subject matter under 35 U.S.C. § 101; *e.g.*, EX1001, cl. 8 (“A system for collecting plasma”). Moreover, the claimed “machine” performs a “new and useful process,” which is also statutorily patentable. Petitioner oversimplifies the claim language and examines each claim element in a vacuum to argue the claims are directed at mathematical equations and conventional machinery. The Federal Circuit has cautioned against such oversimplification, and it should be avoided here. *McRO, Inc. v. Bandai Namco Games Am., Inc.*, 837 F.3d 1299, 1313 (Fed. Cir. 2016); *Enfish, LLC v. Microsoft Corp.*, 822 F.3d 1327, 1337 (Fed. Cir. 2016) (“describing the claims at such a high level of abstraction and untethered from the language of the claims all but ensures that the exceptions to § 101 swallow the rule”).

**i. The challenged claims are directed to an improved plasmapheresis machine.**

Petitioner fails to read the claims “as a whole”. *See CardioNet, LLC v. InfoBionic, Inc.*, 955 F.3d 1358, 1367 (Fed. Cir. 2020). When read in their totality, the challenged claims contain numerous limitations that have nothing to do with mathematical formulations but are essential in performing plasmapheresis—the stated goal of the claimed invention. *E.g.*, EX1001, cl. 8 (reciting a venous-access device, blood component separation device for separating drawn whole blood into a plasma component and separate blood component, first line to transport drawn whole blood and return fluid to the donor, and anticoagulant line). These limitations must be considered along with the controller limitation to determine to what the claims are directed.

As a whole, the claims are directed to improved plasmapheresis systems. Courts have routinely held that claims, such as these, which are directed to improved systems and related methods are not abstract under *Alice* step one. *See, e.g., CardioNet*, 955 F.3d at 1371 (improved cardiac monitoring device); *EcoServices, LLC v. Certified Aviation Serv., LLC*, 830 Fed. App'x 634, 642 (Fed. Cir. 2020) (improved system for washing jet engines); *Core Wireless Licensing S.A.R.L. v. LG Elecs., Inc.*, 880 F.3d 1356 (Fed. Cir. 2018) (improved user interface for computing devices); *McRO*, 837 F.3d at 1314 (improvement in computer

animation); *Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc.*, 827 F.3d 1042, 1048 (Fed. Cir. 2016) (improved method of preserving hepatocytes).

The Court's holding in *CardioNet* is instructive. In *CardioNet*, the Federal Circuit held patent-eligible claims directed to "an improved cardiac monitoring device...that detects beat-to-beat timing of cardiac activity, detects premature ventricular beats, and determines the relevance of the beat-to-beat timing to atrial fibrillation or atrial flutter." 955 F.3d at 1368; EX1001, cls. 1-30 (reciting plasma collection systems, comprising physical components, that receive and consider donor parameters, and determine a target plasma amount to collect). The Court acknowledged that the claims apply "determination logic" to identify variability in beat timing but did not cabin the entirety of the invention to the application of such logic. *See generally CardioNet*, 955 F.3d 1358. Rather, the Court looked to the claims as a whole to conclude the claims recite a "specific means or method that improves' cardiac monitoring technology." *Id.* at 1368. Similarly, the challenged claims recite specific determinations (e.g., hematocrit, total blood volume, and plasma volume) that improved the performance of then-existing plasma apheresis devices.

As another example, the challenged claim at-issue in *EcoServices* is strikingly similar to those here. There, the Court analyzed a challenged claim which recited:

1. A system for washing turbine engines comprising:
  - a washing unit for providing a washing liquid to the turbine engines;
  - an information detector configured to gather information related to engine type; and
  - a control unit configured to accept the information related to engine type from the information detector and to determine a washing program to be used as a function of the information relating to engine type from a set of preprogrammed washing programs, and further configured to regulate the washing unit according to washing parameters associated with the washing program used.

