

Patent Owner's Preliminary Response
U.S. Patent No. 10,980,926

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

TERUMO BCT, INC.,

Petitioner

v.

HAEMONETICS CORP.,

Patent Owner

Case No. IPR2026-00046

U.S. Patent No. 10,980,926

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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

Patent Owner's Preliminary Response
U.S. Patent No. 10,980,926

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. 10,980,926 (the “’926 Patent”), as requested by Petitioner Terumo BCT, Inc. (“Petitioner”), setting forth the reasons why the Petition should be denied.¹

I. INTRODUCTION

Petitioner filed the instant Petition challenging the patentability of all claims of the ’926 Patent. The Petition presents two grounds of unpatentability, but each ground primarily relies on two references: (1) U.S. Patent No. 4,898,675 to Lavender (“Lavender”), in view of (2) U.S. Patent No. 7,072,769 to Fletcher-Haynes (“Fletcher-Haynes”).

Petitioner bears the burden of establishing the invalidity of the ’926 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), often 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 collapse under even modest scrutiny. The Petition is rife with hindsight bias and conclusory statements that rely on mental gymnastics to force the primary references to meet the challenged claims. The majority of Petitioner's “analysis” consists largely of rewriting mathematical equations in Lavender and Fletcher-Haynes 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 '926 Patent and neither the Petition nor Petitioner's expert, Dr. Fletcher, provide any rationale or

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

reasoning as to why a POSITA would have found the challenged claims obvious based on the references' teachings. Indeed, Dr. Fletcher's declaration provides virtually no analysis of what a POSITA would have understood and merely parrots back—often verbatim—what is said in the Petition.

The deficiencies in the Petition do not stop there. In fact, the Petition itself and Dr. Fletcher's declaration are even more lacking regarding the motivation to combine Lavender and Fletcher-Haynes, as well as the motivation to combine a third reference (Min) in Ground II. Again, both the Petition and Dr. Fletcher merely work backwards from the claim language to redo mathematical equations disclosed in Lavender and Fletcher-Haynes to grasp at the claimed invention. Dr. Fletcher does not provide any additional analysis or rationale as to *why* a POSITA would have been motivated to make such a combination 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 '926 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 '926 PATENT

The '926 Patent is directed to plasma apheresis methods and systems that utilize a donor's characteristics to identify a pure plasma amount to be collected. EX1001 at 1:15-17, 1:57-2:15, 2:26-54. 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 10:6-15. 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 10:6-28.

As the specification explains, the '926 Patent provided an improvement over prior art systems. EX1001 at 1:40-53, 9:61-10:20. 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 1:42-47. 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 1:47-53.

The patented invention improved upon these preexisting methods and systems that targeted total collection volume and did not take into account a donor's individual characteristics, such as hematocrit. *Id.* at 9:61-10:20. As the patent explains:

Various embodiment[s] of the present invention provide numerous benefits of prior art plasma collection systems. In particular, as noted above, prior art plasmapheresis devices end plasma collection based on a total volume of anticoagulated plasma (e.g., pure plasma plus the added anticoagulant). Although this is the easiest method because it requires only that the product collection container be weighed, the amount of true product—the pure plasma—is dependent on the donor's hematocrit. In other words, prior art systems will collect more plasma from low hematocrit donors than from high hematocrit donors because of the variation of the percentage of anticoagulant in the product.

Id. at 9:61-10:5. To remedy these issues, the '926 Patent teaches determining a "target volume" of pure plasma for each donor and stopping the collection when that target is reached. *Id.* at 10:6-20, cls. 1, 8, 15, 23. Thus, the '926 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 '926 Patent which relies on a donor's hematocrit to determine a target pure plasma volume to be collected, Lavender is directed to a plasma apheresis system that tries to avoid "rapid degradation in plasma production with time" by utilizing specific structural designs and distribution of blood within the machine. EX1005 at 11:30-32, 13:23-46. This includes uniform distribution of blood across Lavender's disclosed plates, which have shallow grooves to facilitate blood flow and reduce resistance. *Id.* at 13:23-46. According to Lavender, these structural improvements allow for a higher blood flow velocity rate which helps to avoid rapid degradation. *Id.* at 11:30-44, 13:51-14:5.

