

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

TERUMO BCT INC.,

Petitioner

v.

HAEMONETICS CORP.,

Patent Owner

IPR2025-01391
U.S. Patent No. 10,758,652

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

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EXHIBIT LIST

Exhibit	Reference
1001	U.S. Patent No. 10,758,652 (“’652 patent”)
1002	File History of the ’652 patent
1003	Declaration of Dr. Gary D. Fletcher in Support of Petition
1004	Japanese Patent Publication No. JP 2002-282352 A including certified English translation and declaration by Japanese translator (“Takagi”)
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	Sergent 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”)

I. INTRODUCTION

Discretionary denial of Terumo BCT, Inc.'s ("Terumo") Petition for *inter partes* review ("IPR") of U.S. Patent No. 10,758,652 ("the '652 patent") is not warranted for at least two reasons. First, Haemonetics Corporation ("Haemonetics" or "Patent Owner") could not have developed settled expectations in the '652 patent, as it issued only five years ago. This is further confirmed by Patent Owner's ongoing efforts to file additional patent applications within the '652 patent's family and Patent Owner's filing of not one, but two, amended complaints in the parallel district court case—*Haemonetics Corp. v. Terumo BCT, Inc.*, Case No. 1:25-cv-01409-RMR-SBP (D. Colo. filed May 5, 2025) (the "District Court Litigation"). Second, every factor outlined in *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 (P.T.A.B. Mar. 20, 2020) ("*Fintiv*") is either neutral or weighs against discretionary denial. The District Court Litigation is in its early stages, claim construction will not begin until early 2026, there are no set dates for the close of fact or expert discovery, and, as Patent Owner acknowledges, any trial is unlikely to begin until over a year after a final written decision issues in this proceeding. Accordingly, Terumo respectfully submits 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 the District Court Litigation in the United States District Court for the District of Colorado, asserting that Terumo's

Rika System infringed seven of its patents, including the '652 patent. Since then, Patent Owner has filed two amended complaints, adding two additional patents, to bring the total to nine (collectively, "the Asserted Patents"). *See Haemonetics Corp. v. Terumo BCT, Inc.*, Case No. 1:25-cv-01409-RMR-SBP (D. Colo. filed May 5, 2025), Dkt. Nos. 36, 48. The Asserted Patents are in the same patent family, and each issued within the last five years.

On November 7, 2025, Terumo filed a Motion to Stay the District Court Litigation pending resolution of all IPRs and *post grant* reviews ("PGRs") challenging the Asserted Patents. *See Haemonetics Corp. v. Terumo BCT, Inc.*, Case No. 1:25-cv-01409-RMR-SBP (D. Colo. Aug. 12, 2025) at Dkt. 65. That motion is pending before the district court. Even if not stayed, however, the case remains in the early stages. Discovery began two months ago and while initial infringement and invalidity contentions have been served, the Parties have not yet engaged in significant discovery. *See* EX2012 at 9. Claim construction briefing will not begin until March 2026, and the claim construction hearing is not estimated to occur until at least May 2026. *Id.* Given that the claim construction order will set the deadlines for the close of fact and expert discovery, it is not expected that discovery will close before early 2027. *See id.* Further, and as Patent Owner recognizes, trial is unlikely to occur before mid-2028. Paper 7 at 12. In short, the district court has not invested significant resources, and the case is far from reaching substantive milestones.

B. This IPR Proceeding

Not only is the District Court Litigation not far along, but Terumo also acted diligently in filing this IPR. Patent Owner did not allege that Terumo infringed the '652 patent until October 2024. Seven months later, Patent Owner initiated the District Court Litigation. On August 11, 2025, ten months after first learning of any potential infringement of the '652 patent, within 3.5 months of the District Court Litigation being filed, and before infringement contentions were served in the District Court Litigation, Terumo filed its IPR Petition. *See Celco P'ship v. Huawei Device Co., Ltd.*, IPR2020-01117, Paper 10 at 22 (P.T.A.B. Feb. 3, 2021).

