

Patent Owner's Preliminary Response  
U.S. Patent No. 10,980,934

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. IPR2026-00045

U.S. Patent No. 10,980,934

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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>2013</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>2014</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>2015</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>2016</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>2017</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>2018</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>

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 (“Petition”) regarding claims 1-30 of U.S. Patent No. 10,980,934 (the “’934 Patent”), as requested by Petitioner Terumo BCT Inc. (“Petitioner”), setting forth the reasons why the Petition should be denied.<sup>1</sup>

## I. INTRODUCTION

Petitioner filed the instant Petition challenging the patentability of all claims of the ’934 Patent. The Petition presents four grounds of unpatentability, but each ground primarily relies on two references: (1) U.S. Patent No. 4,898,675 to Lavender (“Lavender”); and (2) “Calculations in Apheresis, Journal of Clinical Apheresis by Neyrinck (“Neyrinck”).

Petitioner bears the burden of establishing the invalidity of the ’934 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

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

institution is never required.<sup>2</sup> 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 obviousness theories are lacking. The Petition is rife with hindsight bias and conclusory statements that rely on mental gymnastics to force the references to meet the challenged claims. Much of Petitioner's “analysis” consists largely of rewriting mathematical equations in Neyrinck 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 claimed in the '934 Patent and neither the Petition nor Petitioner's expert, Dr. Fletcher, provide any rationale or reasoning as to why a POSITA would have

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<sup>2</sup> Patent Owner has also requested discretionary denial of institution of the Petition, as explained in Paper 9.

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. Each of the nine grounds rely on a proposed combination of Lavender and Neyrinck; however, Petitioner's motivations to combine those two references 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 mirrors the Petition. Neither Petitioner nor Dr. Fletcher provide sufficient analysis or rationale as to *why* a POSITA would have been motivated to combine Lavender and Neyrinck—and/or any other references—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 '934 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, institution should be denied because:

- The Petition relies on conclusory expert testimony that merely repeats attorney argument. Dr. Fletcher's declaration is nearly word-for-word identical to the Petition, provides no independent analysis, and offers no explanation of what a POSITA would have understood—defects that the Board has repeatedly found insufficient to support institution.
- Petitioner fails to articulate any evidence-based motivation to combine the cited references. Across all grounds, Petitioner asserts only that a POSITA could mathematically rearrange equations from Lavender and Neyrinck, but never explains why a POSITA would have been motivated to do so or identifies any problem in the prior art that such a combination would address.
- The obviousness theories are driven by hindsight reconstruction. Petitioner works backward from the challenged claims, selectively

extracting and swapping formulas from Neyrinck to fill gaps in Lavender—including relying on different alternative formulas depending on the claim limitation—without any teaching or suggestion in the prior art.

- Petitioner fails to establish a reasonable expectation of success. The Petition offers no analysis explaining how the proposed combinations would be implemented in Lavender's disclosed system architecture or why the reworked calculations would operate predictably in practice.
- Objective indicia further negate any reasonable likelihood of success. Unrebutted evidence of commercial success, long-felt need, industry skepticism, praise, and copying—each tied directly to the claimed invention—confirms non-obviousness.

For these reasons, Petitioner has not shown a reasonable likelihood of prevailing on any challenged claim, and the Board should deny institution under 35 U.S.C. § 314(a).

## **II. OVERVIEW OF THE '934 PATENT**

The '934 Patent is directed to plasmapheresis methods and systems utilizing a donor's characteristics to identify a pure plasma amount to be collected. EX1001 at 1:66-2:24, 3:12-25. The disclosed system tailors the plasma collection amount to each donor because “the volume of plasma that is collected from the donor varies

from donor to donor (e.g., because it is based on the donor's height, weight, hematocrit, and blood volume). *Id.* at 15:52-55.

This was an improvement over prior art systems. EX1001 at 1:43-62, 12:40-65, 16:46-17:24. Prior art systems that targeted total collection volume did not consider a donor's individual characteristics, such as height, weight, hematocrit, and blood volume. *Id.* at 16:46-17:4. As the patent explains:

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

*Id.* at 16:44-50. Different donors also have different total plasma volumes, which is based on weight, height, and hematocrit. *Id.* at 4:1-14. The '934 Patent, therefore, teaches determining a "target volume" of plasma to collect tailored to each donor's characteristics and stopping the collection when that target is reached. *Id.* at 4:1-14; *see also id.* at 16:46-17:24, cls. 1, 8, 15, and 23. Thus, the '934 Patent optimizes plasma yields on a donor-by-donor basis by collecting the appropriate amount of plasma from each donor.

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

#### **A. Lavender**

Unlike the '934 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. EX1004 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* EX1004 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.

