

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

TERUMO BCT INC.,

Petitioner

v.

HAEMONETICS CORP.,

Patent Owner

IPR2025-01420
U.S. Patent No. 10,792,416

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

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Director’s *Interim Processes for PTAB Workload Management*.
EX2001 16

EXHIBIT LIST

Exhibit	Reference
1001	U.S. Patent No. 10,792,416 (“’416 patent”)
1002	File History of the ’416 patent
1003	Declaration of Dr. Gary Fletcher in Support of Petition
1004	U.S. Patent No. 4,898,675 (“Lavender”)
1005	“Calculations in Apheresis” (“Neyrinck”)
1006	U.S. Patent Publication No. 2002/0033370 (“Bainbridge”)
1007	U.S. Patent Publication No. 2011/0097344 (“Darashkevich”)
1008	U.S. Patent No. 8,075,468 (“Min”)
1009	U.S. Patent Publication No. 2017/0029762 (“Turgut”)
1010	U.S. Patent No. 6,296,602 (“Headley”)
1011	U.S. Patent No. 9,370,324 (“Barrett”)
1012	“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.
1013	“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.
1014	Bruce C. McLeod, MD, et al., “Apheresis: Principles and Practice,” 3rd Edition, AABB Press 2010.
1015	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
1016	Japanese Patent Publication No. JP 2002-282352 A and certified Japanese to English translation (“Takagi”)
1017	J. Klespitz and L. Kovács, “Identification and control of peristaltic pumps in hemodialysis machines,” 14th IEEE International Symposium on Computational Intelligence and Informatics 83-87 (2013)
1018	Curriculum Vitae (“CV”) of Dr. Gary D. Fletcher
1019	Search Disclosure Declaration (Filing Party and Board Only)
1020	Redacted Search Disclosure Declaration

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1021	U.S. Patent No. 10,758,652 (“’652 patent”)
1022	PTAB Notice of Decisions on Institution, Dec. 11, 2025
1023	PTAB Notice of Decisions on Institution, Jan. 9, 2026

I. INTRODUCTION

Discretionary denial of Terumo BCT, Inc.'s ("Terumo") Petition for *inter partes* review ("IPR") of U.S. Patent No. 10,792,416 ("the '416 patent") is not warranted for at least three reasons.

First, Haemonetics Corporation ("Haemonetics" or "Patent Owner") could not have developed settled expectations in the '416 patent, as it issued only five years ago. This is confirmed by the fact that U.S. Patent No. 10,758,652 ("the '652 patent"), which likewise issued only five years ago, survived discretionary denial consideration. EX1021; EX1022. Further, three other patents in the '416 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. EX1022; EX1023. Moreover, Patent Owner's ongoing efforts to file additional patent applications within the '416 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 '416 patent.

Second, every factor outlined in *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 (P.T.A.B. Mar. 20, 2020) ("*Fintiv*") weighs strongly against discretionary denial or is neutral. Significantly, as Patent Owner concedes, any district court trial is unlikely to occur until well over a year after a final written decision ("FWD").

Third, Petitioner's submission of a compliant Search Disclosure Declaration (SDD) provides for a non-exclusive, non-dispositive favorable discretionary factor supporting institution.

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, asserting that Terumo's Rika System infringed seven of its patents, including the '416 patent. Since then, Patent Owner has filed two amended complaints, bringing the total number of asserted patents to nine (collectively, "the Asserted Patents"). 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 and invalidity contentions have been served, the Parties have not yet engaged in significant discovery, with Patent Owner producing only 395 documents, many of which are duplicates. *See* EX2009 at 9. Claim construction briefing will not begin until March 2026, and the claim construction hearing will not 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, at the earliest. Paper 11 at 7.

On November 7, 2025, Terumo moved to stay the District Court Litigation until all *inter partes* review (“IPRs”) and 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. Patent Owner did not allege that Terumo infringed the '416 patent until October 2024. Seven months later, Patent Owner initiated the District Court Litigation. On October 9, 2025, within a year after first learning of any potential infringement of the '416 patent and within 5 months of the District Court Litigation being filed—and less than a month after infringement contentions were served in the District Court Litigation—Terumo timely and diligently filed IPR2025-01420 among eight other post-grant procedures challenging 238 total claims, four of which have already survived discretionary denial considerations. *See Cellco P'ship v. Huawei Device Co., Ltd.*, IPR2020-01117, Paper 10 at 22 (P.T.A.B. Feb. 3, 2021) (crediting Petitioner's diligence in

filing the Petition less than three months after being served infringement contentions in the parallel case); EX1022; EX1023.

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 '416 patent and that these expectations weigh in favor of discretionary denial. Paper 11 at 2-5. It does not, and they do not. 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); EX1022 at 2. After reviewing Patent Owner's arguments there, the Board reached the correct conclusion that discretionary denial was not warranted. The Board 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 '416 patent has only been in force for five years, which is too short a time for Patent Owner to have developed settled expectations.¹ EX1001,

¹ While Patent Owner notes that the '416 patent was filed in 2017 (Paper 11 at 3), it

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 '416 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 '416 patent.

