

Patent Owner's Preliminary Response  
U.S. Patent No. 12,171,916

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. PGR2025-00078

U.S. Patent No. 12,171,916

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**PATENT OWNER'S PRELIMINARY RESPONSE**

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**List of Exhibits**

<b>Exhibit No.</b>	<b>Description of Document</b>
<b>2016</b>	NexSys PCS® Plasma Collection System Brochure, Haemonetics (2021), available at <a href="https://plasma.haemonetics.com/-/media/files/plasma/nexsys_pcs_brochure.pdf">https://plasma.haemonetics.com/-/media/files/plasma/nexsys_pcs_brochure.pdf</a>
<b>2017</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>2018</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>
<b>2019</b>	“The Transcript of Plasma Innovation Business Seminar on June 23, 2022,” Terumo Corporation, available at <a href="https://www.terumo.com/system/files/document/2022-07/Transcript_220623_PlasmaInnovationBusinessSeminar_E_0.pdf">https://www.terumo.com/system/files/document/2022-07/Transcript_220623_PlasmaInnovationBusinessSeminar_E_0.pdf</a> .
<b>2020</b>	“Q&A Session at the Financial Results Briefing for the FY22,” Terumo Corporation (May 17, 2023), available at <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>
<b>2021</b>	“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), available at <a href="https://www.fresenius-kabi.com/us/news-and-events/receives-fda-510k-">https://www.fresenius-kabi.com/us/news-and-events/receives-fda-510k-</a>

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<b>Exhibit No.</b>	<b>Description of Document</b>
	<a href="#">clearance-adaptive-nomogram-enhancing-plasma-collection-efficiency-aurora-xi-plasmapheresis-system</a>

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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, regarding claims 1-22 of U.S. Patent No. 12,171,916 (the “’916 Patent”), as requested by Petitioner Terumo BCT, Inc. (“Petitioner”). The Petition should be denied.<sup>1</sup>

**I. INTRODUCTION**

Petitioner filed the instant post-grant review petition (“Petition”) challenging the patentability of all claims of the ’916 Patent. The Petition presents seven grounds of unpatentability relating to 35 U.S.C. §§ 102, 103, 101, and 112. Grounds I-V 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 Publication No. 2002/0033370 to Bainbridge (“Bainbridge”). Ground VI relates to 35 U.S.C. § 101. Ground VII relates to 35 U.S.C. § 112. Each Ground fails to establish that it is more likely that 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 of establishing the invalidity of the '916 Patent based on the asserted references. 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 here, institution of the Petition 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 simply mirrors the Petition (or vice versa), almost entirely verbatim. Neither document engages in any real technical analysis. Neither explains what a person of ordinary skill in the art (“POSITA”) would have understood at the time of the invention. Both simply retrofit the prior art to the claims through hindsight reconstruction. The Board has consistently rejected such efforts.

Petitioner's anticipation and obviousness theories are lacking. Each ground is missing at least one, essential element of the independent claims. The Petition is rife with hindsight bias and conclusory statements that rely on mental gymnastics to force the primary references to meet the challenged claims. This is not teaching

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<sup>2</sup> Patent Owner has also requested discretionary denial of institution of the Petition, as explained in Paper 6.

or suggestion, it is reverse engineering. The primary references do not literally disclose what is claimed in the '916 Patent and neither the Petition nor Petitioner's expert, Dr. Fletcher, provide any rationale or reasoning as to why a POSITA would have found the challenged claims obvious based on the references' teachings. Indeed, Dr. Fletcher's declaration provides virtually no analysis of what a POSITA would have understood and merely parrots back—largely verbatim—what is said in the Petition.

Petitioner's motivations to combine references in Grounds II-V are inadequate. Like the remainder of the Petition, Petitioner repeatedly cites Dr. Fletcher's analysis in support of combining Fletcher-Haynes with Bainbridge; however, Dr. Fletcher's analysis repeats verbatim what is included in the Petition. Neither Petitioner nor Dr. Fletcher provide sufficient analysis or rationale as to *why* a POSITA would have been motivated to combine Fletcher-Haynes with Bainbridge nor *why* a POSITA would have a reasonable expectation of success. That does not meet the 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 that practices the '916 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 but unresolved need in the industry, overcame industry skepticism, received widespread industry 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. This objective evidence squarely ties to the claimed invention and confirms non-obviousness. As such, Petitioner's assertions of obviousness should be given little weight.

Petitioner's arguments pursuant to 35 U.S.C. §§ 101 and 112 are similarly unavailing. Petitioner ignores most 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 of the claim terms contains ample support within the specification of the '916 Patent.

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

## **II. OVERVIEW OF THE '916 PATENT**

The '916 Patent is directed to plasma apheresis methods and systems that utilize a donor's characteristics to identify a pure plasma amount to be collected. EX1001 at 1:21-23, 1:63-2:60. The disclosed system calculates the amount of

anticoagulant that is used and the amount of pure plasma that has been collected from a donor. *Id.* at 8:17-61, 10:1-26. The system also stops the collection when the optimized (i.e., target) volume of pure plasma has been collected from a given donor. *Id.* at 10:21-26.

As the specification explains, the '916 Patent provided an improvement over prior art systems. EX1001 at 1:46-59, 10:1-26. Prior art systems and methods relied on the U.S. Food and Drug Administration's upper limits on the total collection volume, which included both plasma and anticoagulant. *Id.* at 1:46-59, 10:1-26. In fact:

Prior art plasma collection systems [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.

*Id.* at 1:53-59.

The patented invention improved upon these preexisting methods and systems that targeted total collection volume and did not take into account a donor's individual characteristics, such as hematocrit. *Id.* at 10:1-21. As the patent explains:

Various embodiment[s] of the present invention provide numerous benefits over prior art plasma collection systems. In particular, as noted above, prior art plasmapheresis devices end plasma collection based on a total volume of anticoagulated plasma (e.g., pure plasma plus the added anticoagulant). Although this is the easiest method because it requires only that the product collection container be

weighed, the amount of true product—the pure plasma—is dependent on the donor's hematocrit. In other words, prior art systems will collect more plasma from low hematocrit donors than from high hematocrit donors because of the variation of the percentage of anticoagulant in the product.

*Id.* at 10:1-12. To remedy these issues, the '916 Patent teaches determining a “target volume” of pure plasma for each donor and stopping the collection when that target is reached. *Id.* at 10:13-26, cls. 1, 3, 7, 14. Thus, the '916 Patent seeks to optimize pure plasma yields on a donor-by-donor basis by collecting the appropriate amount of plasma-only product from each donor.