**B. Neyrinck**

Neyrinck is an article narrowly focused on different methods of apheresis calculations, including calculations for total blood volume, extra corporeal volume, total plasma volume, collection efficiency, and hemoglobin and hematocrit. EX1005 at 38-41. For example, Neyrinck discloses using “Nadler’s formula to calculate the TBV [Total Blood Volume] of a human being based on gender, height, and weight,” (EX1005 at 39, 41) which was cited in the ’934 Patent (EX1001 at Cover p. 3).

Neyrinck also describes calculating total plasma volume (TPV) of a donor utilizing hematocrit and total blood volume (TBV). EX1005 at 39-40. Neyrinck focuses on hematocrit because it affects the duration of the plasma collection procedure. *Id.* (hematocrit “is really influencing the duration of a plasma exchange procedure”); *id.* (“the Hct is influencing the procedure, especially the procedure time”); *id.* (“there will be a longer procedure in patients with a lower Hct”). Neyrinck does not focus on the volume of pure plasma collected in these procedures; rather, only makes reference to plasma collection volume, which includes pure plasma and anticoagulant. *See id.*

**IV. LEVEL OF ORDINARY SKILL**

For the purposes of this Preliminary Response, Patent Owner has applied the same skill level proposed by Petitioner as it pertains to a POSITA. *See Pet.* at 21.

## V. CLAIM CONSTRUCTION

Petitioner asserts that “the Challenged Claims need no construction to demonstrate they are unpatentable.” Pet. at 22. Petitioner’s arguments are unavailing under any construction of the claim terms. Patent Owner agrees that claim construction is not necessary to decide institution. Pet. at 21-22; *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 positions.

## VI. CLAIMS 1-30 ARE NOT UNPATENTABLE OVER PETITIONER’S REFERENCES

### A. **Ground I: Petitioner Has Failed to Show Lavender in view of Neyrinck Renders Obvious the Challenged Claims.**

In Ground I Petitioner avers claims 1, 5, 6, 23-27, and 30 are rendered obvious over Lavender in view of Neyrinck. Pet. at 22. Petitioner has not met its burden to demonstrate the unpatentability of the challenged claims in Ground I.

To demonstrate obviousness, Petitioner must establish that Lavender in view of Neyrinck suggests or renders obvious each claim limitation, that there exists a reason to modify Lavender’s teachings based on the teachings of Neyrinck as

Petitioner proposes, and that a POSITA would have a reasonable 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 a reasonable likelihood it will prevail with respect to any of the challenged claims in Ground I. The Petition does not sufficiently demonstrate that Lavender in view of Neyrinck renders obvious any of the challenged claims. The Petition relies almost exclusively on the expert declaration of Dr. Fletcher to support what is described in Lavender and Neyrinck and what a POSITA would have found obvious based on the teachings of those references. Dr. Fletcher's declaration, however, is nearly identical and merely parrots, almost entirely verbatim, the analysis provided in the Petition, adding no independent reasoning or technical insight. And, the descriptions in the Petition—

as copied in Dr. Fletcher's declaration—fail to adequately explain why a POSITA would have found the challenged claims obvious based on the cited references.

Such conclusory repetition cannot substitute for substantive analysis and should be given no weight. Indeed, the *entirety* of Ground I is almost *identical* to the Petition. In fact, the Petition and Dr. Fletcher's declaration are essentially word-for-word duplicates and even reproduce the exact same typographical errors, footnotes, and emphases added. *E.g., compare* Pet. at 22-37 with EX1003 ¶¶ 64-112 (entirety of analysis regarding claim 1); Pet. at 22-37 with EX1003 ¶¶ 64-112 (interchanging between “p.,” “pp.” and “pg.” citations in the same manner); Pet. at 23 with EX1003 ¶ 67 (same misplaced semi-colon); Pet. at 35, 37 with EX1003 ¶¶ 106, 109 (same straight quotation marks, corrected elsewhere); Pet. at 28 n.3 with EX1003 at 38 n.3 (identical footnote); Pet. at 31 n.4 with EX1003 at 42 n.4 (identical footnote, inadvertently repeated); Pet. at 25-26, 31-32 with EX1003 ¶¶ 70-72, 74, 77-78, 86, 88, 90-92 (same emphases). The *only* differences between the Petition and Dr. Fletcher's declaration regarding claim 1 include minor word changes (e.g., adding “in my opinion” to identical sentences in Dr. Fletcher's declaration).

Despite the facially apparent overlap, Petitioner repeatedly cites to and relies on Dr. Fletcher's declaration as support for what a POSITA would have understood based on the teachings of Lavender and Neyrinck. *See generally* Pet. Because Dr.

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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 Lavender and Neyrinck or why a POSITA would have found the challenged claims obvious over these references. 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 Lavender in view of Neyrinck 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[.]").