In arguing otherwise, Patent Owner raises three main points: (1) that Patent Owner had settled expectations based on the '416 patent's 2020 issuance; (2) that Terumo was allegedly aware of the '416 patent since 2020 when Patent Owner began marking its commercialized product; and (3) that Terumo was put on notice a year before the Petition was filed. Paper 11 at 2-5. As the Board already found, these arguments lack merit and fail to establish settled expectations.

is impossible for Patent Owner's settled expectations to date back to then, as the '416 patent did not issue until October 6, 2020. *See GAF Bldg. Materials Corp. v. Elk Corp. of Dallas*, 90 F.3d 479, 483 (Fed. Cir. 1996).

First, Patent Owner relies on inapposite cases to argue that the '416 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), which Patent Owner cites, three of the four patents that the Board found had settled expectations issued over seven years earlier, and, even then, 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. That is not the case here, where any district court trial would be over a year after any final written decision.

Second, Patent Owner's argument relying on commercialization and marking of Patent Owner's products with the '416 patent merely amount to simple, unsupported, conjecture. Paper 11 at 3-4. Patent Owner's high-level identification of expenses and investment in commercializing its technology is wholly untethered to the claims of the '416 patent. Nowhere in its brief does Patent Owner establish that any of the cited expenditures directly relate to the '416 patent. Without any nexus to the challenged patent, Patent Owner has failed to establish how its investments establish settled expectations in its five-year old patent. Moreover, Patent Owner cites *Empower Clinic Servs., L.L.C. v. Eli Lilly & Co.*, which 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 '416 patent has only been in force for five years and, thus, Patent Owner's arguments are unavailing. 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).

Patent Owner's argument that it has settled expectations because Terumo knew it was entering an industry protected by patents (Paper 11 at 4) also fails because not only is there no evidence that Terumo knew of the '416 patent when it entered the industry, but its knowledge of Patent Owner's commercial system 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® (EX2004; EX2005) as a "Reference" device, which may be different from the submitted product. *See, e.g.*, EX2004 at 2. Patent Owner also cites *Dabico Airport Sols. Inc. v. AXA Power APS*, IPR2025-00408, Paper 21 (P.T.A.B. June 18, 2025) to support its argument that Terumo should have been aware of the '416 patent when it entered the industry in 2022. Paper 11 at 4. But while *Dabico* noted that actual notice is not required to create settled expectations, there the patent had been in force for almost eight years, not the five at issue here, and the Petitioner was faulted for not explaining why an IPR would be an appropriate use of resources. *Id.* at 3. That is not the case here, where the challenged patent has only been in force for five years, and where an IPR would be an appropriate use of Board resources as Patent Owner asserts nine patents in the District Court Litigation, all of which are challenged in IPRs or PGRs pending before the Board.

Third, Terumo's awareness of the '416 patent in October 2024 (EX2007) does not establish settled expectations as Terumo filed its Petition within a year later and within five months of the litigation being filed. Patent Owner's reliance on *Geotab Inc. v. Fractus, S.A.*, IPR2025-00928, Paper 11 (P.T.A.B. Sep. 12, 2025) 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. *Id.* at 2-3. That is not the case here.

Accordingly, for all the above reasons, Patent Owner has no settled expectations in the '416 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 evidence exists that [a stay] may be granted if a proceeding is instituted." *Fintiv, Inc.*, IPR2020-00019, Paper 11 at 12. Patent Owner acknowledges that Terumo moved to stay the District Court Litigation but ignores that case law and statistics overwhelmingly support a stay. *See* Paper 11 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 would simplify the issues in the District Court Litigation. While Patent Owner laments the volume of Terumo's invalidity contentions in the District Court Litigation, *see* Paper 11 at 8, any burden is of Patent Owner's own doing, as it decided to bring a nine-patent case with over 230 asserted claims despite knowing that the litigation is too large and will need to be narrowed. *See* District Court Litigation, Dkt. 67, at 2. Accordingly, the district court will likely grant a stay for the Board to narrow the scope of the dispute.

Further, discovery in the District Court Litigation 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 on discovery because the parties have not raised any disputes with the court. Additionally, the parties have only exchanged preliminary terms for construction. *See* EX2009. Further, and contrary to Patent Owner's characterization of the timing of the claim construction hearing, the Board will have issued institution decisions in eight of the nine IPR and PGR proceedings prior to the hearing. With respect to the remaining PGR proceeding, the PTAB's institution decision is scheduled for May 13, 2026, which may occur before the claim construction hearing occurs as no date for the hearing has been set.