*EcoServices*, 830 Fed. App'x at 636. Just as the claims here, the claim at-issue in *EcoServices* recited an improved washing system that gathered relevant information and comprised a controller to use that information to determine what function should be carried out by the system. *Id.* The Federal Circuit held these claims “when considered as a whole . . . are directed to an improved system for washing jet engines and not to an abstract idea.” *Id.* at 642. The “specific combination of a type of washing unit, information detector, and control unit, configured in a certain way [] create technical improvements to systems for washing jet engines.” *Id.* at 643. Here, the challenged claims recite even more detailed components and perform methods which allow the plasmapheresis machine to produce a higher pure plasma yield per donor and in the aggregate. *E.g.*, EX2008 ¶21.

Importantly, the written description confirms that the claims are directed to an improved plasma apheresis system which provides a technical solution to

deficiencies in preexisting plasma collection systems. The '204 Patent explicitly details the “technical advantages offered by” the patented invention. *Visual Memory LLC v. NVIDIA Corp.*, 867 F.3d 1253, 1259-60 (Fed. Cir. 2017); *see also* EX1001, 12:64-13:22, 17:4-49 (describing benefits over prior art systems resulting in greater plasma collection volumes per donor). Because the challenged claims’ “improvement of an existing technology is bolstered by the specification’s teachings,” the claims are patent eligible. *Enfish*, 822 F.3d at 1337.

**ii. The heart of the challenged claims is not conventional equipment nor mathematical equations.**

Petitioner’s invitation to oversimplify the challenged claims to (1) conventional equipment used as tools and (2) mathematical equations that can be performed by a technician should be declined. *See McRO*, 837 F.3d at 1313; *Enfish*, 822 F.3d at 1337. Contrary to Petitioner’s assertions, Patent Owner did not take a preexisting plasmapheresis machine and merely add a controller. *Cf. Concaten, Inc. v. AmeriTrak Fleet Sols., LLC*, 131 F. Supp. 3d 1166, 1173 (D. Colo. 2015) (holding the addition of a generic computing device was not an “improvement in any specific device”). In other words, the maximum capabilities of the prior art systems are not simply achieved faster because of the inclusion of a controller.

Instead, the challenged claims recite an improved plasma apheresis system comprising a controller and other hardware features that employs a new process

which allows the machine to collect an optimized and greater volume of pure plasma on a per-donor basis. Thus, the controller is not “use[d] as a tool to automate conventional activity”; rather, the controller, and other system equipment, is used to carry out a novel approach, never done before in plasmapheresis. *McRO*, 837 F.3d at 1314 (finding the computer was not used as a tool because there was no evidence prior animators used the same process); *see also CardioNet*, 955 F.3d at 1370 (“Nothing in the record in this case suggests that the claims merely computerize pre-existing techniques”). This new approach is carried out by the controller and other equipment (e.g., pumps) to improve the overall performance of the plasmapheresis machine.

Lastly, Petitioner exhaustively argues that “pen and paper calculations are at the heart of” the challenged claims which can be performed by a technician. Pet. at 62. A technician armed with only “pen and paper” cannot (1) “withdraw[] whole blood from the donor”, (2) “introduc[e] anticoagulant into the withdrawn whole blood”, (3) “separat[e] the withdrawn whole blood into a plasma component and at least a second blood component”, and (4) “collect[] the plasma component from the blood component separation device and at least a second blood component”. EX1001, cl. 1. The “heart” of the challenged claims is an improved system performing plasmapheresis. A technician cannot perform plasmapheresis even if the technician could perform certain calculations involved in that process. *Cf.*

*Trinity Info Media, LLC v. Covalent, Inc.*, 72 F.4th 1355, 1366 (Fed. Cir. 2023) (holding claims directed to collecting and processing information, without more, can be performed by a human and are abstract).

