

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

TERUMO BCT INC.,

Petitioner

v.

HAEMONETICS CORP.,

Patent Owner

IPR2025-01374
U.S. Patent No. 11,738,124

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

TABLE OF CONTENTS

I.	INTRODUCTION	1
II.	LITIGATION BACKGROUND	1
A.	The District Court Litigation.....	1
B.	This IPR Proceeding.....	2
III.	DISCRETIONARY DENIAL IS INAPPROPRIATE UNDER 35 U.S.C. § 314(a)	3
A.	Patent Owner Has Not Established Settled Expectations	3
B.	The <i>Fintiv</i> Factors Do Not Support Discretionary Denial	8
1.	The District Court Will Likely Grant a Stay.....	8
2.	The 2028 Trial Date Weighs Against Denial.....	11
3.	Minimal Investment in the District Court Favors Institution ...	13
4.	Terumo’s <i>Sotera</i> Stipulation Eliminates Overlap and Supports Institution	14
5.	Identical Parties.....	15
6.	The Petition Presents Strong Merits	15
C.	The Patent Office Has Not Previously Adjudicated the Validity of the ’124 Patent Based on the Same Art.....	20
IV.	CONCLUSION.....	20

TABLE OF AUTHORITIES

Cases	Page(s)
<i>Advanced Bionics, LLC v. Med-El Elektromedizinische Geräte Gmbh</i> , IPR2019-01469, Paper 6 (Feb. 13, 2020)	20
<i>Amgen Inc. v. Bristol-Myers Squibb Co.</i> , IPR2025-00601, Paper 9 (PTAB July 24, 2025)	5
<i>Apple Inc. v. Fintiv, Inc.</i> , IPR2020-00019, Paper 11 (PTAB Mar. 20, 2020)	1, 9, 11, 13, 14, 15
<i>Berkshire Hathaway Energy Co. v. Birchtech Corp.</i> , IPR2025-00274, Paper 23 (PTAB July 2, 2025)	3, 6
<i>Cambridge Industries USA, Inc. v. Applied Optoelectronics, Inc.</i> , IPR2025-00434, IPR2025-00436, IPR2025-00437, Paper 11 (PTAB June 26, 2025)	3, 6, 14
<i>Cellco P’ship v. Huawei Device Co.</i> , IPR2020-01117, Paper 10 (PTAB Feb. 3, 2021)	3
<i>Cywee Grp. Ltd. v. Samsung Elecs. Co.</i> , 2019 WL 11023976 (E.D. Tex. Feb. 14, 2019)	14
<i>Datadome S.A. v. Arkose Labs Holdings, Inc.</i> , IPR2025-00693, Paper 13 (PTAB Aug. 14, 2025)	6
<i>Downing Wellhead Equipment, LLC v. Intelligent Wellhead Systems</i> , <i>Inc. et al.</i> , No. 23-cv-01180-RMR-SBP (Oct. 21, 2024)	10
<i>Downing Wellhead Equipment, LLC v. Intelligent Wellhead Systems</i> , <i>Inc. et al.</i> , No. 23-cv-01180-RMR-SBP (Feb. 14, 2024)	10
<i>Embody, Inc. v. Lifenet Health</i> , IPR2025-00248, IPR2025-00249, Paper 13 (PTAB June 26, 2025)	5
<i>eSoft, Inc. v. Blue Coat Sys., Inc.</i> , 505 F. Supp. 2d 784 (D. Colo. 2007)	9
<i>Google LLC, v. Withrow Networks, Inc.</i> , IPR2025-00775, Paper 10 (PTAB August 14, 2025)	6, 11

Petitioner’s Opposition to Patent Owner’s Request for Discretionary Denial
IPR2025-01374

<i>Imperative Care, Inc. v. Inari Med., Inc.</i> , IPR2025-00289, Paper 9 (PTAB. June 12, 2025)	10, 11
<i>Milwaukee Electric Tool Corp. v. Klein Tools, Inc.</i> , IPR2025-00724, Paper 14 (PTAB Sept. 12, 2025).....	8
<i>Murata Mfg. v. Georgia Tech Research Corp.</i> , IPR2025-00383, Paper 14 (PTAB July 29, 2025)	4
<i>Samsung Elecs. Co. v. Genghiscomm Holdings LLC</i> , IPR2025-00793, Paper 12 (PTAB Aug. 22, 2025).....	8, 14
<i>Sotera Wireless, Inc. v. Masimo Corp.</i> , IPR2020-01019, Paper 12 (PTAB Dec. 1, 2020)	15
<i>Tesla, Inc. v. Intellectual Ventures II LLC</i> , IPR2025-00217, Paper 9 (Director June 13, 2025)	15
<i>Tuozhu v. Stratasys, Inc. et al.</i> , IPR2025-00531, Paper 10 (Director July 17, 2025).....	15
<i>Twitch Interactive, Inc. v. RazDog Holdings LLC</i> , IPR2025-00307, Paper 18 (PTAB May 16, 2025)	10, 11
<i>WebGroup Czech Republic, A.S. v. DISH Techs. LLC</i> , IPR2025-00467, Paper 14 (PTAB July 16, 2025)	7
Statutes	
35 U.S.C. § 314(a)	3