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

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

Fletcher-Haynes is directed primarily to a platelet collection system that also can collect additional blood components. *See* EX1005 at 2:56-59; *Id.* at 51:15-16 (describing 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.* at 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.* at 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 type of blood component that is most in demand at a particular center). *Id.* at 3:55-4:48. Fletcher-Haynes also teaches the use of "prediction algorithms" that "predetermine donor eligibility for specific product collections". *Id.* at 5:28-34.

## **B. Bainbridge**

Bainbridge is directed to extracorporeal blood processing and blood component collection. EX1006 at [0002]. Bainbridge uses donor characteristics to determine "a list [of] optional donations this particular donor can provide," including red blood cells, platelets, and/or plasma. *Id.* at [0016]. Because a main focus of Bainbridge is improving device efficiency, the disclosed system determines "what might be preferred or prioritized by the blood center." *Id.*

Bainbridge repeatedly refers to predetermined hematocrit and anticoagulant ratios which it uses throughout a blood collection procedure. *See id.* at Abstract; *see also id.* at [0143] (referring to a "predetermined protocol" that controls the operation of the anticoagulant pump); *Id.* at [0258]-[0259] (describing an established "predetermined hematocrit"); *Id.* at [0262] (discussing the predetermined flow rate of anticoagulant). The "adjusted AC ratio and predetermined hematocrit should be maintained during the subsequent" collection phase. *Id.* at [0259], [0291].

#### **IV. LEVEL OF ORDINARY SKILL**

For the purposes of this Preliminary Response, Patent Owner has applied the same skill level proposed by Petitioner as it pertains to a POSITA. *See* Pet. at 17-18.

#### **V. CLAIM CONSTRUCTION**

Petitioner asserts that “the Challenged Claims need no construction.” Pet. at 18. Patent Owner agrees that claim construction is not necessary to decide institution. *Id.*; *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”) (citing *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)). 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 1-22 ARE NOT UNPATENTABLE OVER PETITIONER’S REFERENCES**

##### **A. Ground I: Petitioner Has Failed to Show Fletcher-Haynes Anticipates and/or Renders Obvious the Challenged Claims.**

In Ground I, Petitioner avers claims 7-8, 14, and 16-21 are anticipated or rendered obvious by Fletcher-Haynes. Pet. at 19-38. Petitioner has not met its burden to demonstrate the unpatentability of the challenged claims in Ground I.

To establish anticipation, Petitioner must show that 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). To demonstrate obviousness, Petitioner must establish that Fletcher-Haynes teaches or suggests each claim limitation, that there exists a reason to modify Fletcher-Haynes’ teachings as Petitioner proposes, and that a POSITA would have an expectation of success in that modification. *See generally KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007); *see also Regents of Univ. of Cal. v. Broad Inst., Inc.*, 903 F.3d 1286, 1291 (Fed. Cir. 2018); *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1361 (Fed. Cir. 2007). Importantly, the Board must “guard against slipping into the use of hindsight. . . and to resist the temptation to read into the prior art the teachings of the invention in issue.” *Graham v. John Deere Co. of Kan. City*, 383 U.S. 1, 36 (1966) (citations omitted).

**1. Ground I impermissibly relies on duplicative expert analysis that fails to provide any rationale or support for Petitioner’s conclusory statements.**

Petitioner has not met its burden of establishing that it is more likely than not that it will prevail with respect to any of the challenged claims in Ground I. The Petition does not sufficiently demonstrate that Fletcher-Haynes discloses—expressly or inherently—or renders obvious any of the challenged claims. The

Petition relies almost exclusively on the expert declaration of Dr. Fletcher (EX1003) to support what is described in Fletcher-Haynes and what a POSITA would have found obvious based on its teachings. Dr. Fletcher's declaration, however, is nearly identical and mostly parrots verbatim 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 I, with the exception of a quotation from another reference, an added sentence, and minor word changes, is *identical* to the Petition. *Compare* Pet. at 19-38 with EX1003 ¶¶ 72-115. In fact, the Petition and Dr. Fletcher's declaration are, for the most part, word-for-word duplicates and even reproduce the same quotation emphases, footnotes, and annotated images. *E.g., compare* Pet. at 19 with EX1003 ¶ 72 (same emphases); Pet. at 21 and 23 with EX1003 ¶¶ 76 and 79 (same annotated figures with no notation of annotation); Pet. at 29 n.2 with EX1003 at 45 n.3 (substantively identical footnote). The *only* "substantive" differences between the Petition and Dr. Fletcher's declaration in Ground I is an added reference in paragraph 85 quoting from another reference with no additional analysis and an added sentence in paragraph 101 expanding on three algorithm choices. EX1003 ¶¶ 98, 101.

Despite the facially apparent overlap, Petitioner repeatedly cites to and relies on Dr. Fletcher's declaration as support for what a POSITA would understand based

on the teachings of Fletcher-Haynes. Pet. at 19-38; *see also id.* at 18 (“The sections below, as supported by Dr. Fletcher’s Declaration, demonstrate how the claims are unpatentable”). Because Dr. Fletcher’s declaration adds nothing beyond what already appears in the Petition, Petitioner has failed to demonstrate how a POSITA would have understood the teachings of Fletcher-Haynes or why a POSITA would have found the challenged claims obvious over Fletcher-Haynes. 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 and/or renders obvious the challenged claims. *See, e.g., 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[.]”); *Activision Blizzard, Inc. v. Milestone Ent., LLC*, IPR2025-00713, Paper 15 at 11 (Oct. 16, 2025) (“Petitioner cannot satisfy its burden of proving obviousness by employing ‘mere conclusory

statements,' but 'must instead articulate specific reasoning, based on evidence of record, to support the legal conclusion of obviousness.'") (quoting *In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1380 (Fed. Cir. 2016)); *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).

Institution should be denied as to Ground I. Under 35 U.S.C. § 324(a), the Board must determine whether Petitioner has shown that it is more likely than not Petitioner will prevail with regard to at least one claim. Petitioner has not made this requisite showing where the Petition and Dr. Fletcher's declaration together amount to little more than a single, unsupported narrative. Institution should be denied.

## **2. Claim 7**

Petitioner has omitted a claim limitation in its entirety from its analysis regarding claim 7. Specifically, the Petition skips the limitation: "a controller programmed . . . to determine a target volume for plasma product and/or raw plasma based at least in part on the weight and hematocrit." EX1001 at cl. 7, 11:55-57. This limitation should appear between what Petitioner lists as limitations 7[g] and 7[h]. *See* Pet. at 25-26. Unsurprisingly, Dr. Fletcher's declaration also skips over this

limitation and mirrors the Petition. *See* EX1003 ¶¶ 82-86. By failing to address a claim limitation, Petitioner necessarily fails to meet its burden regarding claim 7.

