

Patent Owner's Brief Requesting Discretionary Denial  
U.S. Patent No. 12,171,916

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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Case No. PGR2025-00078

U.S. Patent No. 12,171,916

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**PATENT OWNER'S BRIEF REQUESTING  
DISCRETIONARY DENIAL**

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<b>2001</b>	Interim Processes for PTAB Workload Management, Coke Morgan Stewart (Mar. 26, 2025), <i>available at</i> <a href="https://www.uspto.gov/sites/default/files/documents/InterimProcesses-PTABWorkloadMgmt-20250326.pdf">https://www.uspto.gov/sites/default/files/documents/InterimProcesses-PTABWorkloadMgmt-20250326.pdf</a>
<b>2002</b>	Second Amended Complaint, <i>Haemonetics Corp. v. Terumo BCT, Inc.</i> , No. 1:25-cv-01409-RMR-SBP, D.I. 48 (D. Colo. Aug. 12, 2025)
<b>2003</b>	U.S. FDA Clears Terumo Blood and Cell Technologies’ New Plasma Collection Technology, Terumo Global (Mar. 10, 2022), <i>available at</i> <a href="https://www.terumo.com/newsrelease/detail/20220310/683">https://www.terumo.com/newsrelease/detail/20220310/683</a>
<b>2004</b>	510(k) Summary, Rika Plasma Donation System, Terumo Blood and Cell Technologies (2021), <i>available at</i> <a href="https://www.fda.gov/vaccines-blood-biologics/substantially-equivalent-510k-device-information/cleared-510k-submissions-supporting-documents">https://www.fda.gov/vaccines-blood-biologics/substantially-equivalent-510k-device-information/cleared-510k-submissions-supporting-documents</a> ; <a href="https://web.archive.org/web/20241109101055/https://www.fda.gov/media/156913/download?attachment">https://web.archive.org/web/20241109101055/https://www.fda.gov/media/156913/download?attachment</a>
<b>2005</b>	510(k) Summary, Rika Plasma Donation System, Terumo Blood and Cell Technologies (2024), <i>available at</i> <a href="https://www.fda.gov/media/177027/download?utm">https://www.fda.gov/media/177027/download?utm</a>
<b>2006</b>	U.S. Patent No. 10,758,652 to Michael Ragusa, “System and Method for Collecting Plasma” (filed: May 30, 2017; issued: Sept. 1, 2020)
<b>2007</b>	Persona Plasma Collection Solution Brochure, Haemonetics Corporation (2020), <i>available at</i> <a href="https://plasma.haemonetics.com/-/media/files/plasma/persona_brochure.pdf">https://plasma.haemonetics.com/-/media/files/plasma/persona_brochure.pdf</a> .
<b>2008</b>	Information Disclosure Statement by Applicant, Application No. 18/644,259 (filed: Apr. 24, 2024)

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2009	U.S. Patent No. 11,738,124, “System and Method for Collecting Plasma,” to Michael Ragusa (filed: Sep. 13, 2022; issued: Aug. 29, 2023)
2010	PCT Written Opinion of the International Searching Authority, No. PCT/US2024/026191 (Aug. 8, 2024)
2011	Letter from E. Milch to A. Gawin re Notice of Infringement of Haemonetics’ Plasma Collection Patents (Oct. 1, 2024)
2012	Lex Machina Motion Metrics Report for Patent Cases in the District of Colorado since Jan. 1, 2000, <i>available at</i> <a href="https://law.lexmachina.com/court/cod/motion-metrics/?filed_on_from=2000-01-01&amp;case_types-include=27&amp;filters=true&amp;tab=federal_motion_metrics_motion_types&amp;view=analytics">https://law.lexmachina.com/court/cod/motion-metrics/?filed_on_from=2000-01-01&amp;case_types-include=27&amp;filters=true&amp;tab=federal_motion_metrics_motion_types&amp;view=analytics</a> (last accessed Nov. 14, 2025)
2013	Scheduling Order in a Patent Case, <i>Haemonetics Corp. v. Terumo BCT, Inc.</i> , No. 1:25-cv-01409-RMR-SBP, D.I. 54 (D. Colo. Aug. 19, 2025)
2014	Lex Machina Timing for Patent Cases in the District of Colorado since Jan. 1, 2009, <i>available at</i> <a href="https://law.lexmachina.com/court/cod/cases/?status=terminated&amp;case_types-include=27&amp;pending-from=2009-01-01&amp;pending">https://law.lexmachina.com/court/cod/cases/?status=terminated&amp;case_types-include=27&amp;pending-from=2009-01-01&amp;pending</a> (last accessed Nov. 14, 2025)
2015	Guidance on USPTO’s rescission of “Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation,” Scott R. Boalick (Mar. 24, 2025), available at <a href="https://www.uspto.gov/sites/default/files/documents/guidance_memo_on_interim_procedure_rescission_20250324.pdf">https://www.uspto.gov/sites/default/files/documents/guidance_memo_on_interim_procedure_rescission_20250324.pdf</a>