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. Petitioner fails to establish a motivation to combine Lavender and Neyrinck with a reasonable expectation of success.**

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 Lavender and Neyrinck, 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 to address.

As with the remainder of the Petition, the entirety of Petitioner's motivation to combine and expectation of success analysis is merely parroted back in Dr. Fletcher's declaration, without any additional technical analysis or independent reasoning. *Compare* Pet. at 22-25 with EX1003 ¶¶ 64-69. Such “word-for-word” repetition does not transform attorney argument into evidence. Thus, Petitioner's analysis is unsupported, despite citing Dr. Fletcher's verbatim declaration throughout. *TQ Delta*, 942 F.3d at 1359 (“This court's opinions have repeatedly recognized that conclusory expert testimony is inadequate to support an obviousness determination[.]”).

Stripped of this conclusory repetition, Petitioner's alleged motivation to combine reduces to a single premise, that variables from Neyrinck's disclosed calculations *could* be mathematically inserted into Lavender's calculations in an attempt to make the two references fit together. *See* Pet. at 22-25. Petitioner goes to great lengths to reverse engineer the references but never explains *why* a POSITA—starting from either reference—would have been motivated to rework and transpose the references' disclosed calculations in this way (or in any way). Likewise, Dr. Fletcher fails to provide any rationale as to why a POSITA would make the proposed combination. For example, while Petitioner suggests a POSITA could use Neyrinck's disclosed variables, such as height, hematocrit, and total blood volume, in Lavender's calculations for total plasma volume, Petitioner provides no justification for *why* a POSITA would have been motivated to alter Lavender's disclosed equations nor any teachings in either reference that suggest such a modification. Neither Lavender nor Neyrinck suggests modifying Lavender's equations, nor do they identify any deficiency in Lavender that would prompt a POSITA to seek Neyrinck's alternative calculations.

In fact, the Petition and Dr. Fletcher do not consistently suggest that a POSITA *would* have combined these references' teachings; rather, Petitioner and Dr. Fletcher opine that a POSITA *could* do so. *See, e.g.*, Pet. at 24 ("Neyrinck's plasma collection calculations *could* be readily implemented in Lavender's

computation framework”); EX1003 ¶ 69 (same); Pet. at 24-25 (“In one such example, Lavender’s system *could* implement Neyrinck’s TPV calculation”); EX1003 ¶ 69 (same) (emphases added). “[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 that must explain that a POSITA would have been motivated to make the combination. *See InTouch Techs.*, 751 F.3d at 1352. Petitioner’s statements are paradigmatic examples of legally insufficient “could” reasoning, not evidence that a POSITA *would* have made the proposed modifications.

Both the Petition and declaration of Dr. Fletcher are devoid of any explanation as to why a POSITA would rework and transpose the disclosed equations in combining Lavender and Neyrinck. After rearranging these equations to line up the two references, Petitioner baselessly concludes “Lavender’s system *could* implement Neyrinck’s TPV calculation . . . to more accurately calculate a target plasma collection volume and improve collection yield,” but nowhere explains why Neyrinck’s TPV calculation is an improvement over Lavender’s

preexisting calculation. Pet. at 24-25 (emphasis added). Dr. Fletcher provides no further analysis as to why making the proposed combination would, in fact, be more accurate or result in a higher collection yield. See EX1003 ¶ 69 (repeating the Petition verbatim). This type of conclusory statement regarding alleged improvements is insufficient to establish a motivation to combine. See *ActiveVideo Networks, Inc. v. Verizon Commc'ns, Inc.*, 694 F.3d 1312, 1327 (Fed. Cir. 2012) (arguing a POSITA would be motivated to combine references to build a “better” system is insufficient to 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 fail to explain: (1) *why* a POSITA would be motivated to combine portions of Neyrinck's calculations with Lavender's equations; and (2) *how* either reference teaches or suggests a reason for this combination. See *ActiveVideo Networks*, 694 F.3d at 1327 (“The expert failed to explain how specific references could be combined, which combination(s) of elements in specific references would yield a predictable result, or how any specific combination would operate or read on the asserted claims.”). This failure independently dooms Petitioner's showing of a reasonable expectation of success.

Accordingly, the motivation to combine analysis is rife with hindsight bias: 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.”). Petitioner recognized that certain claimed variables were missing from Lavender’s equation and merely found a reference to fill the gap—without providing proper analysis as to why a POSITA would have been motivated to make that change. Indeed, Petitioner uses different calculations that Neyrinck describes as alternatives to fill the holes in Lavender. For example, for certain limitations, Petitioner uses Neyrinck’s disclosure of Nadler’s formula to meet the claim 1[a] (Pet. at 25) and, for other limitations, uses Neyrinck’s *alternative* formula using BMI to meet claim 1[c] and claim 5 (Pet. at 26, 31). Petitioner’s selective use of different, alternative formulas disclosed in Neyrinck—depending on which claim limitation is at issue—underscores the absence of any coherent technical rationale for the proposed combination and further evidences this hindsight-driven gap filling.

