

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

TERUMO BCT INC.,

Petitioner

v.

HAEMONETICS CORP.,

Patent Owner

PGR2026-00009
U.S. Patent No. 12,324,873

**PETITIONER'S OPPOSITION TO PATENT OWNER'S REQUEST FOR
DISCRETIONARY DENIAL**

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EXHIBIT LIST

Exhibit	Reference
1001	U.S. Patent No. 12,324,873 (“’873 patent”)
1002	File History of the ’873 patent
1003	Declaration of Dr. Gary D. Fletcher in Support of Petition
1004	U.S. Patent No. 7,072,769 (“Fletcher-Haynes”)
1005	U.S. Patent No. 4,898,675 (“Lavender”)
1006	U.S. Patent No. 8,075,468 (“Min”)
1007	U.S. Patent Publication No. 2003/0125881 (“Ryan”)
1008	U.S. Patent No. 9,370,324 (“Barrett”)
1009	U.S. Patent No. 6,296,602 (“Headley”)
1010	“Membrane versus centrifuge-based therapeutic plasma exchange: a randomized prospective crossover study,” Carsten Hafer et al., Int. Urol. Nephrol (2016) 48:133-138; Springer Science+Business Media Dordrecht 2015.
1011	U.S. Patent Publication No. 2017/0029762 (“Turgut”)
1012	“Volume Limits – Automated Collection of Source Plasma,” November 4, 1992, Memorandum issued by the FDA Center for Biologics Evaluation and Research, Docket Number FDA-2013-S-0613.
1013	Bruce C. McLeod, MD, et al., “Apheresis: Principles and Practice,” 3rd Edition, AABB Press 2010.
1014	Sergeant SR, Ashurst JV. Plasmapheresis. [Updated 2023 Jul 10]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK560566/?report=printable
1015	Curriculum Vitae (“CV”) of Dr. Gary D. Fletcher
1016	U.S. Patent Publication No. 2012/0175313 (“Barry”)
1017	Japanese Patent Publication No. JP 2002-282352 A and certified Japanese to English translation (“Takagi”)
1018	Corrected Declaration of Dr. Gary D. Fletcher in Support of Petition
1019	Search Disclosure Declaration (Filing Party and Board Only)
1020	Redacted Search Disclosure Declaration
1021	PTAB Notice of Decisions on Institution, Dec. 11, 2025

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1022	PTAB Notice of Decisions on Institution, Jan. 9, 2025
1023	PTAB Notice of Decisions on Institution, Jan. 27, 2026
1024	PTAB Notice of Decisions on Institution, Feb. 3, 2026

I. INTRODUCTION

Discretionary denial of Terumo BCT, Inc.'s ("Terumo") Petition for Post-Grant Review ("PGR") of U.S. Patent No. 12,324,873 ("the '873 patent") is unwarranted for at least two reasons.

First, every non-merit factor in *Apple Inc. v. Fintiv, Inc.* ("*Fintiv*") is either neutral or weighs strongly against discretionary denial. PGR2020-00019, Paper 11 at 5–6 (P.T.A.B. Mar. 20, 2020). Significantly, as Patent Owner concedes, any district court trial is unlikely to occur until well over a year after a final written decision ("FWD").

Second, while Patent Owner attempts to attack the merits of Terumo's Petition, Patent Owner's arguments fall flat. With respect to Terumo's § 103 arguments, Patent Owner manufactures meaningless distinctions between the '873 patent's claims and the prior art, all of which lack merit. With respect to Terumo's § 101 arguments, Patent Owner attempts to cite generic, well-known "hardware elements" of the claimed system to confer patent eligibility, but has never asserted that its plasma collection equipment, or its arrangement, is novel because it is not, highlighting that there is no 'inventive concept' in the claimed application of mathematical calculations in a generic plasma collection machine. Finally, Patent Owner fails to overcome the § 112 deficiencies raised in the Petition despite Patent Owner's insistence that the specification discloses all relevant terms.

In addition to these reasons, Petitioner is entitled to a non-exclusive, non-dispositive favorable discretionary factor supporting institution for submitting a compliant Search Disclosure Declaration (SDD) in accordance with the Director's November 17, 2025 Memorandum. EX2006.