## **I. INTRODUCTION**

Patent Owner respectfully requests that the Board exercise its discretion to deny institution. The challenged patent, U.S. Patent No. 12,171,916 (the "'916 Patent") is one of nine patents asserted in the co-pending district court litigation. The asserted patent portfolio has been in force for over five years. Petitioner did not even enter this highly concentrated market with its competing product until two years after the first patent issued, when it was fully aware of Patent Owner's patent portfolio. That first patent in this portfolio—U.S. Patent No. 10,758,652 (the "'652 Patent")—was filed in 2017, coinciding with Patent Owner's public announcement and commercialization of its patented plasma apheresis system.

Patent Owner immediately began marking its commercialized product upon issuance of the '652 Patent in 2020. Petitioner even referred to Patent Owner's marked, patented devices as "reference devices" in its own 510(k) submissions in 2021. Unlike in some broader industries, there can be no doubt about competitor awareness here. The plasma apheresis market includes only three main competitors—Patent Owner, Petitioner, and one other. In such a tightly confined industry, where each participant closely monitors the others' products, regulatory filings, and patent activity, Petitioner's awareness of the patent portfolio containing the '916 Patent is not speculative—it is undeniable.

Petitioner was also put on explicit notice of infringement concerning this patent portfolio over a year ago and cited to a patent within this portfolio in its own patent filings. Nevertheless, Petitioner made a strategic decision to wait, filing nine *inter partes* review and post-grant review petitions, including this Petition, only *after* district court litigation commenced. This deliberate delay undermines efficiency, fairness, and the integrity of the PTAB's discretionary framework. Patent Owner and the market had settled expectations that the patents within this portfolio would not be subject to further collateral attack. Under these circumstances, discretionary denial is not only justified, but compelled.

The *Fintiv* factors further support discretionary denial. There is no indication that the district court will stay the parallel litigation, both parties have invested in that proceeding, there is overlap of parties and issues in that litigation involving nine related patents, and the arguments in the Petition are meritless. As such, discretionary denial of the Petition is warranted.

## **II. THE PETITION SHOULD BE DISCRETIONARILY DENIED**

In accordance with the Interim Processes for PTAB Workload Management Memorandum, Patent Owner respectfully requests institution of the Petition be discretionarily denied. EX2001. The Patent Office has broad discretion to institute or deny an IPR petition. *See* 35 U.S.C. § 314(a); *Cuozzo Speed Techs., LLC v. Lee*,

579 U.S. 261, 273 (2016); *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1367 (Fed. Cir. 2016). Discretionary denial is appropriate in this case.

**A. Settled Expectations Weigh Heavily in Favor of Denial.**

There is no rigid formula for assessing “settled expectations” as the inquiry is highly fact dependent. Here, those facts weigh decisively in favor of discretionary denial. The '916 Patent is within a patent portfolio that goes back over five years, the unique nature of the highly concentrated technology space, the competitive relationship between the parties, and Petitioner's awareness of this patent portfolio establish Patent Owner's settled expectations that the '916 Patent would not be challenged at the Patent Office. Petitioner's belated filing is the very type of gamesmanship that the Board's discretionary authority is designed to prevent. This factor weighs heavily in favor of discretionary denial.

