

**UNITED STATES PATENT AND TRADEMARK OFFICE**

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**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

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TERUMO BCT INC.,

Petitioner

v.

HAEMONETICS CORP.,

Patent Owner

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PGR2025-00078  
U.S. Patent No. 12,171,916

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

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**EXHIBIT LIST**

<b>Exhibit Number</b>	<b>Description</b>
1001	U.S. Patent No. 12,171,916 (“’916 Patent”)
1002	File History of the ’916 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. Publication No. 2002/0033370 (“Bainbridge”)
1007	U.S. Patent No. 10,195,319 (“Kimura”)
1008	U.S. Patent No. 6,743,192 (“Sakota”)
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	Curriculum Vitae (“CV”) of Dr. Gary D. Fletcher
1011	Bruce C. McLeod, MD, et al., “Apheresis: Principles and Practice,” 3rd Edition, AABB Press 2010.
1012	Japanese Patent Publication No. JP 2002-282352 A and certified Japanese to English translation (“Takagi”)
1013	Sergent SR, Ashurst JV. Plasmapheresis. [Updated 2023 Jul 10]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan-. Available from: <a href="https://www.ncbi.nlm.nih.gov/books/NBK560566/?report=printable">https://www.ncbi.nlm.nih.gov/books/NBK560566/?report=printable</a>
1014	Search Disclosure Declaration (Filing Party and Board Only)
1015	Redacted Search Disclosure Declaration
1016	Persona, Plasma Collection Solution Brochure
1017	U.S. Patent No. 12,186,474
1018	Full File History of U.S. Patent No. 10,758,652
1019	Full File History of U.S. Patent No. 12,377,204
1020	U.S. Patent No. 10,980,926 (“Ragusa”)
1021	PTAB Notice of Decisions on Institution, Dec. 11, 2025

## I. INTRODUCTION

Discretionary denial of Terumo BCT, Inc.'s ("Terumo") Petition for Post Grant Review ("PGR") of U.S. Patent No. 12,171,916 ("the '916 patent") is wholly unwarranted for at least three reasons.

*First*, the notion that Haemonetics Corporation ("Haemonetics" or "Patent Owner") could have developed settled expectations in the '916 patent, which issued just this year, is implausible, bordering on absurd. Recognizing this, Haemonetics focuses on the '652 patent. But the Board already found that any purported settled expectations in the '652 patent, which issued only five years ago, did not warrant discretionary denial. EX1021. The lack of settled expectations is further evidenced by the fact that Patent Owner is still actively prosecuting additional applications in this relatively new family and has twice amended its district court claims against Petitioner as a result of its evolving portfolio.

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

*Third*, the Examiner mistakenly allowed the '916 patent based on an apparent improper understanding of the scope of the claims, among other errors and inconsistencies in the patent family's examination.

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

## **II. LITIGATION BACKGROUND**

### **A. The District Court Litigation**

Patent Owner first raised infringement allegations with Terumo on October 1, 2024. EX2011. Despite mentioning U.S. Patent Application No. 17/205,374, which later issued as the '916 patent, Patent Owner did not allege that Terumo infringed the '916 patent, nor could it have, as it had not yet issued. *Id.*; Paper 6, at 8. Seven months later, Patent Owner initiated *Haemonetics Corp. v. Terumo BCT, Inc.*, Case No. 1:25-cv-01409-RMR-SBP (D. Colo. filed May 5, 2025) (the "District Court Litigation"), asserting that Terumo's Rika System infringed seven patents in the same family. Since then, Patent Owner has filed two amended complaints, adding two additional, later-issued patents, to bring the total to nine (collectively, "the Asserted Patents"). *Compare* District Court Litigation, Dkt. 1 *with* EX2002. The oldest Asserted Patent issued just five years ago.

To date, the district court has not invested significant resources, and the case is far from reaching substantive milestones. Discovery began a few months ago and while initial infringement and invalidity contentions have been served, the Parties have not yet engaged in significant discovery, with Patent Owner producing only 391 documents, many of which are duplicates. *See* EX2012 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 6 at 14. 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 PGR Proceeding**

Terumo acted diligently in filing this PGR. Patent Owner did not allege that Terumo infringed the ’916 patent until it filed its Complaint in May 2025. *See* Paper 6, at 8; EX2011. On September 5, 2025, within nine months of the ’916 patent’s issuance and within 4 months of Patent Owner’s initial Complaint—and before infringement contentions were served in the District Court Litigation—Terumo timely and diligently filed PGR2025-00078 among eight other post-grant procedures challenging 238 total claims, two 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); EX1021.