Accordingly, Terumo respectfully asks that the Director deny Patent Owner's request for discretionary denial.

II. LITIGATION BACKGROUND

A. The District Court Litigation

On May 5, 2025, Patent Owner initiated *Haemonetics Corp. v. Terumo BCT, Inc.*, Case No. 1:25-cv-01409-RMR-SBP (D. Colo. filed May 5, 2025) (the "District Court Litigation"), asserting that Terumo's Rika System infringed seven patents in the same family. Since then, Patent Owner has filed two amended complaints, bringing the total number of asserted patents to nine (collectively, "the Asserted Patents"). Patent Owner's Second Amended Complaint—District Court Litigation's operative pleading—was filed in August 2025. No significant docket activity occurred before Patent Owner filed the Second Amended Complaint.

To date, the district court has not invested significant resources in the case, and the case is far from reaching substantive milestones. Discovery began a month after the Second Amended Complaint was filed. While initial infringement contentions, invalidity contentions, and initial claim construction positions have

been served and responded to, the Parties have not yet engaged in significant discovery, with Patent Owner producing only 395 documents, many of which are duplicates. *See* EX2003 at 8–11. Claim construction briefing will not begin until March 2026, and the claim construction hearing will not occur until at least May 2026. *Id.* at 9. It is not expected that discovery will close before early 2027. *See id.* Further, trial is unlikely to occur before mid-2028, at the earliest. Paper 9 at 4–5. On November 7, 2025, Terumo moved to stay the District Court Litigation until all PGRs and *inter partes* reviews (“IPRs”) are resolved—a request that is likely to succeed and push the trial date back even further. *See* District Court Litigation, Dkt. No. 65. Even if it is not stayed, however, the case remains in the early stages.

B. This PGR Proceeding

Terumo also acted diligently in filing this PGR. On November 3, 2025, within five months of the ’873 patent’s issuance and within two months of the Second Amended Complaint, Terumo timely and diligently filed PGR2026-00009 among eight other post-grant procedures challenging 238 total claims, four of which have already survived discretionary denial considerations, and two of which have been instituted. EX1021 at 2; EX1022 at 2; EX1023 at 2; EX1024 at 1; *See Cellco P’ship v. Huawei Device Co., Ltd.*, PGR2020-01117, Paper 10 at 22 (P.T.A.B. Feb. 3, 2021); EX1001; District Court Litigation, Dkt. No. 48.

**III. DISCRETIONARY DENIAL IS INAPPROPRIATE UNDER
35 U.S.C. § 324(a)**

A. The *Fintiv* Factors Do Not Support Discretionary Denial

Patent Owner's request for discretionary denial exclusively focuses on the *Fintiv* factors. Because the *Fintiv* factors are either neutral or strongly favor institution, as described below, the Director should deny Patent Owner's request for discretionary denial.¹ *Apple Inc. v. Fintiv, Inc.*, PGR2020-00019, Paper 15 at 7–17 (P.T.A.B. May 13, 2020); *see also* EX2001.

1. The District Court Will Likely Grant a Stay

The first *Fintiv* factor asks “whether the court granted a stay or evidence exists that one may be granted if a proceeding is instituted.” *Apple Inc. v. Fintiv, Inc.*, PGR2020-00019, Paper 11 at 6 (P.T.A.B. Mar. 20, 2020). Patent Owner acknowledges that Terumo has moved to stay the District Court Litigation but ignores that case law and statistics overwhelmingly support a stay. *See* Paper 9 at 4–5. Before issuing a stay, district courts consider (1) whether a stay will simplify the issues in question and streamline the trial; (2) whether discovery is complete and whether a trial date has been set; (3) whether a stay would unduly prejudice the

¹ Patent Owner does not argue that discretionary denial is warranted due to settled expectations. *See generally* Paper 9. That is because, as Patent Owner seemingly recognizes, it does not have settled expectations in the '873 patent, which issued on June 10, 2025, less than six months before the initiation of this PGR.

nonmoving party or present a clear tactical advantage for the moving party; and (4) whether a stay will reduce the burden of litigation on the parties and on the court. *See eSoft, Inc. v. Blue Coat Sys., Inc.*, 505 F. Supp. 2d 784, 787 (D. Colo. 2007).