EXHIBIT LIST

Exhibit	Reference
1001	U.S. Patent No. 11,738,124 (“’124 patent”)
1002	File History of the ’124 patent
1003	Declaration of Dr. Gary Fletcher in Support of Petition
1004	U.S. Patent No. 4,898,675 (“Lavender”)
1005	U.S. Patent No. 7,072,769 (“Fletcher-Haynes”)
1006	U.S. Patent No. 8,075,468 (“Min”)
1007	U.S. Patent No. 9,370,324 (“Barrett”)
1008	U.S. Patent No. 6,296,602 (“Headley”)
1009	U.S. Patent Publication No. 2017/0029762 (“Turgut”)
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	“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.
1012	Curriculum Vitae (“CV”) of Dr. Gary D. Fletcher
1013	Bruce C. McLeod, MD, et al., “Apheresis: Principles and Practice,” 3rd Edition, AABB Press 2010.
1014	Japanese Patent Publication No. JP 2002-282352 A and English translation (“Takagi”)
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	U.S. Patent No. 10,758,652 (“’652 patent”)

I. INTRODUCTION

Discretionary denial of Terumo BCT, Inc.'s ("Terumo") Petition for *inter partes* review ("IPR") of U.S. Patent No. 11,738,124 ("the '124 patent") is not warranted for at least two reasons. First, Haemonetics Corporation ("Haemonetics" or "Patent Owner") has not developed settled expectations regarding the '124 patent, which issued just two years ago. The patent's recent issuance undermines any claim of settled expectations, and Haemonetics' ongoing efforts to file additional applications within the '124 patent's family further confirms that the scope of the family remains everchanging and, thus, unsettled. Second, every factor outlined in *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Pap. 11 (PTAB Mar. 20, 2020) ("*Fintiv*") is either neutral or weighs against discretionary denial. The related district court proceeding is still in its early stages, claim construction will not begin until early 2026, and there are no set dates for the close of fact or expert discovery. Even Patent Owner acknowledges that 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 '124 patent. Since then,

Patent Owner has expanded the District Court Litigation to include two additional patents, bringing the total to nine (collectively, "the Asserted Patents"). 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 the case is not stayed, however, it 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. *Id.* Further, and as Patent Owner recognizes, trial is not likely to occur until mid-2028. Paper 9 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 first alerted Terumo to potential

infringement of the '124 patent in October 2024. Seven months later, Patent Owner initiated the District Court Litigation. Terumo filed its Petition challenging the validity of all claims in the '124 patent on August 4, 2025, ten months after first learning of any potential infringement of the '124 patent, within 3.5 months of the date Patent Owner initiated the District Court Litigation, and before infringement contentions were served in the District Court Litigation. *See Cellco P'ship v. Huawei Device Co.*, IPR2020-01117, Paper 10 at 22 (PTAB Feb. 3, 2021).

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

A. Patent Owner Has Not Established Settled Expectations

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 '124 patent has only been in force for two years. Simply put, two years is too short a time for Haemonetics to have developed settled expectations in the '124 patent. *See Cambridge Industries USA, Inc. v. Applied Optoelectronics, Inc.*, IPR2025-00434, IPR2025-00436, IPR2025-00437, Paper 11 at 2-3 (PTAB 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 (PTAB July 2, 2025) (same). Moreover, the family of patents that includes the '124 patent remains active with continuing applications still pending. Haemonetics cannot credibly assert settled expectations

when the contours of the patent family are still evolving. Accordingly, the Board should not deny institution based on Haemonetics' purported expectations.

In its brief, Patent Owner argues that it had settled expectations in the '124 Patent and that these expectations weigh in favor of discretionary denial. Paper 9 at 3. In making this argument, 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 since at least 2023, and (4) that the recent issuance of the '124 patent does not overcome Patent Owner's purported settled expectations. *Id.* at 3-10. These arguments lack merit and fail to establish settled expectations.