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

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

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

B. Fletcher-Haynes

Fletcher-Haynes is directed primarily to a platelet collection system that also can collect additional blood components. *See* EX1004 at 2:56-59; *Id.* at 51:15-16 (describing the “primary equation” to be solved by the invention is platelet yield). Fletcher-Haynes purports to simultaneously manage “a large number of variables” to “meet the blood bank collection goals” when collecting different types of blood components, “including platelets, red blood cells, white blood cells, stem cells and plasma.” *Id.* at 1:24-26, 2:32-35. The reference explains:

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

Id. at 3:50-54. These objectives are achieved by Fletcher-Haynes' invention through centralized management of the machine, blood center customization of collections, donor recruitment, and optimizing collections by targeting the highest need (e.g., the

type of blood component that is most in demand at a particular center). *Id.* at 3:55-4:48. Fletcher-Haynes also teaches the use of “prediction algorithms” that “predetermine donor eligibility for specific product collections”. *Id.* at 5:28-34.

IV. LEVEL OF ORDINARY SKILL

For the purposes of this Preliminary Response, Patent Owner has applied the same skill level proposed by Petitioner as it pertains to a POSITA. *See* Pet. at 21-22.

V. CLAIM CONSTRUCTION

Petitioner asserts that “the Challenged Claims need no construction to demonstrate they are unpatentable.” Pet. at 22. Petitioner’s arguments are unavailing under any construction; thus, Patent Owner agrees that claim construction is not necessary to decide institution. Pet. at 22; *see also Nidec Motor Corp. v. Zhongshan Broad Ocean Motor, Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (constructions are only needed when “necessary to resolve the controversy”) (citing *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)). For the purpose of this Preliminary Response, Patent Owner does not urge any construction of any claim terms, but reserves the right to do so should the Board institute trial and further clarification become necessary in view of Petitioner’s inconsistent positions.

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

A. Ground I: Petitioner Has Failed to Show Lavender in View of Fletcher-Haynes Renders Obvious the Challenged Claims.

In Ground I, Petitioner avers claims 1-4, 6-11, 13-18, 20-28, and 30 are “rendered obvious by Lavender in view of Fletcher-Haynes.” Pet. at 23. To demonstrate obviousness, Petitioner must establish that Lavender in view of Fletcher-Haynes teaches or suggests each claim limitation, that there exists a reason to modify Lavender's teachings with Fletcher-Haynes' teachings as Petitioner proposes, and that a POSITA would have an expectation of success in that modification. *See generally KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007); *see also Regents of Univ. of Cal. v. Broad Inst., Inc.*, 903 F.3d 1286, 1291 (Fed. Cir. 2018); *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1361 (Fed. Cir. 2007). Importantly, the Board must “guard against slipping into the use of hindsight. . . and to resist the temptation to read into the prior art the teachings of the invention in issue.” *Graham v. John Deere Co. of Kan. City*, 383 U.S. 1, 36 (1966) (citations omitted).

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 Fletcher-Haynes renders obvious at least limitations 1[c], 1[d], 1[e], or 1[j] or the corresponding limitations

of independent claims 8, 15, and 23. Instead, the Petition relies almost exclusively on the expert declaration of Dr. Fletcher to support what a POSITA would have found obvious based on the teachings of Lavender and Fletcher-Haynes. Dr. Fletcher's declaration, however, is substantively identical and merely parrots verbatim the analysis provided in the Petition, adding no independent reasoning or technical insight.

Such conclusory repetition cannot substitute for substantive analysis and should be given no weight. Based on this reason alone, Petitioner has failed to carry its burden of demonstrating that Lavender in view of Fletcher-Haynes renders obvious the challenged claims. *See, e.g., TQ Delta, LLC v. CISCO Sys., Inc.*, 942 F.3d 1352, 1359 (Fed. Cir. 2019) ("This court's opinions have repeatedly recognized that conclusory expert testimony is inadequate to support an obviousness determination[.]"). Institution should be denied as to Ground I.