Courts do not find claims to be abstract merely because they employ mathematical equations. *E.g.*, *Diehr*, 450 U.S. at 177 (holding claims that use “well-known” mathematical formulas performed by a computer as part of a process for curing rubber were not abstract); *Thales Visionix, Inc. v. United States*, 850 F.3d 1343, 1348 (Fed. Cir. 2017) (finding claims patent-eligible despite using mathematical combinations in combination with sensors); *XY, LLC v. Trans Ova Genetics, LC*, 968 F.3d 1323, 1331 (Fed. Cir. 2020) (claims involving mathematical equations are actually directed to an “improved method of operating a flow cytometry apparatus”). The challenged claims do not simply recite mathematical equations, but they recite detailed “step-by-step” processes which are carried out by the claimed system to “accomplish[] a physical process.” *XY, LLC*, 968 F.3d at 1331 (citing *Diehr*, 450 U.S. at 184). The challenged claims only utilize mathematical equations to carry out the new and improved technical approach to plasma apheresis and collection. *Thales*, 850 F.3d at 1349.

**4. Alice Step 2: the challenged claims recite an inventive concept.**

Because the challenged claims are not directed to an abstract idea, the Board need not address step two of the *Alice* test. Should the Board so choose, however, the challenged claims recite an inventive concept. Properly viewed as an ordered combination, the challenged claims do not recite “well-understood, routine, [and] conventional activity previously engaged in by researchers in the field.” *Aatrix Software, Inc. v. Green Shades Software, Inc.*, 882 F.3d 1121, 1128 (Fed. Cir. 2018). Quite the opposite, the patented invention provides benefits “over prior art plasma collection system” by targeting pure plasma collection volume on an individualized basis and using donor hematocrit in a new way. EX1001, 12:64-13:22.

**i. Petitioner examines the claim elements individually, instead of as an ordered combination.**

Taken together, the challenged claims are directed to improved plasma apheresis systems that are more efficient, result in optimized plasma collections, and are safe for plasma donors.

Once again, Petitioner focuses on the controller limitations and calculations. Pet. at 68-72. This argument misses the mark. A technician's potential to perform specific mathematical calculations is tangential to the step two analysis and was already addressed at step one. At *Alice* step two, the Court searches for an inventive

concept within the challenged claims. Whether a technician could manually perform certain functions provided by the patented plasma apheresis machine is of no import to the inventiveness of the underlying *machine* itself nor the innovative processes, as a whole, that it performs.

**ii. Considered as an ordered combination, the challenged claims recite an inventive concept.**

The challenged claims recite an improved plasmapheresis machine that employs an innovative method to safely optimize plasma collections and increase plasma yield, on average, per donor. There are at least two specific improvements to a conventional plasma apheresis machine—embodied in the challenged claims—that demonstrate the inventiveness of the improved system.

*First*, the challenged claims identify target plasma volumes, including pure plasma volume. *See* EX1001, cls. 1, 5, 8, 14, 15, 18, 23, 28. Prior art systems were unable to determine pure plasma volume and only collected based on total collection volume. *Id.*, 1:64-2:16, 12:64-13:22 (describing this prior art approach as the “easiest method”). One of the main inventive concepts of these patented systems, therefore, is the systems’ ability to collect a “target volume” of pure plasma from each donor. *Id.* Determining a target pure plasma volume, monitoring the collection until that exact volume is reached, and stopping the collection

accordingly, results in a higher plasma yield, on average, per donor. *See* EX1001, cls. 1, 5, 8, 14-15, 18, 23, 28, 12:64-13:22, 17:4-49.

*Second*, the challenged claims rely on individualized characteristics of the donor, including total blood volume and hematocrit, to optimize collections. *E.g.*, EX1001, cl. 1. Preexisting systems utilized the 1992 FDA Guidance, which involved determining a donor's weight category and targeting a total collection volume accordingly. *Id.*, 1:64-2:10; EX1007. Preexisting systems did not tailor collections to individual donors, instead "collect[ing] more plasma from low hematocrit donors than from high hematocrit donors." EX1001, 13:6-9. The system claimed in the '204 Patent is not bound by the weight category caps of the 1992 FDA Guidance and, instead, can collect an optimized, but safe, amount of plasma per donation.

