

Patent Owner's Preliminary Response
U.S. Patent No. 10,758,652

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

TERUMO BCT INC.,

Petitioner

v.

HAEMONETICS CORP.,

Patent Owner

Case No. IPR2025-01391

U.S. Patent No. 10,758,652

PATENT OWNER'S PRELIMINARY RESPONSE

Table of Contents

I. Introduction	1
II. Overview of the '652 Patent	4
III. Overview of Primary Prior Art References	6
A. Takagi	6
B. Lavender	7
IV. Level of Ordinary Skill	8
V. Claim Construction	8
VI. Claims 1-20 Are Not Unpatentable Over Petitioner’s References	9
A. Ground 1: Petitioner Has Failed to Show Takagi Anticipates and/or Renders Obvious the Challenged Claims.....	9
1. Ground 1 impermissibly relies on duplicative expert analysis that fails to provide any rationale or support for Petitioner’s conclusory statements.	10
2. Limitation 1[i]: calculating a volume of pure plasma collected within the plasma collection container based, at least in part, on the calculated volume of anticoagulant in the collected plasma component.....	13
3. Claim 11	15
B. Ground 2: Petitioner Has Failed to Show Lavender Anticipates and/or Renders Obvious the Challenged Claims.....	16
1. Limitation 1[d]: withdrawing whole blood from the donor through the venous-access device and a draw line, the draw line connected to a blood component separation device	17
2. Limitation 1[i]: calculating a volume of pure plasma collected within the plasma collection container based, at least in part, on the calculated volume of anticoagulant in the collected plasma component.....	19
3. Limitation 1[j]: continuing steps (d) through (i) until a target volume of pure plasma is collected within the plasma collection container	22
4. Claim 11	23
C. Grounds 3-5: Petitioner Has Failed to Show a Reasonable Likelihood of Success on Grounds 3-5 Nor Provided Legally Sufficient Motivations to Combine.	24

D.	Relevant Objective Indicia of Non-Obviousness Refutes Petitioner’s Obviousness Arguments.....	29
1.	There is a nexus between the NexSys Systems and ’652 Patent Challenged Claims.....	30
2.	The NexSys System was commercially successful.	31
3.	The NexSys System met a long-felt need in the plasma industry.	32
4.	The plasma collection industry was skeptical of the NexSys System and patented method.....	35
5.	The NexSys Systems have received industry praise.....	35
6.	Patent Owner’s two competitors in the plasma collection industry have copied the NexSys System.....	36
VII.	Conclusion.....	38

TABLE OF AUTHORITIES

	Page(s)
CASES	
<i>Activision Blizzard, Inc. v. Milestone Ent., LLC</i> , IPR2025-00713, Paper 15 (Oct. 16, 2025)	20
<i>Belden Inc. v. Berk-Tek LLC</i> , 805 F.3d 1064 (Fed. Cir. 2015)	27
<i>Graham v. John Deere Co. of Kan. City</i> , 383 U.S. 1 (1966).....	10
<i>Haemonetics Corp. v. Terumo BCT, Inc.</i> , No. 1:25-cv-01409 (D. Colo. May 5, 2025)	37
<i>In re Kahn</i> , 441 F.3d 977 (Fed. Cir. 2006)	25
<i>In re Magnum Oil Tools Int’l, Ltd.</i> , 829 F.3d 1364 (Fed. Cir. 2016)	21, 26
<i>In re Van Os</i> , 844 F.3d 1359 (Fed. Cir. 2017)	27, 28
<i>InTouch Techs., Inc. v. VGO Commc’ns, Inc.</i> , 751 F.3d 1327 (Fed. Cir. 2014)	27, 28
<i>KSR Int’l Co. v. Teleflex Inc.</i> , 550 U.S. 398 (2007).....	10
<i>Nautilus Hyosung Inc. v. Diebold, Inc.</i> , IPR2016-00633, Paper 9 (Aug. 22, 2016)	27
<i>Nidec Motor Corp. v. Zhongshan Broad Ocean Motor, Co.</i> , 868 F.3d 1013 (Fed. Cir. 2017)	9
<i>PersonalWebTechs., LLC v. Apple, Inc.</i> , 848 F.3d 987 (Fed. Cir. 2017)	26

Patent Owner’s Preliminary Response
U.S. Patent No. 10,758,652

<i>Pfizer, Inc. v. Apotex, Inc.</i> , 480 F.3d 1348 (Fed. Cir. 2007)	10
<i>Polaris Indus., Inc. v. Artic Cat, Inc.</i> , 882 F.3d 1056 (Fed. Cir. 2018)	31
<i>Quanergy Sys., Inc. v. Velodyne Lidar USA, Inc.</i> , 24 F.4th 1406 (Fed. Cir. 2022)	29, 31
<i>Regents of Univ. of Cal. v. Broad Inst., Inc.</i> , 903 F.3d 1286 (Fed. Cir. 2018)	10
<i>Robert Bosch Tool Corp. v. SD3, LLC</i> , IPR2016-01753, Paper 15 (Mar. 22, 2017)	29
<i>TQ Delta, LLC v. CISCO Sys., Inc.</i> , 942 F.3d 1352 (Fed. Cir. 2019)	12, 17, 21, 27
<i>Verdegaal Bros. v. Union Oil Co. of Cal.</i> , 814 F.2d 628 (Fed. Cir. 1987)	10
<i>Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.</i> , 200 F.3d 795 (Fed. Cir. 1999)	9
<i>Xerox Corp. v. Bytemark, Inc.</i> , IPR2022-00624, Paper 12 (Feb. 10, 2023)	<i>passim</i>