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

**A. Patent Owner Has Not Established Settled Expectations**

Patent Owner argues that its alleged settled expectations in the '916 patent weigh in favor of discretionary denial. Paper 6 at 3. This argument borders on the absurd. 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. The '916 patent has been in force for less than a year, which is far too short a time to develop settled expectations. EX1001, cover; *see Cambridge Indus. USA, Inc. v. Applied Optoelectronics, Inc.*, IPR2025-00434, Paper 11 at 2-3 (P.T.A.B. June 26, 2025) (finding no settled expectations on three patents that were in force for six years or less); *Berkshire Hathaway Energy Co. v. Birchtech Corp.*, IPR2025-00274, Paper 23 at 3 (P.T.A.B. July 2, 2025) (same).

Moreover, the '916 patent's family remains active with pending continuing applications. Patent Owner's ongoing efforts to file additional applications, in addition to its filing of *two* amended complaints in the District Court Litigation to account for this dynamic expansion, underscores the evolving nature of its patent portfolio. *See* EX2002. Patent Owner cannot credibly assert settled expectations when the '916 patent issued so recently and when the contours of the patent family are still evolving. Accordingly, the Board should find that Patent Owner has no settled expectations in the '916 patent.

In arguing otherwise, Patent Owner argues that: (1) the plasma collection

industry contains only three main competitors, (2) Patent Owner has invested in its patented invention for eight years, (3) Terumo was allegedly aware of Patent Owner's patent portfolio when it filed a 510(k) submission referencing Haemonetics products; and (4) the '916 patent's recent issuance does not overcome Patent Owner's purported settled expectations. Paper 6 at 3-11. These arguments fail to establish "settled expectations" in a patent that only just issued.

*First*, if there were only three main competitors in the plasma collection industry, as Patent Owner asserts (*id.* at 3-4), that alone cannot create settled expectations. Settled expectations can arise only when the patents have been in force for a significant amount of time, and Terumo had a clear reason to be aware of them. Patent Owner concedes that the '916 patent had not issued when it sent its October 2024 letter (*id.* at 8; EX2011), and Patent Owner did not assert its patents against any player in this industry until filing the District Court Litigation in May.

*Second*, Patent Owner's purported eight years of research into the patented technology is irrelevant to the discretionary denial analysis. As established in Patent Owner's own-cited case, discretionary denial for settled expectations is only warranted for IPRs challenging patents issued six and seven years earlier, not when 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 Services, L.L.C. v. Eli Lilly & Co.*, which Patent Owner also cites, is inapposite because, the

challenged patent had issued nearly *nine years* prior. IPR2025-01024, Paper 15, at 2 (P.T.A.B. Oct. 10, 2025). The '916 patent has been in force for less than a year 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 '916 patent, especially because Patent Owner does not mark its products with the '916 patent. *See* EX1016, at 4.

*Third*, awareness of the patent portfolio does not establish settled expectations in the newly issued '916 patent. The first patent in the family—U.S. Patent No. 10,758,652 (“the '652 patent”)—issued five years ago. EX2006. But under Patent Owner's theory, it should automatically have settled expectations in the '916 patent the day it issued despite its family lineage, its different claim scope, and cursory, erroneous examination. *See* Section IV, *infra*. This amounts to a desperate attempt to retroactively establish settled expectations for newly issued claims, and indirectly suggests that Patent Owner should have challenged this patent the day it issued or, impossibly, beforehand. Even if the portfolio as a whole could retroactively form settled expectations for the '916 patent—a notion that is not only illogical but unsupported by any of Patent Owner's cited cases—this portfolio goes back only five years, which is insufficient to establish settled expectations, and an IPR challenging the '652 patent has already survived discretionary denial considerations, presumably because Patent Owner has no settled expectations in that patent.