Patent Owner recognizes that Petitioner has since filed a motion for correction of the Petition and to serve an amended declaration of Dr. Fletcher. *See* Paper 9. Patent Owner has opposed that request because the Petition was filed three months ago, Patent Owner brought this omission to Petitioner's attention in Patent Owner's discretionary denial brief, and Patent Owner was already preparing this Preliminary Response. *See* Paper 10. The motion for correction remains pending.

Because the omitted limitation contains substantive requirements materially different from the other limitations addressed in the Petition, Patent Owner cannot know what arguments Petitioner may ultimately attempt to advance. A complete rebuttal is therefore not possible at this stage. That said, no plausible argument could cure the omission: Fletcher-Haynes fails to teach determining "target" plasma volumes. And, neither Petitioner nor Dr. Fletcher sufficiently explain why any plasma volume is based in part on donor weight and hematocrit. *Cf.* Pet. at 32 (arguing, instead, that target pure plasma volume is based on total blood volume and plasma product volume is based on pure plasma and anticoagulant volume).

For these reasons alone, Petitioner has not demonstrated that it is more likely than not to prevail on claim 7, and the challenge to that claim should be denied.

**3. Limitation 7[h]<sup>3</sup>: to control the system to operate draw and return phases to withdraw whole blood from the donor and separate the whole blood into the plasma product and the second blood component and to return the second blood component to the donor**

The plain and ordinary meaning of “draw and return phases” necessarily requires more than one draw phase and more than one return phase because the claim term is plural. *Cf.* EX1001 at cl. 1[h] (“to control the system to operate a draw and return cycle”). Focusing only on the single-needle configuration of Fletcher-Haynes (which also discloses a dual-needle configuration that does not include any phases), Petitioner argues that the blood draw portion is a distinct step from the return blood portion of the disclosed process. *Pet.* at 27-28. But Petitioner tacitly concedes that Fletcher-Haynes discloses only one draw period followed by one return period. Indeed, Petitioner acknowledges Fletcher-Haynes teaches drawing blood from the donor “continuously”. *Pet.* at 27; EX1005 at 45:24-26. This continuous draw can, at best, be defined as one draw phase, followed by one return phase of blood components back to the donor, which cannot satisfy the claim requirement of draw and return phases.

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<sup>3</sup> Petitioner incorporates its analysis regarding limitation 7[h] for the entirety of its analysis regarding limitation 14[i]. Petitioner has, therefore, failed to establish that it is likely to prevail regarding claim 14 for the same reasons.

To remedy this gap in Fletcher-Haynes, Petitioner concludes that a POSITA would have found it obvious to repeat the draw and return phases in Fletcher-Haynes' system. Pet. at 28. Petitioner's rationale for this apparent obviousness is lacking. Fletcher-Haynes explicitly teaches a system with one continuous blood draw phase, presumably to reach an optimized volume of platelet collection, at which point the one return phase begins. There is no reason—and neither Petitioner nor Dr. Fletcher provide any—to modify Fletcher-Haynes' system to include multiple draw and return phases.

Petitioner's obviousness rationale is sparse and unsupported. Petitioner argues providing multiple draw and return phases would “maximize donor comfort and/or accommodate a centrifugal separator whose total volume is less than that of the required amount of whole blood needed to collect a target amount of pure plasma.” Pet. at 28. But Petitioner never explains *how* or *why* donor comfort would be maximized nor *why* a separator of smaller volume would be used if the disclosed separator in Fletcher-Haynes is sufficient to complete the entire draw needed in one cycle. These unsupported assertions do not constitute a reasoned rationale. Dr. Fletcher merely repeats the same conclusory statements verbatim in his declaration. EX1003 ¶ 85. He then cites an unrelated reference that uses an optical sensor to detect a cell-plasma interface that triggers a return cycle and repeats the process. *Id.* Yet he fails to explain why such a system would be incorporated into Fletcher-

Haynes' system or why a POSITA would want to modify Fletcher-Haynes' system accordingly.

At base, Petitioner's arguments regarding this claim limitation are woefully inadequate and unsupported. The entirety of the analysis relies upon expert testimony that merely restates or, in most instances, directly copies, the language used in the Petition—precisely the type of inadequate showing the Board has rejected. *See Xerox*, IPR2022-00624, Paper 12 at 5 (denying institution where “the [expert] declaration copies, word-for-word, Petitioner's conclusory assertions”). Neither the Petition nor Dr. Fletcher's declaration provide any substantive explanation as to why a POSITA would make such a modification nor expect success in doing so. The absence of any clear explanation or technical rationale is telling: there is no reason a POSITA would have understood Fletcher-Haynes to teach or suggest using draw and return phases.

Because Petitioner has not established that Fletcher-Haynes discloses, explicitly or implicitly, multiple draw and return phases, and has failed to articulate a rationale for modifying Fletcher-Haynes to include them, Petitioner has failed to show it is more likely than not that Fletcher-Haynes anticipates and/or renders obvious claim 7.

**4. Limitation 14[h]: to determine a target volume for plasma product and/or raw plasma based at least in part on the donor parameters**

Petitioner's argument concerning limitation 14[h] is a series of reproduced equations from Fletcher-Haynes with little to no analysis of what those equations mean, the variables included therein, how they interrelate, nor how a POSITA would have interpreted them. *See* Pet. at 31-33. In fact, Petitioner does not even cite Fletcher-Haynes in support of these equations, instead relying exclusively on Dr. Fletcher's declaration, which itself is almost entirely duplicative of the Petition, without citation to the purported prior art reference. *See id.*; EX1003 ¶¶ 98-103.

Petitioner rests its argument regarding plasma volume on two equations: (1) an alleged "target volume of pure plasma ( $V_{SP}$ )," and; (2) an alleged "volume of plasma product ( $V_{SPB}$ )." Pet. at 32. Regarding the volume of plasma product, Petitioner merely reproduced an equation from Fletcher-Haynes:  $V_{SPB} = V_{SP}(1+f_{ACP})$  without explaining how this relates to the claimed requirement that the target volume be based on "the parameters." Pet. at 32; EX1001, cl. 14[h]. This equation does not facially support that Fletcher-Haynes teaches determining a volume of plasma product is based, in any part, on donor parameters, as required by the claim. Indeed, after reproducing this equation, Petitioner merely argues that " $V_{SPB}$  is a sum of volume of pure plasma ( $V_{SP}$ ) and volume of added anticoagulant ( $V_{SP} * f_{ACP}$ )." Pet. at 32. That observation says nothing about whether the calculation

is based on donor parameters. And Petitioner only cites Dr. Fletcher's declaration in support of this limitation which, as with the rest of the Petition, merely parrots back the same equations and statements with no further analysis or reasoning. *Id.*; EX1003 ¶¶ 102-103.