**1. This industry contains only three main competitors.**

The '916 Patent is directed to a plasma apheresis machine that withdraws blood from a donor, separates a specific amount of plasma, and returns remaining blood components and saline back to the donor. *See generally* EX1001. By the nature of this invention, the patent can only be asserted in a limited technological space. While the demand for plasma is great, there are only three main competitors

in this industry: (1) Patent Owner, (2) Petitioner, and (3) Fresenius Kabi<sup>1</sup>. Notably, Patent Owner has been a leader in this industry for over 20 years marketing its PCS<sup>®2</sup> plasmapheresis system. EX2002 ¶16. Petitioner, however, did not enter the industry with the accused products until 2022 and would have been aware of the two existing market participants, including Patent Owner, at that time. EX2003. Accordingly, “Petitioner was aware that Patent Owner was involved in the same technology space for a significant amount of time before filing its Petition challenging Patent Owner’s patent. A failure to seek early review of the patent favors denial[.]” *Murata Mfg. Co. v. Georgia Tech Rsch. Corp.*, IPR2025-00383, Paper 14 (July 29, 2025) at 2-3; *cf. Home Depot U.S.A., Inc. v. H2 Intellect LLC*, IPR2025-00480, Paper 11 (Sep. 4, 2025) at 2-3 (finding a lack of settled expectations because, unlike the instant case, the patents were previously used to target *other* industries).

**2. Patent Owner has invested in, developed, commercialized, and marketed the patented invention for 8 years.**

Even where a patent portfolio has only been in force for five years, “there may be good reasons why a patent owner has strong settled expectations” including “an

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<sup>1</sup> Patent Owner has a pending district court litigation asserting the ’916 Patent against Fresenius Kabi/Fenwal, Inc. *See Haemonetics Corp. v. Fresenius Kabi USA, LLC, et al.*, No. 1:25-cv-08680 (N.D. Ill. July 25, 2025).

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extraordinary amount of investment, time, and resources dedicated to research, [and] development[.]” *Amgen Inc. v. Bristol-Myers Squibb Co.*, IPR2025-00601, Paper 9 (July 24, 2025) at 2 (denying patent owner’s request where it failed to “sufficiently articulate[] such reasons”). Here, Patent Owner has invested significant resources into commercialization of its patented technology, including \$64 million in research and development in 2024 alone. EX2002 ¶14. That research and development went directly towards the development of the technology claimed within the ’916 Patent and commercialization of the covered system. Patent Owner has been improving upon its plasma apheresis systems since 1971 and continues to be the industry leader in plasma collection systems. *Id.* ¶¶13-15. Indeed, Patent Owner “has made, and continues to make, substantial investments of time, money, and resources in the research, development, and commercialization of [products] which embody the claimed invention.” *Empower Clinic Servs., L.L.C. v. Eli Lilly & Co.*, IPR2025-01024, Paper 15 (Oct. 10, 2025) at 2.

These improvements have culminated in commercialized versions of the patented invention. Patent Owner announced its NexSys PCS<sup>®</sup> device with YES<sup>®</sup> technology in 2018, which provides higher plasma yields by stopping blood collection when a target pure plasma volume is reached (just like the ’916 Patent). EX2002 ¶16. And in 2020, the same year the ’652 Patent issued, Patent Owner released its NexSys<sup>®</sup> PCS device with PERSONA<sup>®</sup> technology, which tailors the

amount of plasma collected based on an individual donor's characteristics. *Id.* ¶¶16, 20-21. As such, Patent Owner has been publicly commercializing its patented systems since 2018, further underscoring its settled expectations that the patents covering these systems would not be challenged. *Cf. Intel Corp. v. Proxense LLC*, IPR2025-00327, Paper 12 (June 26, 2025) at 2-3 (considering a petition where the patent has *not* “been commercialized . . . or otherwise applied in a petitioner's particular technology space”). Petitioner was not merely aware of Patent Owner's patented commercial system, it relied on and identified it as the “reference device” in its 2021 510(k) submission (EX2004) and again in its 2024 filing (EX2005).

**3. Petitioner was aware of Patent Owner's patent portfolio relating to plasma-collection systems.**

When Petitioner entered this industry in 2022 with its accused system, the parent '652 Patent had already issued and the '916 Patent had already been filed and published (US 2021/0205526). EX2006; EX1001. Thus, Petitioner joined the market with full awareness that it was entering an industry protected by patents covering the very type of plasma collection system it sought to market and sell. *See Dabico Airport Sols. Inc. v. AXA Power APS*, IPR2025-00408, Paper 21 (June 18, 2025) at 3 (“[P]atent applications . . . and issued patents are almost always publicly available to provide notice to the public, . . . competitors, and commercial interests.”).