Here, invalidity proceedings before the PTAB will simplify the issues in the District Court Litigation. Terumo has challenged all nine of the Asserted Patents and the Board is best positioned to resolve the invalidity disputes. The Board's decisions will necessarily affect the scope of the dispute between the Parties in the District Court Litigation. *See Samsung Elecs. Co. Ltd. v. Wilus Inst. of Standards & Tech. Inc.*, IPR2025-00933, Paper 11 at 3 (P.T.A.B. October 10, 2025). Accordingly, the district court will likely stay the District Court Litigation for the Board to narrow the scope of the dispute.

Further, discovery is in its infancy, and a trial date has not been set. The parties have just begun fact discovery, there is no fact or expert discovery deadline, and no depositions have been noticed or scheduled. The court has not expended any resources on discovery because the parties have not raised any disputes with the court. Additionally, the parties have only exchanged terms for construction and corresponding intrinsic and extrinsic evidence. Moreover, Patent Owner speaks out of turn when asserting that the *Markman* hearing will occur in May. Paper 9 at 5. The scheduling order has only proposed a month, not set a date, for the *Markman* hearing. See EX2003 at 9. Under the court's standard, these factors favor granting a

stay.

While Patent Owner asserts that there is no reason to believe the district court will stay the litigation, Patent Owner itself recognizes that the District of Colorado frequently grants stays pending PGRs and/or PGRs. *See* Paper 9 at 2 (recognizing that cases are stayed pending a PTO proceeding in 69% of cases); *see also Twitch Interactive, Inc. v. RazDog Holdings LLC*, PGR2025-00307, Paper 18 at 2 (P.T.A.B. May 16, 2025) (finding that motion to stay statistics to be “persuasive evidence that ‘[t]here is good reason to believe that a stay will be granted’” in a parallel litigation); *Imperative Care, Inc. v. Inari Med., Inc.*, PGR2025-00289, Paper 9 at 2 (P.T.A.B. June 12, 2025) (same). The 69% grant number increases when looking at the Judge presiding over the District Court Litigation's statistics, as she adopted the Magistrate's recommendation and stayed a case pending PGR in the one instance where the request was raised. *See Downing Wellhead Equipment, LLC v. Intelligent Wellhead Systems, Inc.*, No. 23-cv-01180-RMR-SBP (D. Colo. Oct. 21, 2024), Dkt. No. 74. Similarly, the Magistrate Judge who will hear the Motion has granted a motion to stay pending post-grant proceedings, at least in part, in 100% of the cases where the question was presented.² *See Downing Wellhead Equipment, LLC*, No.

² In the one case where it was granted in part, some third-party discovery was allowed to continue. *Downing Wellhead Equipment, LLC*, No. 1:23-cv-01180-RMR-

23-cv-01180-RMR-SBP (D. Colo. Feb. 14, 2024), Dkt. No. 65. This includes when the PGRs had not yet been instituted. *See id.* Concerns regarding inconsistent outcomes or significant duplication of efforts are significantly reduced when, like here, the likelihood of a stay is statistically high.

As the District Court Litigation is in the early stages, all Asserted Patents are challenged in post-grant proceedings, and the District of Colorado’s statistics support a stay being granted, this factor weighs against discretionary denial.

2. The 2028 Trial Date Weighs Against Denial

The second *Fintiv* factor assesses the “proximity of the court’s trial date to the Board’s projected statutory deadline for a written decision.” *Fintiv, Inc.*, PGR2020-00019, Paper 11 at 6, 9.

Patent Owner concedes that the FWD in this proceeding would issue over a year before any trial would occur in the District Court Litigation. *See* Paper 9 at 4. The FWD for this proceeding is projected to issue in May 2027 and no trial date has been set in the District Court Litigation. *See Twitch Interactive, Inc.*, PGR2025-00307, Paper 18 at 2–3 (denying request for discretionary denial where there was no scheduled trial date); *Imperative Care, Inc.*, PGR2025-00289, Paper 9 at 2 (same). As Patent Owner also recognizes, the median time-to-trial statistics in the District of

SBP, Dkt. No. 65, at 22. Here, no party has begun third-party discovery.