Taken together, a plasmapheresis machine, containing all the components and performing all the functions recited within the challenged claims, which is configured to collect plasma in a new way (i.e., targeting pure plasma volume based on individual donor characteristics) is inventive. *See, e.g., BASCOM Glob. Internet Servs., Inc. v. AT&T Mobility, LLC*, 827 F.3d 1341, 1350 (Fed. Cir. 2016) (finding the placement of a filtering tool inventive where it was placed at a specific location and configured in a specific way that was non-conventional). The application within a plasmapheresis machine of a new targeted plasma volume collection strategy that

Patent Owner's Preliminary Response  
U.S. Patent No. 12,377,204

also leverages individual donor characteristics is “itself far from routine and conventional.” *Rapid Litig.*, 827 F.3d at 1050-51 (Fed. Cir. 2016) (finding that repetition of a known preservation process was inventive as it was not previously done in the art); *Mayo Collaborative Servs. v. Prometheus Lab'y, Inc.*, 566 U.S. 66 71 (2012) (“an *application* of a law or nature or mathematical formula to a known structure or process may well be deserving of patent protection”); *Diehr*, 450 U.S. at 188 (“a new combination of steps in a process may be patentable even though all the constituents of the combination were well known and in common use before the combination was made”).

The inventiveness of the '204 Patent is underscored by the demonstrable improvements to the apheresis machine. *See BASCOM*, 827 F.3d at 1350 (holding an improvement that improved the performance of the machine was inventive); *cf. ChargePoint, Inc. v. SemaConnect, Inc.*, 920 F.3d 759, 774 (Fed. Cir. 2019) (finding no inventive concept where “the claims do nothing to improve how charging stations function”). Petitioner focuses on the alleged improvement as one of mere speed or efficiency based on the implementation of a controller. Pet. at 70. But that's not right. The increased efficiency of the machine is not because it calculates volumes faster; rather, the machine is able to extract plasma in a new way resulting in optimized and increased collections. *Cf. Trinity*, 72 F.4th at 1366 (“Trinity's arguments as to inventiveness merely reflect the improved speed

inherent with applying the abstract idea using a computer”); *cf. Recentive Analytics, Inc. v. Fox Corp.*, 134 F.4th 1205, 1214 (Fed. Cir. 2025) (rejecting the argument that the addition of a computer made the invention more efficient and, therefore, faster); *cf. OIP Techs., Inc. v. Amazon.com, Inc.*, 788 F.3d 1359, 1363 (Fed. Cir. 2015) (same); *but see Aatrix Software*, 882 F.3d at 1127 (taking increased efficiencies into account when recognizing an inventive concept).

The challenged claims plainly recite an inventive concept within the claimed plasmapheresis machine that can collect an optimized volume of plasma using an approach—targeted plasma volume and individual donor characteristics—that had never been done before. The optimization of plasma collection is borne out both in the claims and in the specification. The patented invention is inventive under *Alice* step two. “To require something more at step two would be to discount the human ingenuity that comes from applying a natural discovery in a way that achieves a ‘new and useful end.’” *Rapid Litig.*, 827 F.3d at 1051-52 (citing *Alice*, 573 U.S. at 217). Institution should be denied.

**E. Ground VI: Claims 3, 6, 12, 20-21, and 28-29 Have Adequate Written Description Under 35 U.S.C. § 112(a).**

Petitioner invites the Board to find a lack of written description for terms and concepts that are supported squarely within the four corners of the ’204 Patent. But Petitioner proposes an incorrect written description standard—one requiring the

specification to recite, verbatim, every detail found in the claims. That is not the law.

A written description is adequate when it “reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date.” *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). Written description does not require “ipsis verbis” support. *Id.* at 1350; *Martin v. Johnson*, 454 F.2d 746, 751 (CCPA 1972). As is the case here, the written description requirement can be satisfied “if in the knowledge of the art the disclosed function is sufficiently correlated to a particular, known structure.” *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1332 (Fed. Cir. 2003).