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 Fletcher-Haynes 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

Fletcher-Haynes 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 repeats, 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 entirely *identical* to the Petition. The Petition and Dr. Fletcher's declaration are essentially word-for-word duplicates and even reproduce the exact same typographical errors and footnotes. *E.g., compare* Pet. at 23-42 *with* EX1003 ¶¶ 37-114 (entirety of analysis regarding claim 1); Pet. at 36 *with* EX1003 ¶ 99 (same missing comma); Pet. at 35 n. 4 *with* EX1003 ¶ 46 n.3 (nearly identical footnote); Pet. at 35 n.5 *with* EX1003 ¶ 47 n.4 (identical footnote); Pet. at 41 n.6 *with* EX1003 ¶ 53 n.5 (inadvertently repeating the same identical footnote). The *only* differences between the Petition and Dr. Fletcher's declaration regarding claim 1 are the phrase "In my opinion" sprinkled throughout Dr. Fletcher's declaration and case citations added to the Petition.

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

on the teachings of Lavender and Fletcher-Haynes. *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 Fletcher-Haynes or why a POSITA would have found the challenged claims obvious over those 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 Fletcher-Haynes 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 Fletcher-Haynes 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 Fletcher-Haynes, 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.

Petitioner's motivation to combine argument boils down to rewriting Lavender's mathematical equations to substitute in portions and variables from Fletcher-Haynes in an attempt to make the two references fit together. *See* Pet. at 23-26. The only reason Petitioner combines the particular equations, in the particular manner identified, is because the challenged claims already specify the end result. Absent the claims, nothing in Lavender or Fletcher-Haynes suggests rewriting one system's core equations to algebraically mirror the other's outputs. Petitioner goes to great lengths to line up equations from both references, but never explains *why* a POSITA would rework and combine the references' disclosed calculations in this way (or in any way). Notably, while the Petition repeatedly cites to and relies on Dr.

Fletcher's declaration, Dr. Fletcher's analysis once again merely repeats nearly identical language to the Petition, with no further independent analysis or technical explanation. Dr. Fletcher also fails to provide any rationale as to why a POSITA would make the proposed combination. At most, Petitioner shows that a POSITA *could* algebraically reconcile the two systems—not that a POSITA *would have been motivated* to do so in the absence of the '926 Patent. “[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)).

Both the Petition and declaration of Dr. Fletcher are devoid of any explanation as to why a POSITA would go to great lengths to rework, rewrite, transpose, and reduce the disclosed equations in combining Lavender and Fletcher-Haynes. Petitioner never identifies any deficiency in Lavender that would have prompted a POSITA to look to Fletcher-Haynes. As Petitioner alleges, Lavender already determines donor-specific target plasma and anticoagulant volumes using weight, fixed ratios, and real-time scale feedback. Fletcher-Haynes is directed to a different optimization problem—predicting yields and optimizing procedure parameters

using predictive models—rather than replacing a real-time control algorithm that already achieves the stated objective.

At best, Petitioner suggests a POSITA would have been motivated to combine Lavender and Fletcher-Haynes to provide “a more accurate determination of the optimal amount of pure plasma to collect.” Pet. at 24; EX1003 ¶ 66 (repeated verbatim). This conclusory statement is given without any evidentiary or technical support, either from the cited references or from Dr. Fletcher's expertise. *Id.* Dr. Fletcher provides no further analysis as to why making the proposed combination would, in fact, improve accuracy. This type of conclusory statement regarding accuracy 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”); *see also Personal Web Techs., LLC v. Apple, Inc.*, 848 F.3d 987, 994 (Fed. Cir. 2017).

Petitioner also fails to establish that a POSITA would have had a reasonable expectation of success in combining Lavender and Fletcher-Haynes. The Petition offers no analysis, evidence, or explanation addressing whether the proposed combination would have functioned as intended or produced predictable results.

Instead, Petitioner assumes—without support—that the two distinct systems, which rely on different control architectures and calculation frameworks, could simply be merged and operate harmoniously. Dr. Fletcher likewise provides no discussion of technical compatibility, implementation challenges, or feasibility. Such silence cannot satisfy Petitioner's burden.