Accordingly, neither the Petition nor Dr. Fletcher's declaration, identifies an actual evidence-based motivation to combine Lavender and Neyrinck past the conclusory allegations 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.").

Nor does Petitioner establish a reasonable expectation of success. Petitioner offers no analysis showing that transplanting Neyrinck's calculations into Lavender's system would function as intended, maintain system stability, or yield predictable results in the context of Lavender's disclosed architecture. Absent any explanation of how the reworked equations would operate together in practice, Petitioner fails to meet its burden on expectation of success as well.

**3. Limitation 1[c]<sup>3</sup>: calculating a donor plasma volume based, at least in part, on the height and weight of the donor and the hematocrit of the donor**

Petitioner's arguments regarding limitation 1[c] are unavailing. Petitioner begins by noting that "Lavender calculates a **donor's circulating plasma volume**

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<sup>3</sup> Limitations 8[f], 15[c], and 23[f] contains substantively identical language.

Petitioner refers back to its arguments regarding limitation 1[c] for those limitations

as 5% of donor **weight**. Lavender then collects 18% of that calculated volume.” Pet.at 26 (emphases in original). Thus, Petitioner acknowledges that Lavender teaches a method of calculating donor circulating plasma volume which is a straightforward, single-variable calculation taking a percentage of donor weight. Lavender does not teach or suggest calculating donor plasma volume based on height, weight, and hematocrit of the donor.

Because this straightforward calculation does not line-up with the challenged claims, Petitioner relies on pure hindsight to combine Lavender with Neyrinck to meet limitation 1[c]. But neither Petitioner nor Dr. Fletcher provide any rationale as to why a POSITA would have been motivated to entirely rework Lavender's equation.

According to Petitioner's proposed combination, instead of simply taking a percentage of donor bodyweight, a POSITA would, instead, *first* calculate total blood volume using one of Neyrinck's disclosed formulas based on height and weight, and *then* calculate donor plasma volume based on total blood volume and donor hematocrit. Not only is the motivation to combine Lavender and Neyrinck

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without additional analysis. As such, the Petition fails to establish that Lavender in view of Neyrinck renders obvious claims 8, 15, and 23, and all associated dependent claims, for the same reasons as described herein.

generally unsupported—as explained above—but Petitioner fails to explain why a POSITA would convert the basic plasma volume equation in Lavender to the complex, two-step equations taught by Neyrinck.

Petitioner baselessly concludes that this rewriting of Lavender's equation would “more accurately calculate a donor's plasma volume,”<sup>4</sup> however, that conclusion is not taught by Lavender or Neyrinck nor does Dr. Fletcher provide any explanation as to why Neyrinck's equations are more accurate. Pet. at 27; EX1003 ¶¶ 76-79 (repeating the Petition verbatim).

Petitioner also fails to explain how these equations would be carried out by Lavender's system nor worked into Lavender's Main Loop. There is no discussion of how the proposed calculations would be integrated into Lavender's disclosed Main Loop, how the additional variables would be introduced into the system, or how the modified equations would operate within Lavender's control logic. This silence further underscores that Petitioner's analysis is not grounded in how a

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<sup>4</sup> Petitioner makes a similar conclusory statement, alleging this combination “would improve donor safety and product yield.” Pet. at 27. Although this statement cites Dr. Fletcher's declaration in support, Dr. Fletcher repeats this conclusion word-for-word, without further analysis, explanation, or evidence.

POSITA would have understood or modified the prior art, but rather in reconstructing the claimed invention with hindsight.

At base, Petitioner's argument regarding limitation 1[c] merely begins with the claim language and works backward from Neyrinck and Lavender to come up with a combination of the systems that calculates donor plasma volume based on height, weight, and donor hematocrit because the claims require it. This hindsight approach should be rejected and cannot form the basis for institution.

Because Petitioner's reasoning rests on unsupported conclusions rather than evidence, Petitioner has failed to demonstrate a reasonable likelihood of prevailing on limitation 1[c].

**4. Limitation 1[d]<sup>5</sup>: calculating a target plasma volume to collect based, at least in part, on the calculated donor plasma volume and a target percentage of plasma**

Petitioner's arguments regarding limitation 1[d] fare no better than its failed showing for limitation 1[c]. As Petitioner acknowledges, Lavender calculates donor

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<sup>5</sup> Limitations 8[g], 15[d], and 23[g] contain substantively identical language. Petitioner refers back to its arguments regarding limitation 1[d] for those limitations without additional analysis. As such, the Petition fails to establish that Lavender in view of Neyrinck renders obvious claims 8, 15, and 23, and all associated dependent claims, for the same reasons as described herein.

circulating plasma volume by taking a percentage of donor weight and then calculates a target plasma volume “that is 18% of a donor’s circulating plasma volume.” Pet. at 27.