Colorado indicate that trial is likely to occur in or around June 2028, well after the Board's FWD. Paper 9 at 4–5. Moreover, Patent Owner neither argues for nor establishes settled expectations for the '873 patent, a six-month-old patent, and thus, the facts at bar are not analogous to situations where the Board has denied institution despite an FWD in advance of a trial date. *Murata Mfg. Co. v. Georgia Tech Rsch. Corp.*, IPR2025-00383, Paper 14 at 2 (P.T.A.B. July 29, 2025); *See Hisense USA Corp. v. VideoLabs, Inc.*, PGR2025-00880, Paper 11 at 2–3 (P.T.A.B. Oct. 10, 2025).

Because Fintiv Factor Two weighs strongly in favor of Terumo, Patent Owner points to *Murata* and *Hisense* to argue that this factor is not dispositive. Paper 9 at 4–5. But *Murata* and *Hisense* are inapposite. In both *Murata* and *Hisense*, the Director recognized that the likelihood that an FWD would issue before the district court trial occurred counseled against discretionary denial. *Murata Mfg. Co.*, IPR2025-00383, Paper 14 at 2; *See Hisense USA Corp.*, IPR2025-00880, Paper 11 at 2. Despite that, in both cases, the Director relied on settled expectations in patents that had been issued for 16 years (*Murata*) and 11 and 12 years (*Hisense*) to support discretionary denial. *Murata Mfg. Co.*, IPR2025-00383, Paper 14 at 2; *See Hisense USA Corp.*, IPR2025-00880, Paper 11 at 2. Here, however, Patent Owner has failed to establish settled expectations in the '873 Patent. Thus, there is no countervailing factor to offset the fact that this proceeding's FWD date strongly supports institution.

Moreover, as Terumo has challenged all nine of the Asserted Patents, the Board is uniquely positioned to best resolve these disputes due to the complexity and numerosity of the Asserted Patents and invalidity grounds. *See Samsung Elecs. Co. Ltd. v. Wilus Inst. of Standards & Tech. Inc.*, PGR2025-00933, Paper 11 at 3 (P.T.A.B. October 10, 2025).

In sum, the projected timing of trial well after the Board's decision weighs strongly against discretionary denial and support institution.

3. Minimal Investment in the District Court Favors Institution

The third *Fintiv* factor assesses the “investment in the parallel proceedings by the court and the parties.” *Fintiv, Inc.*, PGR2020-00019, Paper 11 at 6, 9–12. “If, at the time of the institution decision, the district court has not issued orders related to the patent at issue in the petition, this fact weighs against exercising discretion to deny institution.” *Id.* at 9.

Here, the District Court has not issued any orders specifically related to the '873 patent. In fact, despite the fact that the District Court Litigation has been pending for eight months, the Parties and Court have not significantly invested in it. While Terumo has filed a Partial Motion to Dismiss in the District Court Litigation, Terumo has not yet answered the Second Amended Complaint, discovery has just begun, and the District Court's resources have been focused primarily on rote case-management issues.

Patent Owner's argument that the case is far enough along to warrant discretionary denial is not supported by PTAB precedent. Initial invalidity contentions were just served and responded to, the parties exchanged claim construction terms and corresponding intrinsic and extrinsic evidence less than eleven days ago, and the parties will not have completed the claim construction process by this institution deadline. *See* EX2003 at 9. Moreover, again, while Patent Owner suggests claim construction will finish in May, no *Markman* hearing has been scheduled, and the scheduling order only gives a *proposed* month for the hearing. Paper 9 at 5; EX2003 at 9. Further, there are no set deadlines for the close of fact or expert discovery, and both will likely be ongoing when any FWD issues. This factor favors institution. *See Cambridge Indus. USA, Inc. v. Applied Optoelectronics, Inc.*, IPR2025-00434, Paper 11 at 1, 2 (P.T.A.B. June 26, 2025) (denying discretionary denial with respect to three patents because parallel litigation that did not have a trial date or even a *Markman* hearing scheduled).