At base, Petitioner and Dr. Fletcher fail to explain: (1) *why* a POSITA would be motivated to combine portions of Fletcher-Haynes' teachings with Lavender's equations; (2) *why* a POSITA would have a reasonable expectation of success in doing so; and (3) *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.”).

Petitioner's asserted motivation to combine Lavender with Fletcher-Haynes is further undermined by Petitioner's own treatment of a materially similar limitation in a related petition. *See Terumo BCT Inc. v. Haemonetics Corp.*, IPR2025-01374, Petition for *Inter Partes* Review (Paper 1) at 25-29 (Aug. 4, 2025). There, Petitioner contends that Lavender alone satisfies a requirement to calculate a volume of anticoagulant in the collected plasma component based, at least in part, on the donor's hematocrit—without resort to Fletcher-Haynes. *Id.* That position confirms

that, from the perspective of a POSITA, Lavender already provides a complete solution for hematocrit-based anticoagulant calculations. Where Petitioner argues Lavender itself is sufficient to meet a substantially similar limitation, Petitioner cannot then credibly identify any reason why a POSITA would have been motivated to further modify Lavender by importing Fletcher-Haynes' distinct predictive equations. This internal inconsistency highlights the absence of any technical need, design problem, or performance deficiency that would have driven a POSITA to pursue the proposed combination and reinforces that the asserted motivation to combine arises only from hindsight informed by the challenged claims themselves.

As with the remainder of the Petition, 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."). Accordingly, neither the Petition nor Dr. Fletcher's declaration, identifies an actual evidence-based motivation to combine Lavender and Fletcher-Haynes 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.”). Institution should be denied.

3. Limitation 1[c]³: calculating a volume of anticoagulant to be collected with a plasma component in a plasma collection container, the volume of anticoagulant to be collected with the plasma component based, at least in part, on the hematocrit of the donor

Petitioner concedes that Lavender does not expressly disclose this limitation: “While the donor’s hematocrit is not explicitly used to determine *MAXCF*, Lavender’s system determines the donor’s hematocrit.” Pet. at 28.

Recognizing the gap in Lavender’s teachings, Petitioner proposes to combine Lavender with Fletcher-Haynes for this limitation. Petitioner argues Fletcher-Haynes teaches calculating anticoagulant volume as “ f_{ACP} ” based on donor

³ Limitations 8[f], 15[c], and 23[f] contain substantively identical language. Petitioner refers back to its arguments regarding limitation 1[c] for limitations 8[f], 15[c], and 23[f] without additional analysis other than pointing to a microprocessor to carry out these calculations. Pet. at 52, 57, 61. As such, the Petition fails to establish that Lavender in view of Fletcher-Haynes renders obvious the remaining independent claims (claims 8, 15, and 23), and all associated dependent claims, for the same reasons as described herein.

hematocrit. *Id.* Petitioner's proposed combination of Lavender and Fletcher-Haynes fails to render limitation 1[c] obvious for at least three reasons.

First, Petitioner offers only a bare conclusion that “[a] POSITA would look to Fletcher-Haynes’ equations using hematocrit to determine target volumes in Lavender’s system to better determine the volume of anticoagulant to be collected.” Pet. at 29. This conclusion is repeated verbatim by Dr. Fletcher in his declaration, with no additional explanation or rationale as to why replacing Lavender’s equations with Fletcher-Haynes’ equations would improve, or even meaningfully affect, the determination of anticoagulant volume. EX1003 ¶ 82. Neither the Petition nor Dr. Fletcher identifies any teaching in either reference suggesting that incorporating hematocrit in the Lavender’s anticoagulant equation would increase accuracy, address a known deficiency, or solve a recognized problem. Instead, Petitioner baselessly suggests a POSITA would incorporate three separate equations from Fletcher-Haynes to determine anticoagulant volume based on hematocrit, as claimed. Pet. at 29 (citing an unspecified paragraph in Dr. Fletcher’s declaration, which contains no additional analysis in general). This type of unsupported assertion does not supply the required articulated reasoning with rational underpinning.