Applying the correct standard, the '204 Patent easily satisfies Section 112(a). Each limitation challenged by Petitioner is described in the figures and narrative and is part of the disclosed system that a POSITA would readily understand from the specification as a whole.

**1. Written description support exists for “calculating an optimized, safe target plasma donation volume.”**

Petitioner argues the specification lacks support for an “optimized” and “safe” target plasma collection volume. The law is clear that written description does not require the specification to use the same words as the claims. The question is possession, not magic words.

The premise of the '204 patented invention is to optimize plasma collection volumes on a donor-specific basis while maintaining donor safety, even if the patent does not use the exact wording.

For example, the specification explains that preexisting plasma collection systems were not optimized because they targeted collections per the FDA's weight-based guidelines. EX1001, 17:4-8. The patent states, however, that donors in the same weight category may have varying total blood volumes and hematocrits which results in an inefficient—and potentially unsafe—collections per donor under the prior art approach. *Id.*, 17:9-20. The patent explains:

By tailoring the plasma collection to the donor (e.g., based on the donor's height, weight, BMI, hematocrit, total blood volume, and/or total plasma volume) and collecting a predetermined percent of plasma from each donor, embodiments of the preset [sic] invention are able to collect a greater volume of plasma (e.g., pure plasma) from some donors but less plasma from more vulnerable donors (e.g., smaller donors with high hematocrit, donors with lower plasma volume, etc.), as compared to systems that do not base the collection volume on the individual donor.

*Id.*, 17:20-29. A POSITA would have understood this description to describe both optimization and safety in objective, technical terms. The collection amount is *optimized* because it collects a more accurate amount of plasma from each donor based on their characteristics, collects more plasma per-donor on average, and is calculated using concrete donor-specific inputs (e.g., total blood volume and hematocrit) to maximize plasma yield. *Id.*, 12:64-13:22.

Moreover, a POSITA would have understood this tailored approach remains safe for vulnerable donors who, based on the preexisting FDA methods, may be providing too much plasma based purely on their weight category. *Id.*, 11:67-12:8. The system reduces collection from donors with lower plasma volume or higher hematocrit and operates within known safety constraints governing plasma donation. *Id.*, 17:20–29.

The words “optimized” and “safe” are not subjective labels, but shorthand descriptors for a donor-specific control strategy grounded in disclosed physiological parameters and stop conditions. A POSITA would not require those terms to be repeated verbatim in the specification to understand that the inventors possessed the claimed subject matter.

**2. Written description for “anticoagulated plasma target volume” is satisfied.**

Petitioner's argument here is misplaced. Petitioner argues that “Haemonetics uses the term ‘plasma product’ sparsely in its specification.” Pet. at 76. Throughout the entirety of its argument, Petitioner refers to the lack of support for “plasma product”. *Id.* at 76-78. But the term “plasma product” is not at-issue; rather, Petitioner purports to challenge the term “anticoagulated plasma.” *Id.*

Regardless, Petitioner's argument that the patent does not support limitations relating to “anticoagulated plasma target volume”—or “plasma product”—is

legally and factually incorrect. Petitioner's argument seems to be that Patent Owner included in its claim something that is in the prior art, but that does not violate the written description requirement. The specification repeatedly discloses plasma in the plasma collection container mixed with anticoagulant, as well as the total volume of fluid in the collection container, and separating pure plasma volume from anticoagulant volume. *E.g.*, EX1001, 10:26–28; 11:30–34; 11:62–12:8; Fig. 3. A POSITA would understand this to be “anticoagulated plasma” (or “plasma product”). Inventors are not required to provide elaborate descriptions of what is known in the field. *Enzo Biochem*, 323 F.3d at 964. The fact that anticoagulated plasma was known strengthens—not weakens—the conclusion that the inventors were in possession of it.