**III. DISCRETIONARY DENIAL IS INAPPROPRIATE UNDER
35 U.S.C. § 314(a)**

A. Patent Owner Has Not Established Settled Expectations

Patent Owner argues that it had settled expectations in the '652 patent and that these expectations weigh in favor of discretionary denial. Paper 7 at 3. It does not, and they do not. Settled expectations are based on how long a patent has been in force and whether that length of time provides expectations that the patent's validity will not be challenged. Here, the '652 patent has only been in force for five years, which is too short a time for Patent Owner to have developed settled expectations.¹

¹ While Patent Owner notes that the '652 patent was filed in 2017 (Paper 7 at 1), it is impossible for Patent Owner's settled expectations to date back to then, as the '652

EX1001, cover; *See Cambridge Indus. USA, Inc. v. Applied Optoelectronics, Inc.*, IPR2025-00434, Paper 11 at 2-3 (P.T.A.B. June 26, 2025) (finding no settled expectations on three patents that were in force for six years or less); *Berkshire Hathaway Energy Co. v. Birchtech Corp.*, IPR2025-00274, Paper 23 at 3 (P.T.A.B. July 2, 2025) (same). Moreover, the '652 patent's family remains active with continuing applications still pending. This activity is evidenced by Patent Owner's filing of multiple amended complaints in the District Court Litigation to add two newly issued patents. Patent Owner cannot credibly assert settled expectations when the contours of the patent family are still evolving. Accordingly, the Board should find that Patent Owner has no settled expectations in the '652 patent.

In arguing otherwise, Patent Owner raises four main points: (1) that the plasma collection industry contains only three main competitors, (2) that Patent Owner has invested in its patented invention for eight years, (3) that Terumo was aware of Patent Owner's patent portfolio, and (4) that Patent Owner had settled expectations based on the totality of the circumstances. *Id.* at 3-9. These arguments lack merit and fail to establish settled expectations.

First, even if there were only three main competitors in the plasma collection

patent did not issue until September 1, 2020. *See GAF Bldg. Materials Corp. v. Elk Corp. of Dallas*, 90 F.3d 479, 483 (Fed. Cir. 1996).

industry—Patent Owner, Terumo, and Fresenius Kabi—as Patent Owner asserts (Paper 7 at 3-4), that alone is insufficient to establish settled expectations. In addition to the parties being in the same field, the patents must also have been in force for a significant amount of time and Terumo must have had some reason to be aware of them for there to be settled expectations. Patent Owner's own cited case, *Murata Mfg. v. Georgia Tech Rsch. Corp.*, IPR2025-00383, Paper 14 (P.T.A.B. July 29, 2025), supports this. In *Murata*, settled expectations were found when the challenged patent had been in force for **more than 16 years** and the parties had discussed the technology **over 18 years** before the petitioner challenged the patent's validity. *Murata Mfg*, IPR2025-00383, Paper 14 at 2. That is not the case here. Here, Patent Owner did not raise the patents with Terumo until October 2024 and did not assert its patents against either Terumo or Fresenius Kabi until earlier this year. That both Terumo and Fresenius entered the market and, in at least Terumo's case, were in the market for years before Patent Owner even approached them with the '652 patent, shows that there are no settled expectations.

Second, that Patent Owner purportedly spent eight years researching the patented technology is irrelevant to the discretionary denial analysis. As established in Patent Owner's own cited case, discretionary denial for settled expectations was only warranted for IPRs challenging patents issued six and seven years earlier, not for IPRs challenging newer patents. *See Amgen Inc. v. Bristol-Myers Squibb Co.*,

IPR2025-00601, Paper 9 at 2-3 (P.T.A.B. July 24, 2025). Similarly, *Empower Clinic Servs., L.L.C. v. Eli Lilly & Co.*, which Patent Owner also cites, is inapposite to this proceeding because, while the Board found that continued investments in drugs embodying the claimed technology supported settled expectations, the challenged patent had issued nearly **nine years** prior. *Empower Clinic Servs., L.L.C. v. Eli Lilly & Co.*, IPR2025-01024, Paper 15, at 2 (P.T.A.B. Oct. 10, 2025). The '652 patent has only been in force for five years and, thus, Patent Owner's arguments are unavailing. Moreover, Patent Owner's high-level identification of expenses and investment in commercializing its technology is wholly untethered to the claims of the '652 patent. Patent Owner provides no specific evidence or information to establish that its expenditures directly relate to the '652 patent's claimed technology and thus has failed to establish how its investments establish settled expectations.