This approach is riddled with, and emblematic of, hindsight. Petitioner noticed that Lavender’s equations—which already determine anticoagulant volume—do not use the claimed variables and simply substituted a set of other equations from

Fletcher-Haynes that do include the required variables with little to no explanation of why a POSITA would have made that choice absent knowledge of the claims. As explained regarding Petitioner's insufficient motivation to combine arguments above, the Petition and expert declaration do not provide any rationale as to why a POSITA would make this combination nor explain why a POSITA would have this understanding.

Second, Petitioner's suggested combination of Lavender and Fletcher-Haynes for this limitation is not simply a substitution or routine modification of equations; rather, Petitioner fundamentally rewrites how Lavender calculates its pure plasma collection volume, total collection volume, and anticoagulant collection volume. *See* Pet. at 30-32. Petitioner devotes over five pages deconstructing three separate equations in Fletcher-Haynes and then recombining them to create "new" equations that are materially different from Lavender's taught algorithms. *See id.* For example, Petitioner's analysis concludes with a "*new MAXCF*" (anticoagulant volume to collect) that purportedly meets the claim language. Pet. at 31.

Lavender, however, teaches that MAXCF is calculated as $MAXCF = BW * C3$, which is anticoagulant volume determined by multiplying donor bodyweight by a specific conversion factor of citrate filtered per pound of bodyweight. EX1005 at 41-44. Instead of this simplistic equation focused on determining anticoagulant

collection volume based on donor bodyweight, as taught by Lavender, Petitioner suggests:

$$\text{newMAXCF} = \text{MAXPF}(1 + [(R - 1)(H - 1)]^{-1}) - \text{MAXPF}$$

Pet. at 31.

This new, convoluted equation is a far cry from Lavender's initial calculation of anticoagulant volume based purely on body weight. While the Petition goes to great lengths to explain why, mathematically, Fletcher-Haynes' variables and equations could be retrofit into Lavender's, it is devoid as to an explanation of why a POSITA would be motivated to fundamentally abandon Lavender's simple, weight-based MAXCF equation in favor of this proposed, and far more complex, construct. Petitioner acknowledges that the only purpose of entirely rewriting this equation is "to determine *new MAXCF* using both the donor's weight and hematocrit," as required by this claim limitation. Pet at 32. That admission confirms that the modification is driven by the claim language, not by any teaching, suggestion, or design need arising from the prior art itself. Again, this is basic hindsight that is not accompanied by expert analyses explaining why a POSITA would make this change. *See generally* EX1003 ¶¶ 77-89 (repeating the Petition verbatim, other than adding the words "In my opinion").

Third, even where Fletcher-Haynes discusses calculating anticoagulant volume based on hematocrit, Fletcher-Haynes fails to distinguish between

anticoagulant volume in the plasma collection bag and anticoagulant volume in other collection bags (e.g., the platelet collection bag). EX1004 at 50:36-38 (explaining under the “plasma collect factor” that “ Q_{IN} is proportional to the total AC flow . . . which includes the AC that flows to the platelet collect bag 38 and the plasma collect bag 54”); *Id.* at 49:24-25 (prediction model generates the “AC in the platelet *and* plasma collect bags 38, 54”) (emphasis added). Thus, Fletcher-Haynes’ does not distinguish anticoagulant volume collected with the plasma component from anticoagulant collected with other blood components. Petitioner therefore fails to show that Fletcher-Haynes teaches, or that a POSITA would derive, a calculation of anticoagulant volume collected specifically in the plasma component based on donor hematocrit. Petitioner has not met its burden to establish a reasonable likelihood that limitation 1[c] would have been obvious.

4. Limitation 1[d]⁴: calculating a target volume of pure plasma to collect in the plasma collection container based, at least in part, on the weight of the donor

For this limitation, Petitioner again relies on a newly constructed equation, derived from the previously proposed *new MAXCF* calculation. Petitioner asserts

⁴ Limitations 8[g], 15[d], and 23[g] contain substantively identical language.

