

Patent Owner's Preliminary Response
U.S. Patent No. 10,792,416

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

TERUMO BCT, INC.,

Petitioner

v.

HAEMONETICS CORP.,

Patent Owner

Case No. IPR2025-01420

U.S. Patent No. 10,792,416

PATENT OWNER'S PRELIMINARY RESPONSE

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OTHER AUTHORITIES

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List of Exhibits

Exhibit No.	Description of Document
2013	NexSys PCS® Plasma Collection System Brochure, Haemonetics (2021), available at https://plasma.haemonetics.com/-/media/files/plasma/nexsys_pcs_brochure.pdf
2014	“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
2015	“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/
2016	“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 .
2017	“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
2018	“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-

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

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 1-30 of U.S. Patent No. 10,792,416 (the “’416 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 ’416 Patent. The Petition presents nine 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 ’416 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 obviousness theories are lacking. 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 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 '416 Patent and neither the Petition nor Petitioner's expert, Dr. Fletcher, provide any rationale or reasoning as to why a

² Patent Owner has also requested discretionary denial of institution of the Petition, as explained in Paper 11.

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. 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 repeats verbatim what is included in the Petition. Neither Petitioner nor Dr. Fletcher provide sufficient analysis or rationale as to *why* a POSITA would have been motivated to combine Lavender and Neyrinck 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 '416 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 '416 PATENT

The '416 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 1:12-14, 1:60-2:18, 3:6-19. 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 10:50-11:28. The system also stops the collection when the optimized (e.g., target) volume of pure plasma has been collected from a given donor. *Id.* at 11:38-51.

As the specification explains, the '416 Patent provided an improvement over prior art systems. EX1001 at 1:37-56, 12:35-60, 16:40-17:19. 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 1:37-50.

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 1:44-50.

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 12:40-47. As the patent explains:

The various embodiment[s] of the present invention described above 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 12:35-47. To remedy these issues, the '416 Patent teaches determining a “target volume” of pure plasma for each donor and stopping the collection when that target is reached. *Id.* at 12:35-60, cls. 1, 17. Thus, the '416 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. Lavender

Unlike the '416 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 ’416 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 19-20.

V. CLAIM CONSTRUCTION

Petitioner asserts that “the Challenged Claims need no construction to demonstrate they are unpatentable.” Pet. at 20. 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 20; *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, 7, 9, 11, 14, and 15 are rendered obvious over Lavender in view of Neyrinck. Pet. at 20. 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, largely verbatim, the analysis provided in the Petition, adding no independent reasoning or technical insight. And, the descriptions in the Petition—and 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 20-34 with EX1003 ¶¶ 67-101 (entirety of analysis regarding claim 1); Pet. at 24 with EX1003 ¶ 78 (same typographical change from using "p." citations to using "pg." citations); Pet. at 33

with EX1003 at 46 (reproducing same typographical error in the claim language)³; Pet. at 30 n.3 *with* EX1003 ¶ 90 n.3 (nearly identical footnote); Pet. at 34 n.5 *with* EX1003 ¶ 101 n.4 (identical footnote); Pet. at 24-25, 34 *with* EX1003 ¶¶ 73-75, 77, 80-81, 101 (same quotation emphases). The **only** differences between the Petition and Dr. Fletcher's declaration in regarding claim 1 include minor word changes (e.g., adding "in my opinion" to identical sentences in Dr. Fletcher's declaration) and a paragraph in the body that appears, verbatim, in a footnote in the Petition instead of in the body. *Compare* Pet. at 33 n.4 *with* EX1003 ¶ 98 (repeating the same legal conclusions about claim meaning and disavowal).

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. 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

³ Petitioner filed a Motion for Correction and to file an amended declaration for Dr. Fletcher to fix this error. *See* Paper 9. It is not surprising that both are required to fix the error as the Petition and declaration are duplicates.

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. *Compare* Pet. at 20-23 with EX1003 ¶¶ 67-72. 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[.]”).

The entirety of Petitioner’s motivation to combine argument consists of inputting variables from Neyrinck’s disclosed calculations into Lavender’s calculations in an attempt to make the two references fit together. *See* Pet. at 20-23. 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 and hematocrit, in Lavender's calculations for total blood volume and total plasma volume, Petitioner provides no justification for *why* a POSITA would be 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 23 ("Neyrinck's plasma collection calculations *could* be readily implemented in Lavender's computation framework"); EX1003 ¶ 72 (same); Pet. at 23 ("In one such example, Lavender's system *could* implement Neyrinck's TPV calculation"); EX1003 ¶ 72 (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 be 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 23. 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 ¶ 72 (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.”).

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 24) and, for other limitations, uses Neyrinck's *alternative* formula using BMI to meet claim 1[c] (Pet. at 25). 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 allegation repeated verbatim in the Petition and declaration. *See In re Van Os*, 844 F.3d 1359, 1361-62 (Fed. Cir. 2017) ("This type of finding, without more, tracks the *ex post* reasoning *KSR* warned of and fails to identify any actual *reason* why a skilled artisan would have combined the elements in the manner claimed.").

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[j]⁴: 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[j] are unavailing. First, Petitioner's argument that Lavender 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 32 (citing EX1003 ¶ 96 (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."