Regarding the determination of pure plasma volume, Petitioner argues: "Fletcher-Haynes calculates a target volume of pure plasma ( $V_{SP}$ ) using total blood volume  $V_B$ ." Pet. at 31 (citing EX1003 ¶ 90 (repeating this statement verbatim)). Notably, nowhere does Petitioner allege that total blood volume is a "donor parameter" nor does Petitioner allege any other donor parameters are involved in the pure plasma volume equation. Fletcher-Haynes discloses "four choices" for calculating what it calls "source plasma volume," only one of which, as Petitioner notes, includes total blood volume as a variable. EX1005 at 50:55-62. Each of these choices calculates source plasma volume based on source platelet volume ( $V_C$ ).

Neither Petitioner nor Dr. Fletcher explain when each choice in Fletcher-Haynes is used or how the specific choice that includes donor total blood volume as a variable is indicative of a donor parameter used to generate a target value. Petitioner—as repeated verbatim by Dr. Fletcher—further concludes that the disclosed plasma volume calculations are "target values because Fletcher-Haynes can run the prediction model 'before the collection procedure is actually initiated.'" Pet. at 32 (citing EX1005 at 53:36-38). While seemingly true that Fletcher-Haynes

discloses a prediction model which runs before the procedure begins, Petitioner fundamentally misreads Fletcher-Haynes.

Fletcher-Haynes discloses two distinct models that Petitioner conflates. Fletcher-Haynes discloses an “optimization model” that is used to optimize parameters for a “desired blood component yield” or from total procedure time. EX1005 at 9:20-27, Figs. 9B, 9C. Fletcher-Haynes separately teaches a “prediction model for predicting a yield of a particular blood component to be collected before a collection procedure is initiated using a compilation of algorithms.” *Id.* at 48:1-3. The equations on which Petitioner relies come from the prediction model, including source plasma volume. *Id.* at 49:19-26. These predicted yields of plasma components are essentially guesses before a procedure—not optimized, ideal target values as the claim requires.

In fact, Fletcher-Haynes does not teach or suggest determining target plasma volumes at all. The optimization model in Fletcher-Haynes concerns platelet yield ( $Y$ ). *Id.* at 54:52-58. Fletcher-Haynes, however, never discusses optimizing plasma yield in a comparable way. Plasma collection in Fletcher-Haynes is incidental to platelet collection. Indeed, the plasma-related calculations themselves are a function of the platelet collection volume ( $V_C$ ). Neither the Petition nor Dr. Fletcher explains why an estimated plasma volume produced as part of a platelet-focused

prediction model should have been 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 parameters, it has not carried its burden to establish that Fletcher-Haynes likely anticipates or renders obvious limitation 14[h]. The argument does not address the claim language, misinterprets Fletcher-Haynes, and lacks the analysis needed to connect the cited equations to the required claim elements. Petitioner has, therefore, failed to establish that Fletcher-Haynes invalidates independent claim 14.

The remaining claims within Ground I are dependent claims that depend from either claim 7 or claim 14, and Petitioner's failure to establish a likelihood of prevailing on those independent claims is fatal to the dependent claims as well. Institution should be denied.

**B. Grounds II-V: Petitioner Has Failed to Show How Fletcher-Haynes in view of Bainbridge Renders the Challenged Claims Obvious.**

The deficiencies that doom Ground I permeate the remainder of the Petition. In Grounds II–V, Petitioner again relies on the same cut-and-paste analysis and the same conclusory expert testimony—this time attempting to combine Fletcher-Haynes with Bainbridge to fill the gaps in Fletcher-Haynes' disclosure. Yet Petitioner never articulates why a POSITA would have been motivated to modify

Fletcher-Haynes' system, how the references could be coherently integrated, or why a POSITA would have expected success in doing so. Instead, Petitioner simply works backward from the challenged claims, selectively retrofitting teachings from Bainbridge into Fletcher-Haynes' disclosed system until they result in a system resembling the claimed invention. This hindsight-driven approach cannot satisfy Petitioner's burden under 35 U.S.C. § 324(a).

Grounds II-V rely on the combination of Fletcher-Haynes and Bainbridge. *See* Pet. at 39-72. Because, as explained below, the Petition fails to provide a sufficient motivation to combine Fletcher-Haynes and Bainbridge, Petitioner has not shown it is more likely than not that Petitioner will prevail for any of the challenged claims in Grounds II-V. Moreover, Petitioner again relies on Fletcher-Haynes alone regarding similar limitations at issue in Ground I (limitations 1[h], 10[h], and 14[h]), and those arguments remain unpersuasive for the same reasons already discussed.

As with Ground I, the Petition repeatedly cites Dr. Fletcher's declaration which, for Grounds II-V, remains substantively identical to the arguments made in the Petition with no further explanation or analysis. As such, these conclusory statements should be given no weight and Petitioner has failed to carry its burden of demonstrating that Fletcher-Haynes renders obvious the challenged claims in combination with Bainbridge. *See TQ Delta*, 942 F.3d at 1359; *see also KSR Int'l*,

550 U.S. at 418 (“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.”) (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)). As such, Petitioner has failed to carry its burden for Grounds II-V.

### **1. Motivation to Combine Fletcher-Haynes and Bainbridge**

To establish a motivation to combine two or more references for an obviousness assertion, 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 Dr. Fletcher’s declaration are devoid of fulsome rationale explaining why a POSITA would have been motivated to combine Fletcher-Haynes with Bainbridge, or why a POSITA would have had a reasonable expectation of success in that combination. When the conclusory language is stripped away, there is little substance left for Patent Owner or the Board to address.

The entirety of Petitioner’s motivation to combine argument is repeated, nearly verbatim, by Dr. Fletcher. *Compare* Pet. at 39-42 *with* EX1003 ¶¶ 116-121. Dr. Fletcher fails to provide any additional technical explanation, rationale, or reasoning as to (1) what a POSITA would have known from the references, (2) why a POSITA would have sought to modify Fletcher-Haynes’ system in the manner

alleged, or (3) what a POSITA would have expected to result from the proposed combination of Fletcher-Haynes and Bainbridge. Nonetheless, Petitioner repeatedly cites Dr. Fletcher's declaration as supposed support for what a POSITA would have found obvious and would have been motivated to do. *See* Pet. at 39-42. This is precisely the sort of unadorned expert parroting that provides no meaningful evidentiary value.