“[A]ctual notice of a patent or of possible infringement is not necessary to create settled expectations.” *Id.*

Petitioner's awareness was not theoretical, it was direct and documented. Patent Owner marked its commercialized system—that Petitioner used as a reference device in its 510(k) submission—with the '652 Patent. EX2004-2005; EX2007. Patent Owner began marking its devices five years ago, before Petitioner even released its competing system. EX2007. Despite years of awareness of Patent Owner's portfolio, and its clear relevance to Petitioner's plasma collection system, Petitioner waited until now, after entering the market and facing litigation, to mount its challenges to the patents within Patent Owner's portfolio.

**4. Petitioner monitors and had actual knowledge of Patent Owner's patent portfolio containing the '916 Patent.**

Not only was Petitioner aware of the patent portfolio containing the '916 Patent by virtue of its entry into this market as a competitor and Patent Owner's marking of its product, but Petitioner also monitored Patent Owner's activity.

Petitioner's own patent prosecution history confirms this. During prosecution of Petitioner's patent application 18/644,259, Petitioner cited the published application of U.S. Patent No. 11,738,124 (the “'124 Patent”) in an Information Disclosure Statement. EX2008 (citing US 2023/0001059 to Ragusa). The '124 Patent is a continuation of the '652 Patent and is also directed to a plasma collection

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system. EX2009. The same published application of the '124 Patent was discussed by the examiner in 2024 regarding Petitioner's International App. No. PCT/US 2024/026191. EX2010. The same Information Disclosure Statement also cites a patent owned by Fenwal, Inc., a subsidiary of Fresenius Kabi, demonstrating that Petitioner was monitoring its two competitors' patent portfolios in the industry. EX2008 (citing US 2022/0168,486 to Fenwal, Inc.).

Patent Owner also made Petitioner explicitly aware of Petitioner's infringement of this patent portfolio on October 1, 2024. EX2011. Patent Owner explicitly listed the '916 Patent pending application in the letter. *See id.* Patent Owner then initiated the district court litigation in May 2025. Petitioner still waited until August to begin mounting its IPR and PGR challenges to this patent portfolio and filed the instant Petition in September. *See Geotab Inc. v. Fractus, S.A.*, IPR2025-00928, Paper 11 (Sep. 12, 2025) at 2-3 (discretionarily denying institution where petitioner had a patent brought to its attention but did nothing until litigation began). Because Petitioner has been aware of "Patent Owner's patent portfolio in general since at least [2020]," Patent Owner's settled expectations in 2025 warrant discretionary denial. *Datadome S.A. v. Arkose Labs Holdings, Inc.*, IPR2025-00693, Paper 13 (Aug. 14, 2025) at 2 (discretionary denial is appropriate where Petitioner was aware of the patent portfolio since 2022 and the challenged patent since 2023).

**5. The recency of the ’916 Patent’s issuance does not counsel against discretionary denial.**

Although PGR Petitions are often favored because they may “occur before expectations in the patent rights are strongly settled,” the Board routinely considers a particular PGR petition in context, particularly where it is one of several contemporaneously filed IPR and/or PGR petitions challenging related patents within the same portfolio. *E.g., Milwaukee Electric Tool Corp. v. Klein Tools, Inc.*, PGR2025-00048, Paper 14 at 2 (Sept. 12, 2025); *Phison Elecs. Corp. v. Vervain, LLC*, PGR2025-00010, Paper 14 (July 10, 2025); *Intas Pharms. Ltd. v. Atossa Therapeutics, Inc.*, PGR2025-00043, Paper 12 (Aug. 29, 2025).

Here, the instant Petition is one of nine related PGR and IPR challenges Petitioner has filed against the nine patents asserted in the parallel district court litigation.<sup>2</sup> *See* EX2002 ¶1. As the Board has recognized, while one patent has “not been in force as long as the other patents challenged . . . the district court will be considering the validity of the patents challenged,” making Board review “an

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<sup>2</sup> For some of these Petitions, Patent Owner has already requested a discretionary denial and will be requesting a discretionary denial of institution for the others. *See* IPR2025-01374 (Paper 9); IPR2025-01391 (Paper 7); PGR2025-00077; IPR2025-01420; IPR2026-00046; PGR2026-00006; IPR2026-00045; PGR2026-00009.