In sum, the '204 Patent specification, as a whole, demonstrates possession of the full invention. Petitioner's challenge demands an improper level of textual specificity that the law does not require and ignores the detailed narrative in the written description explaining how the disclosed system operates. Ground VI should be denied.

**F. Ground VII: Claims 3, 8, 12, 20, 23, and 29 are Not Indefinite Under 35 U.S.C. § 112(b).**

A claim is indefinite only if it fails to “inform, with reasonable certainty, those skilled in the art about the scope of the invention.” *Nautilus, Inc. v. Biosig*

*Instruments, Inc.*, 134 S. Ct. 2120, 2124 (2014). Applying this standard, each challenged term here is definite.

**1. The “optimized” and “safe” plasma collection amount terms are readily ascertainable by a POSITA.**

Petitioner argues that “optimized” and “safe” are subjective terms of degree. But terms of degree are not indefinite where the specification provides objective boundaries or contextual guidance. *Nautilus*, 134 S. Ct. at 2129-30. The specification distinctly explains how optimization is achieved—by calculating donor-specific plasma collection targets using donor characteristics and stopping collection once the calculated pure plasma volume is reached. *E.g.*, EX1001, 12:64-13:22; 17:20-29. A POSITA would readily understand “optimized” to mean a donor-specific plasma collection target calculated from the disclosed physiological inputs and control logic, and “safe” to mean compliance with the safety constraints inherent in that donor-specific calculation and applicable plasma collection limits. The fact that the optimal amount varies from donor to donor is not ambiguity—it is the point of the invention.

**2. The claim terms requiring the flow through the first line being controlled by a first pump are not indefinite.**

Petitioner's first argument regarding this term is essentially that the claim refers to “the” flow through the first line—of whole blood and return fluids—uses the term “the” instead of “a” and, therefore, is indefinite. However, the lack of

antecedent basis is not sufficient, alone, to render a claim indefinite. “When the meaning of the claim would reasonably be understood by persons of ordinary skill when read in light of the specification, the claim is not subject to invalidity upon departure from the protocol of ‘antecedent basis.’” *Energizer Holdings, Inc. v. Int’l Trade Com’n*, 435 F.3d 1366, 1370 (Fed. Cir. 2006); MPEP § 2173.05(e).

Here, the entirety of the challenged claim limitation is as follows:

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.

*E.g.*, EX1001, cl. 8. A POSITA would readily understand “the flow” to refer to the flow of fluid through the first line in both operational states, draw and return. The fact that valves or a controller may also participate in controlling flow does not render the claim indefinite. Pet. at 82. As a “comprising” claim, it does not exclude additional flow-control structures<sup>9</sup>. The claim simply requires that the first pump controls flow, alone or in addition to other flow-related structures, through the first line, which a POSITA would readily understand.

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<sup>9</sup> Nothing in this response should be read as asserting that the pump must be the sole flow-control mechanism or as adopting a narrow construction inconsistent with the specification.

**G. Ground VIII: Claims 3, 12, 20, and 29 are Enabled Under 35 U.S.C. § 112(a).**

Enablement requires that a POSITA be able to make and use the full scope of the claimed invention without undue experimentation. *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). That requirement is easily met here. *Id.* (including factors: (1) quantity of experimentation necessary; (2) amount of direction or guidance provided; (3) presence or absence of working examples; (4) nature of the invention; (5) state of the prior art; (6) relative skill of those in the art; (7) predictability of the art; and (8) breadth of the claims). The crux of the enablement inquiry is whether a POSITA could practice the invention without “undue experimentation.” *Id.* at 736-37. To practice the '204 Patent as claimed, and as described in the specification, resulting in a target collection volume that is optimized and safe would not require “undue experimentation.”