Petitioner's alleged motivation to combine arguments have little to do with the disclosed systems of Fletcher-Haynes and Bainbridge and much more to do with the challenged claims. For example, every exemplary motivation to combine Petitioner provides relates to a claim limitation that Fletcher-Haynes alone could not fill. *Id.* This type of hindsight bias is improper: using the challenged claims "as a roadmap to reconstruct the claimed invention using disparate elements from the prior art." *TQ Delta*, 942 F.3d at 1361; *see also Nautilus Hyosung, Inc. v. Diebold, Inc.*, IPR2016-00633, Paper 9 at 21 (Aug. 22, 2016) ("An assertion that something could be done does not articulate a reason why something would be done by one of ordinary skill in the art at the time of the invention and, therefore, raises a specter of impermissible hindsight bias in an obviousness analysis."). Neither the Petition nor Dr. Fletcher's declaration identifies an actual evidence-based motivation to combine Fletcher-Haynes and Bainbridge past the conclusory allegation repeated verbatim in the Petition and declaration. *See In re Van Os*, 844 F.3d 1359, 1361-62

(Fed. Cir. 2017) (“This type of finding, without more, tracks the *ex post* reasoning *KSR* warned of and fails to identify any actual *reason* why a skilled artisan would have combined the elements in the manner claimed.”).

Even where Petitioner provides a nominal rationale for the combination, such rationale is unsupported—and taught against—by the cited references. For example, Petitioner argues that “a POSITA would have been motivated to incorporate . . . repeating draw and return phases during collection.” Pet. at 40. Petitioner avers that combining this feature into Fletcher-Haynes’ system would be obvious to “minimize[] the amount of blood withdrawn from a donor at once and maximize[] donor comfort.” *Id.* Petitioner, and Dr. Fletcher, however, ignore the actual teachings of Fletcher-Haynes in their proposed combination. Fletcher-Haynes emphasizes the need for shorter donation time periods yielding maximum blood component quantities. EX1005 at 2:20-31. Specifically, Fletcher-Haynes notes:

Moreover, the supply of donors is unfortunately inadequate in many cases, and donor time constraints are becoming more prevalent.

*Id.* at 2:26-28. Indeed, Fletcher-Haynes focuses on collecting blood components “in a ‘minimum’ amount of time” or using a fixed time to collect “a ‘maximum’ quantity” of a blood component. *Id.* at 3:6-9. One of Fletcher-Haynes’ main

embodiments is a “time-based optimization model” that is set around donor availability. *Id.* at 7:59-63.

Accordingly, a POSITA would not seek to modify Fletcher-Haynes in a way that would *increase* the amount of time required per donation. Modifying Fletcher-Haynes' system to perform intermittent, repeated draw and return phases or cycles would require more donor time and/or less collection within a fixed time procedure, as taught by Fletcher-Haynes. “[O]bviousness concerns whether a skilled artisan not only *could have made* but *would have been motivated to make* the combinations or modifications of prior art to arrive at the claimed invention.” *Belden, Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1073 (Fed. Cir. 2015) (emphasis in original) (quoting *InTouch Techs., Inc. v. VGO Commc'ns, Inc.*, 751 F.3d 1327, 1352 (Fed. Cir. 2014)). Thus, Petitioner's suggestion that Fletcher-Haynes and Bainbridge could 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. *See InTouch Techs.*, 751 F.3d at 1352; *ActiveVideo Networks, Inc. v. Verizon Commc'ns, Inc.*, 694 F.3d 1312, 1327 (Fed. Cir. 2012) (a petitioner 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).

Petitioner and Dr. Fletcher therefore fail to explain: (1) *why* a POSITA would be motivated to combine these portions of Bainbridge 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' time- and yield-focused design. Equally important, Petitioner also fails to establish that a POSITA would have had a reasonable expectation of success in combining Fletcher-Haynes and Bainbridge. 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. Dr. Fletcher likewise provides no discussion of technical compatibility, implementation challenges, or feasibility, as his motivation to combine section is a carbon copy of the Petition. This conclusory analysis cannot satisfy Petitioner's burden under § 324(a).

**2. Limitation 1[h]: to determine a target volume for plasma product and/or raw plasma**

The Petition and expert declaration merely cite back to the analysis from Ground I for limitation 14[h], relying exclusively on Fletcher-Haynes. *See Pet.* at

44; EX1003 ¶ 130. Patent Owner, therefore, incorporates its argument in Part VI.A.4 above regarding limitation 14[h] explaining that Fletcher-Haynes fails to teach or suggest target plasma volumes. Petitioner's argument in Ground II is insufficient for the same reasons.

**3. Limitation 1[j]: to establish a current value of the hematocrit of the donor and a new target volume for plasma product and/or raw plasma**

Petitioner purports to combine Fletcher-Haynes and Bainbridge to render limitation 1[j] obvious. Pet. at 44. For the reasons explained above, Petitioner has not provided an adequate motivation to combine and reasonable expectation of success in its proposed combination; therefore, Petitioner has failed to establish it is more likely than not that it will prevail with regard to claim 1.

Moreover, Petitioner repeats its incorrect assertion that Fletcher-Haynes' prediction model algorithms are "target" volumes. The "downstream optimization" process that Petitioner refers to—which may be performed "during a given collection procedure"—is part of the optimization model, not the prediction model. Pet. at 44-45<sup>4</sup>. Thus, Petitioner's proposal to incorporate the teachings of

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<sup>4</sup> Petitioner utilizes the same faulty analysis regarding target plasma volumes for limitations 1[j], 1[k], 10[h], 10[i], 14[h], in Ground II. For the same reasons described herein, Petitioner has failed to establish that it is likely to prevail

Bainbridge into Fletcher-Haynes' "prediction model" still fails to teach or suggest a target value of raw plasma or plasma product. *See id.*; also Part VI.A.4, *supra*.

**4. Limitation 1[k]<sup>5</sup>: to control the system to operate a subsequent draw and return cycle, whereby the donor's changing hematocrit is taken into account in calculating the new target volume for plasma product and/or raw plasma**

Petitioner relies upon the combination of Fletcher-Haynes and Bainbridge to render limitation 1[k] obvious. Pet. at 46. Petitioner proposes simply incorporating repeated draw and return phases from Bainbridge into Fletcher-Haynes' disclosed system that only teaches a continuous blood draw cycle, followed by a single return step. *Id.* But as explained above, Fletcher-Haynes prioritizes reduced donor time, time-based optimization, or a fixed time procedure that teach away from a system such as Bainbridge's that has a multi-phase, interruptive approach, which increases the total donation time. *See* Part VI.B.1, *supra*.

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regarding claims 1, 10, 14, and claim 7 to the extent Petitioner is permitted to correct its omission of this claim limitation.

<sup>5</sup> Petitioner reiterates the same arguments regarding limitation 1[k] and the draw and return cycles or phases into its analysis regarding limitations 7[h], 10[j], and 14[i] in Ground II. For the same reasons described herein, Petitioner has failed to establish that it is likely to prevail regarding claims 1, 7, 10, and 14.