EX1021; *see also Google LLC, v. Withrow Networks, Inc.*, IPR2025-00775, Paper 10 at 2 (P.T.A.B. August 14, 2025) (no 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; *see also Embody, Inc. v. Lifenet Health*, IPR2025-00248, IPR2025-00249, Paper 13 at 2-3 (P.T.A.B. June 26, 2025) (denying discretionary denial of IPRs challenging a three-year-old patent and its parent).<sup>1</sup>

Patent Owner's similar assertion—that it should have settled expectations because Terumo knew it was entering an industry protected by patents—similarly fails. Importantly, Terumo launched the accused Rika System in 2022, *before* the '916 patent issued. As previously explained, it is axiomatic that settled expectations do not develop before a patent's issuance. Moreover, not only is there no evidence that Terumo knew of the patent portfolio generally 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

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<sup>1</sup> Patent Owner's reliance on *Datadome S.A. v. Arkose Labs Holdings, Inc.*, IPR2025-00693, Paper 13 (P.T.A.B. Aug. 14, 2025) is similarly misplaced because the patents had been in force for *ten* and *seventeen years*. *Id.* at 2.

Persona® (EX2005) as a “Reference” device, which may be different from the submitted product. *See, e.g.*, EX2005 at 2.

Similarly, Patent Owner does not identify any evidence that Terumo knew of the '916 patent, or its patent family, before April 24, 2024 when an IDS citing a published application corresponding to another family member—U.S. Patent No. 11,738,124 (the “'124 patent”)—was filed. Paper 6 at 7; EX2008. This April 2024 date establishes Terumo's diligence, not Patent Owner's settled expectations, as, less than two years later, Terumo filed IPRs and/or PGRs challenging the Asserted Patents.<sup>2</sup> Indeed, as Patent Owner acknowledges, PGRs are often favored because, as here, they may “occur before expectations in the patent rights are strongly settled.” Paper 6 at 9.

**Fourth**, Patent Owner's assertion that the recency of the '916 patent's issuance does not counsel against discretionary denial rises and falls with its assumption that it has settled expectations in its '652 patent. **None** of its cases

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<sup>2</sup> Patent Owner's reliance on *Geotab Inc. v. Fractus, S.A.*, IPR2025-000928, Paper 11 (P.T.A.B. Sept. 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. That is not the case here.

support this. For example, the Director found no settled expectations when the PGR was filed seven months after the patent issued and referred the Petition for merits review despite a related patent challenged in an IPR being in force since 2022. *Intas Pharms. Ltd. v. Atossa Therapeutics, Inc.*, PGR2025-00043, Paper 12 at 11 (P.T.A.B. Aug. 29, 2025); *see also Milwaukee Elec. Tool Corp. v. Klein Tools, Inc.*, IPR2025-00724, PGR2025-00048 Paper 14 at 2 (P.T.A.B. Sept. 12, 2025) (finding no “strong settled expectations” in patents that issued in 2022, 2023, and 2025).

Patent Owner cites to some cases where the Board denied institution for patents that were part of a larger, older patent family, (Paper 6 at 9–11) but in those decisions, other facts, not “settled expectations” supported denial. Indeed, in *Amazon.com v. Audio Pod IP, LLC* the Board recognized that a five-year-old patent, the youngest at issue there, would “ordinarily ... counsel against discretionary denial,” but denied institution on efficiency grounds because it was already denying institution of petitions challenging different, much older patents. IPR2025-00757, Paper 15 (P.T.A.B. Aug. 14, 2025) at 3 (discussing IPR2025-00768 challenging U.S. Patent No. 10,805,111, granted in 2020). In *Samsung Elecs. Co. v. Icashe, Inc.*, the Board denied institution in IPRs challenging patents granted in 2022 and 2023 because the district court trial date preceded a FWD by six months and because it was already denying institution of IPRs challenging related patents that had been in force *for at least nine years*. IPR2025-00639, Paper 11 (P.T.A.B. Aug. 14, 2025) at

2–3. Patent Owner's other cases also are inapposite. *See Azurity Pharms., Inc. v. Helsinn Healthcare S.A.*, IPR2025-00949, Paper 11 at 2–3 (P.T.A.B. Sep. 19, 2025) (*denying* discretionary denial despite that patent issued over seven years earlier); *WebGroup Czech Republic, A.S. v. DISH Techs. LLC*, IPR2025-00467, Paper 14 at 2–3 (P.T.A.B. July 16, 2025) (*denying* institution where some of the challenged patents had “already been the subject of multiple proceedings,” which is not the case here); *Samsung Elecs. Co. v. Genghiscomm Holdings LLC*, IPR2025-00780, Paper 11 at 2 (P.T.A.B. Aug. 22, 2025) (trial set to occur six months before FWD would issue).