Nonetheless, Petitioner again combines Lavender with Neyrinck for limitation 1[d], not because Lavender lacks a target percentage or a target volume calculation, but because it relies upon the same redefined “calculated donor plasma volume” as referenced in its hindsight-driven theory from limitation 1[c]. *Id.*

Just as with limitation 1[c], neither Petitioner nor Dr. Fletcher provide any rationale, justification, explanation, or evidence for why a POSITA would stray from the straightforward calculations in Lavender to the two-step calculations in Neyrinck. The only logical conclusion is that Petitioner had to fill the gaps in Lavender with Neyrinck to meet the challenged claims. What’s more, after arguing a POSITA would completely rewrite Lavender’s equation in favor of Neyrinck’s two-step total plasma volume calculation, Petitioner then suggests a POSITA would revert to Lavender’s basic target plasma volume calculation of 18% of a donor’s plasma volume. Pet. at 27-28.

Petitioner’s reliance on Dr. Fletcher’s declaration only underscores the weakness of its position. Pet. at 27-28. The cited paragraph of Dr. Fletcher’s declaration for this limitation is a verbatim recitation of the Petition’s conclusory assertions—other than the phrase “it is my opinion”—and contains no additional

reasoning or technical analysis. EX1003 ¶ 80; *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).

Again, Petitioner’s argument is not based on any teaching or suggestion in Lavender or Neyrinck. Rather, Petitioner has merely retrofitted the teachings of the two references to meet the challenged claims. This rewriting is improper hindsight and is insufficient to meet Petitioner’s burden for institution of limitation 1[d]. This is impermissible hindsight and cannot establish a reasonable likelihood of prevailing.

**5. Limitation 1[i]<sup>6</sup>: continuing steps (e) through (h) until the target plasma volume to collect is reaching in the plasma collection container**

For this limitation, Petitioner again relies on conclusory assertions rather than a faithful application of the cited prior art. Petitioner asserts that Lavender teaches continuing the previous steps until a target volume of plasma is collected.

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<sup>6</sup> Limitations 8[j] and 15[f] contain substantively identical language. Petitioner refers back to its arguments regarding limitation 1[i] for those limitations without additional analysis. As such, the Petition fails to establish that Lavender in view of

Although Petitioner makes no reference of Neyrinck regarding this limitation, Petitioner's suggested "target plasma volume" is based on Neyrinck's calculations, as explained regarding limitation 1[d]. Once again, this conclusion is unsupported by independent expert analyses (only expert repetition) and flawed by pure hindsight bias, working backwards from the claim language. Lavender does not teach or suggest modifying its loop termination condition to track Neyrinck's calculations, nor does it disclose continuing collection until a target volume defined by Petitioner's reconstructed equations is reached.

As with limitations 1[c] and 1[d], Petitioner's analysis of limitation 1[i] is irredeemably tainted by hindsight. Rather than identifying a teaching or suggestion in the prior art that would have led a POSITA to modify Lavender's stopping condition, Petitioner assumes that once it has mathematically engineered values to satisfy the claim language, Lavender's system would necessarily operate in accordance with them. That assumption is not grounded in the cited references and does not satisfy Petitioner's burden at institution.

Given these glaring deficiencies in Ground I, Petitioner has failed to carry its burden to show that Lavender in view of Neyrinck renders the challenged claims

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Neyrinck renders obvious claims 8 and 15, and all associated dependent claims, for the same reasons as described herein.

obvious. Indeed, Petitioner's duplicative and unsupported analysis across the entirety of Ground I falls far short of demonstrating a reasonable likelihood that it will prevail regarding any of the challenged claims. Institution should therefore be denied.

**B. Grounds II-IV: Petitioner Has Failed to Show a Reasonable Likelihood of Success on Grounds II-IV.**

The deficiencies that doom Ground I permeate the remainder of the Petition. Grounds II-IV challenge additional claims based on the same proposed combination of Lavender and Neyrinck, merely appending one or two additional references to supply discrete, missing limitations. As with Ground I, Petitioner fails to articulate any evidence-based motivation to combine, fails to establish a reasonable expectation of success, and relies on conclusory assertions repeated largely verbatim in Dr. Fletcher's declaration.