Despite all this, Patent Owner asserts “[t]here is no reason to believe the district court will stay the litigation pre-institution” because the District of Colorado grants stays “in only 69% of cases.” Paper 11 at 5. But Patent Owner’s statistic is “persuasive evidence that a stay will be granted”—not a “speculative” or “remote” possibility. *Twitch Interactive, Inc. v. RazDog Holdings LLC*, IPR2025-00307, Paper 18 at 2 (P.T.A.B. May 16, 2025); *Imperative Care, Inc. v. Inari Med., Inc.*, IPR2025-00289, Paper 9 at 2 (P.T.A.B. June 12, 2025) (citing *id.*, Paper 8 at 7-9).

Further, while Patent Owner may not be convinced by District of Colorado’s 69% grant rate, that probability increases when looking at the judges presiding over the District Court Litigation. Magistrate Judge Prose, 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 Equip., LLC v. Intelligent Wellhead Sys., Inc.*, No. 1:23-cv-01180-RMR-SBP (D. Colo. Feb. 14, 2024). This includes when the proceedings had not yet been instituted. See *id.* Judge Rodriguez adopted the magistrate’s recommendation and stayed a case pending IPR in the one instance where the request was raised. See *Downing Wellhead Equip., LLC v. Intelligent Wellhead Sys., Inc.*, No. 1:23-cv-01180-RMR-SBP (D. Colo. Oct.

² In the one case where it was granted in part, some third-party discovery was allowed to continue. *Downing Wellhead Equipment, LLC v. Intelligent Wellhead Sys., Inc.*, No. 1:23-cv-01180-RMR-SBP, Dkt. 65, at 22 (D. Colo. Feb. 14, 2024). Here, no party has begun third-party discovery.

21, 2024).

Accordingly, and contrary to Patent Owner's assertions and cited cases (Paper 11 at 6-7), there is sufficient evidence that the Court is likely to stay the District Court 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 12.

Patent Owner concedes that the final written decision 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 trial is unlikely to occur before June 2028, which is over a year after the FWD would issue. Paper 11 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); *See 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 issued **sixteen** years (*Murata*) and **eleven and twelve** years (*Hisense*) prior to support discretionary denial. *See Murata Mfg. Co.*, IPR2025-00383, Paper 14 at 2; *Hisense USA Corp.*, IPR2025-00880, Paper 11 at 2. Here, however, Patent Owner has failed to establish settled expectations in the '416 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 13. “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 '416 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 along enough 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 8-9. Moreover, while Patent Owner alleges that the parties will have completed all *Markman* briefing in May of 2026, see Paper 11 at 8, 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 FWD issues. *See Cambridge Indus. 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). This factor favors institution.

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)). In fact, the Board recently denied a discretionary denial request on a Petition filed after the parties had exchanged infringement and invalidity contentions, and when claim construction was in its 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 230 asserted claims

despite knowing that its assertions would need to be narrowed. Paper 11 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 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. Stratasyss, Inc.*, IPR2025-00531, Paper 10 at 3 (P.T.A.B. July 17, 2025).

Patent Owner's cited cases do not establish otherwise. Paper 11 at 9 (citing *Ericsson Inc. v. Procomm Int'l Pte. Ltd.*, Paper 15, IPR2024-01455 (P.T.A.B. May

16, 2025), and *ARM Ltd. v. Daedalus Prime LLC*, Paper 14, 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 13. Patent Owner notes that the parties are the same. Paper 11 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 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.

First, Patent Owner asserts the Petition is weak by declaring Dr. Fletcher's declaration duplicative of the Petition. Paper 11 at 10. While the Petition and the declaration cite the same specific disclosures that prove the '416 patent is invalid, and thus have textual overlap, this overlap is neither improper nor conclusory.

Second, 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 '416 patent improves prior systems by determining and targeting pure plasma volume for collection. Paper 11 at 11. But as Patent Owner recognizes, "the purpose of a patent is not necessarily coextensive with everything it discloses," and here Lavender, like the '416 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." EX1004 at Abstract; Figures 25A-D and Table V; Paper 11 at 11. Specifically, Lavender Table VI sets forth the algorithms for collecting plasma. EX1004 at 20:55-22:67; Table VI at cols. 41-44. As further discussed below, Lavender's algorithm calculates pure plasma (TPF) to control collection of plasma until a target pure plasma volume (MAXPF) is reached. EX1004 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 11 at 12. 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 14, 34, 47 (citing EX1004, Table VI, Section 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 34, 47; EX1004 at 20:55-22:67; Table VI at cols. 41-44; EX1003 at ¶100-101, 145.

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 '416 patent's collected plasma differs from Lavender's target total collection volume. Paper 11 at 12-13. However, the '416 Patent uses the weight sensor to "measure[] the amount of plasma collected," and to continue the collection process "until the target volume of pure plasma . . . is collected within the plasma collection container." EX1001 at 9:64-66, 14:30-33. Lavender also determines the amount of plasma using a weight sensor to determine

the total weight of the dilute plasma, "TDPW." EX1004 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 '416 Patent does not include any claim that expressly states that targeting and stopping a collection is based on the volume of pure plasma ***alone***.

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 11 at 14 *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* EX1019 *and* EX1020. 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; EX1019; EX1020.

V. CONCLUSION

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

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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