STATUTES

35 U.S.C. § 314(a)	2, 12, 27
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OTHER AUTHORITIES

37 C.F.R. § 42.107	1
37 C.F.R. § 42.120(a)	1

List of Exhibits

Exhibit No.	Description of Document
2015	NexSys PCS® Plasma Collection System Brochure, Haemonetics (2021), available at https://plasma.haemonetics.com/-/media/files/plasma/nexsys_pcs_brochure.pdf
2016	“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 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
2017	“Peer-Reviewed Results of Haemonetics’ Improving Plasma Collection (IMPACT) Trial Published in the Journal Transfusion,” Haemonetics Press Release (Apr. 29, 2021), available at https://haemonetics.gcs-web.com/news-releases/news-release-details/peer-reviewed-results-haemonetics-improving-plasma-collection/
2018	“The Transcript of Plasma Innovation Business Seminar on June 23, 2022,” Terumo Corporation, available at https://www.terumo.com/system/files/document/2022-07/Transcript_220623_PlasmaInnovationBusinessSeminar_E_0.pdf .
2019	“Q&A Session at the Financial Results Briefing for the FY22,” Terumo Corporation (May 17, 2023), available at https://www.terumo.com/system/files/document/2023-05/Presentation_23Q4_E_qa.pdf
2020	“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 https://www.fresenius-kabi.com/us/news-and-events/receives-fda-510k-

Patent Owner's Preliminary Response
U.S. Patent No. 10,758,652

Exhibit No.	Description of Document
	<u>clearance-adaptive-nomogram-enhancing-plasma-collection-efficiency-aurora-xi-plasmapheresis-system</u>

Pursuant to 37 C.F.R. § 42.107, Patent Owner Haemonetics Corporation (“Patent Owner”) files this Preliminary Response to the Petition for *inter partes* review, setting forth the reasons why claims 1-20 of U.S. Patent No. 10,758,652 (the “’652 Patent”), as requested by Petitioner Terumo BCT Inc. (“Petitioner”), should be denied.¹

I. INTRODUCTION

Petitioner filed the instant *inter partes* review petition (“Petition”) challenging the patentability of all claims of the ’652 Patent. The Petition presents five grounds of unpatentability, but each ground primarily relies on two references: (1) Japanese Patent Application Publication No. 2002-282352 to Takagi (“Takagi”); and (2) U.S. Patent No. 4,898,675 to Lavender (“Lavender”).

Petitioner bears the burden of establishing the invalidity of the ’652 Patent based on the asserted references. The Petition must demonstrate “there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition” for institution to be authorized, although

¹ 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 *inter partes* review. 37 C.F.R. § 42.120(a).

institution is never required.² 35 U.S.C. § 314(a). 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, typos and all. 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 theories are lacking. Each ground is missing at least one, essential element of the independent claims. Petitioner's obviousness theories similarly collapse under even modest scrutiny. 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. Much of Petitioner's “analysis” consists largely of rewriting mathematical equations in Takagi and Lavender to resemble the steps required in the challenged claims. This is not teaching or suggestion, it is reverse engineering. The primary references do not literally disclose what is

² Patent Owner has also requested discretionary denial of institution of the Petition, as explained in Paper 7.

claimed in the '652 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.

The deficiencies in the Petition do not stop there. While Grounds 3-5 fail because they rely on Grounds 1-2, Petitioner's motivations to combine references in Grounds 3-5 are inadequate. Like the remainder of the Petition, Petitioner repeatedly cites Dr. Fletcher's analysis in support of combining multiple references together; 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 make these combinations 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 indicia of non-obviousness based on its commercialized product that practices the '652 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.

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 '652 PATENT

The '652 Patent is directed to plasma apheresis methods and systems that utilize a donor's characteristics and identify a pure plasma amount to be collected. EX1001 at 1:6-8, 1:48-2:6, 2:61-3:7. 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 9:65-10:6. 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 10:6-11.

As the specification explains, the '652 Patent provided an improvement over prior art systems. EX1001 at 1:31-44, 9:53-10:11. 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 1:33-38.

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 1:38-44.

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 9:53-10:11. 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 9:53-64. To remedy these issues, the '652 Patent teaches determining a "target volume" of pure plasma for each donor and stopping the collection when that target

is reached. *Id.* at 9:65-10:11, cls. 1, 11. Thus, the '652 Patent sought 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. Takagi

Takagi is directed to a blood collection system that collects a predetermined amount of certain blood components from a donor. EX1004 at [0001]. After inputting donor parameters, the disclosed system “determines the number of cycles E [iterations] required to collect the true target plasma collection amount.” *Id.* at [0078]. The disclosed system then proceeds to collect blood components from the donor and stops the collection when certain conditions are met:

the blood component collection operation is terminated when the current collection amount of the predetermined blood component collected in the blood component collection bag reaches 70 to 100% of the target collection amount for the predetermined blood component, or when the blood component collection operation has been performed for the predetermined number of cycles.