Despite Patent Owner's arguments to the contrary, in similar situations where the most burdensome parts of the case lie ahead, the Director has found that this factor weighs against discretionary denial. For example, the Director has found parallel proceedings still in early stages when no orders have addressed the patents in the Petition. *See Fintiv*, PGR2020-00019, Paper 11 at 10 n.18 (first citing *Facebook, Inc. v. Search and Social Media Partners, LLC*, PGR2018-01620, Paper

8, at 24–25 (P.T.A.B. Mar. 1, 2019) and then citing *Amazon.com, Inc. v. CustomPlay, LLC*, PGR2018-01496, Paper 12, at 8–9 (P.T.A.B. Mar. 7, 2019)). Moreover, the Director recently denied discretionary denial on a Petition filed after the parties had exchanged infringement and invalidity contentions, and when claim construction is in a preliminary phase. *See e.g., Samsung Elecs. Co. Ltd., v. Wilus Inst. of Standards and Tech. Inc.*, PGR2025-01164, Paper 7, at 16 (P.T.A.B. October 14, 2025); *id.*, Paper 11 at 5.

Additionally, while Patent Owner laments the volume of Terumo’s invalidity contentions in the District Court Litigation, any burden is Patent Owner’s own doing as Patent Owner decided to bring a nine-patent case with over 200 asserted claims despite knowing that its assertions would need to be narrowed. Paper 9 at 5; District Court Litigation Dkt. No. 67, at 1. Furthermore, the court will not be responsible for evaluating invalidity contentions until such time as the contentions have been finalized. Accordingly, invalidity proceedings before the PTAB would undoubtedly simplify the issues in the parallel litigation because the PTAB would narrow the vast assertions before they reached the District Court.

At base, the litigation remains in early procedural stages and the most burdensome parts of the case lie ahead. Accordingly, this factor favors institution.

4. There is Little Risk of Overlapping Issues

The fourth *Fintiv* factor assesses the “overlap between the issues raised in the

petition and in the parallel proceeding.” *Fintiv, Inc.*, PGR2020-00019, Paper 11 at 6, 12–13. Petitioner will be estopped from asserting “any ground that was raised or reasonably could have been raised during the post-grant review” more than a year before the expected trial date, reducing the risk of inconsistent decisions. 35 U.S.C. § 325(e)(1); *see also Phison Elecs. Corp. v. Vervain, LLC*, PGR2025-00010, Paper 14 at 3 (P.T.A.B. July 10, 2025); EX2004. Plus, the District Court Litigation is expected to be stayed, further mitigating the risk of inconsistent decisions. *See Intas Pharms. Ltd. v. Atossa Therapeutics, Inc.*, PGR2025-00043, Paper 12 at 2-3 (P.T.A.B. Aug. 29, 2025). A stipulation, therefore, is unnecessary. Patent Owner has also indicated that it will drop claims in the District Court Litigation. District Court Litigation, Dkt. No. 67, at 2. Therefore, Board review of the expansive claim set will be both more efficient and more comprehensive. This factor is at least neutral and is considered “on a holistic assessment of all of the evidence and arguments presented” with other *Fintiv* factors. *See Anthony, Inc. v. Controlotec, LLC*, IPR2025-00636, Paper 9 at 3 (P.T.A.B. July 16, 2025) (referring IPR to merits panel despite Petitioner not filing a *Sotera* stipulation); *see also id.*, Paper 6 at 7-9 (P.T.A.B. June 10, 2025).

5. Identical Parties

The fifth *Fintiv* factor assesses the “whether the petitioner and the defendant in the parallel proceeding are the same party.” *Fintiv, Inc.*, PGR2020-00019, Paper 11 at 6, 13–14. Patent Owner notes the parties are the same. Paper 9 at 7. This factor

is neutral and expected in parallel proceedings. It does not weigh against institution.

