

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

TERUMO BCT INC.,

Petitioner

v.

HAEMONETICS CORP.,

Patent Owner

IPR2026-00046
U.S. Patent No. 10,980,926

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

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EXHIBIT LIST

Exhibit	Reference
1001	U.S. Patent No. 10,980,926 (“’926 Patent”)
1002	File History of the ’926 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	“Membrane versus centrifuge-based therapeutic plasma exchange: a randomized prospective crossover study,” Carsten Hafer et al., <i>Int. Urol. Nephrol</i> (2016) 48:133-138; Springer Science+Business Media Dordrecht 2015.
1009	“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.
1010	Bruce C. McLeod, MD, et al., “Apheresis: Principles and Practice,” 3rd Edition, AABB Press 2010.
1011	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
1012	Curriculum Vitae (“CV”) of Dr. Gary D. Fletcher
1013	U.S. Patent No. 9,283,316 (“Flexman”)
1014	Japanese Patent Publication No. JP 2002-282352 A and certified Japanese to English translation (“Takagi”)
1015	Search Disclosure Declaration (Filing Party and Board Only)
1016	Redacted Disclosure Declaration
1017	PTAB Notice of Decisions on Institution, Dec. 11, 2025
1018	PTAB Notice of Decisions on Institution, Jan. 9, 2025

I. INTRODUCTION

Discretionary denial of Terumo BCT, Inc.'s ("Terumo") Petition for *inter partes* Review ("IPR") of U.S. Patent No. 10,980,926 (the '926 patent") is unwarranted for at least two reasons.

First, Haemonetics Corporation ("Haemonetics" or "Patent Owner") could not have developed settled expectations in the '926 patent, as it issued only four years before the initiation of this IPR. This is confirmed by the fact that an IPR challenging the '926 patent's parent patent, U.S. Patent No. 10,758,652 ("the '652 patent"), which issued five years ago, survived discretionary denial considerations. Further, three other patents in the 926 patent's family that are also at issue 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") survived discretionary denial. Moreover, Patent Owner's ongoing efforts to file additional patent applications within the '926 patent's family and Patent Owner's filing of not one, but two, amended complaints in District Court Litigation establish that there are no settled expectations in the '926 patent.

Second, every factor in *Apple Inc. v. Fintiv, Inc.* ("*Fintiv*") weighs strongly against discretionary denial or is neutral. IPR2020-00019, 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").

In addition to these reasons, Petitioner submitted a compliant Search Disclosure Declaration (SDD), which provides for a non-exclusive, non-dispositive favorable discretionary factor supporting institution.

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 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—the 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* EX2009 at 8–9. 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. 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, at the earliest. Paper 9 at 7–8.

On November 7, 2025, Terumo moved to stay the District Court Litigation until all IPRs and Post Grant Reviews (“PGRs”) are resolved—a request that is likely to succeed and push the trial date back even further. *See* District Court Litigation, Dkt. 65. Even if not stayed, however, the case remains in the early stages.

B. This IPR Proceeding

Terumo also acted diligently in filing this IPR. On October 17, 2025, within four years of the ’926 patent’s issuance, just over a year after Patent Owner’s first mention of the ’926 patent to Terumo, and within two months of the Second Amended Complaint—Terumo timely and diligently filed IPR2026-00046 along with eight other post-grant proceedings challenging the Asserted Patents’ 238 total claims. *See Cellco P’ship v. Huawei Device Co., Ltd.*, IPR2020-01117, Paper 10 at 22 (P.T.A.B. Feb. 3, 2021); EX 2007; District Court Litigation, Dkt. 48. Four of these proceedings have already survived discretionary denial considerations. EX1017 at 2; EX1018 at 2.

**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 '926 patent and that these expectations weigh in favor of discretionary denial. Paper 9 at 2–5. Not only is neither claim true, but the Board has already considered the very arguments Patent Owner raises here when assessing whether discretionary denial was warranted in an IPR challenging the '652 patent. *See Terumo BCT, Inc. v. Haemonetics Corp.*, IPR2025-01391, Paper 7 at 4–7, 9 (P.T.A.B. Oct. 24, 2025); EX1017 at 2. After reviewing Patent Owner's arguments there, the Director reached the correct conclusion that discretionary denial was not warranted. The Director should reach the same conclusion here.

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 '926 patent has only been in force for four years, one year less than the '652 patent, which is too short a time for Haemonetics to have developed settled expectations. EX1001, cover; EX1017 at 2; *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 '926

patent's family remains active with continuing applications still pending. This activity is evidenced by Haemonetics' filing of multiple amended complaints in the District Court Litigation to add two newly issued patents. Haemonetics cannot credibly assert settled expectations when the contours of the patent family are still evolving. Accordingly, the Board should find that Haemonetics has no settled expectations in the '926 patent.