Id. at [0012]. Accordingly, Takagi's system tracks both the “target plasma collection amount” (e.g., the predetermined amount) and the “current plasma collection amount” (e.g., the 70-100% or amount collected in the set number of cycles). *Id.* at [0069]; *see also id.* at [0131].

The predetermined collection amounts are calculated before the blood component collection system begins the procedure. *Id.* at [0099]. Specifically, the “apparent plasma collection amount [] per cycle,” which is the amount of pure plasma and anticoagulant collected per cycle, “is obtained in the condition setting step,” prior to the collection. *Id.* at [0115], [0078], [0067]. That condition setting step also includes calculating the amount of anticoagulant within the apparent plasma collection amount per cycle. *Id.* at [0078]-[0098].

B. Lavender

Unlike the '652 Patent which determines a target pure plasma volume to be collected, Lavender is directed to a plasma apheresis system that tries to avoid “rapid degradation in plasma production with time” by utilizing specific structural designs and distribution of blood within the machine. EX1005 at 11:30-32, 13:23-46. This includes uniform distribution of blood across Lavender's disclosed plates, which have shallow grooves to facilitate blood flow and reduce resistance. *Id.* at 13:23-46. According to Lavender, these structural improvements allow for a higher blood flow velocity rate which helps to avoid rapid degradation. *Id.* at 11:30-44, 13:51-14:5.

An additional purpose of Lavender's invention is to add an appropriate amount of anticoagulant to the donor blood at an appropriate rate to prevent blood clots. *See* EX1005 at 13:49-50, 22:35-46. As the reference explains:

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

Id. at 3:2-7. Accordingly, Lavender teaches pumping anticoagulant (citrate) based on donor hematocrit “at a rate sufficient to dilute incoming plasma to 68% of the initial concentration.” *Id.* at 22:37-39. Lavender therefore contemplates the relation between anticoagulant delivery rate on the front end—not calculating the volume of anticoagulant that has been administered on the backend—to avoid coagulation during the procedure.

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 21-22.

V. CLAIM CONSTRUCTION

Petitioner asserts that “the Challenged Claims need no construction to demonstrate they are unpatentable.” Pet. at 22. Despite that assertion, Petitioner advances shifting and inconsistent understandings of certain claim terms and how they should be interpreted by the Board. *E.g.*, Pet. at 29, 43, 53. For example, regarding the term “based, at least in part, on” Petitioner first contends it should be given its plain and ordinary meaning, then refers to a “narrower meaning[]” without

explaining what that interpretation is. Pet. at 29. The Petition offers no coherent or detailed explanation reconciling these interpretations, leaving the Board, and Patent Owner, to guess at Petitioner's intended meaning.

Even so, Petitioner's arguments are unavailing under any construction of "based, at least in part, on." Patent Owner agrees that claim construction is not necessary to decide institution. Pet. at 22; *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 in view of Petitioner's inconsistent positions.

VI. CLAIMS 1-20 ARE NOT UNPATENTABLE OVER PETITIONER'S REFERENCES

A. Ground 1: Petitioner Has Failed to Show Takagi Anticipates and/or Renders Obvious the Challenged Claims.

In Ground 1, Petitioner avers claims 1, 5, 6, 8, 10, 11, 16, 17, and 19 are anticipated by or rendered obvious by Takagi. Pet. at 23-36. Petitioner has not met its burden to demonstrate the unpatentability of the challenged claims in Ground 1.

To establish anticipation, Petitioner must show a reasonable likelihood that "each and every element as set forth in the [challenged] claim is found, either

expressly or inherently described, in” Takagi. *Verdegaal Bros. v. Union Oil Co. of Cal.*, 814 F.2d 628, 631 (Fed. Cir. 1987). To demonstrate obviousness, Petitioner must establish that Takagi teaches or suggests each claim limitation, that there exists a reason to modify Takagi’s 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 1 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 a reasonable likelihood it will prevail with respect to any of the challenged claims in Ground 1. The Petition does not sufficiently demonstrate that Takagi discloses—expressly or inherently—any of the challenged claims. The Petition relies almost exclusively on the expert declaration of Dr. Fletcher to support what is described in Takagi and what a POSITA would have found obvious based on the teachings of Takagi. Dr. Fletcher’s

declaration, however, is nearly identical and merely 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, the *entirety* of Ground 1, with the exception of one added paragraph regarding a dependent claim, is *identical* to the Petition. *See* Pet. at 23-36; EX1003 ¶¶ 66-89, 91-101. In fact, the Petition and Dr. Fletcher's declaration are word-for-word duplicates and even reproduce the same typographical errors. *E.g., compare* Pet. at 23-31 with EX1003 ¶¶ 66-83 (entirety of analysis regarding claim 1); Pet. at 29 *with* EX1003 ¶ 79 (same typos with a missing space and extra period). The *only* difference between the Petition and Dr. Fletcher's declaration in Ground 1 is an added paragraph in the declaration regarding dependent claim 10—which is irrelevant as it relates to Lavender, not Takagi. EX1003 ¶ 90.