Third, awareness of Patent Owner's patent portfolio does not establish settled expectations. While Patent Owner insinuates that the portfolio covering the '652 patent has been in force for a long time, that representation is farcical. Patent Owner's portfolio goes back only five years and five years is insufficient to establish settled expectations. *See* EX1001; *see also Google LLC, v. Withrow Networks, Inc.*, IPR2025-00775, Paper 10 at 2 (P.T.A.B. August 14, 2025) (holding there were not settled expectations for a five-year-old patent); *Cambridge Indus. USA, Inc.*, IPR2025-00434, Paper 11 at 2-3; *Berkshire Hathaway Energy Co.*, IPR2025-00274,

Paper 23 at 3.² And while the '652 patent may have issued before Terumo launched its Rika product, Patent Owner cites to nothing establishing that Terumo knew of the '652 patent, or its patent family, before April 24, 2024. Paper 7 at 7; EX2007. But this April 24, 2024 date does not establish Patent Owner's settled expectations, it establishes Terumo's diligence as, less than two years later, Terumo filed IPRs and/or PGRs challenging the issued patents in this family.³

That Patent Owner submits it has settled expectations because Terumo knew it was entering an industry protected by patents (Paper 7 at 6) fails for the same reason. Not only is there no evidence that Terumo knew of the '652 patent when it entered the industry, but its knowledge of the NexSys product does not establish that Terumo should have challenged Patent Owner's patents sooner. As Patent Owner

² Patent Owner's reliance on *Datadome S.A. v. Arkose Labs Holdings, Inc.*, IPR2025-00693, Paper 13 (P.T.A.B Aug. 14, 2025) is similarly misplaced. In *Datadome*, the Board found settled expectations because the patents had been in force for *ten* and *seventeen years*. *Id.* at 2.

³ Patent Owner's reliance on *Geotab Inc. v. Fractus, S.A.*, IPR2025-000928 is also misplaced. There, the patent owner had raised the patent at issue with petitioner *four years* earlier and had been in discussions with petitioner about the challenged patent during the four-year period before the IPR was filed. That is not the case here.

recognizes, Terumo's FDA 510(k) statements refer to the NexSys PCS® Plasma Collection System with Persona® (EX2005) as a "Reference" device, which may be different from the submitted product. *See, e.g.*, EX2005 at 2.

Fourth, Patent Owner relies on inapposite cases to argue that the '652 patent's 2020 issuance creates settled expectations. For example, in *Azurity Pharms., Inc. v. Helsinn Healthcare S.A.*, IPR2025-00949, Paper 11 (P.T.A.B. Sep. 19, 2025), while the Board noted that settled expectations existed in four patents, three of the four issued over seven years earlier, and, even with the acknowledgement that there were settled expectations, the Board denied issuing a discretionary denial. *Id.* at 2-3. Patent Owner's reliance on *WebGroup Czech Republic, A.S. v. DISH Techs. LLC*, IPR2025-00467, Paper 14 (P.T.A.B. July 16, 2025) is similarly misplaced. While the Board there denied instituting an IPR challenging a patent issued in 2023, that patent was one of four being challenged in concurrent IPRs, some of which had "already been the subject of multiple proceedings," which weighed in favor of discretionary denial. *Id.* at 2-3. Likewise, Patent Owner's reliance on *Milwaukee Elec. Tool Corp. v. Klein Tools, Inc.*, IPR2025-00724, Paper 14 (P.T.A.B. Sept. 12, 2025) is also unfounded. There, the Board expressly found that Patent Owner "ha[d] not developed strong settled expectations that favor discretionary denial" in patents that issued in 2022, 2023, and 2025 and relied on the patents' involvement in an investigation before the U.S. International Trade Commission as a reason for

discretionary denial. *Id.* at 2-3. Lastly, in *Samsung Elecs. Co. v. Genghiscomm Holdings LLC*, IPR2025-00793, Paper 12 (P.T.A.B. Aug. 22, 2025), the Board issued a discretionary denial because the challenged patents were also involved in a district court case scheduled for trial six months before any final written decision would issue.⁴ That is not the case here, where any district court trial would be over a year after any final written decision.

Accordingly, for all the above reasons, Patent Owner has no settled expectations in the ’652 patent, and discretionary denial is not warranted.