Petitioner refers back to its arguments regarding limitation 1[d] for limitations 8[g], 15[d], and 23[g] without additional analysis. Pet. at 52, 57, 62. As such, the

that, through additional mathematical manipulation, Lavender combined with Fletcher-Haynes yields a *new MAXPF* that purportedly represents a calculated target volume of pure plasma to collect. Pet. at 33-34. The Petition describes a series of algebraic substitutions and ultimately concludes “through mathematical substitution Lavender in view of Fletcher-Haynes calculates a target amount of pure plasma to collect in the plasma collection container based, at least in part, on the weight of the donor.” Pet. at 34.

That conclusion, however, rests entirely on post hoc mathematical reconstruction rather than any articulated technical rationale. Instead, Petitioner simply argues “a POSITA would be able to derive [a] new equation for *new MAXPF*” that meets the claim language. Pet. at 34. Capability alone, however, does not establish motivation.

Even if true, however, this analysis suffers from the same hindsight bias that permeates the entire Petition. The hindsight nature of Petitioner's analysis is particularly stark here because Petitioner itself acknowledges that Lavender already calculates a target volume of pure plasma to collect based on donor bodyweight.

Petition fails to establish that Lavender in view of Fletcher-Haynes renders obvious the remaining independent claims (claims 8, 15, and 23), and all associated dependent claims, for the same reasons as described herein.

Having taken that position, Petitioner offers no rationale for *why* a POSITA would be motivated to abandon or rework Lavender's disclosed straightforward MAXPF equation in favor of a more complex, derivative construct assembled from Fletcher-Haynes' equations, particularly where Petitioner itself contends that Lavender already calculates a target volume of pure plasma to collect based on bodyweight. Nor does the Petition identify any deficiency, inaccuracy, or limitation in Lavender's existing target plasma calculation that would have motivated a POSITA to seek an alternative approach.

Dr. Fletcher's declaration does not cure these defects. Rather than supplying an independent technical explanation or rationale, Dr. Fletcher merely repeats the Petition's mathematical substitutions and conclusions. *See* Pet. at 32-35; EX1003 ¶¶ 90-95. His declaration therefore adds no meaningful analysis to the record addressing why a POSITA would have been motivated to perform the proposed calculation or reasonably expected it to improve upon Lavender's disclosed calculations.

In short, Petitioner's showing for limitation 1[d] relies on the same claim-driven hindsight that permeates its analysis of limitation 1[c]: starting with the claimed result and working backward to construct equations that satisfy the claim language, without identifying any reason grounded in the prior art that would have

led a POSITA to do so. Petitioner has therefore failed to establish a reasonable likelihood that limitation 1[d] is unpatentable.

5. Limitation 1[e]⁵: determining a target collection volume based, at least in part, on the calculated volume of anticoagulant and the calculated volume of pure plasma

As explained regarding limitations 1[c] and 1[d], Petitioner arrives at this limitation only by working backwards from the claim language and constructing new equations based on the combination of Lavender and Fletcher-Haynes that do not appear in either lavender or Fletcher-Haynes. *See* Parts VI.A.3, VI.A.4, *supra*. Petitioner then uses these new equations to create a “target collection volume” based on those prior two equations: *new MAXCF* and *new MAXPF*. *See* Pet. at 35-37. This analysis merely layers one hindsight-driven construct on top of another and suffers from the same defects discussed above, namely, the absence of any articulated

⁵ Limitations 8[g], 15[d], and 23[g] contain substantively identical language.

Petitioner refers back to its arguments regarding limitation 1[d] for limitations 8[g], 15[d], and 23[g] without additional analysis. Pet. at 52, 57, 62. As such, the Petition fails to establish that Lavender in view of Fletcher-Haynes renders obvious the remaining independent claims (claims 8, 15, and 23), and all associated dependent claims, for the same reasons as described herein.

rationale grounded in the prior art for why a POSITA would have performed these calculations in the first place.