Accordingly, for all the above reasons, Patent Owner has no settled expectations in the '916 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 has moved to stay the District Court Litigation but ignores that case law and statistics overwhelmingly support a stay. *See* Paper 6 at 12. 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. The court has not expended any resources at all on discovery because the parties have not raised any disputes with the court. Additionally, claim construction has not yet begun. These factors favor a stay.

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 6 at 12. 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); *see also 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).

Patent Owner may not be convinced by District of Colorado’s 69% grant rate, but 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. *See Downing Wellhead Equip., LLC*, No. 23-cv-01180-RMR-SBP (Feb. 14, 2024). This includes when the IPRs had not yet been instituted. *See id.* In the one case where a stay was granted in part, portions of the case involving patent invalidity were stayed. 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. 23-cv-01180-RMR-SBP (D. Colo. Oct. 21, 2024).

## **2. The 2028 Trial Date Weighs Strongly 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 FWD is projected to issue in February 2027, and no trial date has been set in the District Court Litigation. *See Twitch Interactive, Inc.*, IPR2025-00307, Paper 18 at 2-3 (denying 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 trial is likely to occur in or around June 2028, well after the FWD. Paper 6 at 14. Nonetheless, Patent Owner attempts to minimize these facts, arguing that even if the Board’s FWD precedes trial, it would not eliminate duplication or inconsistency. *Id.* This argument mischaracterizes the relevance of *Fintiv* Factor 2.

*See Google LLC*, IPR2025-00775, Paper 10 at 2 (denying discretionary denial where no trial date was set and statistics suggested any trial would be after the FWD). The “proximity of the court’s trial date,” factor compares the district court’s trial date and the PTAB’s projected statutory FWD deadline because, if the PTAB is likely to complete its review before the trial concludes, there is less risk of inconsistent outcomes or significant duplication of efforts. *See id.* Those concerns are significantly reduced when, like here, the projected PTAB decisions precede the projected trial date by **over a year**.

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). Patent Owner has failed to establish settled expectations for a year-old patent, and thus, these facts are not analogous to situations where the Board denied institution despite a FWD in advance of a trial date. *See Hisense USA Corp. v. VideoLabs, Inc.*, IPR2025-00880, Paper 11 at 2-3 (P.T.A.B. Oct. 10, 2025).

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

### **3. Minimal Investment in the District Court Favors Institution**

The third *Fintiv* factor assesses the “investment in the parallel proceedings by

the court and the parties.” *Fintiv, Inc.*, IPR2020-00019, Paper 11 at 13. While the District Court Litigation has been pending for six months, the Parties and the Court have not significantly invested in it. While Terumo has filed a Partial Motion to Dismiss, Terumo has not yet answered the Second Amended Complaint, discovery has just begun, and the District Court's resources have been focused primarily on standard case-management issues. While initial invalidity contentions were just served, the claim construction process has not yet begun, and will not begin until early 2026, right around the institution deadline in this proceeding. EX2012 at 9. Moreover, no *Markman* hearing has been scheduled and there are no set deadlines for the close of fact or expert discovery, and both will likely be ongoing when any FWD issues. *See Cambridge Indus. USA, Inc.*, IPR2025-00434, Paper 11 at 1, 3 (denying discretionary denial because parallel litigation that did not have a trial date or even a *Markman* hearing scheduled). In similar situations where the most burdensome parts of the case lie ahead the Board has found that this factor weighs against discretionary denial. This factor favors institution.

#### **4. There is Little Risk of Overlapping Issues**

The fourth *Fintiv* factor assesses the “overlap between the issues raised in the petition and in the parallel proceeding.” *Fintiv, Inc.*, IPR2020-00019, Paper 11 at 12. Petitioner will be estopped from asserting “any ground for invalidity that was raised or could have been raised during the PGR” more than a year before the expected trial