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inefficient use of Board resources and tips the balance to discretionary denial[.]”  
*Samsung Elecs.*, IPR2025-00639, Paper 11 (Aug. 14, 2025) at 3; *see also*  
*Amazon.com, Inc. v. Audio Pod IP, LLC*, IPR2025-00757, Paper 15 (Aug. 14, 2025)  
at 3. While the patents in *Samsung* were more mature, the totality of the  
circumstances, as explained herein, establishes Patent Owner’s settled expectations  
in a patent portfolio that has been in force for five years. As such, Petitioner’s settled  
expectations as to the entire patent portfolio—not merely the challenged patent—are  
relevant to the discretionary denial analysis. *See Samsung Elecs. Co. v. Icashe, Inc.*,  
IPR2025-00639, Paper 11 (Aug. 14, 2025) at 3 (holding a newly-issued patent in a  
large patent family does not weigh against discretionary denial).

The ’652 Patent—to which the ’916 Patent claims priority, issued over five  
years ago. EX2006. The maturity of this patent portfolio creates settled expectations  
for Patent Owner. *See Azurity Pharms., Inc. v. Helsinn Healthcare S.A.*, IPR2025-  
00949, Paper 11 (Sep. 19, 2025) at 2-3 (finding that issuance in 2020 “creat[es]  
strong settled expectations for Patent Owner”). Even if five years is considered a  
recent issuance, the fact that the challenged patent “ha[s] not been in force for a  
significant period of time” does not preclude discretionary denial. *WebGroup Czech*  
*Republic, A.S. v. DISH Techs. LLC*, IPR2025-00467, Paper 14 (July 16, 2025) at 2  
(discretionarily denying an IPR petition challenging a patent that issued in 2023);  
*Milwaukee Electric Tool Corp. v. Klein Tools, Inc.*, IPR2025-00724, Paper 14 (Sep.

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12, 2025) at 2 (same); *Samsung Elecs. Co. v. Genghiscomm Holdings LLC*, IPR2025-00793, Paper 12 (Aug. 22, 2025) at 2 (that the patent issued in 2022 does not “tip the balance against discretionary denial”)<sup>3</sup>.

In sum, Petitioner entered the plasma collection industry in 2022 fully aware that Patent Owner had commercialized a patented system and marked its devices with this patent portfolio since 2020. Yet Petitioner waited five years to challenge that patent and waited until the end of the nine-month window after issuance to file this PGR against the ’916 Patent. During that time, Petitioner monitored Patent Owner’s portfolio, cited a patent within this portfolio in its own patent prosecution, and received a notice letter alleging infringement and providing notice of the ’916 patent application. Nevertheless, it intentionally waited until after litigation began to file this Petition. By that time, Patent Owner had reasonable settled expectations that the ’916 Patent would not face a validity challenge in the patent office. Under these facts, discretionary denial is not only justified, but warranted.

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<sup>3</sup> In a parallel IPR proceeding, Petitioner shadow boxes with arguments Patent Owner has not made, and the cited case speak for themselves. *Terumo BCT, Inc. v. Haemonetics Corp.*, IPR2025-01374, Paper 11 (Nov. 13, 2025).

**B. The *Fintiv* Factors Weigh in Favor of Discretionary Denial.**

In addition to the Patent Owner's settled expectations, the *Fintiv* factors<sup>4</sup> further merit discretionary denial of the Petition. *See Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 15 (May 13, 2020) at 7-17; *see also* EX2001.

**1. The district court litigation has not been stayed and there is no indication a stay will be granted here.**

The parallel district court litigation has not been stayed and is currently advancing on schedule. There is no indication that the litigation will be stayed. Two weeks ago, Petitioner moved for a stay in the district court, which Patent Owner will oppose. There is no reason to believe the district court will stay the litigation pre-institution. The case statistics for the District of Colorado indicate that a stay pending a Patent Office proceeding is not always granted. *See* EX2012 (stating a stay pending a PTO proceeding was granted in only 69% of cases).

Given that a pre-institution stay of all asserted patents is speculative at best, the likelihood of any post-institution stay is remote. By the time institution decisions issue across all petitions (anticipated around May 2026) the district court will have held a claim construction hearing and advanced even deeper into discovery.