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 Takagi. *See id.* 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 Takagi nor why a POSITA would have found the challenged claims obvious over Takagi. 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 (Feb. 10, 2023) at 4 (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 Takagi 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[.]"). Institution should be denied as to Ground 1. Under 35 U.S.C. § 314(a), the Board must determine whether Petitioner has shown a reasonable likelihood of prevailing. Petitioner has not shown a reasonable likelihood here, where the Petition and Dr. Fletcher's declaration together amount to little more than a single, unsupported narrative. Institution should be denied.

2. Limitation 1[i]³: calculating a volume of pure plasma collected within the plasma collection container based, at least in part, on the calculated volume of anticoagulant in the collected plasma component

Petitioner fails to demonstrate that Takagi anticipates and/or renders obvious limitation 1[i] because Takagi does not teach or suggest calculating pure plasma volume based on the calculated volume of anticoagulant **in the collected plasma component**. *See* Pet. at 28-30.

Petitioner acknowledges that Takagi teaches calculating an amount of anticoagulant each collection cycle. Pet. at 29 (“Anticoagulant admixture amount (*X*) is a volume of anticoagulant collected in plasma collection bag 25 **during a cycle**”) (emphasis added). *Id.* Takagi discloses a calculation for the “true current plasma collection amount” (*Z*) as follows with annotations:

$$Z \text{ (true plasma amount)} = Y \text{ (previous pure plasma collected amount)} + (W \text{ (plasma + anticoagulant amount in current cycle)} - X \text{ (anticoagulant amount in current cycle)})$$

³ Limitation 11[f] contains similar language. Petitioner refers back to its arguments regarding limitation 1[i] for limitation 11[f] without additional analysis. As such, the Petition fails to establish that Takagi anticipates and/or renders obvious claim 11, and all associated dependent claims, for the same reasons as described herein.

EX1004 at [0126]-[0127]. Thus, Takagi teaches calculating true plasma amount based on the previous amount of pure plasma collected, the total volume collected in the current cycle, and the anticoagulant volume collected in the current cycle. The amount of anticoagulant volume collected in one cycle, however, is not equivalent to the “calculated volume of anticoagulant in the collected plasma component” as is required by the claim. Takagi does not take into account the full volume of anticoagulant in the collection bag when calculating pure plasma volume. Accordingly, Takagi does not anticipate claim limitation 1[i].

The Petition similarly fails to establish that Takagi renders this limitation obvious. The entirety of Petitioner's obviousness argument regarding this limitation is as follows:

[A] POSITA would understand⁴ that Takagi discloses a system that calculates the total volume of pure plasma collected within the plasma collection container (i.e., (Z) after the final collection cycle) based, at least in part, on a calculated volume of anticoagulant in the collected plasma component due to the inclusion of anticoagulant admixture amount (X) in each cycle of Takagi's collection procedure.

Pet. at 30 (citing EX1003 ¶ 81). This threadbare, conclusory statement fails to explain why a POSITA would have found it obvious to include the entirety of

⁴ Notably, Petitioner does not argue that a POSITA would have had this understanding at the time of invention.

anticoagulant volume within the collection bag in the calculation for pure plasma where Takagi teaches doing so on a cycle-by-cycle basis. Moreover, Petitioner's entire support for this conclusion is paragraph 81 of Dr. Fletcher's declaration which is a word-for-word recitation of the Petition.

Petitioner's arguments regarding this claim limitation are woefully inadequate and unsupported. The entirety of the analysis relies upon expert testimony that directly copies the language used in the petition. *See Xerox*, IPR2022-00624, Paper 12 at 5 (denying institution where "the [expert] declaration copies, word-for-word, Petitioner's conclusory assertions"). Petitioner has failed to show a reasonable likelihood that Lavender anticipates and/or renders obvious limitation 1[i] and the corresponding limitation in claim 11.

3. Claim 11

Petitioner has omitted a claim limitation in its entirety from its analysis regarding claim 11. Specifically, the Petition skips the limitation: "a blood component separation device for separating the drawn blood into a plasma component and a second blood component, the blood component separation device having an outlet and being configured to send the plasma component to a plasma container." EX1001 at cl. 1, 11:38-42. This limitation should appear between what Petitioner lists as limitations 11[a] and 11[b] in the Petition. *See Pet.* at 34-35. Unsurprisingly, Dr. Fletcher's declaration also skips over this limitation and mirrors

the Petition. *See* EX1003 ¶¶ 92-93. By failing to address a claim limitation, Petitioner has failed to meet its burden regarding claim 11.

Patent Owner recognizes that Petitioner has just recently requested to file a Corrected Petition to add this missing limitation into the Petition and Dr. Fletcher's declaration. Patent Owner has opposed this request as the Petition was filed three months ago and Patent Owner has already filed its discretionary denial brief and prepared this Preliminary Response.