Petitioner then summarily concludes, without support that “[i]t would have been obvious to a POSITA to set this *new MAXPF* as a target collection volume in Lavender, and thus determine a target collection volume based on this *new MAXPF*.” Pet. at 36. That assertion is conclusory. As with the remainder of the Petition, Petitioner does not explain why a POSITA would have concocted the newly derived equations to determine a collection endpoint, or how the cited references teach or suggest determining a target collection volume in this manner. Instead, Petitioner simply assumes that once the claim-mandated variables appear in its newly constructed equations, a POSITA would necessarily adopt them—an assumption that reflects hindsight, not the teachings of the prior art.

Because Petitioner's showing for limitation 1[e] depends entirely on the same unsupported, claim-driven reconstruction underlying limitations 1[c] and 1[d], and because neither the Petition nor Dr. Fletcher's declaration supplies any contemporaneous technical rationale for the asserted modification, Petitioner has failed to establish a reasonable likelihood that limitation 1[e] is unpatentable.

6. Limitation 1[j]⁶: continuing steps (f) through (i) until the target collection volume is reached within 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 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 41; EX1005 at 21:62-22:6. Yet Petitioner contend that the disclosed “volume of plasma” is the “target volume of pure plasma” claimed in limitation 1[j].

Unable to bridge that gap using the references' actual teachings, Petitioner again turns to its manifested equations—*new MAXCF* and *new MAXPF*—and concludes that Lavender's looping system would continue until reaching the *new*

⁶ Limitations 8[i] and 15[f] contain substantively identical language. Petitioner refers back to its arguments regarding limitation 1[j] for limitations 8[i] and 15[f] without additional analysis. Pet. at 52, 57-58. As such, the Petition fails to establish that Lavender in view of Fletcher-Haynes renders obvious the remaining independent claims (claims 8 and 15), and all associated dependent claims, for the same reasons as described herein.

MAXPF, which Petitioner declares “is equivalent to the target collection.” Pet. at 42. 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 Petitioner's newly derived values, nor does it disclose continuing collection until a target volume defined by Petitioner's reconstructed equations is reached.

As with limitations 1[c], 1[d], and 1[e], Petitioner's analysis of limitation 1[j] 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, which includes all the independent claims, Petitioner has failed to carry its burden to show that Lavender in view of Fletcher-Haynes renders the challenged claims 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. Ground II: Petitioner Has Failed to Show Lavender in View of Fletcher-Haynes and in Further View of Min Renders Obvious the Challenged Claims.

The deficiencies that doom Ground I permeate the remainder of the Petition. Ground II only relates to dependent claims and expressly relies on the same alleged deficiencies in Lavender and Fletcher-Haynes that Petitioner failed to establish in Ground I. Because Ground I failed to demonstrate a likelihood that Petitioner will prevail regarding the independent claims, Ground II should be denied for the same reasons.

In Ground II, Petitioner again relies on the same cut-and-paste analysis and the same conclusory expert testimony—this time attempting to combine Lavender and Fletcher-Haynes with a new reference, Min, to fill the gaps in certain dependent claims. Yet Petitioner never articulates why a POSITA would have been motivated to make such a combination, how the references could be coherently integrated, or why a POSITA would have expected success in doing so. Instead, Petitioner again works backward from the challenged claims, rewriting mathematical relationships in each reference until they superficially resemble the claimed invention. This hindsight-driven approach cannot satisfy Petitioner's burden under 35 U.S.C. § 314(a).

For example, Petitioner adds Min to the combination of Lavender and Fletcher-Haynes because Min purportedly includes weigh sensors that “provide an

additional way to determine the amount of anticoagulant in the plasma collection container.” Pet. at 65. Neither Petitioner nor Dr. Fletcher provide any explanation as to why a POSITA would have viewed an additional way of determining anticoagulant volume as necessary or desirable in view of Lavender’s existing techniques, or why Min’s approach would have been selected over or integrated with the prior art systems already relied on. In fact, Dr. Fletcher provides no additional rationale whatsoever.

As with Ground I, the Petition repeatedly cites Dr. Fletcher’s declaration, which, for Ground II, remains substantively identical to the arguments made in the Petition with no further explanation or analysis. As such, these conclusory statements should be given no weight and Petitioner has failed to carry its burden of demonstrating that Lavender in view of Fletcher-Haynes and Min renders obvious the challenged claims. *See TQ Delta*, 942 F.3d at 1359; *see also KSR Int’l*, 550 U.S. at 418 (“Rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.”) (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)).