To satisfy enablement, “only a sufficient description enabling a person of ordinary skill in the art to carry out an invention is needed.” *Allergan, Inc. v. Sandoz Inc.*, 796 F.3d 1293, 1310 (Fed. Cir. 2012). The '204 Patent specification makes clear how to tailor target plasma collection volume based on various individualized donor characteristics—each of which are spelled out in the challenged claims. EX1001, 17:4-29; cls. 1, 8, 15, 23. For example, the claims recite calculating target plasma collection amounts based on donor total blood volume and hematocrit. *Id.*,

cls. 1, 8, 15, 23. As Petitioner acknowledges, “[w]hat is safe or optimal for one donor may not be for another.” Pet. at 85. The ’204 Patent recognizes this and teaches tailoring a collection to a donor’s individual characteristics to ensure collection volumes are optimized and safe on a per-donor basis.

The claims further recite targeting pure plasma collection amounts and stopping the collection based on reaching that pure plasma amount which, as the specification explains, is an optimized collection volume and an improvement over preexisting systems. EX1001, cls. 5, 14, 18, 28, 12:64-13:22. Tailoring collections to a donor’s specific characteristics, such as total blood volume and hematocrit, and collecting based on pure plasma amounts are optimal and safe. Indeed, by practicing the independent claims, a target collection amount would be optimized and safe as claimed.

A POSITA would not have to undergo undue experimentation to practice the claims of the ’204 Patent. Even Petitioner’s suggestion that a POSITA would have to conduct clinical trials—which would not be necessary—would not constitute undue experimentation. *E.g., Cephalon, Inc. v. Watson Pharms., Inc.*, 707 F.3d 1330, 1338 (Fed. Cir. 2013). And, “a reasonable amount of routine experimentation required to practice a claimed invention does not violate the enablement requirement.” *Id.* at 1336.

In sum, Petitioner has not met the high burden of establishing the invalidity of any challenged claim term pursuant to Section 112. This is further evidenced by the fact that Fletcher's declaration repeats, almost entirely verbatim, Petitioner's Section 112 arguments. Pet. at 71-85; EX1003 ¶¶172-194. While Petitioner includes certain case law and expands upon background legal principles, the substance of the invalidity arguments under Section 112 in the Petition are repeated by Fletcher without any additional explanation of what a POSITA would, or wouldn't, understand based on the teachings of the '204 Patent. This blanket copying cannot meet Petitioner's clear and convincing burden to demonstrate the invalidity of the '204 Patent and it is not sufficient to merit institution of the Petition.

## **VII. CONCLUSION**

For the foregoing reasons, Petitioner has failed to establish it is more likely than not that Petitioner will prevail on any challenged claim. Across each asserted ground, the Petition relies on conclusory expert testimony, hindsight reconstruction, and unsupported assertions rather than evidence or reasoned analysis tied to the claim language. Petitioner has not articulated a legally sufficient anticipation or obviousness theory, nor has it shown that the challenged claims are directed to patent-ineligible subject matter or lack adequate written description, definiteness,

Patent Owner's Preliminary Response  
U.S. Patent No. 12,377,204

or enablement. Because Petitioner has not met its burden under 35 U.S.C. § 324(a),

Patent Owner respectfully requests that the Board deny institution.

Respectfully submitted,

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Dated: January 22, 2026

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

Pursuant to 37 C.F.R. § 42.24(b), Patent Owner hereby certifies of the above-captioned Patent Owner's Preliminary Response for PGR2026-00006 of U.S. Patent No. 12,377,204, in accordance with and reliance on the word count provided by the word-processing system used to prepare this Response, that the number of words in this paper is 13,616. Pursuant to 37 C.F.R. § 42.24(b)(1), this word count is in compliance and excludes the table of contents, table of authorities, certificate of service, certificate of word count, appendix of exhibits, and any claim listing. This word count was prepared using Microsoft Word.

Date: January 22, 2026

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

Pursuant to 37 C.F.R. § 42.6(e), I hereby certify that on January 22, 2026, I caused a complete copy of Patent Owner's Preliminary Response to the Petition regarding U.S. Patent No. 12,377,204 and all exhibits, to be served on the Petitioner as follows:

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