In arguing otherwise, Patent Owner raises three main points: (1) that Terumo was aware of Patent Owner's patent portfolio because of Terumo's reference to Patent Owner's commercialized system, marked with the '652 patent, in its FDA filings, (2) that Patent Owner has invested millions in its patent portfolio, and (3) that Terumo delayed filing an IPR petition despite its prior knowledge of the '926 patent. Paper 9 at 2–5. As the Director already found, these arguments lack merit and fail to establish settled expectations.

First, awareness of Patent Owner's patent portfolio does not establish settled expectations. While Patent Owner insinuates that the portfolio covering the '926 patent has been in force for a long time, that representation is incorrect. Patent Owner's portfolio goes back only five years, which 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 (P.T.A.B. July 2, 2025). And while the '926 patent may have issued before Terumo launched its Rika product, Patent Owner cites to nothing establishing that Terumo knew of the '926 patent, or its patent family, before October 1, 2024. Paper 9 at 4; EX2007. But this October 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.¹

That Patent Owner submits it has settled expectations because Terumo knew it was entering an industry protected by patents (Paper 9 at 4) fails for the same reason. Not only is there no evidence that Terumo knew of the '926 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 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. Moreover, Patent

¹ Patent Owner's reliance on *Geotab Inc. v. Fractus, S.A.*, IPR2025-000928 is 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.

Owner goes so far as to say that the marking of the '652 *patent* on the referenced device in the FDA filing is enough to give notice to Terumo of the '926 patent. Paper 9 at 3. Patent Owner fails to provide any reasoning why a product marked with one patent would provide notice of a separate, unmentioned patent.

Second, that Patent Owner purportedly spent \$64 million in one year 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. IPR2025-01024, Paper 15, at 2 (P.T.A.B. Oct. 10, 2025). The '926 patent has only been in force for four 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 '926 patent. Patent Owner provides no specific evidence or information to establish that its expenditures directly relate to the '926 patent's claimed technology and thus has

failed to establish how its investments establish settled expectations. Paper 9 at 3 n.2.

Third, Patent Owner relies on inapposite cases to argue that the '926 patent's 2021 issuance creates settled expectations. For example, in *WebGroup Czech Republic, A.S. v. DISH Techs. LLC*, IPR2025-00467, Paper 14 (P.T.A.B. July 16, 2025), while the Board 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 FWD would issue. That is not the case here, where any district court trial would be over a year after any FWD.

Accordingly, for all the above reasons, Patent Owner has no settled expectations in the ’926 patent, and discretionary denial is not warranted.

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

In addition to the absence of settled expectations, the *Fintiv* factors further demonstrate that discretionary denial is not warranted. *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, 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.*, IPR2020-00019, 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 5-7. 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, 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 in the District Court Litigation 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 preliminary terms for construction, and Patent Owner speaks out of turn when asserting that the *Markman* hearing will occur in May. Paper 9 at 6. The scheduling order has only proposed a month, not set a date, for the *Markman* hearing. *See EX2009* at 9. Accordingly, 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 IPRs and/or PGRs. *See Paper 9* at 5–6 (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). 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 IPR in the one instance where the request was raised. *See Downing Wellhead Equipment, LLC v. Intelligent Wellhead Systems, Inc.*, No. 1:23-cv-01180-RMR-SBP (D. Colo. Oct. 21, 2024), Dkt. 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. 23-cv-01180-RMR-SBP (D. Colo. Feb. 14, 2024), Dkt. 65. This includes when the IPRs had not yet been instituted. *See id.*

Accordingly, and contrary to Patent Owner's assertions and cited cases (Paper 9 at 6-7), there is sufficient evidence that the Court is likely to stay the District Court

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

Litigation, the risk of this proceeding and the District Court Litigation proceeding in parallel is minimal, and thus 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.*, IPR2020-00019, 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. The FWD for this proceeding is projected to issue in April 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). As Patent Owner acknowledges, the median time-to-trial statistics in the District of Colorado indicate that trial is unlikely to occur before June 2028, which is over a year after Board’s FWD. Paper 9 at 7–8.

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 11 at 7-8. But both *Murata* and *Hisense* are inapposite. In both *Murata* and *Hisense*, the Board recognized that the likelihood that a FWD would issue before the district court trial occurred counseled against discretionary denial. *Murata Mfg. Co. v. Georgia*

Tech Rsch. Corp., IPR2025-00383, Paper 14 at 2 (P.T.A.B. July 29, 2025); *Hisense USA Corp. v. VideoLabs, Inc.*, IPR2025-00880, Paper 11 at 2 (P.T.A.B. Oct. 10, 2025). Despite that, in both cases, the Board 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 '926 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.*, IPR2025-00933, 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.*, IPR2020-00019, 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 9-10 (emphasis added).