date, reducing the risk of inconsistent decisions. 35 U.S.C. §325(e)(2); *see also Phison Elecs. Corp. v. Vervain, LLC*, PGR2025-00010, Paper 14 at 3 (P.T.A.B. July 10, 2025); EX2013. Plus, the District Court Litigation is expected to be stayed, further mitigating the risk of inconsistent decisions. *See Intas Pharms. Ltd. v. Atossa Therapeutics, Inc.*, PGR2025-00043, Paper 12 at 2-3 (P.T.A.B. Aug. 29, 2025). A stipulation, therefore, is unnecessary. Moreover, Patent Owner has also indicated that it will drop claims in the District Court Litigation. District Court Litigation, Dkt. 67, at 2. Therefore, Board review of the more expansive claim set will not only be more efficient but more comprehensive. This factor is at least neutral and is considered “on a holistic assessment of all of the evidence and arguments presented” with other *Fintiv* factors. *See Anthony, Inc. v. Controlotec, LLC*, IPR2025-00636, Paper 9 at 3 (P.T.A.B. July 16, 2025) (referring IPR to merits panel despite no *Sotera* stipulation); *see also id.*, Paper 6 at 7-9 (June 10, 2025).

## **5. Identical Parties**

Patent Owner notes that the parties here are the same as in the parallel proceeding. Paper 6 at 16. Therefore, this factor is neutral and does not weigh against institution. *See Fintiv, Inc.*, IPR2020-00019, Paper 11 at 13.

## **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. Here, discretionary denial is unwarranted considering the compelling merits of the unpatentability grounds set forth in the Petition. *See* 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 '916 patent is invalid, and thus have textual overlap, this overlap is neither improper nor conclusory.

Patent Owner mischaracterizes the strength of the Petition by focusing on an inadvertent clerical error omitting a limitation, whose substance, Patent Owner admits, is "present in other independent claims." Paper 6, at 17-18. Petitioner diligently filed a motion to correct the clerical error, noting that the missing analysis due to the clerical omission is present in other portions of the petition. Paper 9.

Patent Owner then accuses Petitioner of merely listing equations without explaining how they render obvious claim limitations 10[h]-[i] and 14[h]. Paper 6, at 18. But Petitioner explains both the relationship of all of the variables and how a POSITA would have understood them to render obvious the challenged claims. For example, Terumo explains that Fletcher-Haynes' "successive approximation approach" calculates an AC ratio,  $R$ , using a donor's hematocrit,  $H$ ; calculates a fraction of anticoagulant in the collected plasma component,  $f_{ACP}$  using  $R$  and  $H$ ; calculates a total blood volume,  $V_B$ , using donor weight,  $W$ , and height,  $L$ ; and then uses  $V_B$  and  $f_{ACP}$  to calculate a volume of pure plasma  $V_{SP}$  and plasma product  $V_{SPB}$ .

As the Petition and Dr. Fletcher explain, this discloses the claimed target volumes based at least in part on the claimed donor parameters. *E.g.*, Pet. at 31-33, 51-53; EX1005 49:40-51-23. Additionally, while Patent Owner takes issue with the level of detail provided in the Petition, it does not assert that Fletcher-Haynes does not render obvious these limitations. *See* Paper 6 at 17-18. Accordingly, Patent Owner's rebuttal is without merit.

Tellingly, Patent Owner does not address most of Petitioner's Section 112 arguments, because it cannot. Petitioner and Dr. Fletcher provide compelling evidence that there is *no* textual support for most claims in the '916 patent. In its sole rebuttal, Patent Owner wrongly suggests that mentioning "plasma product" satisfies the written description requirement. Paper 6, at 19-20. These appearances of "plasma product," however, do not "blaze a trail through the forest[,] one that runs close by [Patent Owner's] proposed tree." *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571 (Fed. Cir. 1996). Rather, Patent Owner raises them when distinguishing its claimed approach from prior art systems that "end plasma collection based on a total volume of anticoagulated plasma." EX1001, 10:1-6. Further, "[t]he question is not whether a claimed invention is an obvious variant of that which is disclosed in the specification," *i.e.*, that Petitioner understood the meaning of "plasma product." *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997). To satisfy the written description requirement, "a prior application itself must describe an

invention.” *Id.* The '916 patent only describes calculating a target volume of *pure* plasma by weight, not plasma product. Pet. at 91-92; EX1001, 2:52-53.