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<sup>4</sup> The Board considers the *Fintiv* factors when analyzing discretionary denial of PGR proceedings as well as IPR proceedings. *See, e.g., Supercell Oy v. Gree, Inc.*, PGR2020-00041, Paper 17 (Nov. 18, 2020).

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EX2013. The substantial progress of the litigation at that point further supports discretionary denial under *Fintiv*.

This factor is material to the discretionary denial analysis and often given considerable weight. *Cf. Arm Ltd. v. Daedalus Prime LLC*, IPR2025-00207, Paper 14 (Aug. 6, 2025) at 2-3 (vacating a discretionary denial only after the underlying litigation was dismissed); *Mim Software Inc. v. Exini Diagnostics AB, Inc.*, IPR2025-00827, Paper 12 (Aug. 22, 2025) at 2 (referring a petition to the Board where the court had already granted a stay). Where “there is insufficient evidence that the district court is likely to stay its proceeding even if the Board were to institute trial,” this factor supports discretionary denial. *AT&T Servs. Inc. v. RightQuestion, LLC*, IPR2025-00360, Paper 12 (July 29, 2025) at 2; *see also Milwaukee*, PGR2025-00048, Paper 14 at 3. As there is no indication a stay will be granted, allowing both proceedings to proceed in parallel risks significant duplication of efforts and inconsistent outcomes. *See Intas*, PGR2025-00043, Paper 12 at 2 (not exercising discretion to deny where there was no parallel proceeding, therefore “no concern of inconsistent outcomes or significant duplication of efforts”). To reserve the Board’s resources for cases where a co-pending district court litigation will not proceed in parallel, this factor weighs in favor of exercising discretionary denial.

**2. The proximity of the court's likely trial date to the Board's final written decision is not dispositive.**

Assuming the Petition is instituted, the final written decision for this proceeding should issue in March of 2027. Although there has been a Scheduling Order entered in the district court, the Court has not yet set a trial date. EX2013. The fact that a trial date has not been set does not mean discretionary denial is improper. *See Murata Mfg. Co. v. Georgia Tech Rsch. Corp.*, IPR2025-00383, Paper 14 (July 29, 2025) at 2-3. Looking at average court statistics, the median time-to-trial in a patent case in the District of Colorado is 1,125 days which would put the estimated trial date in or around June 2028. EX2014.

“As with other non-dispositive factors considered for institution under 35 U.S.C. § 314(a),” the trial date is weighed as part of the “balanced assessment” of the relevant factors regarding discretionary denial. *See Apple Inc. v. Fintiv*, IPR2020-00019, Paper 11 (Mar. 20, 2020) at 5. As such, the likelihood that a final written decision may occur before the district court trial, by itself, is not dispositive. *See Hisense USA Corp. v. VideoLabs, Inc.*, IPR2025-00880, Paper 11 (Oct. 10, 2025) at 2-3 (finding discretionary denial appropriate although a final written decision would likely occur before a trial date because Patent Owner had settled expectations).

**3. The parties and the court have already invested in the district court proceeding.**

The district court litigation has been pending since May of 2025. The parties, and the court, have substantively invested in that litigation. For example, Patent Owner served infringement contentions and Petitioner served responses to those contentions and invalidity contentions. EX2013. Discovery has also begun, including written discovery and document productions. Prior to the expected institution decision, the parties will have served contention responses, continued collecting and producing documents, and served opening *Markman* briefings. *Id.*

Additionally, Petitioner filed a motion to dismiss pursuant to 35 U.S.C. § 101 and the parties have completed briefing. *See Haemonetics Corp. v. Terumo BCT, Inc.*, No. 1:25-cv-01409-RMR-SBP, D.I. 58, 63, 64 (D. Colo. May 5, 2025). In considering this motion, the Court is currently substantively engaging with the '916 Patent from a validity perspective, performing the exact analysis that Petitioner seeks from the Board in Ground VI of its Petition. Pet. at 72-84. Accordingly, this factor weighs in favor of discretionary denial.