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

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.*, IPR2020-00019, Paper 11 at 12 (P.T.A.B. Mar. 20, 2020). Patent Owner asserts this factor weighs in favor of a discretionary denial. Paper 7 at 10. But, since Patent Owner’s Discretionary Denial brief, Terumo has moved to stay the District Court Litigation. On November 7, 2025, less than a week after filing its final post-grant

⁴ *Samsung Elecs. Co. v. Genghiscomm Holdings LLC*, IPR2025-00793, Paper 12 (PTAB Aug. 22, 2025) is inapposite for the same reason, because there the district court trial was set to occur six months before any final written decision would issue.

challenge to the nine Asserted Patents, Terumo moved to stay the District Court Litigation, arguing that the caselaw overwhelmingly supports a stay pending IPR and PGR challenges because the case is at an early stage of litigation and all Asserted Patents are challenged in post-grant proceedings.

Ample evidence exists that the District Court Litigation will likely be stayed. 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 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, discovery is at 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 at all on discovery because the parties have not raised any disputes with the court. Additionally, the claim construction process has not yet begun. These factors favor granting a stay.

Further, as Patent Owner recognizes, the District of Colorado frequently grants stays pending post-grant proceedings. *See* Paper 7 at 11 (recognizing that cases are stayed pending a PTO proceeding in 69% of cases); *see also Twitch*

Interactive, Inc. v. RazDog Holdings LLC, IPR2025-00307, 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.*, IPR2025-00289, Paper 9 at 2 (P.T.A.B. June 12, 2025) (same). That 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 IPR in the one instance where the request was raised. *See Downing Wellhead Equipment, LLC v. Intelligent Wellhead Systems, Inc. et al.*, No. 23-cv-01180-RMR-SBP (D. Colo. Oct. 21, 2024). 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.⁵ *See Downing Wellhead Equipment, LLC*, No. 23-cv-01180-RMR-SBP (Feb. 14, 2024). This includes when the IPRs had not yet been instituted. *See id.*

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.

⁵ In the one case where it was granted in part, some third-party discovery was allowed to continue. Here, no party has begun third-party discovery.

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.*, IPR2020-00019, Paper 11 at 12.

Patent Owner concedes that the final written decision for this proceeding is projected to issue in February 2027, and no trial date has been set in the parallel district court litigation. *See Twitch Interactive, Inc.*, IPR2025-00307, Paper 18 at 2-3 (denying request for discretionary denial where there was no scheduled trial date); *Imperative Care, Inc.*, IPR2025-00289, Paper 9 at 2 (same). Patent Owner also acknowledges that median time-to-trial statistics in the District of Colorado indicate that trial is likely to occur in or around June 2028, well after the Board’s final written decision. Paper 7 at 12. Nonetheless, Patent Owner attempts to minimize the significance of these facts by arguing that even if the Board’s final written decision precedes trial, it would not eliminate duplication or inconsistency. *Id.* This argument mischaracterizes the relevance of *Fintiv* Factor 2. *See Google LLC*, IPR2025-00775, Paper 10 at 2 (holding that a trial date after a final written decision “reduc[ed] the concern of inconsistent outcomes or significant duplication of efforts” and denying discretionary denial when there was no scheduled trial date and time to trial statistics suggested any trial would be after the final written decision issued).

The “proximity of the court’s trial date,” factor compares the district court’s

trial date and the PTAB's projected statutory deadline for a final written decision because, if the PTAB is likely to complete its review before the trial concludes, any decision to deny institution would be less likely to be based solely on this factor. Concerns regarding inconsistent outcomes or significant duplication of efforts are significantly reduced when, like here, the projected PTAB decisions precede the projected trial date by **over a year**.

Patent Owner also relies on the fact that Terumo had not yet challenged all nine of the Asserted Patents at the time it filed its Discretionary Denial brief as a reason why this factor does not weigh in favor of discretionary denial. Paper 7 at 12-13. But Terumo has now filed post-grant proceedings against all of the Asserted Patents, and has submitted a *Sotera* Stipulation in this case to eliminate overlap between this proceeding and the District Court Litigation. *See* Paper 6. Moreover, the Board is uniquely positioned to best resolve these invalidity disputes due to the complexity and numerosity of the Asserted Patents and invalidity challenges. *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). Lastly, as discussed above, Patent Owner has failed to establish settled expectations in the '652 patent, and thus they do not weigh in favor of denying institution when the district court trial is likely to occur over a year after any final written decision would issue.