6. The Petition Presents Strong Merits

The sixth *Fintiv* factor assesses “other circumstances that impact the Board’s exercise of discretion, including the merits.” *Fintiv, Inc.*, PGR2020-00019, Paper 11 at 6, 14–16. Here, discretionary denial is unwarranted considering the compelling merits of the unpatentability grounds set forth in the Petition, consistent with the Director’s Interim Processes for PTAB Workload Management. EX2001 at 2.

Patent Owner asserts the Petition is weak by declaring Dr. Fletcher’s declaration duplicative of the Petition. While the Petition and the declaration cite the same specific disclosures that prove the ’873 patent is invalid, and thus have textual overlap, this overlap is neither improper nor conclusory.

Patent Owner also argues that the Petition “boils down to conclusory statements with no substantive analysis.” Paper 9 at 8. This is false. Contrary to Patent Owner’s allegations, Petitioner provided numerous reasons why the claims of the ’873 patent are invalid, and specifically why a POSITA would be motivated to combine Lavender with Fletcher-Haynes and the other relied-upon prior art references. See generally Pet. at 21–87. For example, the Petition explains that “Fletcher-Haynes teaches using a donor’s height, weight, and hematocrit to determine the total amount of pure plasma to collect from the donor . . . By adding the height parameter to Lavender’s data collection steps, Lavender’s systems would

more accurately determine the optimal amount of pure plasma to collect.” *See id.* at 47. As the Petition describes, Lavender and Fletcher-Haynes “each relate to the same well-known technologies, both apply substantially similar techniques to achieve similar results, and Lavender’s functionality would not change in the combination as Fletcher-Haynes is used for the same purpose as Lavender’s system—using donor parameters to determine the total amount of pure plasma to collect.” *Id.* at 47.

Patent Owner argues that Terumo’s primary reference, U.S. Patent Number 4,898,674 (“Lavender”) focuses on “an anticoagulant problem” related to varying donor hematocrits, while the ’873 patent improves prior systems by determining and targeting pure plasma volume for collection. Paper 9 at 8. But, as Patent Owner recognizes, “the purpose of a patent is not necessarily coextensive with everything it discloses,” and, here, Lavender, like the ’873 patent, also discloses operating the blood component separation device “under program control to calculate, based on the donor data, the amount of plasma to be collected and the amount of anticoagulant to be added.” EX1005 at Abstract, Figures 25A-D, Tables V and VI; Paper 9 at 9. Specifically, Lavender’s Table VI provides algorithms for collecting plasma. EX1005 at 20:55-22:67; Table VI at cols. 41-44. As discussed below, Lavender’s algorithm calculates pure plasma (*TPF*) to control collection of plasma until a target pure plasma volume (*MAXPF*) is reached. EX1005 at Table VI at cols. 43-44.

Patent Owner’s attempts to refute this are based on conjecture, not Lavender’s

express disclosures, and thus fall flat. Patent Owner argues that Lavender's "*TPF* (total plasma filtered, ml)," variable, which Terumo relies on, is not used to explain when the system stops the blood draw. Paper 9 at 9-10. This is incorrect. As the Petition explains, Lavender's algorithm expressly **states** that "Lavender executes a main loop of the algorithm until the total plasma filtered (*TPF*) in plasma bag 325 is equal to or greater than a determined maximum total plasma volume to collect (*MAXPF*)." Petition at 16, citing EX1005 at 43-44, claim 33. Table VI of Lavender specifically recites, "[c]ompare *TPF* [Total plasma filtered (pure plasma) volume in the collection container] with *MAXPF* [Total plasma filtered (pure plasma) volume to collect]." See EX1005 at 43-44. "*MAXPF*" is defined as "total plasma to collect" and thus, *TPF* is not anticoagulated plasma or dilute plasma, it is "total plasma." See *id.* Accordingly, Lavender's system stops when the total plasma, "*TPF*" is equal to the total plasma to collect, "*MAXPF*." Paper 5 at 15, 35; EX1005 at 20:55-22:67; Table VI at cols. 41-44; EX1018 at ¶ 62, 104, 111-112.