⁴ Limitation 17[i](4) contains similar language. Petitioner refers back to its arguments regarding limitation 1[j] for limitation 17[i](4) without additional analysis, despite the fact that this limitation is required to be calculated by a controller. As such, the Petition fails to establish that Lavender in view of Neyrinck renders obvious claim 17, and all associated dependent claims, for the same reasons as described herein.

Pet. at 31 (emphases added). Lavender's own equations confirm this sequence, that total plasma filtered (TPF) is a variable within the anticoagulant volume calculation (TCF). *See* EX1004 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 31-33. Lavender at best teaches calculating total anticoagulant filtered volume based on total dilute plasma filtered volume. Lavender does not disclose or suggest limitation 1[j].

Second, Petitioner's argument that Lavender renders limitation 1[j] obvious is likewise deficient. Pet. at 33. Petitioner and Dr. Fletcher use identical language to conclude: "a POSITA would have found this limitation obvious in view of Lavender's discloses because of (i) the interdependency between the predefined ratio of citrate added . . . , and (ii) the understanding 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 ¶ 99. Yet neither the Petition nor Dr. Fletcher provide any explanation or rationale as to why a POSITA would perceive such 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 at 11 (Oct. 16, 2025) (“Petitioner cannot satisfy its burden of proving obviousness by employing ‘mere conclusory statements,’ but ‘must instead articulate specific reasoning, based on evidence of record, to support the legal conclusion of obviousness.’”) (quoting *In re Magnum Oil Tools Int’l, Ltd.*, 829 F.3d 1364, 1380 (Fed. Cir. 2016)); *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 suggests nor renders obvious 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[j].

4. Limitation 1[k]⁵: continuing steps (e) through (j)⁶ until the calculated volume of pure plasma collected within the plasma collection container equals the target plasma collection volume

In conclusory fashion, Petitioner asserts that Lavender teaches continuing the previous steps until the 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 44; EX1004 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[k].

⁵ Limitation 17[j] contains similar language. Petitioner refers back to its arguments regarding limitation 1[k] for limitation 17[j] without additional analysis. In fact, limitation 17[j] adds that “the controller is configured to stop the first pump,” which is not included in limitation 1[k], but Petitioner fails to provide any evidence of where that disclosure is found in Lavender or Neyrinck. *See* Pet. at 47. As such, the Petition fails to establish that Lavender alone and/or in view of Neyrinck renders obvious claim 17, and all associated dependent claims, for the same reasons as described herein.

⁶ *See* n. 3, *supra*.

As the '416 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 12:37-40. Petitioner fails to explain why, in 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[k]. 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 33-34. 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 ¶¶ 100-101; *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).

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

The deficiencies that doom Ground I permeate the remainder of the Petition. Grounds II-IX challenge additional claims based on the same proposed combination of Lavender and Neyrinck, merely appending one or more 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-IX 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—Bainbridge, Darashkevich, Min, Turgut, Headley, and Barrett—not because the prior art teaches their integration, but because 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.

For example, several grounds rely on Bainbridge—to allegedly disclose returning fluid to the donor, yet the Petition never explains why a POSITA would

modify Lavender's membrane-based system to incorporate Bainbridge's centrifuge-based, single-needle architecture while preserving Lavender's disclosed calculations. Petitioner assumes, without analysis, that disparate systems could simply be merged limitation-by-limitation. That same unsupported assumption recurs throughout Grounds III-IX as additional references are layered on to fill remaining claim gaps.

Nor does Petitioner cure these defects through expert testimony. As in Ground I, the analyses in Grounds II-IX 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-IX suffer from the same conclusory reasoning, improper hindsight, and lack of articulated motivation 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-IX.

**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 '416 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[®] PCS systems with YES[®] and PERSONA[®] technology ("NexSys Systems") are coextensive with the challenged claims of the '416 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 '416 Patent Challenged Claims.

The NexSys System is “[a] system for collecting plasma” that performs the claimed method. EX1001 at cl. 17; *see also id.* at cl. 1. 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 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 collection volume based, at least in part, on the calculated donor plasma volume and a target percentage of plasma, (3) a volume of anticoagulant in the collected plasma component as the plasma component is being collected in the plasma container, and (4) a volume of pure plasma collected within the plasma container based, at least in part, upon the volume of anticoagulant in the collected plasma component; and (f) the controller configured to stop the first pump when the calculated volume of pure plasma collected within the plasma collection container equals the target plasma collection volume. *Id.* at cl. 17; *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 11), 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 Patent Owner remains the industry leader. *Id.* ¶¶ 13-15.

By employing the method claimed in the '416 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.,* EX2014-2016.

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

As the '416 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 1:45-50; EX1013. 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). EX1013. 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 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 ’416 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.” EX2014. 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* 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 '416 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 '416 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 '416 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 reasoned analysis. Accordingly, Patent Owner respectfully requests that the Board deny institution of *inter partes* review of the '416 Patent in its entirety.

Respectfully submitted,

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Dated: January 21, 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 IPR2025-01420 of U.S. Patent 10,792,416, 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 7,103. 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 21, 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 21, 2026, I caused a complete copy of Patent Owner's Preliminary Response to the Petition regarding U.S. Patent No. 10,792,416 and all exhibits, to be served on the Petitioner as follows:

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