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.*, IPR2020-00019, Paper 11 at 13. While the District Court Litigation has been pending since May 2025, the Parties and the Court have not significantly invested in it over the last six months. 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. While initial invalidity contentions were just served, the claim construction process has not yet begun, and will not begin until early 2026, right around the institution deadline in this proceeding. EX2012 at 9. Moreover, no *Markman* hearing has been scheduled and there are no set deadlines for the close of fact or expert discovery, and both will likely be ongoing when any final written decision issues in this proceeding. *See Cambridge Industries USA, Inc.*, IPR2025-00434, Paper 11 at 1, 3 (denying discretionary denial with respect to three patents because parallel litigation that did not have a trial date or even a *Markman* hearing scheduled).

At base, the litigation remains in early procedural stages and the most burdensome parts of the case lie ahead. In similar situations the Board has found that this factor weighs against discretionary denial. Accordingly, Terumo submits that

this factor therefore favors institution.

4. Terumo’s *Sotera* Stipulation Eliminates Overlap and Supports Institution

The fourth *Fintiv* factor assesses the “overlap between the issues raised in the petition and in the parallel proceeding.” *Fintiv, Inc.*, IPR2020-00019, Paper 11 at 12. While Patent Owner asserts that Terumo’s *Sotera* stipulation is not dispositive, the Board has consistently found that a broad stipulation weighs strongly against discretionary denial when considered alongside other factors. *See Sotera Wireless, Inc. v. Masimo Corp.*, IPR2020-01019, Paper 12 at 18–19 (P.T.A.B. Dec. 1, 2020) (precedential); *Tesla, Inc. v. Intell. Ventures II LLC*, IPR2025-00217, Paper 9 at 2–3 (P.T.A.B. June 13, 2025); *Shenzhen Tuozhu Tech. Co., Ltd. v. Stratasys, Inc. et al*, IPR2025-00531, Paper 10 at 3 (P.T.A.B. July 17, 2025).

Patent Owner’s cited cases do not establish otherwise. Paper 7 at 14 (citing *Ericsson Inc. v. Procomm Int’l Pte. Ltd.*, IPR2024-01455, and *ARM Ltd. v. Daedalus Prime LLC*, IPR2025-00207). In those cases, the Board found other factors—like advanced litigation posture or lack of strong merits—tipped the balance. Here, Terumo’s stipulation is accompanied by strong merits, minimal district court investment, and no scheduled trial date. In this context, the stipulation strongly supports institution.

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.*, IPR2020-00019, Paper 11 at 13. Patent Owner notes that the parties are the same. Paper 7 at 14. This factor is neutral and expected in parallel proceedings. It does not weigh against institution.

6. The Petition Presents Strong Merits

The sixth and final *Fintiv* factor assesses “other circumstances that impact the Board’s exercise of discretion, including the merits.” *Fintiv, Inc.*, IPR2020-00019, Paper 11 at 13. Discretionary denial is unwarranted considering the strong merits of the unpatentability grounds set forth in the Petition, consistent with the Director’s *Interim Processes for PTAB Workload Management*. EX2001 at 2. Here, the Petition’s merits are not only strong—they are compelling. The challenged claims recite well-known techniques and the prior art references teach or suggest each limitation. While Patent Owner argues otherwise, its arguments mischaracterize the references and fail to rebut the merits.

For example, Patent Owner wrongly argues that Japanese Patent Publication No. 1001-181352 A (“Takagi”) does not “continu[e] the [collection] process until the target volume is collected” because Takagi discloses multiple ways that its system can stop plasma collection involving collecting percentages of the target plasma volume and cycle tracking. Paper 7 at 14-16. However, as the very portions of Takagi that Patent Owner cites show, Takagi collects plasma until “the actual current plasma collection amount Z (ml) has reached $M(\%)$,” which is “*preferably*

70% to **100%**,” “of the actual target plasma collection amount *D* (mL).” EX1004 at ¶¶[0130]-[0132] (citation modified); Paper 7 at 15. Takagi, thus, clearly continues plasma collection until a current volume of pure plasma reaches 100% of the target volume of pure plasma, *D*.