**4. Petitioner has not filed a *Sotera* stipulation.**

Petitioner has not submitted a *Sotera* stipulation, or any stipulation regarding what invalidity grounds it would pursue in district court litigation, which weighs in favor of discretionarily denying the Petition. Even where a PGR challenges a

recently-issued Patent, this Board has found discretionary denial appropriate where “Petitioner has not offered a stipulation to address concerns of duplicative efforts and potentially conflicting decisions” in the district court. *Phison*, PGR2025-00010, Paper 14 at 3. Petitioner has already raised a duplicative invalidity theory before the district court (§ 101) demonstrating the overlap of issues between both proceedings.

Even if Petitioner does file a *Sotera* stipulation, which by itself would be insufficient to address all invalidity grounds raised in the Petition, it is relevant to the *Fintiv* analysis, but it is not dispositive. *See* EX2015.

**5. The parties are identical in the district court proceeding.**

The parties to this proceeding are identical to the parties in the parallel district court proceeding and Petitioner here is the defendant in district court. “Because the petitioner and the defendant in the parallel proceeding are the same party, this factor weighs in favor of discretionary denial.” *Fintiv*, IPR2020-00019, Paper 15 at 15.

**6. The arguments in the Petition are weak.**

As Patent Owner will explain in more detail in its forthcoming Preliminary Response to the Petition, the Petition lacks merit. Petitioner has challenged the '916 Patent under seven Grounds, including under 35 U.S.C. §§ 102, 103, 101, and 112. Each of Petitioner's challenges fail to demonstrate that it is more likely than not that any challenged claims are unpatentable.

*First*, Petitioner argues the challenged claims are invalid under 35 U.S.C. §§ 102, 103 over Fletcher-Haynes alone and/or in view of Bainbridge (Grounds I-V). Petitioner supports Grounds I-V with a declaration of its expert, Dr. Gary Fletcher, and cites Dr. Fletcher's declaration (EX1003) for support throughout. *See generally* Pet. at 19-72. Dr. Fletcher's declaration, however, is nearly identical to the Petition itself, repeating Petitioner's argument verbatim in many instances. *Compare, e.g.,* Pet. at 19-26 *with* EX1003 at ¶¶ 72-84. Dr. Fletcher's declaration provides no further analysis or evidence in support of Petitioner's arguments as to why the cited references anticipate or render obvious the challenged claims, nor why a POSITA would have been motivated to combine any of the cited references. The Petition, therefore, boils down to conclusory statements with no substantive analysis and should be denied. *See, e.g., TQ Delta, LLC v. CISCO Sys., Inc.*, 942 F.3d 1352, 1359 (Fed. Cir. 2019) ("conclusory expert testimony is inadequate to support an obviousness determination on substantial evidence review.").

Petitioner's primary reference for Grounds I-V—Fletcher-Haynes—also does not provide a sufficient basis for institution. In Grounds I and II, Petitioner omits an entire claim element within claim 7, specifically: "the controller coupled to the touchscreen and programmed to ... determine a target volume of plasma product and/or raw plasma based at least in part on the weight and hematocrit." EX1001 at cl. 7, 11:53-57; Pet. at 25-26 (skipping this limitation); *Id.* at 48-49 (same). Similar

claim elements are present in the other independent claims, however, Petitioner's arguments regarding those claim elements are also insufficient.

For example, regarding claim 10[h]-[i], Petitioner lists various equations from Fletcher-Haynes but does nothing to explain how the variables within the first equation (anticoagulant ratio) have any bearing on the ultimate equation (plasma product volume) nor how a person of ordinary skill in the art would have understood plasma product volume to be "based, at least in part" on donor weight and hematocrit as required by the claims. *See* Pet. at 51-53. For claim 14[h]<sup>5</sup>, Petitioner lists the same equations to conclude that Fletcher-Haynes teaches plasma volume based on total blood volume and plasma product based on plasma volume and anticoagulant, but nowhere explains how those equations are based, at least in part, on donor parameters as required by the claim. Pet. at 31-33.

*Second*, Petitioner argues that the challenged claims are invalid under 35 U.S.C. § 101 (Ground VI). Petitioner already mounted this challenge against the '916 Patent in the district court litigation. As in the district court litigation, Petitioner has oversimplified the patented invention to "pen and paper calculations." Pet. at 75. Petitioner, thus, ignores all the hardware elements of the claimed system in purportedly-representative claim 7. The challenged claims are directed to an

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<sup>5</sup> Petitioner incorporates its analysis for limitation 14[h] into claim 1[h]. Pet. at 44.