First, even if there were only three main competitors in the plasma collection industry, that alone does not establish settled expectations. While the Parties being in the same field may support settled expectations, the patents must still have been in force for a significant time, and Terumo must have had some reason to be aware of them, for settled expectations to exist. Patent Owner's own cited case, *Murata Mfg. v. Georgia Tech Research Corp.*, IPR2025-00383, Paper 14 (PTAB 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. The mere fact

that the industry is small does not support a finding of settled expectations.

Second, Patent Owner's purported eight years researching the patented technology does not support discretionary denial. In fact, the case Patent Owner cites to support its proposition that settled expectations can be based on investment in the patented technology ***did not*** issue a discretionary denial for the IPR challenging the patent issued in 2022. *See Amgen Inc. v. Bristol-Myers Squibb Co.*, IPR2025-00601, Paper 9 (PTAB July 24, 2025) at 2-3 (finding patent owner had "not demonstrated that it has developed strong settled expectations that favor discretionary denial" when challenging a three-year-old patent). The same result should occur here. Patent Owner's high-level identification of expenses and investment in commercializing its technology is wholly untethered to the claims of the '124 patent. Nowhere in its brief does Patent Owner establish that any of the cited expenditures directly relate to the '124 patent. Without any nexus to the challenged patent, Patent Owner has failed to establish how its investments establish settled expectations in its two-year old patent.

Third, awareness of Patent Owner's patent portfolio does not establish settled expectations. While Patent Owner insinuates that the portfolio covering '124 patent has been in force for a significant amount of time, in actuality the portfolio goes back only five years, with the first patent in the family—U.S. Patent No. 10,758,652 ("the '652 patent")—issuing in September 2020. *See* EX1016; *see also Embody, Inc. v. Lifenet Health*, IPR2025-00248, IPR2025-00249, Paper 13 at 2-3 (PTAB June 26,

2025) (denying discretionary denial of IPRs challenging a three-year-old first patent and the first patent's parent, because it [was] an efficient use of Board resources to address the related patent"). Even if the '652 patent's issue date affected settled expectations for the '124 patent, which Terumo asserts it does not, five years is insufficient to establish settled expectations. *See Google LLC, v. Withrow Networks, Inc.*, IPR2025-00775, Paper 10 at 2 (PTAB August 14, 2025) (holding there were not settled expectations for a five-year-old patent); *Cambridge Industries USA, Inc.*, Paper 11 at 2-3; *Berkshire Hathaway Energy Co.*, IPR2025-00274, Paper 23 at 3.¹ Thus, Haemonetics should not have settled expectations in the '124 patent, or any other patent in the '124 patent's family.

Patent Owner's similar assertion—that it should have settled expectations because Terumo knew it was entering an industry protected by patents—fails for the same reason. Importantly, Terumo launched its Rika System, which Patent Owner asserts infringes the '124 patent, in 2022, ***before*** the '124 patent was ever publicly disclosed. It is axiomatic that the time clock for settled expectations cannot start

¹ Patent Owner's reliance on *Datadome S.A. v. Arkose Labs Holdings, Inc.*, IPR2025-00693, Paper 13 (PTAB 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.

before the patent even issues.

Similarly, Patent Owner does not identify any evidence that Terumo knew of the '124 patent, or its patent family, before April 24, 2024, which is when the IDS citing the '124 patent's published application was filed. Paper 9 at 7; EX2008. Patent Owner's remaining arguments amount to simple, unsupported, conjecture, or rely on marking Patent Owner's products with the '652 patent, which again is not at issue here, and issued only five years ago. Paper 9 at 6-8. Thus, while Patent Owner may have established that Terumo was monitoring Patent Owner's patent portfolio in 2024, this finding does not establish settled expectations as Terumo filed an IPR challenging the '124 patent within one and a half years of citing it in the IDS, within a year of its citation in Patent Owner's Notice of Infringement (EX2010), and within 3.5 months of the filing of the District Court Litigation.

Fourth, Patent Owner's assertion that the recency of the '124 patent's issuance does not counsel against discretionary denial relies on inapposite cases that present facts wholly different from those at issue here. Patent Owner first cites to *WebGroup Czech Republic, A.S. v. DISH Techs. LLC*, IPR2025-00467, Paper 14 (PTAB July 16, 2025). 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. Patent Owner's reliance on

Milwaukee Electric Tool Corp. v. Klein Tools, Inc., IPR2025-00724, Paper 14 (PTAB Sept. 12, 2025) is similarly misplaced. 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 (PTAB Aug. 22, 2025), the Board issued a discretionary denial because the challenged patents were also involved in a district court case with a scheduled trial date that was six months before any final written decision would issue.² That is not the case here where any district court trial would be over a year after a final written decision issues.