Given these glaring deficiencies, Petitioner's duplicative and unsupported analysis across the entirety of Ground 1 falls far short of demonstrating a reasonable likelihood that it will prevail regarding any of the challenged claims under Ground 1. Institution should therefore be denied.

B. Ground 2: Petitioner Has Failed to Show Lavender Anticipates and/or Renders Obvious the Challenged Claims.

As with Ground 1, Petitioner's analysis in Ground 2 relies exclusively on verbatim, conclusory statements in Dr. Fletcher's declaration. In fact, the repetition between the Petition and Dr. Fletcher's declaration is even more egregious in Ground 2: it is identical, even reproducing the same typographical errors. *E.g., compare* Pet. at 39 *with* EX1003 ¶ 109 (same missing space); Pet. at 51 *with* EX1003 ¶ 136 (same extraneous quotation marks); Pet. at 55 *with* EX1003 ¶ 145 (same extra period). Institution should be denied because in Ground 2, like Ground

1, “the declaration copies, word-for-word, Petitioner’s conclusory assertions” which is insufficient to demonstrate a reasonable likelihood that Petitioner will prevail at trial. *Xerox*, IPR2022-00624, Paper 12; *see also TQ Delta, LLC v. CISCO Sys., Inc.*, 942 F.3d 1352, 1359 (Fed. Cir. 2019).

In addition to Petitioner’s reliance on a cumulative expert declaration, Petitioner also fails to establish that the Lavender reference teaches and/or renders obvious each limitation of the challenged independent claims. For example, Petitioner fails to show that Lavender teaches and/or renders obvious limitations 1[d], 1[i], and 1[j], along with the corresponding limitations in independent claim 11. As such, Petitioner has failed to carry its burden with respect to Ground 2.

1. Limitation 1[d]⁵: withdrawing whole blood from the donor through the venous-access device and a draw line, the draw line connected to a blood component separation device

Limitation 1[d] requires that “whole blood” be withdrawn from the donor through a venous-access device. Petitioner’s analysis concerning this claim

⁵ Limitation 11[a] contains similar language that requires “drawing whole blood from a subject”. In the Petition, Petitioner refers back to its arguments regarding claim 1 for claim 11 without additional analysis. As such, the Petition fails to establish that Lavender anticipates and/or renders obvious claim 11, and all associated dependent claims, for the same reasons as described herein.

element, in its entirety, is: “The drawn blood is whole blood because it is a mixture of ‘a variety of blood fractions.’” Pet. at 38 (citing EX1005 at 5:44 and EX1003 ¶ 106). This excerpted portion of Lavender, however, does not support that what is being withdrawn from a donor is, in fact, “whole blood.” In the cited portion from Lavender, the entirety of the quotation states that “the blood fractionator 25 of the present invention along with the system 20 disclosed herein may be useful to produce a variety of blood fractions.” EX1005 at 5:42-44. This excerpt says nothing about the blood drawn from the donor and merely explains that “a variety of blood fractions” may be extracted by the claimed system. *Id.*

Dr. Fletcher's declaration adds nothing beyond what already appears in the Petition. The paragraph of his declaration that Petitioner cites (¶ 106) is a verbatim recitation of the Petition's own language for the entirety of limitation 1[d]. The same pattern holds for the entirety of Ground 2, where the sections of the Petition and Dr. Fletcher's analysis are identical, even though the Petition repeatedly cites Dr. Fletcher's declaration as purported support. Petitioner has not shown a reasonable likelihood of success where, as here, the Petition and Dr. Fletcher's declaration together amount to little more than a single, unsupported narrative.

2. Limitation 1[i]⁶: calculating a volume of pure plasma collected within the plasma collection container based, at least in part, on the calculated volume of anticoagulant in the collected plasma component

Petitioner's arguments regarding limitation 1[i] are unavailing. First, Petitioner's argument that Lavender expressly or inherently teaches this limitation is wrong. Petitioner asserts that a volume of pure plasma is calculated "based on" the calculated volume of anticoagulant in the collected plasma component because both volumes "are dependent on the predefined ratio of citrate added" and therefore "as one value changes, the other necessarily changes." Pet. at 44 (citing EX1003 ¶ 119 (providing a verbatim recitation of the Petitioner's conclusory statement)). As the Petition itself demonstrates, Petitioner has this relationship backwards.

Petitioner acknowledges that "Lavender *first* calculates" total plasma filtered and "*Next*, Lavender calculates the anticoagulant volume in the plasma container." Pet. at 43 (emphases added). Lavender's own equations confirm this sequence, that

⁶ Limitation 11[f] contains similar language. Petitioner refers back to its arguments regarding limitation 1[i] for limitation 11[f] without additional analysis other than pointing to a microprocessor to carry out these calculations. As such, the Petition fails to establish that Lavender anticipates and/or renders obvious claim 11, and all associated dependent claims, for the same reasons as described herein.

total plasma filtered (TPF) is a variable within the anticoagulant volume calculation (TCF). *See* EX1005 at 43 ($TPF = TDPF * PDF$; $TCF = TPF * CF$). Thus, it is the anticoagulant volume that depends on total plasma filtered, not the other way around. Petitioner is incorrect in concluding that Lavender discloses calculating pure plasma “based on” anticoagulant volume. Pet. at 43-45. Lavender at best teaches calculating total anticoagulant filtered volume based on total dilute plasma filtered volume. Lavender does not anticipate limitation 1[i].