Petitioner's § 101 arguments are similarly thin. While Patent Owner asserts that Petitioner ignores generic “hardware elements” of the claimed system, these hardware elements need to be specialized to confer patent eligibility. *See Life Techs., Inc. v. Nintendo of Am., Inc.*, No. 3:13-cv-4987, 2020 WL 13281800, at \*3-4 (N.D. Tex. Jan. 17, 2020). That is why, for example, claims for an “improved digital camera” in *Yu* were patent-ineligible despite claiming the lenses, image sensor, and other generic hardware elements. *Yu v. Apple Inc.*, 1 F.4th 1040, 1043-44 (Fed. Cir. 2021). Patent Owner has never asserted that its plasma collection equipment or their arrangement is novel because it is not. *See BASCOM Global Internet Servs., Inc. v. AT&T Mobility LLC*, 827 F.3d 1341, 1350 (Fed. Cir. 2016). Its purported invention lies in its mathematics, but surviving the § 101 inquiry requires “more than simply stating the abstract idea while adding the words ‘apply it’” on a generic device. *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 573 U.S. 208, 221 (2014) (cleaned up) (quoting *Mayo Collaborative Servs. v. Prometheus Laby's, Inc.*, 566 U.S. 66, 72 (2012)); *see also BSG Tech LLC v. Buyseasons, Inc.*, 899 F.3d 1281, 1290-91 (Fed. Cir. 2018). Thus, even when considering the “ordered combination” of elements, the '916 patent is patent ineligible because there is “no ‘inventive concept’ in the claimed application of the formula[s]” in a generic plasma collection machine. *Mayo*, 566

U.S. at 72-73, 82; *Parker v. Flook*, 437 U.S. 584, 594 (1978); *Diamond v. Diehr*, 450 U.S. 175, 191-92 (1981). That is especially true where the FDA has provided guidance on, and codified, taking a weight, determining hematocrit, and identifying a donor's sex before collecting plasma. *See* EX1009.

Accordingly, the Petition's compelling merits favor institution.

#### **IV. THE EXAMINER ERRED IN ALLOWING THE '916 PATENT**

The prosecution history reflects three material errors that undermine validity.

*First*, the Examiner misunderstood the scope of the '916 patent's pending claims, as reflected in the Examiner's cursory obviousness-type double patenting rejections over claim 11 of the parent '652 patent and claim 11 of the '926 patent, both in view of U.S. 2012/0165658 (Weasler). EX1002, at 68-73. The '916 claims recite a *target* volume "for plasma product and/or raw plasma," but claim 11 of the '652 patent recites a *collected* volume of "pure plasma," and claim 8 of the '926 patent recites "pure plasma" and "a target collection volume." *Compare* EX1001, cls. 1, 8, 11 *with* EX2006, cl. 11 *and* EX1020, cls. 1, 8, 15, 23. The Examiner did not perform an element-by-element mapping that would have clearly highlighted the differences, and Weasler, which the Examiner cited for disclosing a touchscreen, does not cure this deficiency. Indeed, the '916 claims appear directed to subject matter found in a separate patent that is not in the '916 priority chain. *Compare* EX1001, cls. 1-22 *with* EX1017, cls. 1-26. The Examiner should have noticed the

differences in claimed subject matter, reviewed the specification of the '916 and '652 patents for written description support, realized such support was lacking, and/or considered Patent Owners' own admitted prior art for disclosing "plasma product." *See* MPEP §§ 2163 and 211.02; Pet. Ground VII (discussing § 112).

**Second**, this error likely materially affected the search for and application of prior art. Terumo submitted a Search Disclosure Declaration that a diligent examiner should have at least identified Fletcher-Haynes during prosecution of the '916 patent. EX1014, 1015. But the Examiner did *not* identify Fletcher-Haynes during prosecution. *See* EX1001, at 2-3. Had the Examiner understood the potential scope of the claims, she would have at least performed a revised search, which should have identified at least Fletcher-Haynes. *See* EX1014, 1015.

**Third**, the Examiner was aware of patent eligibility issues in Patent Owner's family but neglected to raise them. The same Examiner raised Section 101 concerns in a related family member of the '916 patent but never issued a Section 101 rejection for either patent. EX1019, at 156. The Examiner's arguments there do not comport with the applicable subject matter eligibility guidance, *see* MPEP §2106 (incorporating 2019 Patent Eligibility Guidance), and the Examiner should have more fully analyzed the '916 claims under § 101 using that multi-step process.

## V. CONCLUSION

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

Petitioner's Opposition to Patent Owner's Request for Discretionary Denial  
PGR2025-00078

Respectfully submitted,

Date: December 15, 2025

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**CERTIFICATE OF SERVICE**

The undersigned hereby certifies that a copy of the foregoing PETITIONER'S OPPOSITION TO PATENT OWNER'S REQUEST FOR DISCRETIONARY DENIAL was served on December 15, 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:

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