Here, the District Court has not issued any orders specifically related to the '926 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 Board precedent. Initial invalidity contentions were just served and responded to, the parties exchanged claim construction terms less than two weeks ago, and the parties will not have completed the claim construction process by this institution deadline. EX2009 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 8–9; EX2009 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, 3 (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 Board has found that this factor weighs against discretionary denial. For example, the Board has found parallel proceedings still in early stages when there has been no order on the patents in the Petition. See *Fintiv*, IPR2020-00019, Paper 11 at 10 n.18 (first citing *Facebook, Inc. v. Search and Social Media Partners, LLC*, IPR2018-01620, Paper 8, at 24–25 (P.T.A.B. Mar. 1, 2019) and then citing *Amazon.com, Inc. v. CustomPlay, LLC*, IPR2018-01496, Paper 12, at 8–9 (P.T.A.B. Mar. 7, 2019)). Moreover, the Board 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.*, IPR2025-01164, 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 8; District Court Litigation Dkt. 67, at 2. Furthermore, the court will not be responsible for

evaluating invalidity contentions until such time as the contentions have been finalized. To that end, 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. 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 6, 12–13. 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. Stratasy, Inc.*, IPR2025-00531, Paper 10 at 3 (P.T.A.B. July 17, 2025).

Patent Owner's cited cases do not establish otherwise. Paper 9 at 9 (citing *Ericsson Inc. v. Procomm Int'l Pte. Ltd.*, IPR2024-01455 (P.T.A.B. May 16, 2025), and *ARM Ltd. v. Daedalus Prime LLC*, IPR2025-00207 (P.T.A.B. Aug. 6, 2025)). 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 6, 13–14. Patent Owner notes that the parties are the same. Paper 9 at 9. 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 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 ’926 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 11. This is patently false. Contrary to Patent Owner's allegations, Petitioner has provided numerous reasons why the claims of the '926 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 23–70. For example, the Petition explains that “[a] POSITA would be motivated to include Fletcher-Haynes' height parameter as one of the donor parameters to consider in Lavender's system when determining the total amount of pure plasma to collect from the donor (the target volume of pure plasma) because including additional donor-specific parameters would result in a more accurate determination of the optimal amount of pure plasma to collect.” *See* Pet. at 23-24. As further described in the Petition, Lavender and Fletcher-Haynes “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 24.

The combination of Lavender and Fletcher-Haynes teaches “look[ing] at the donor's hematocrit to calculate how much AC is collected”, the exact feature that the Patent Owner asserted was missing in the prior art during prosecution of the '926 patent. *See* EX1002 at 14. As recited in the Petition, “Fletcher-Haynes determines

the fraction of AC [or anticoagulant] in the collected plasma component f_{ACP} using an AC ratio and the donor's hematocrit," and uses f_{ACP} to determine a maximum volume of pure plasma to collect. *See* Pet. at 28-29. "[A] POSITA would simply solve for *new MAXCF* [the amount of anticoagulant to be collected in Lavender] using Fletcher-Haynes' equations to determine *new MAXCF* using both the donor's weight and hematocrit." Pet. at 32.

In addition, Lavender recognized the need to account for donor hematocrit in determining an anticoagulant volume to collect, and recites, "[b]ecause 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." *See* EX1005 at 3:2-8. As described in the Petition and Dr. Fletcher's Declaration, a POSITA would look to Fletcher-Haynes' equations to incorporate hematocrit in the determination of the amount of anticoagulant to be collected (*MAXCF*) in Lavender, "resulting in a more accurate determination of the anticoagulant volume to collect during the plasma collection process." *See* Petition at 28; EX1003, ¶78. Patent Owner's contention that the Petition and Dr. Fletcher's Declaration are conclusory overlooks these well-reasoned arguments, along with other cogent arguments that the '926 patent's claims are obvious over the cited prior art.

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 12 *with* EX2012, at 1–2. Petitioner's SDD merits favorable credit supporting institution, as it discloses the databases and repositories in which the prior art was located, the general search approach, other analytics or publicly accessible resources consulted, the amount of time spent on the search, and the amount of time reviewing search results. *Compare* EX2012 *with* EX1015 *and* EX1016. Nevertheless, the paper art Petitioner used in its Petition is the result of a search strategy that differs from the USPTO's search methods and thus merits additional credit for revealing “new or underutilized pathways relevant to Office search practice.” *See* EX2012; EX1015; EX1016.

V. CONCLUSION

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

Petitioner's Opposition to Patent Owner's Request for Discretionary Denial
IPR2026-00046

Respectfully submitted,

Date: January 21, 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 January 21, 2026 by filing this document through the P-TACTS platform as well as by delivering a copy via the delivery method indicated to the attorneys of record for the Patent Owner as follows:

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