Petitioner's alternative argument, that Lavender renders limitation 1[i] obvious, is likewise deficient. Pet. at 44-45. Petitioner and Dr. Fletcher use identical language to conclude: “a POSITA would (i) recognize the interdependency between the predefined ratio of citrate added . . . , and (ii) understand that the plasma volume in the collection bag is based, at least in part, on the volume of anticoagulant in the collection bag.” *Id.*; EX1003 ¶ 120. Yet neither the Petition nor Dr. Fletcher provide any explanation or rationale as to why a POSITA would perceive such an interdependency, much less find it obvious to calculate total pure plasma volume in a way that is not taught or suggested by Lavender.

Conclusory allegations such as these are insufficient to carry Petitioner's burden. *See Activision Blizzard, Inc. v. Milestone Ent., LLC*, IPR2025-00713, Paper 15 (Oct. 16, 2025) at 11 (“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)); *see also TQ Delta, LLC v. CISCO Sys., Inc.*, 942 F.3d 1352, 1359 (Fed. Cir. 2019) (holding conclusory expert opinions cannot support an obviousness determination); *Xerox*, IPR2022-00624, Paper 12 at 5 (“the Board was correct in giving little weight to Petitioner’s expert because the expert declaration merely offered conclusory assertions without underlying factual support and repeated, *verbatim*, Petitioner’s conclusory arguments”) (emphasis in original). Petitioner merely relies on hindsight, working backwards from the challenged claim language to retrofit the teachings of Lavender to resemble the claimed invention.

Because Lavender neither teaches nor suggests calculating pure plasma volume based on anticoagulant volume, and because Petitioner’s reasoning rests on unsupported conclusions rather than evidence, Petitioner has failed to demonstrate a reasonable likelihood of prevailing on limitation 1[i].

3. Limitation 1[j]⁷: continuing steps (d) through (i) until a target volume of pure plasma is collected within the plasma collection container

In conclusory fashion, Petitioner asserts that Lavender teaches continuing the previous steps until a target volume of pure plasma is collected. Petitioner points to two disclosures in Lavender to support the target volume of pure plasma, which refer to “a desired amount of plasma” and “a predetermined . . . volume of plasma.” Pet. at 45; EX1005 at 21:62-22:6. Yet nowhere does Petitioner contend that the disclosed “volume of plasma” is the “target volume of pure plasma” claimed in limitation 1[j].

As the '652 Patent explains, “prior art plasmapheresis devices end plasma collection based on a total volume of anticoagulated plasma (e.g., pure plasma plus the added anticoagulant).” EX1001 at 9:55-58. Petitioner fails to explain why, in

⁷ Limitation 11[g] contains similar language. Petitioner refers back to its arguments regarding limitation 1[j] for limitation 11[g] without additional analysis. In fact, limitation 11[g] adds that “the controller is configured to stop the blood draw pump,” which is not included in limitation 1[j], but Petitioner fails to provide any evidence of where that disclosure is found in Lavender. As such, the Petition fails to establish that Lavender anticipates and/or renders obvious claim 11, and all associated dependent claims, for the same reasons as described herein.

light of this well-understood state of the art, a POSITA would read Lavender's "volume of plasma" to mean pure plasma and not the conventional anticoagulated plasma, which was the traditional collection method. In fact, while Petitioner points to Lavender's use of an acronym—TPF (total plasma filtered)—to refer to pure plasma without any explanation, the acronym "TPF" or term "total plasma filtered" is notably absent from these disclosures in Lavender describing when the procedure is stopped, which is a requirement of claim limitation 1[j]. Dr. Fletcher likewise fails to explain why a POSITA would read Lavender in this way.

Petitioner's reliance on Dr. Fletcher's declaration only underscores the weakness of its position. Pet. at 45. The cited paragraphs of Dr. Fletcher's declaration for this limitation are verbatim recitations of the Petition's conclusory assertions and contain no additional reasoning or technical analysis. EX1003 ¶¶ 94-96; *see also Xerox*, IPR2022-00624, Paper 12 at 5 (denying institution where the "expert declaration merely offered conclusory assertions without underlying factual support and repeated, *verbatim*, Petitioner's conclusory arguments") (emphasis in original).

4. Claim 11

As with Ground 1, Petitioner has omitted the limitation: "a blood component separation device for separating the drawn blood into a plasma component and a second blood component, the blood component separation device having an outlet

and being configured to send the plasma component to a plasma container” from its analysis regarding claim 11. *See* EX1001 at cl. 1, 11:38-42; Pet. at 50-51. Dr. Fletcher's declaration also skips over this limitation and mirrors the Petition. *See* EX1003 ¶¶ 133-134. By failing to address a claim limitation, Petitioner has failed to meet its burden regarding claim 11.