As such, Petitioner has failed to carry its burden for Ground II, and 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 '926 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 '926 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 '926 Patent challenged claims.

The NexSys System is “[a] system for collecting plasma” that performs the claimed method. EX1001 at cls. 8, 23. Patent Owner's system includes: (a) a venous-access device for drawing whole blood from a donor and returning blood components to the donor; (b) a blood component separation device for separating the drawn blood into a plasma component, the blood component separation device having an outlet and being configured to send the plasma component to a plasma container; (c) a blood draw line fluidly connected to the venous-access device and configured to transport drawn whole blood to the blood component separation device, the flow through the blood draw line being controlled by a blood draw pump; (d) an anticoagulant line connected to an anticoagulant source, the anticoagulant line configured to introduce anticoagulant into the drawn whole blood; (e) a controller configured to control the operation of the blood component separation device and calculate (1) a volume of anticoagulant to be collected with plasma component in the plasma container based, at least in part, on the hematocrit of the donor, (2) a target volume of pure plasma to collect in the plasma container based, at least in part,

on the weight of the donor, and (3) a target collection volume based, at least in part, on the calculated volume of anticoagulant and the calculated volume of pure plasma; and (f) the controller configured to stop the blood draw pump when the target collection volume is collected within the plasma container. *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[®] 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 '926 Patent, the NexSys Systems achieve higher plasma collection volumes per donation, on average, and optimize collections by targeting *pure plasma* yield, instead of the preexisting focus on total collection volume (including plasma and anticoagulant) like prior systems. For example, a study performed in 2020 concluded that the NexSys Systems increased plasma yield by more than 26 mL per donation. *Id.* ¶ 21. Considering these donations at commercial scale, the 26 mL plasma yield increase per donation has resulted in hundreds of thousands of liters of additional plasma collected—an extraordinary improvement in both efficiency and output.

The plasma collection industry has overwhelmingly adopted the NexSys 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 '926 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

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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 1:48-53; 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 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 significant amount of money both from the private sector and from the government dedicated to finding solutions to the problem, but as of yet there has been no satisfactory solution.

EX1005 at 11:23-29. Over 30 years later, Petitioner itself reiterated this notion at its Plasma Innovation Business Seminar, “[t]here is a huge unmet need for plasma-derived therapies.” 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 '926 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 Patent Owner’s results of its plasma yield trial with this patented technology were peer reviewed and published in the TRANSFUSION journal for medical research. *See* 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: (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 '926 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. Petitioner's newest Rika Plasma System with iNomi Nomogram received FDA clearance in 2024. *See* EX2005-2006. Patent Owner has accused both systems of infringing the '926 Patent in the co-pending district court litigation. *See Haemonetics Corp. v. Terumo BCT, Inc.*, No. 1:25-cv-01409 (D. Colo. May 5, 2025). Recognizing the similarities between its systems and the NexSys System, Petitioner cites to the NexSys Systems in its 510(k) summaries as the "Reference Device." *See* EX2004; EX2005.

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

Q&A session hosted by Petitioner, investors referenced the Patent Owner's patented technology and "hope[d] [Petitioner] will be able to exceed or equal Haemonetics' yield." *See* 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 '926 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 hindsight, conclusory expert testimony, 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 '926 Patent in its entirety.

Respectfully submitted,

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Dated: January 22, 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 IPR2026-00046 of U.S. Patent 10,980,926, 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 8,681. Pursuant to 37 C.F.R. § 42.24(b)(1), this word count is in compliance and excludes the table of contents, table of authorities, certificate of service, certificate of word count, appendix of exhibits, and any claim listing. This word count was prepared using Microsoft Word.

Date: January 22, 2026

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), I hereby certify that on January 22, 2026, I caused a complete copy of Patent Owner's Preliminary Response to the Petition regarding U.S. Patent No. 10,980,926 and all exhibits, to be served on the Petitioner as follows:

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