Grounds II-IV are particularly deficient because they rely on serial, hindsight-driven combinations. After identifying alleged gaps in the Lavender-Neyrinck combination, Petitioner turns to additional references—Fletcher-Haynes and Darashkevich—not because the prior art teaches their integration, but because allegedly those references conveniently disclose isolated claim elements. The Petition never explains why a POSITA would have been motivated to combine *all*

of the cited references together, nor how a POSITA would have reconciled their materially different system architectures, sensing modalities, and control strategies.

Critically, Petitioner also fails to establish a reasonable expectation of success for these multi-reference combinations. There is no discussion of how the proposed systems would function as integrated, how the additional references would interact with Lavender's or Neyrinck's disclosed frameworks, or how the resulting combinations would operate predictably in practice. Instead, Petitioner again relies on claim-driven reconstruction—adding references only after identifying which claim elements are missing from the prior art.

Nor does Petitioner cure these defects through expert testimony. As in Ground I, the analyses in Grounds II-IV are rife with the same conclusory analyses, hindsight bias, and nearly identical declaration of Dr. Fletcher. Dr. Fletcher offers no independent technical reasoning or explanation of why a POSITA would have made the proposed multi-reference combinations with a reasonable expectation of success.

Accordingly, Grounds II-IV suffer from the same conclusory reasoning, improper hindsight, lack of articulated motivation to combine, and failure to demonstrate a reasonable expectation of success that independently preclude institution under 35 U.S.C. § 314(a). Because Petitioner has not shown a reasonable

likelihood of prevailing on any of these grounds, institution should also be denied as to Grounds II–IV.

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

Petitioner's motivation-to-combine analysis for Ground II suffers from the same fundamental defects as Ground I—only magnified. The entirety of Petitioner's motivation to combine argument is copied by Dr. Fletcher, with the exception of the added phrase "it is my opinion." Pet. at 37-42; EX1003 ¶¶ 113-122. Dr. Fletcher fails to provide any additional, independent, technical explanation, rationale, or reasoning as to what a POSITA would have known from the references, why a POSITA would seek to modify Fletcher-Haynes, or what result would be expected. Nonetheless, Petitioner repeatedly cites Dr. Fletcher's declaration as support for what a POSITA would have found obvious and been motivated to do. Pet. at 37-42.

Petitioner's motivation to combine argument is simply a recitation of similarities between the disclosures of Fletcher-Haynes and Lavender. But identifying overlapping subject matter is not a motivation to combine. Nowhere does Petitioner offer a reason why a POSITA would want to modify the teachings of Lavender, let alone any suggestion of that modification in Fletcher-Haynes', Lavender's, or Neyrinck's disclosure. Petitioner also fails to explain the likely

outcome of the combination or why a POSITA would have reasonably expected success in combining the disclosed systems.

The lack of a coherent motivation is particularly apparent given the stark differences between the systems. Petitioner relies on Fletcher-Haynes to allegedly disclose certain calculations and returning fluid to the donor, yet the Petition never explains why a POSITA would modify Lavender's membrane-based system to incorporate Fletcher-Haynes' centrifuge-based, single-needle architecture while preserving Lavender's and Neyrinck's disclosed calculations. Petitioner assumes, without analysis, that the disparate systems could simply be merged limitation-by-limitation. That same unsupported assumption recurs throughout Ground II as incorporated into the respective claim limitations.

Petitioner's analysis also includes over a page of mathematical equations, reworking and transcribing the equations in Fletcher-Haynes to line them up with the equations in Lavender. But mathematical manipulability is not a motivation to combine. This analysis has no bearing on the motivation to combine and Petitioner fails to explain why a POSITA would have been motivated to rewrite and breakdown Lavender's equations to demonstrate mathematical equivalence with certain, other equations in Fletcher-Haynes, nor why a POSITA would view such algebraic alignment as a reason to combine the underlying systems. This certainly does not support the conclusion that a POSITA would have been motivated to

combine these two references—and their respective equations—merely because certain equations contain similar variables.

What is notably lacking from Petitioner's motivation to combine analysis is an actual *reason* to combine Lavender, Neyrinck, and Fletcher-Haynes. Petitioner provides no reasoning or suggestion in any of the references as to why a POSITA would have been motivated to look past Lavender and Neyrinck or would have sought to modify Lavender's existing equations even further. This highlights the hindsight-driven nature of Petitioner's analysis: Lavender is invoked not because a POSITA would have been motivated to combine the references, but because Petitioner needs Fletcher-Haynes to force Lavender and Neyrinck to resemble the claimed invention.