Patent Owner recognizes that Petitioner has just recently requested to file a Corrected Petition to add this missing limitation into the Petition and Dr. Fletcher's declaration. Patent Owner has opposed this request as the Petition was filed three months ago, Patent Owner has already filed its discretionary denial brief, and prepared this Preliminary Response.

At base, Petitioner has failed to carry its burden to show that Lavender anticipates or renders obvious independent claims 1 and 11. Petitioner's duplicative and unsupported analysis across the entirety of Ground 1 falls far short of demonstrating a reasonable likelihood that it will prevail regarding any of the challenged claims under Ground 1. Institution should therefore be denied.

C. Grounds 3-5: Petitioner Has Failed to Show a Reasonable Likelihood of Success on Grounds 3-5 Nor Provided Legally Sufficient Motivations to Combine.

The deficiencies that doom Grounds 1 and 2 permeate the remainder of the Petition. Grounds 3-5 only challenge dependent claims and refer back to Grounds 1 and 2 for support regarding independent claims 1 and 11. As such, and for the

reasons described above, Grounds 3-5 similarly fail to establish a reasonable likelihood of success. Even more, Grounds 3-5 rely on a series of combinations of references, each of which lacks an adequately explained motivation to combine.

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 977, 988 (Fed. Cir. 2006). The Petition and Dr. Fletcher's declaration are devoid of any rationale explaining why a POSITA would have been motivated to combine Petitioner's references, or why a POSITA would have had a reasonable expectation of success in such combinations. When the conclusory language is stripped away, there is little substance left for Patent Owner to address.

In Ground 3, Petitioner purports to combine Takagi with U.S. Patent No. 8,075,468 to Min (“Min”). In its explanation of “Reasons to Combine Takagi and Min,” Petitioner repeatedly cites to Dr. Fletcher's declaration. Pet. at 57-60. Dr. Fletcher's declaration, however, again copies the Petition verbatim for this section, with the exception of case law cites in the Petition. *See* Pet. at 57-60; EX1003 ¶¶ 153-160. The Petition is rife with conclusory statements that “it would have been obvious” to combine Takagi and Min without explaining *why* a POSITA would have found such a combination obvious. *See* Pet. at 59; EX1003 ¶ 158. Petitioner's conclusory statements repeating basic tenets of motivation to combine analyses

(e.g., a POSITA would have had a reasonable expectation of success) without any supporting analysis from its expert fails to demonstrate a reasonable expectation of success for Ground 3.

Ground 4 is similarly lacking. In Ground 4, Petitioner purports to combine Lavender and Takagi with two additional references: (1) U.S. Patent No. 6,296,602 to Headley (“Headley”); and (2) U.S. Patent No. 9,370,324 to Barrett (“Barrett”). Petitioner begins by discussing Headley, but nowhere does Petitioner provide a specific rationale or motivation to combine Headley with the other references. Pet. at 65; *see. e.g., PersonalWeb Techs., LLC v. Apple, Inc.*, 848 F.3d 987, 994 (Fed. Cir. 2017) (vacating Board’s decision on obviousness for failing to “clearly explain[], or cite[] evidence showing, how the combination of the two references was supposed to work.”). Dr. Fletcher also fails to provide any analysis and repeats, verbatim, Petitioner’s assertions (with the exception of case law citations). *See* Pet. at 64-68; EX1003 ¶¶ 170-180. The remainder of Petitioner’s motivation to combine analysis is a scattershot recanting of specific portions within each reference that Petitioner retrofits together to meet the challenged claims. Pet. at 64-68; *In re Magnum Oil Tools Int’l, Ltd.*, 829 F.3d 1364, 1381 (Fed. Cir. 2016) (“a petitioner cannot simply show that each element of a claim was known in the prior art. The petitioner must articulate specific reasoning, based on evidence of record, to support the legal conclusion of obviousness.”). This hindsight-driven approach cannot

satisfy Petitioner's burden under 35 U.S.C. § 314(a). *See TQ Delta, LLC v. CISCO Sys., Inc.*, 942 F.3d 1352, 1361 (Fed. Cir. 2019) (a Petitioner may not use the challenged claims "as a roadmap to reconstruct the claimed invention using disparate elements from the prior art"); *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.").

"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." *Nautilus Hyosung Inc. v. Diebold, Inc.*, IPR2016-00633, Paper 9 at 21 (Aug. 22, 2016). Yet, Petitioner and Dr. Fletcher refer to what a POSITA "could" do in combining these four references. Pet. at 67 ("This equation could simply be added into the Main Loop algorithm of Lavender"); EX1003 ¶ 178. "[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, merely concluding that references could be combined in a particular way is insufficient to

support a motivation to combine argument which must explain that a POSITA would be motivated to make the combination. *See InTouch Techs.*, 751 F.3d at 1352.

Petitioner fails to sufficiently explain why a POSITA would have been motivated to combine Lavender, Takagi, Headley, and Barrett and, as such, Ground 4 also fails.