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improved plasma apheresis system that optimizes plasma collections by targeting pure plasma collection volumes and tailoring that target collection volume to the individual characteristics of a donor, including height, weight, and hematocrit. Such a system is patent-eligible. *E.g.*, *CardioNet, LLC v. InfoBionic, Inc.*, 955 F.3d1358, 1371 (Fed. Cir. 2020); *EcoServices, LLC v. Certified Aviation Serv., LLC*, 830 F. App'x 634, 642 (Fed. Cir. 2020).

Petitioner also fails to consider the claim elements in their totality, as required, at *Alice* step two. When considered as a whole, the challenged claims recite an inventive concept by reciting and implementing a novel approach of plasma collection, never before seen in the industry as the '916 Patent itself acknowledges. *See* EX1001 at 10:1-26 (noting “prior art plasmapheresis devices end plasma collection based on a total volume of anticoagulated plasma (*e.g.*, pure plasma plus the added anticoagulant)”). Thus, the challenged claims are not invalid under *Alice* step two either. *See Amdocs (Isr.) Ltd. v. Openet Telecom, Inc.*, 841 F.3d 1288, 1302 (Fed. Cir 2016) (claims must be considered as an “ordered combination”); *BASCOM Global Internet Servs., Inc. v. AT&T Mobility, LLC*, 827 F.3d 1341, 1350 (Fed. Cir. 2016). (“As is the case here, an inventive concept can be found in the non-conventional and non-generic arrangement of known-conventional pieces.”).

*Third*, Petitioner argues that certain challenged claims are invalid under 35 U.S.C. § 112 (Ground VII). Petitioner attacks a litany of claim elements under

Section 112, but each of its attacks fail as will be explained in detail in Patent Owner's Preliminary Response. As an example, Petitioner argues there is no support in the '916 written description for the claimed "plasma product." Pet. at 88-89. Petitioner acknowledges the term "plasma product" appears in the specification and that it understands the meaning of "plasma product" in the '916 Patent. *Id.* As such, there is no meaningful challenge that this term lacks written description support. Moreover, targeting "plasma product" based on a donor's individual characteristics is within the scope of the claimed invention and a far cry from prior art systems that did not individualize collection targets on a per-donor basis.

These deficiencies are exemplary of the weaknesses in the Petition. In its forthcoming Preliminary Response, Patent Owner expects to point to additional flaws in Petitioner's argument and explain why strong evidence of secondary considerations relating to Patent Owner's commercialized systems undermine Petitioner's obviousness arguments. Because the merits of the Petition are weak, this factor weighs in favor of exercising discretionary denial. Considered as a whole, the *Fintiv* factors weigh in favor of discretionary denial under 35 U.S.C. § 314(a).

### **III. CONCLUSION**

For the foregoing reasons, Patent Owner respectfully requests that the Board grant its request for discretionary denial of institution of the Petition.

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Respectfully submitted,

/Erik B. Milch/

Erik B. Milch (Reg. No. 42,887)

Proskauer Rose LLP

1001 Pennsylvania Ave., NW

Suite 600

Washington, DC 20004

Tel: (202) 416-6800

emilch@proskauer.com

Dated: November 17, 2025

*Attorney for Patent Owner*

**CERTIFICATE OF SERVICE**

Pursuant to 37 C.F.R. §§ 42.6(e) and 42.105, I hereby certify that on November 17, 2025, I caused a complete copy of Patent Owner's Brief Requesting Discretionary Denial of the Petition regarding U.S. Patent No. 12,171,916 and all exhibits, to be served on the Petitioner as follows:

*Via and Electronic Mail to Petitioner's attorneys of record:*

John M. Caracappa, Reg. No. 43,532  
jcaracappa@steptoe.com

Katherine D. Cappaert, Reg. No. 71,639  
kcappaert@steptoe.com

Matthew Y. Sim, Reg. No. 77,422  
msim@steptoe.com

Scott Chappell, Reg. No. 76,333  
schappell@steptoe.com

STEPTOE LLP  
1330 Connecticut Avenue N.W.  
Washington, D.C. 20036  
Tel: (202) 429-3000  
Fax: (202) 429-3902

/Erik B. Milch/  
Erik B. Milch (Reg. No. 42,887)