Patent Owner further alleges that Petitioner fails to “connect the dots” between the collection being completed and a controller stopping the pump once *M*% equals 100% of the target amount. Paper 7 at 16. This is incorrect. Petitioner cites to Takagi’s disclosure that control unit 55 controls the collection of plasma, determines whether the actual plasma collection amount has reached *M*% of the target amount, and controls first fluid supplying pump 11, which draws whole blood from the donor into the blood component collection device 1. Petition at 36; *see also id.* at 14-15, 24. The cited portions of Takagi explain that this occurs in step S104, which is the termination step, in which “the control unit 55 stops . . . operation of the first fluid supplying pump 11.” Petition at 14, 15, 24, 36; *see also* EX1004 at ¶¶[0134], [0118].

Patent Owner further contends that U.S. Patent Number 4,898,674 (“Lavender”) focuses on “an anticoagulant problem” related to varying donor hematocrits, while the ’652 patent improves prior systems by determining and targeting pure plasma volume for collection. Paper 7 at 16. But as Patent Owner recognizes, “the purpose of a patent is not necessarily coextensive with everything it discloses,” and here, Lavender, like the ’652 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, and Table V; Paper 7 at 16-17. Specifically, Lavender Table VI sets forth the algorithms for calculating pure plasma (*TPF*) to control collection of plasma until a target pure plasma volume (*MAXPF*) is reached. EX1005 at Table VI at cols. 41-44, 20:55-22:67.

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 7 at 17. This is incorrect. As the Petition explains, Lavender's algorithm expressly *states* that “[i]f *TPF* is less than *MAXPF*, repeat the loop” and [i]f equal or greater, **stop the program.**” Petition at 19, 36, 42-45, 52 (citing EX1005, Table VI, Section 5(C)). “*MAXPF*” is defined as “total plasma to collect” and thus, *TPF* is not anticoagulated plasma or dilute plasma, it is “total plasma.” Accordingly, Lavender's system stops when the total plasma, “*TPF*” is equal to the total plasma to collect, “*MAXPF*,” and thus Lavender teaches the recited claim limitation. Petition at 36, 42-45, 52; EX1005 at 20:55-22:67; Table VI at cols. 41-44; EX1003 at ¶¶54-60, 121-123.

Patent Owner also argues a person of ordinary skill in the art (“POSITA”) would not have understood Lavender's “volume of plasma” to correspond to *TPF*,

and purports that Lavender “does not teach targeting and stopping collection based on the volume of pure plasma alone.” Paper 7 at 17-18. Patent Owner mischaracterizes Lavender. As in the '652 patent, Lavender determines the amount of plasma using a weight sensor to determine the total weight of the dilute plasma, “*TDPW*.” EX1005 at 16:50-53, Table VI at cols. 43-44. *TDPW* 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 as the '652 Patent's claims do not recite targeting and stopping a collection based on the volume of pure plasma *alone*.

Accordingly, the Petition's compelling merits favor institution.

C. The Patent Office Has Not Previously Adjudicated the Validity of the '652 Patent Based on the Same Art

Discretionary denial under 35 U.S.C. § 325(d) is not warranted where the Office did not materially consider the same, or substantially the same, prior art. *Advanced Bionics, LLC v. Med-El Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 (Feb. 13, 2020) (precedential). Patent Owner relies on the misguided argument that U.S. Patent App. Pub. No. 2003/0125881 to Ryan (“Ryan”), which was considered during the '652 patent's prosecution, is substantially the same art as Lavender and Takagi. Paper 7 at 19. As discussed above, however, unlike Ryan,

Lavender and Takagi both track volumes of pure plasma in real-time and stop pumps when the target volume of pure plasma is reached. Patent Owner points to a single citation that Lavender stops at a total collection volume based on the weight of the plasma and anticoagulant mixture, but ignores Lavender's related disclosures: Lavender converts this weight to a volume of pure plasma and stops at the target volume of pure plasma. Accordingly, Patent Owner's arguments are misplaced and fail to establish that discretionary denial is warranted.

IV. CONCLUSION

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

Date: November 25, 2025

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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 November 25, 2025 by filing this document through the P-
TACTS platform as well as by delivering a copy via the delivery method indicated
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