Lastly, in Ground 5, Petitioner purports to combine Lavender, Takagi, Min, and a new reference, U.S. Patent Publication No. 2017/0029762 to Turgut (“Turgut”). Again, Dr. Fletcher’s analysis copies the language in the Petition and does not provide any additional rationale or reasoning. *See* EX1003 ¶¶ 183-188. Without explanation, Petitioner groups Lavender, Takagi, and Min together and only attempts to explain why a POSITA would be motivated to combine Turgut with those three references. Pet. at 70-72. Even if this were sufficient—it is not—Petitioner’s analysis is conclusory and fails to explain *why* a POSITA would have combined Turgut with Lavender, Takagi, and Min nor *why* a POSITA would have had a reasonable expectation of success in doing so. *In re Van Os*, 844 F.3d at 1361-62. As with Grounds 3 and 4, Petitioner has not carried its burden with regard to Ground 5.

**D. 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 '652 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[®] PCS systems with YES[®] and PERSONA[®] technology ("NexSys Systems") are coextensive with the challenged claims of the '652 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 '652 Patent Challenged Claims.

The NexSys System is “[a] system for collecting plasma” that performs the claimed method. EX1001 at cls. 1, 11. Patent Owner's system includes: (a) a venous-access device for drawing whole blood from a subject and returning blood components to the subject; (b) a blood component separation device for separating the drawn blood into a plasma component and a second blood component, the blood component separation device having an outlet and being configured to send the plasma component to a plasma container; (c) a blood draw line fluidly connected to the venous-access device and configured to transport drawn whole blood to the blood component separation device, the flow through the blood draw line being controlled by a blood draw pump; (d) an anticoagulant line connected to an anticoagulant source, the anticoagulant line configured to introduce anticoagulant into the drawn whole blood; (e) a controller that controls the operation of the blood component separation device and the blood draw pump, calculates anticoagulant volume in the collected plasma component as the plasma component is being collected, and calculates pure plasma volume collected based, at least in part, on anticoagulant volume in the plasma component; and (f) the controller stops the blood draw pump once a target pure plasma volume is collected. *Id.* at cl. 11; *see generally* EX2015 (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 System was commercially successful.

As explained in Patent Owner's Request for Discretionary Denial (Paper 7), Patent Owner released two versions of its NexSys System, in 2018 and 2020, respectively. EX2002 ¶¶ 16, 20. The 2018 device included Patent Owner's patented YES[®] technology and the 2020 system further included Patent Owner's PERSONA[®] technology. *Id.* Both of these systems have revolutionized the plasma collection industry and Haemonetics remains the industry leader. *Id.* ¶¶ 13-15.

By employing the method claimed in the '652 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 System 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 System, which has 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 System. *See, e.g.*, EX2016-2018.

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

As the '652 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 1:38-44; EX1012. 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

Patent Owner's Preliminary Response
U.S. Patent No. 10,758,652

both pure blood plasma and anticoagulant). EX1012. This “simplified” nomogram is described in the 1992 FDA Guidelines as shown below:

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

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

Id. For nearly three decades, plasma collections followed this outdated guidance and plasma collection companies targeted the “Collection Volume” (plasma and anticoagulant) because it was easier to measure. While the FDA acknowledged 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.

EX1005 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[.]” EX2018. 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 System and patented method.

Prior to releasing the NexSys System, 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 '652 Patent. Despite this general skepticism and regulatory uncertainty, Patent Owner successfully obtained FDA clearance for its NexSys Systems with YES[®] and PERSONA[®] 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 System, 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[®] 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[®] implementation." *Id.*

As another example, in 2021 Haemonetics' results of its plasma yield trial with this patented technology were peer reviewed and published in the TRANSFUSION journal for medical research. *See* EX2017. "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 System.

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 system and the first to release a commercialized version practicing those patents (including the '652 Patent). Both Petitioner and Fresenius Kabi/Fenwal

were quick to follow, releasing very similar systems to the NexSys System in recent years.

In 2022, Petitioner was given FDA clearance for its Rika Plasma Donation System with Nomogram A which was first used in a plasma collection center just a few months later. *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 '652 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 System 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* EX2019. 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 System. *Id.*

Patent Owner's other competitor, Fresenius Kabi/Fenwal, received FDA clearance for its Aurora Xi System with an "Adaptive Nomogram" on January 24, 2025. *See* EX2020. 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.

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 '652 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.

VII. CONCLUSION

For the foregoing reasons, Petitioner has failed to establish a reasonable likelihood of prevailing on any challenged claim. The Petition relies on conclusory expert testimony, hindsight, and unsupported assertions rather than evidence or

Patent Owner's Preliminary Response
U.S. Patent No. 10,758,652

reasoned analysis. Accordingly, Patent Owner respectfully requests that the Board deny institution of *inter partes* review of the '652 Patent in its entirety.

Respectfully submitted,

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Dated: November 25, 2025

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

Pursuant to 37 C.F.R. §42.24(b), Patent Owner hereby certifies of the above-captioned Patent Owner's Preliminary Response for IPR2025-01391 of U.S. Patent 10,758,652, 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 7,875. 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: November 25, 2025

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§ 42.6(e) and 42.105, I hereby certify that on November 25, 2025, I caused a complete copy of Patent Owner's Preliminary Response to the Petition regarding U.S. Patent No. 10,758,652 and all exhibits, to be served on the Petitioner as follows:

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