Thus, Petitioner's suggestion that Lavender, Neyrinck, and Fletcher-Haynes be combined in this way is legally insufficient to support a motivation to combine argument, which must explain why a POSITA would be motivated to make this combination. *InTouch Techs, Inc. v. VGO Commc'ns, Inc.*, 751 F.3d 1327, 1352 (Fed. Cir. 2014); *ActiveVideo Networks, Inc. v. Verizon Commc'ns, Inc.*, 694 F.3d 1312, 1327 (Fed. Cir. 2012) (petitioners must explain "why a person of ordinary skill in the art would have combined elements from specific references in the way the claimed invention does"); *Personal Web Techs., LLC v. Apple, Inc.*, 848 F.3d 987, 994 (Fed. Cir. 2017). At base, Petitioner and Dr. Fletcher fail to explain: (1)

*why* a POSITA would be motivated to combine Lavender's system with Neyrinck's equations and Fletcher-Haynes' system and equations; (2) *how* either reference teaches or suggests a reason for this combination; or (3) *how* the proposed combined system would operate consistently with Lavender's design.

Equally important, Petitioner also fails to establish that a POSITA would have had a reasonable expectation of success in combining Lavender with Neyrinck and Fletcher-Haynes. 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 simply copies the Petition.

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

**2. Petitioner fails to articulate a sufficient motivation to combine Lavender with Neyrinck and Darashkevich (Ground III).**

Petitioner's purported motivation to combine in Ground III is legally and factually deficient. Here, Petitioner seeks to modify Lavender and Neyrinck with Darashkevich for one claim—claim 7—which requires “the target percentage of plasma is between 26.5 and 29.5 of the donor's plasma volume.” Petitioner offers no evidence-based rationale explaining why a POSITA would have been motivated to make this modification, nor why a POSITA would have reasonably expected success in doing so.

At base, Petitioner—as echoed by Dr. Fletcher—fails to provide any rationale or teaching in the references suggesting this combination other than pointing to the fact that each reference relates to apheresis devices. Pet. at 61-62. Petitioner fails to explain *why* a POSITA would have sought to modify Lavender's and Neyrinck's teachings with any other reference, let alone Darashkevich, nor *why* a POSITA would have expected success in this combination.

More importantly, Petitioner's proposed combination with Darashkevich is belied by the references themselves. As explained previously, and as Petitioner acknowledges, Lavender teaches “a target plasma collection volume that is 18% of donor circulating plasma volume.” Pet. at 62 (citing EX1004 at 22:39-46). According to Petitioner, Darashkevich similarly teaches [“]removing between

about 15% [to] 30% of the patient's total circulating plasma." *Id.* (citing EX1007 at ¶ 0083). A POSITA viewing these disclosures would have recognized that Lavender already teaches removing a percentage of donor plasma volume that is within the disclosed range in Darashkevich. As such, a POSITA would have no reason to try modifications outside of the disclosed 18% and Petitioner cannot point to any reason why a POSITA would have modified or experimented with this percentage based on Darashkevich's teachings.

Petitioner's approach to this combination is pure hindsight and transparently results-driven. Recognizing that neither Lavender nor Neyrinck teach a percentage of plasma volume within the claimed range, Petitioner identified a wider range that could better map to the challenged claims. Petitioner's arguments, however, stop there. Petitioner points to no teachings in Lavender, Darashkevich, or Neyrinck for this suggested modification, and there are none.

Dr. Fletcher likewise provides no further analysis or explanation for why a POSITA would have viewed a higher percentage of donor plasma as more accurate, more individualized, more optimized, safer, or more suitable for the combined Lavender-Neyrinck system. His declaration merely repeats the conclusory and unsupported allegations in the Petition. EX1003 ¶¶ 194-196. Such conclusory testimony cannot supply the required motivation to combine.

Because Petitioner failed to provide a sufficient rationale and motivation to combine Lavender, Neyrinck, and Darashkevich, and failed to establish a reasonable expectation of success, Petitioner has not met its burden under 35 U.S.C. § 314(a).

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

Petitioner proposes combining Lavender with Neyrinck, Fletcher-Haynes, and Darashkevich to render obvious claim 14 in Ground IV. Pet. at 56-58. This proposed four-reference combination merely repackages the same unsupported rationales advanced in Ground III and is utilized for the same purpose (to map to claim 14 which requires a target percentage of plasma between 26.5 and 29.5 percent). Petitioner's argument, therefore, fails for the same reasons as discussed above.

Ground IV relies on the same alleged modifications previously asserted: incorporation of Fletcher-Haynes' single-needle centrifuge system and equations into the combined Lavender-Neyrinck membrane system with combined equations, and Darashkevich's wider range of target plasma percentages with the Lavender-Neyrinck system, which already teaches collecting 18% of donor plasma. Pet. at 63. Petitioner offers no additional motivation to combine these references beyond what was already asserted (and unsupported) in Grounds II and III, nor does it identify

any teaching in the references suggesting that these distinct modifications should be implemented in tandem.