Patent Owner also argues that Lavender's disclosed system continues its process until "the program determines whether the desired weight of plasma has been collected," and that the weight of the '873 patent's collected plasma differs from Lavender's target total collection volume. Paper 9 at 9-10. However, the '873 Patent uses the weight sensor to "measure[] the amount of plasma collected," and to continue the collection process "until a target volume of pure plasma . . . is collected

within the plasma collection container.” EX1001 at 7:30-32, 9:4-12. Lavender also determines the amount of plasma using a weight sensor to determine the total weight of the dilute plasma, “TDPW.” EX1005 at 16:50-53, 43-44. The total weight of the dilute plasma is in turn used to calculate a volume of total plasma, “*TPF*,” which is the volume of pure plasma. *Id.* Therefore, Patent Owner’s argument that a POSITA would not have understood the “volume of plasma” to correspond to *TPF* is unfounded. Further, Patent Owner’s statement that Lavender does not teach targeting and stopping a collection based on the volume of pure plasma alone is baseless because the ’873 Patent does not include any claim that expressly states that targeting and stopping a collection is based on the volume of pure plasma ***alone***.

Patent Owner also argues that Lavender does not disclose calculating a volume of pure plasma in the collection container based, at least in part, on hematocrit. Paper 9 at 10. Terumo disagrees. As Patent Owner acknowledges, Lavender recognizes that the plasma volume of whole blood varies with hematocrit. Paper 9 at 8-9; EX1005 at 2:15-17, 3:2-10. As the Petition explains, Lavender thus uses the donor’s hematocrit both directly and indirectly to calculate plasma collection flow rates and volumes, including a total volume of pure plasma in the collection container—defined by “*TPF*.” See Paper 5 at 25-28 and 45-50; EX1005 at 41-44. Lavender’s use of hematocrit prevents blood from donors with low

hematocrits from receiving too little anticoagulant and blood from donors with high hematocrits from receiving too much anticoagulant. EX1005 at 3:2-7 and 41-44.

In addition to this anticoagulant problem, Lavender solves the same problem that the '873 purports to solve of determining "the total volume of plasma that has been collected (e.g., because the product collected is a mixture of plasma and anticoagulant)." Paper 9 at 9; EX1001 1:56-60. Specifically, Lavender calculates both the target amount of pure plasma to collect from a donor (e.g., *MAXPF*) prior to the start of a procedure, and the volume of total pure plasma collected in the plasma collection container during a procedure, "*TPF*." EX1005 at 41-44. Despite Patent Owner's attempt to assert otherwise, Lavender teaches targeting and stopping collection based on the volume of pure plasma alone, the exact concept that Patent Owner alleges is novel, or a purported improvement upon prior art systems, in the '873 patent. See Paper 9 at 9; EX1005 at 41-44.

Patent Owner's arguments attacking Fletcher-Haynes fare no better. First, Patent Owner's assertion that Fletcher-Haynes' is directed to a platelet collection system that uses "prediction algorithms" to "predetermine donor eligibility" ignores the clear teachings of Fletcher-Haynes. Paper 9 at 11. Fletcher-Haynes discloses collecting plasma without collecting platelets. See EX1004 at 31:9-12. Specifically, Fletcher-Haynes describes how an operator selects the type of blood product to collect from the donor, and recites, "[t]he three choices are platelets, plasma and red

blood cells. Any combination hereof may be checked.” *See id.* Fletcher-Haynes also discloses real-time calculation of parameters, such as collected pure plasma volume (“source plasma volume”). *See* Paper 5 at 17; EX1004 at 34:8-24; 48:66-49:26; EX1018 at ¶ 66. Accordingly, as discussed above and as blatantly ignored by Patent Owner, Lavender and Fletcher-Haynes “each relate to the same well-known technologies, both apply substantially similar techniques to achieve similar results, and Lavender’s functionality would not change in the combination as Fletcher-Haynes is used for the same purpose as Lavender’s system—using donor parameters to determine the total amount of pure plasma to collect.” Pet. at 46.