This limitation also requires taking a donor's changing hematocrit into account when calculating a new target volume for plasma product and/or raw plasma. Petitioner again relies on its erroneous assertion that Fletcher-Haynes' prediction model calculates a target volume. As explained above, Petitioner conflates Fletcher-Haynes prediction model—which guesses the amount of plasma that will be collected—with Fletcher-Haynes' adaptive, optimization model—which changes parameters in real-time to optimize platelet yield—throughout its Petition. This limitation fails for the same reason.

These defects in Petitioner's analyses permeate the analysis of the challenged independent claims and, consequently, the dependent claims in Grounds II-V. Petitioner has, therefore, failed to establish it is more likely than not that Petitioner will prevail as to any of the challenged claims. As such, 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 '916 Patent is compelling and independently confirms that the challenged claims are not obvious. "Evidence of objective indicia of nonobviousness, 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); *see also Robert Bosch Tool Corp. v. SD3, LLC*, IPR2016-01753, Paper 15 at 28 (Mar. 22, 2017) (“known evidence of secondary considerations should be addressed in the Petition”).

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 of the '916 Patent. 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. There is a nexus between the NexSys Systems and the '916 Patent Challenged Claims.**

The NexSys System is “[a] system for collecting plasma” that performs the claimed method. EX1001 at cls. 1, 7, 10, 14. Patent Owner's system includes:

- (a) a venipuncture needle configured to draw whole blood from a donor;
- (b) a blood separator configured to separate the whole blood into a plasma product and a second blood component comprising red blood cells, the blood separator having a plasma output port coupled to a plasma line configured to send the plasma product to a plasma product collection container;
- (c) a donor line fluidly coupled to the venipuncture needle configured to introduce the whole blood from the donor to the blood separator, flow through the donor line being controlled by a first pump;

- (d) an anticoagulant line coupled to an anticoagulant source, the anticoagulant line configured to combine anticoagulant with the whole blood from the donor, flow through the anticoagulant line being controlled by a second pump;
- (e) a user interface configured to receive input from an operator; and
- (f) a controller programmed to control operation of the system, the controller coupled to the user interface and programmed to receive at least a donor's weight and hematocrit, to determine a target volume for plasma product and/or raw plasma, to control the system to operate a draw and return cycle to withdraw the whole blood from the donor and separate the whole blood into the plasma product and the second blood component and to return the second blood component to the donor, to establish a current value of the hematocrit of the donor and a new target volume for plasma product and/or raw plasma, and to control the system to operate a subsequent draw and return cycle, whereby the donor's changing hematocrit is taken into account in calculating the new target volume for plasma product and/or raw plasma.

*Id.* at cl. 1; *see generally* EX2016 (describing the NexSys System); *see also* <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.**

As explained in Patent Owner's Request for Discretionary Denial (Paper 6), Patent Owner released two versions of its NexSys Systems, in 2018 and 2020, respectively. EX2002 ¶¶ 16, 20. The 2018 device included Patent Owner's patented YES<sup>®</sup> technology and the 2020 system further included Patent Owner's patented PERSONA<sup>®</sup> technology. *Id.* Both of these systems have revolutionized the plasma collection industry and Patent Owner remains the industry leader. *Id.* ¶¶ 13-15.

By employing the method claimed in the '916 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 total collection volume (including plasma and anticoagulant) like prior systems. For example, a study performed in 2020 concluded that the NexSys Systems increased plasma yield by more than 26 mL per donation. *Id.* ¶ 21. Considering these donations 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 system. Moreover, key players in the

plasma collection industry have affirmed the success of the NexSys Systems. *See, e.g.,* EX2017-2019.

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

As the '916 Patent indicates, preexisting plasma apheresis systems relied on U.S. 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 at 1:53-59; EX1009. 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). EX1009. This “simplified” nomogram is described in the 1992 FDA Guidelines as shown below:

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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 that 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 an individual donor. The industry long sought a method to determine and target a plasma-only volume on a per-donor basis, taking into account the donor’s individual characteristics, like hematocrit.

At the same time, the plasma 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 at 11:23-29. Over 30 years later, Petitioner itself reiterated this notion at its Plasma Innovation Business Seminar, “[t]here is a huge unmet need for plasma-derived therapies[.]” EX2019. 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 technology.**

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 simplified FDA-approved nomogram that had been in place for so many years).

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 claims of the '916 Patent. 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 employs those systems in plasma collection centers throughout the United States, 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 Chief Executive Officer 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.” EX2016. He acknowledged that the NexSys System 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. *See* EX2018. "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.**

As explained in Patent Owner's Request for Discretionary Denial, the plasma industry is small and only three companies provide the vast majority of plasma apheresis systems in the United States: (1) Patent Owner; (2) Petitioner; and (3) Fresenius Kabi/Fenwal. Patent Owner was the first to file patents covering its innovative systems and the first to release a commercialized version practicing those patents (including the '916 Patent). Both Petitioner and Fresenius Kabi/Fenwal were quick to follow, releasing very similar systems to the NexSys Systems 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. *See* EX2003. Petitioner's newest Rika Plasma System with iNomi Nomogram received FDA clearance in 2024. *See* EX2005. Patent Owner has accused both systems of infringing the '916 Patent in the co-pending district court litigation. *See 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 System, Petitioner cites to the NexSys Systems in its 510(k) summaries as the "Reference Device." *See* EX2004; EX2005.

Petitioner informed its investors of the similarities between its Rika System and Patent Owner's NexSys System. At the May 15, 2023 financial results briefing Q&A session hosted by Petitioner, investors referenced the Patent Owner's patented technology and "hope[d] [Petitioner] will be able to exceed or equal Haemonetics' yield." *See* EX2020. 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). She further noted that Petitioner's Rika System is "a very similar model" to the NexSys Systems. *Id.*

Patent Owner's other competitor, Fresenius Kabi/Fenwal, received FDA clearance for its Aurora Xi System with an "Adaptive Nomogram" on January 28, 2025. *See* EX2021. Just like Patent Owner's NexSys System, the Aurora Xi System

considers individual donor characteristics to determine the correct total amount of pure plasma to be collected. Patent Owner has accused Fresenius Kabi/Fenwal of infringing the '916 Patent in another district court litigation. *See Haemonetics Corp. v. Fresenius Kabi USA, LLC, et al.*, No. 1:25-cv-08680 (N.D. Ill. July 25, 2025).

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 of the '916 Patent. 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 VI: The Challenged Claims are Not Invalid Under 35 U.S.C. § 101**

The challenged claims of the '916 Patent are directed to improved plasma apheresis 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 35 U.S.C. § 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, 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. As a result, these preexisting machine configurations 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.