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

Petitioner likewise fails to establish that a POSITA would have had a reasonable expectation of success in implementing both modifications simultaneously. Petitioner provides no explanation of how Fletcher-Haynes single-needle centrifuge configuration and calculations and Darashkevich's wider percentage ranges would be integrated into the already combined Lavender-Neyrinck system's architecture, nor any discussion of compatibility, feasibility, or predictable operation of the resulting system. Again, Fletcher's declaration fails to provide any expert analysis and merely repeats the entirety of Ground IV. EX1003 ¶ 198. 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 '934 Patent is compelling and independently confirms that the challenged claims are not obvious. "Evidence of objective indicia of non-obviousness, if present, must always be considered before reaching a determination on the issue of obviousness." *Quanergy Sys., Inc. v. Velodyne Lidar USA, Inc.*, 24 F.4th 1406, 1417 (Fed. Cir. 2022). Importantly, Patent Owner put Petitioner on notice of evidence of secondary considerations in the parallel district court litigation prior to the filing of the Petition. Specifically, in Patent Owner's briefing regarding Petitioner's motion to dismiss filed on September 23, 2025, Patent Owner described its covered products and the commercial success thereof. Nevertheless, Petitioner failed to address this "known evidence of secondary considerations [which] should be addressed in the Petition." *Robert Bosch Tool Corp. v. SD3, LLC*, IPR2016-01753, Paper 15 at 28 (Mar. 22, 2017).

Patent Owner's NexSys<sup>®</sup> PCS systems with YES<sup>®</sup> and PERSONA<sup>®</sup> technology ("NexSys Systems") are coextensive with the challenged claims of the '934 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 '934 Patent challenged claims.**

The NexSys System is “[a] system for collecting plasma” that performs the claimed method. EX1001 at cl. 8, 23. Patent Owner's system includes: (a) a venous-access device for drawing whole blood from a donor and returning blood components to the donor; (b) a blood component separation device for separating the drawn 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 collection container; (c) a first line fluidly connected to the venous-access device and configured to transport drawn whole blood to the blood component separation device and return fluid within the blood component separation device to the donor, the flow through the first line being controlled by a first pump; (d) an anticoagulant line connected to an anticoagulant source, the anticoagulant line configured to introduce anticoagulant into the drawn whole blood; (e) a controller configured to control the operation of the blood component separation device and the first pump, and configured to calculate (1) a donor plasma volume based, at least in part, on a weight and height of the donor and a hematocrit

of the donor, (2) a target plasma volume to collect based, at least in part, on the calculated donor plasma volume and a target percentage of plasma, and (3) a volume of plasma component collected within the plasma collection container; and (f) the controller configured to stop the first pump when the calculated volume of pure plasma component collected within the plasma collection container equals the target plasma volume to collect. *Id.* at cl. 8; *see generally* EX2013 (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 9), 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<sup>®</sup> technology and the 2020 system further included Patent Owner's

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 '934 Patent, the NexSys Systems achieve higher plasma collection volumes per donation, on average, and optimize collections by targeting pure plasma yield based on individualized donor characteristics, 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.,* EX2014-2016.

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

As the '934 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 1:50-56; 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:

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 total plasma volume, height, weight, and 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 primary 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[.]” EX2016. 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 '934 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 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<sup>®</sup> technology and the opening of ADMA’s newest plasma collection center directly advances the Company’s near term and ongoing strategic objectives.” EX2014. He acknowledged that the NexSys System provided an “anticipated yield enhancement resulting from Persona<sup>®</sup> 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* EX2015. “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 '934 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* EX2004; EX2006. 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 '934 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* EX2017. 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* EX2018. 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 '934 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-driven combinations, and unsupported assertions rather than evidence or reasoned analysis grounded in the prior art. Petitioner has not articulated a legally sufficient motivation to combine the cited references, nor has it established a reasonable expectation of success for any proposed combination. Accordingly, Patent Owner respectfully requests that the Board deny institution of *inter partes* review of the '934 Patent in its entirety.

Respectfully submitted,

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Dated: January 29, 2026

*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 IPR2026-00045 of U.S. Patent 10,980,934, 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 9,327. Pursuant to 37 C.F.R. § 42.24(b)(1), this word count is in compliance and excludes the table of contents, table of authorities, certificate of service, certificate of word count, appendix of exhibits, and any claim listing. This word count was prepared using Microsoft Word.

Date: January 29, 2026

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

Pursuant to 37 C.F.R. § 42.6(e), I hereby certify that on January 29, 2026, I caused a complete copy of Patent Owner's Preliminary Response to the Petition regarding U.S. Patent No. 10,980,934 and all exhibits, to be served on the Petitioner as follows:

*Via and Electronic Mail to Petitioner's attorneys of record:*

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