Patent Owner’s § 101 arguments are similarly thin. While Patent Owner asserts that Petitioner ignores generic “hardware elements” of the claimed system, these hardware elements need to be specialized to confer patent eligibility. *See Life Techs., Inc. v. Nintendo of Am., Inc.*, No. 3:13-cv-4987, 2020 WL 13281800, at *3-4 (N.D. Tex. Jan. 17, 2020). That is why, for example, claims for an “improved digital camera” in *Yu* were patent-ineligible despite claiming the lenses, image sensor, and other generic hardware elements. *Yu v. Apple Inc.*, 1 F.4th 1040, 1043-44 (Fed. Cir. 2021). Patent Owner has never asserted that its plasma collection equipment or the arrangement of the equipment is novel because it is not. *See BASCOM Global Internet Servs., Inc. v. AT&T Mobility LLC*, 827 F.3d 1341, 1350 (Fed. Cir. 2016). Its purported invention lies in its mathematics, but surviving the § 101 inquiry

requires “more than simply stating the abstract idea while adding the words ‘apply it’” on a generic device. *Alice Corp. Pty. Ltd. v. CLS Bank Int’l*, 573 U.S. 208, 221 (2014) (cleaned up) (quoting *Mayo Collaborative Servs. v. Prometheus Lab’ys, Inc.*, 566 U.S. 66, 72 (2012)); *see also BSG Tech LLC v. Buyseasons, Inc.*, 899 F.3d 1281, 1290-91 (Fed. Cir. 2018). Thus, even when considering the ordered combination of elements, the ’873 patent is patent ineligible because there is “no ‘inventive concept’ in the claimed application of the formula[s]” in a generic plasma collection machine. *Mayo*, 566 U.S. at 72-73, 82; *Parker v. Flook*, 437 U.S. 584, 594 (1978); *Diamond v. Diehr*, 450 U.S. 175, 191-92 (1981). That is especially true where the FDA has provided guidance on, and codified, taking a weight, determining hematocrit, and identifying a donor’s sex before collecting plasma. *See* EX1012.

Tellingly, Patent Owner does not address most of Petitioner’s § 112 arguments, because it cannot. Petitioner and Dr. Fletcher provide compelling evidence that there is **no** textual support for measuring/calculating target volumes of anticoagulated plasma in the ’873 patent. Patent Owner wrongly suggests that merely mentioning “plasma component,” “plasma product,” or “anticoagulated plasma” satisfies the written description requirement. Paper 9 at 12-13. These appearances of “plasma component,” “plasma product,” and “anticoagulated plasma” however, do not “blaze a trail through the forest[,] one that runs close by [Patent Owner’s] proposed tree.” *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571 (Fed.

Cir. 1996). Rather, Patent Owner raises them when distinguishing its claimed approach from prior art systems that “collect[] based on a total volume of anticoagulated plasma.” EX1001, 10:1-6; *see also id.* 1:56-62. Further, “[t]he question is not whether a claimed invention is an obvious variant of that which is disclosed in the specification,” *i.e.*, that Petitioner understood the meaning of “plasma component.” *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997). To satisfy the written description requirement, “a prior application itself must describe an invention.” *Id.* The '873 patent does not do that as it only describes calculating and using a target volume of *pure* plasma, not anticoagulated plasma. Pet. at 83-88; EX1001, 1:56-62, 3:13-16, 4:23-25; 7:33-36, 8:17-22.

Accordingly, the Petition's compelling merits favor institution.

IV. PETITIONER'S SDD MERITS FAVORABLE CREDIT SUPPORTING INSTITUTION

Patent Owner's argument that petitions must not rely upon patents or patent publications to earn favorable discretionary credit is not found in the Director's SDD memorandum. *Compare* Paper 9, at 14 *with* EX2006, at 1-2. Petitioner's SDD merits favorable credit supporting institution because it meets all disclosure requirements and reveals “new or underutilized pathways relevant to [U.S.P.T.O.] search practice.” *See* EX2006; EX1019; EX1020.

V. CONCLUSION

For the above reasons, Terumo submits discretionary denial is not warranted.

Date: February 13, 2026

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing PETITIONER'S
OPPOSITION TO PATENT OWNER'S REQUEST FOR DISCRETIONARY
DENIAL was served on February 13, 2026 by filing this document through the P-
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