Section 101 provides: "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) (citations omitted). A patented invention is, therefore, not ineligible merely for involving a potentially abstract concept, such as a mathematical formula. *Id.* (citing *Diamond v. Diehr*, 450 U.S. 175, 187 (1981)). 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 Plasma Apheresis Machines.**

As the '916 Patent specification explains, “[p]rior art plasma collection systems [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 at 1:53-59. Additionally, “prior art systems will collect more plasma from low hematocrit donors than from high hematocrit donors” and failed to tailor pure plasma collection to specific donor characteristics, such as hematocrit. *Id.* at 10:6-26.

Not only does the specification of the Asserted Patents discuss the specific improvements made to preexisting plasma collection systems, which are embodied in Patent Owner's NexSys PCS<sup>®</sup> systems, but these exact improvements are recited

in the patent claims. For example, independent claims 1, 7, and 14 recite determining a target raw plasma volume, which is an improvement over the preexisting approach of only targeting total collection volume. Additionally, the challenged claims rely on individual donor characteristics, such as donor weight 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 plasma apheresis machine. The improved machine is more efficient than preexisting plasma apheresis machines in that it results, on average, in a higher yield of plasma per donation while remaining safe for the donor. *See* EX2002 ¶ 21; EX1001 at 10:1-26.

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. *See* Pet. at 73, 76-79. The patented system, however, is not so simple. As explained above, 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 '916 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, monitors the operation of the anticoagulant pump, calculates target plasma collection volumes based on individual donor characteristics, and determines when to stop a collection. *See generally* EX1001, cls. 1-22. Considered as a whole, the challenged claims cannot be boiled down to a conventional system.

Moreover, Petitioner's focus on the role of the technician in using the patented system is misplaced. As the claims make clear, the technician's role is interacting with the user interface of the patented system. *See, e.g.*, '916 Patent, cl. 1 ("a user interface configured to receive input from an operator"). The claimed functions performed by the controller are not performed by the technician but are determined by the controller in conjunction with the plasma apheresis system hardware.

**2. Claim 7 is Not "Representative" of the Challenged Claims of the '916 Patent.**

Petitioner selected claim 7 as "representative" of the challenged claims in the '916 Patent. Pet. at 73-74. However, patent subject matter eligibility is decided on a claim-by-claim basis. *Ulramercial, 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 & 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 7 fails to include some of the limitations found in the other independent claims that recite additional inventive aspects of the '916 Patent. For example, claim 7 does not include certain limitations found within claim 1, including “establish[ing] a current value of the hematocrit of the donor” and using that value to calculate “the new target volume for plasma product and/or raw plasma.” EX1001 at cl. 1. Utilizing a donor's hematocrit to determine a target plasma volume is one of the inventive aspects of the '916 Patent. *See, e.g., id.* at 10:15-26 (“embodiments of the present invention accomplish [collecting a target volume of pure plasma] by using knowledge of the donor's hematocrit”).

The nuances in the claims are important where, as here, Petitioner is arguing they rise or fall together. As explained above, 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. *See 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 Plasma Apheresis Machines, Not Mathematical Calculations.**

The challenged claims are apparatus claims and, as such, are specifically directed to a “machine” which is patent-eligible subject matter under 35 U.S.C. § 101; *see also e.g.*, EX1001 at cl. 1 (“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. *See McRO, Inc. v. Bandai Namco Games Am., Inc.*, 837 F.3d 1299, 1313 (Fed. Cir. 2016); *see also English LLC v. Microsoft Corp.*, 822 F.3d 1327, 1367 (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 plasma apheresis machine, not an abstract idea.**

Petitioner fails to read the claims “as a whole”. *See CardioNet, LLC v. InfoBionic, Inc.*, 955 F.3d 1358, 1368 (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 plasma apheresis—the

stated goal of the claimed invention. *See, e.g.*, EX1001 at cl. 1 (reciting a venous-access device, blood drawn line, blood component separation device from separating drawn whole blood into a plasma component and separate blood component, 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 plasma apheresis 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.” *CardioNet*, 955 F.3d at 1368; *compare with* challenged

claims (reciting plasma collection systems comprising physical components, receive and consider donor parameters, and determine a target plasma volume). 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 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 challenged 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 plasma apheresis machine to produce a higher pure plasma yield per donor and in the aggregate. *See, e.g.*, EX2002 ¶ 21.

Importantly, the written description of the '916 Patent 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 '916 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 at 10:1-26 (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 plasma apheresis 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 as a tool 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 plasma apheresis. *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”)<sup>6</sup>. This new approach is carried out by the controller and other equipment (e.g., pumps) to improve the overall performance of the plasma apheresis 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 75. A technician armed with only “pen and paper” cannot (1) “draw whole blood from a donor”, (2) “separate the whole blood into a plasma product and a second blood component comprising red blood cells”, (3) “send the plasma product to a plasma product collection container”, (4) “introduce the whole blood from the donor to the blood separator”, (5) “combine anticoagulant with the whole blood from the donor”, and (6) “establish a current value of the hematocrit of the donor”. EX1001 at cl. 1. The “heart” of the challenged claims is an improved system performing plasma apheresis. A technician cannot perform plasma apheresis even

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<sup>6</sup> The same is true here. There is no evidence that the novel process employed by the patented system (targeting pure plasma volume using individual donor characteristics) was used prior to this invention.

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. *See, 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 (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 its 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, as the '916 Patent explains, 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 way not previously done. EX1001 at 10:1-26.

**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 almost exclusively<sup>7</sup> focuses on the controller limitations and calculations. *E.g.*, Pet. at 82. 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. *See* Part VI.D.3, *supra*. 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 plasma apheresis machine that employs an innovative method to safely optimize plasma collections and increase

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<sup>7</sup> Petitioner asserts that Patent Owner “may” raise arguments concerning certain dependent claims. Pet. at 82 (referring to a weight sensor). But in doing so, Petitioner cites dependent claims that do not exist in the ’916 Patent. Unlike Petitioner’s omission of an actual claim limitation (see Part VI.A.2), this error reflects a different problem: Petitioner’s § 101 analysis is premised on claims from a different patent, not the one challenged here. Because the referenced claims are not part of the ’916 Patent, there is nothing for Patent Owner to rebut.

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 pure plasma volumes as well as plasma product volume. *See* EX1001 at cls. 1, 7, 14. Prior art systems were not able to determine pure plasma volume and only collected based on total collection volume. *Id.* at 1:46-59, 10:1-26 (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.* at 10:1-26. Determining a target raw 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, 7, 14; *Id.* at 10:1-26.