Accordingly, for all the above reasons, Patent Owner has no settled expectations in the ’124 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

² *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.

that one may be granted if a proceeding is instituted.” *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Pap. 11 (Mar. 20, 2020) at 12. Patent Owner asserts this factor weighs in favor of a discretionary denial. Paper 9 at 10. But since the filing of this Opposition, Terumo has moved to stay the District Court Litigation. On November 7, 2025, less than a week after filing its final post-grant 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 in situations like this, where the case is at an early stage of litigation and all Asserted Patents are challenged in post-grant proceedings.

Ample evidence exists that a stay is likely to be granted in this case. 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 9 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 (PTAB 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 (PTAB 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 (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.³ *See Downing Wellhead Equipment, LLC*, No. 23-cv-01180-RMR-SBP (Feb. 14,

³ In the one case where it was granted in part, some third-party discovery was allowed to continue.

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.

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 9 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. Paper 9 at 13. 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 under this timeline where, as is the case 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 9 at 12-13. But Terumo has now challenged all of the Asserted Patents in post-grant proceedings and submitted a *Sotera* Stipulation in this case to eliminate overlap between the proceedings. *See* Paper 8. Further, Patent Owner has raised secondary considerations arguments in this proceeding, (Paper 10 at 32-41) and thus any secondary considerations arguments could be resolved by this tribunal. Moreover, the Board is uniquely positioned to best resolve these invalidity disputes better than the District Court due to the complexity and numerosity of the asserted patents and

invalidity challenges. IPR2025-00933, Paper 11 (October 10, 2025) at 3.

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, Pap. 11 at 13. While this matter has been pending since May 2025, a period of six months does not establish a significant investment by the parties and the court. To the contrary, Patent Owner's analysis further supports Terumo's position. While Terumo has filed a Partial Motion to Dismiss in the District Court Litigation, Terumo has not yet answered the Second Amended Complaint. Also, given that discovery has just begun, the court has not had to expend any resources resolving discovery disputes.

Other key milestones like claim construction briefing, depositions, and expert reports have not yet occurred. EX2012 at 9. In fact, when an institution decision issues, most these deadlines will still not have happened. For example, when the institution decision issues, claim construction will just be beginning. When the final written decision issues, fact and expert discovery will likely still be ongoing. At base, the litigation remains in early procedural stages.

The District Court actions thus far have primarily dealt with case-management issues and not Terumo's invalidity challenges. While initial invalidity contentions

were just served, the claims construction process has not yet begun, meaning the district court has not conducted a *Markman* hearing or entered a related order. *Cambridge Industries USA, Inc.*, IPR2025-00434, Paper 11 at 2-3 (denying discretionary denial with respect to three patents because parallel litigation that did not have a trial date or even a *Markman* hearing scheduled). Similarly, significant work remains in the district court regarding invalidity.

The Board has consistently found that when the most burdensome aspects of litigation—such as expert discovery, dispositive motions, and trial preparation—lie ahead, this factor weighs against discretionary denial. *See Cywee Grp. Ltd. v. Samsung Elecs. Co.*, 2019 WL 11023976, at *6 (E.D. Tex. Feb. 14, 2019) (“[T]he most burdensome parts of the case—filing and responding to pretrial motions, preparing for trial, going through the trial process, and engaging in post-trial motions practice—all lie in the future[.]”). Here, the district court has not yet engaged with the merits of the asserted patents, and Terumo's prompt filing of the Petition further supports institution. 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 (PTAB Dec. 1, 2020) (precedential); *Tesla, Inc. v. Intellectual Ventures II LLC*, IPR2025-00217, Paper 9 at 2–3 (PTAB June 13, 2025); *Tuozhu v. Stratasys, Inc. et al*, IPR2025-00531, Paper 10 at 3 (PTAB July 17, 2025).

Patent Owner cites *Ericsson Inc. v. Procomm Int’l Pte. Ltd.*, IPR2024-01455, and *ARM Ltd. v. Daedalus Prime LLC*, IPR2025-00207, to argue that stipulations are not dispositive. But 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. 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 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 '124 patent improves prior systems by determining and targeting pure plasma volume for collection. Paper 9 at 15. But as Patent Owner recognizes, "the purpose of a patent is not necessarily coextensive with everything it discloses," and here Lavender, like the '124 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 9 at 15. 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. *Id.* 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, 33, 44 (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 33, 44; EX1004 at 20:55-22:67; Table VI at cols. 41-44; EX1003 at ¶¶94-96, 155.

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 '124 patent's collected plasma differs from Lavender's target total collection volume. Paper 9 at 16, 20. However, the '124 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 7:32-35, 21:63-22:6. 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 '124 Patent does not include any claim that expressly states that targeting and stopping a collection is based on the volume of pure plasma *alone*.