*Second*, the challenged claims rely on individualized characteristics of the donor, including weight and hematocrit, to optimize collections. *See, e.g.*, EX1001, claim 1. Preexisting systems utilized the November 1992 FDA Guidance, which involved determining a donor’s weight category and targeting a total collection volume accordingly. *Id.* at 1:46-59; EX1009. Preexisting systems did not tailor collections to individual donors, instead “collect[ing] more plasma from low hematocrit donors than from high hematocrit donors.” EX1001 at 10:9-12. The

system claimed in the '916 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 plasma apheresis machine, containing all the components recited within the challenged claims, 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 plasma apheresis machine of a new targeted plasma volume collection strategy that 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 '916 Patent is underscored by the demonstrable improvements to the apheresis machine. *See, e.g.,* EX2002 ¶ 21; *see also* *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 82. But that’s not right. The increased efficiency of the machine is not because it can calculate 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 plasma apheresis machine that can collect an optimized volume of plasma using an approach—targeted raw 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 on this basis.

**E. Ground VII: Claims 1-4, 6-7, and 10-21 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 ’916 Patent. But Petitioner proposes an incorrect written description standard—one requiring the specification to recite, verbatim, every detail found in the claims and to provide step-by-step programming instructions. 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.

*Ariad*, 598 F.3d 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 '916 Patent easily satisfies 35 U.S.C. § 112(a). Each limitation challenged by Petitioner is described in the figures and narrative or falls within what a POSITA would understand from the disclosed system.

**1. The Specification Adequately Describes a Controller That Performs the Claimed Functions.**

Petitioner argues that the specification lacks written description support for “programming a controller” despite that term not appearing in the claims. Petitioner seems to argue that because the specification does not repeatedly use the word “programmed” that somehow the claimed “controller programmed to...” lacks support. But the Federal Circuit has long rejected any requirement that the patent disclose source code or programming instructions. *Fonar Corp. v. Gen. Elec. Co.*, 107 F.3d 1543, 1549 (Fed. Cir. 1997); *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 323 F.3d 956, 964 (Fed. Cir. 2002).

Here, the '916 Patent repeatedly attributes computational and control operations to the controller. *See, e.g.*, EX1001 at 3:9-38; 3:59-63, 6:23-33, 9:13-25. A POSITA would understand that a controller performing these explicit logical steps must necessarily be programmed to do so. *Ariad*, 598 F.3d at 1351.

**2. Written Description for “Plasma Product” Is Satisfied.**

Petitioner's argument that the patent does not support limitations relating to “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 written description discloses plasma in the plasma collection container and anticoagulant mixed with that plasma, as well as the total volume of fluid in the collection container. A POSITA would understand this to be “plasma product.” Inventors are not required to provide elaborate description of what is known in the field. *Enzo Biochem*, 323 F.3d at 964. The fact that plasma product collection was known strengthens—not weakens—the conclusion that the inventors were in possession of it.

**3. Draw and Return Cycle, Including Repetition, Are Supported.**

Petitioner argues the specification lacks support for “draw and return cycles.” The law is clear that written description does not require the specification to use the same words as the claims. The figures and written description disclose the claimed

cycles. The system (1) withdraws whole blood, (2) introduces anticoagulant, (3) separates blood, (4) collects plasma, (5) determines whether the target is met, and (6) either repeats earlier steps or returns blood components to the donor. EX1001 at Figs. 4 and 5. This is a draw and return cycle, and the diamond-shaped decision symbol in the flow charts demonstrates an iterative process. A POSITA would recognize the structure of Figures 4 and 5 as a repeating plasma-collection/return cycle. Nothing more is required under Section 112. But the specification has more and is replete with disclosure that is sufficient to describe draw and return cycles. *See e.g.*, EX1001 at 2:15-21, 7:33-36, 8:17-23, 9:4-12.

The parent application to which the '916 patent claims priority, U.S. Patent No. 10,758,652, included an originally filed claim that recites “returning, after collecting at least a portion of the target volume of pure plasma, the second blood component to the donor through a return line.” EX2006 at cl. 10. The inventors possessed the concept of iterative cycles at least based on the originally filed claims in the parent application. *In re Koller*, 613 F.2d 819 (CCPA 1980).

#### **4. The Specification Supports Calculating New Target Volumes During the Procedure.**

Petitioner asserts that the patent supports only a “single” target calculation. But the specification describes ongoing measurement and recalculation steps. The system continuously monitors anticoagulant container weight, plasma container

weight, and the change in those weights. The system recalculates the amount of anticoagulant and pure plasma during the procedure. Figures 4 and 5 show calculations and comparisons occurring after plasma has already begun to accumulate, not only beforehand. Written description does not require the specification to recite the phrase “new target volume.” Instead, the question is whether the inventor was in possession of a system that uses donor parameters and ongoing measurements to determine when collection should end. The iterative calculations and repeated decision point (“Volume of Pure Plasma = Target Volume?”) demonstrate possession of the control logic required for target-based termination under varying conditions.

**5. The Specification Supports the Use of a “Control System” Communicating With the Controller.**

Petitioner argues that the term “control system” appears only in the claims. But written description does not require a specification to use the same nomenclature as the claims. *Ariad*, 598 F.3d at 1352. Figures and text of the '916 patent disclose multiple cooperating control components—a controller, weight sensors, pump controls, centrifuge bowl motor control, venous access controls, and user interface components. A POSITA would recognize that these components together form a control system, regardless of whether that term is used expressly. The Federal Circuit has recognized that where the structure and function are

disclosed, the precise label is irrelevant. *Capon v. Eshhar*, 418 F.3d 1349, 1357 (Fed. Cir. 2005).

**6. The Specification, Taken as a Whole, Demonstrates Possession of the Full Invention.**

When read as a whole, the '916 Patent demonstrates that the inventors possessed each of the challenged claim elements. Petitioner's challenge rests on requiring an improper level of textual specificity and mischaracterizing the technical disclosures of Figures 4 and 5 and the detailed narrative in the written description. Because the specification reasonably conveys to a POSITA that the inventors were in possession of the claimed system and methods, Ground VII should be denied in its entirety.

**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. The Petition relies on conclusory expert testimony, hindsight reconstruction, and unsupported assertions rather than evidence or reasoned analysis. Moreover, Petitioner's arguments pursuant to 35 U.S.C. §§ 101 and 112 are legally unsupported and unavailing. Accordingly, Patent Owner respectfully requests that the Board deny institution of post-grant review of the '916 Patent.

Patent Owner's Preliminary Response  
U.S. Patent No. 12,171,916

Respectfully submitted,

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Dated: December 15, 2025

*Attorney for Patent Owner*

**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 PGR2025-00078 of U.S. Patent No. 12,171,916, 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 13,290. 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: December 15, 2025

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

Pursuant to 37 C.F.R. § 42.6(e), I hereby certify that on December 15, 2025, I caused a complete copy of Patent Owner's Preliminary Response to the Petition regarding U.S. Patent No. 12,171,916 and all exhibits, to be served on the Petitioner as follows:

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