Patent Owner also argues that Lavender does not disclose calculating anticoagulant volume in the collected plasma component based on hematocrit, as required by the claims. Terumo disagrees. Paper 9 at 17. As Patent Owner acknowledges, Lavender solves an anticoagulant problem inherent in the prior art that the plasma volume of whole blood varies with hematocrit, and basing anticoagulant volume on the whole blood volume would be inaccurate. *Id.* at 15; EX1004 at 2:15-17, 3:2-10. Accordingly, Lavender incorporates the donor's hematocrit to calculate various plasma collection volumes, including a total volume of citrate (anticoagulant) in the plasma container, as defined by "TCF." EX1004 at 41-44. Any change in the donor's hematocrit value (HCTD) would require a corresponding change in the calculated volume of citrate, TCF, in order to solve the anticoagulant problem as discussed above. Petition at 27; EX1003 at 39.

Patent Owner's arguments attacking Fletcher-Haynes fare no better. First, Patent Owner's assertion that Fletcher-Haynes' anticoagulant calculations do not accurately calculate the plasma in the plasma collection bag because platelets can also be collected ignore the clear teachings of Fletcher-Haynes. Fletcher-Haynes discloses collecting plasma without collecting platelets. *See* EX1005 at 31:9-12. Specifically, Fletcher-Haynes describes how an operator selects the type of blood product to collect from the donor, and recites, "[t]he three choices are platelets, plasma and red blood cells. Any combination hereof may be checked." *See id.* Thus, as described in Terumo's IPR Petition, when Fletcher-Haynes is viewed in the correct light, it is clear that when Fletcher-Haynes collects plasma alone, the volume of anticoagulant in only the plasma source bag is determined by the system. Petition at 14-17, 43-45, 49-52; EX1005 at 22:66-23:3, 31:9-12.

Patent Owner also asserts that Terumo has defined " f_{ACP} " as "anticoagulant volume," but this mischaracterizes the Petition. Nowhere in the submitted Petition is f_{ACP} defined as only an "anticoagulant volume." Instead, Terumo explained that f_{ACP} is the "anticoagulant volume expressed as a fraction of pure plasma volume," which is equivalent to Lavender's conversion factor CF, and the anticoagulant volume is calculated based on f_{ACP} through Equation 22 of Fletcher-Haynes. Petition at 44-45, 49; EX1005 at 49:19-52:18. Further, because $f_{ACP} = [(R - 1) * (1 - H)]^{-1}$, where H is the donor's hematocrit and thus the use of f_{ACP} to calculate

the anticoagulant volume makes it “based, at least in part, on” the donor’s hematocrit. *Id.*

C. The Patent Office Has Not Previously Adjudicated the Validity of the ’124 Patent Based on the Same Art

Under *Advanced Bionics*, 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 argues discretionary denial under 35 U.S.C. § 325(d) is warranted based on the consideration of U.S. Patent App. Pub. No. 2003/0125881 to Ryan (“Ryan”) during the ’652 patent’s (the ’124 patent’s parent) prosecution. Paper 9 at 19. But not only was Ryan not considered during the ’124 patent’s prosecution, Patent Owner’s argument that Ryan is substantially the same as Lavender is also flawed. As discussed above, Lavender calculates a target plasma collection volume, not a plasma and anticoagulant volume. 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, 13, 2025

Respectfully submitted,

// John M. Caracappa, Reg. No. 43,532

John M. Caracappa, Reg. No. 43,532

Katherine D. Cappaert, Reg. No. 71,639

Matthew Y. Sim, Reg. No. 77,422

Scott Chappell, Reg. No. 76,333

STEPTOE LLP

1330 Connecticut Avenue N.W.

Washington, D.C. 20036

Tel: (202) 429-3000

Fax: (202) 429-3902

Counsel for Terumo BCT, Inc.

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 13, 2025 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:

Via Email:

Erik B. Milch
emilch@proskauer.com
Joseph Drayton
jdrayton@proskauer.com
Elizabeth Shrieves
eshrieves@proskauer.com
Alan S. Teran
ateran@proskauer.com
Connor J. Villar
cvillar@proskauer.com

Date: November 13, 2025

Respectfully submitted,
/ John M. Caracappa, Reg. No. 43,532/
John M. Caracappa, Reg. No. 43,532
STEPTOE LLP
1330 Connecticut Avenue N.W.
Washington, D.C. 20036
Tel: (202) 429-3000
Fax: (202) 429-3902

Counsel for Terumo BCT, Inc.