

Patent Owner's Brief Requesting Discretionary Denial
U.S. Patent No. 10,758,652

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

TERUMO BCT INC.,

Petitioner

v.

HAEMONETICS CORP.,

Patent Owner

Case No. IPR2025-01391

U.S. Patent No. 10,758,652

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

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List of Exhibits

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2001	Interim Processes for PTAB Workload Management, Coke Morgan Stewart (Mar. 26, 2025), <i>available at</i> https://www.uspto.gov/sites/default/files/documents/InterimProcesses-PTABWorkloadMgmt-20250326.pdf
2002	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)
2003	U.S. FDA Clears Terumo Blood and Cell Technologies' New Plasma Collection Technology, Terumo Global (Mar. 10, 2022), <i>available at</i> https://www.terumo.com/newsrelease/detail/20220310/683
2004	510(k) Summary, Rika Plasma Donation System, Terumo Blood and Cell Technologies (2021), <i>available at</i> https://www.fda.gov/vaccines-blood-biologics/substantially-equivalent-510k-device-information/cleared-510k-submissions-supporting-documents ; https://web.archive.org/web/20241109101055/https://www.fda.gov/media/156913/download?attachment
2005	510(k) Summary, Rika Plasma Donation System, Terumo Blood and Cell Technologies (2024), <i>available at</i> https://www.fda.gov/media/177027/download?utm
2006	Persona Plasma Collection Solution Brochure, Haemonetics Corporation (2020), <i>available at</i> https://plasma.haemonetics.com/-/media/files/plasma/persona_brochure.pdf .
2007	Information Disclosure Statement by Applicant, Application No. 18/644,259 (filed: Apr. 24, 2024)
2008	U.S. Patent No. 11,738,124, "System and Method for Collecting Plasma," to Michael Ragusa (filed: Sep. 13, 2022; issued: Aug. 29, 2023)

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Exhibit No.	Description of Document
2009	PCT Written Opinion of the International Searching Authority, No. PCT/US2024/026191 (Aug. 8, 2024)
2010	Letter from E. Milch to A. Gawin re Notice of Infringement of Haemonetics’ Plasma Collection Patents (Oct. 1, 2024)
2011	Lex Machina Motion Metrics Report for Patent Cases in the District of Colorado since Jan. 1, 2000, <i>available at</i> https://law.lexmachina.com/court/cod/motion-metrics/?filed_on-from=2000-01-01&case_types-include=27&filters=true&tab=federal_motion_metrics_motion_types&view=analytics (last accessed Oct. 8, 2025)
2012	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)
2013	Lex Machina Timing for Patent Cases in the District of Colorado since Jan. 1, 2009, <i>available at</i> https://law.lexmachina.com/court/cod/cases/?status=terminated&case_types-include=27&pending-from=2009-01-01&pending (last accessed Oct. 8, 2025)
2014	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), <i>available at</i> https://www.uspto.gov/sites/default/files/documents/guidance_memo_on_interim_procedure_rescission_20250324.pdf

I. INTRODUCTION

Patent Owner respectfully requests that the Board exercise its discretion to deny institution. The challenged patent, U.S. Patent No. 10,758,652 (the "'652 Patent") 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 '652 Patent issued, fully aware of Patent Owner's patent portfolio. The '652 Patent was filed in 2017, coinciding with Patent Owner's public announcement and commercialization of its patented plasma apheresis system.

The '652 Patent issued in 2020 and Patent Owner immediately marked its commercialized product with that patent. Petitioner then 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 '652 Patent is not speculative—it is undeniable.

Petitioner was also put on explicit notice of infringement concerning the '652 Patent over a year ago and cited to a continuation application of the '652 Patent in its own patent filings. Nevertheless, Petitioner made a strategic decision to wait,

filing its 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 '652 Patent 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. The Patent Office has already adjudicated the validity of the patent during prosecution, analyzing substantially the same prior art as Petitioner puts forth now. 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 Discretionary 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 '652 Patent's maturity, 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 '652 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. The plasma collection industry contains only three main competitors.

The '652 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 Kabi¹. Notably, Patent Owner has been a leader in this industry for over 20 years marketing its PCS[®]2 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 in this niche industry for 8 years.

“[T]here may be good reasons why a patent owner has strong settled expectations in a patent that has only been in force for [five] years” including “an

¹ Patent Owner has a pending district court litigation pertaining to plasma collection system patents against Fresenius Kabi. *See Haemonetics Corp. v. Fresenius Kabi USA, LLC, et al.*, No. 1:25-cv-08680 (N.D. Ill. July 25, 2025).

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. 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. 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[®] device with YES[®] technology in 2018, which provides higher plasma yields by stopping blood collection when a target pure plasma volume is reached (just like the '652 Patent). EX2002 ¶16. And in 2020, the same year the '652 Patent issued, Patent Owner released its NexSys[®] PCS device with PERSONA[®] 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”). Importantly, Petitioner was not merely aware of Patent Owner’s patented commercial system, it relied on it, expressly identifying 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, the ’652 Patent had already issued. EX1001; EX1002 at 1. 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. EX2004-2006. Patent Owner

began marking its devices five years ago, before Petitioner even released its competing system. EX2006. Despite years of awareness of Patent Owner's portfolio, and its clear relevance to Petitioner's plasma collection system, Petitioner has waited until now, after entering the market and facing litigation, to mount this challenge.

4. Petitioner monitors Patent Owner's patent portfolio and had actual knowledge of the '652 Patent.

Not only was Petitioner aware of the '652 Patent by virtue of its entry into this market as a competitor and Patent Owner's marking of its product with the '652 Patent, 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. EX2007 (citing US 2023/0001059 to Ragusa). The '124 Patent is a continuation of the '652 Patent. EX2008. 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. EX2009. 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. EX2007 (citing US 2022/0168,486 to Fenwal, Inc.).

Patent Owner also made Petitioner explicitly aware of Petitioner's infringement of the '652 Patent on October 1, 2024. EX2010. Nevertheless, Petitioner waited until after Patent Owner initiated the district court litigation in May 2025 to file its Petition in August 2025. *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. Considering the totality of the circumstances, Patent Owner has settled expectations.

The '652 Patent issued in 2020—over five years ago. EX1001. The maturity of the patent 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 (considering the fact that the patent has been in force since 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 render discretionary denial inappropriate. *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. 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”).

In sum, Petitioner entered the plasma collection industry in 2022 fully aware that Patent Owner had commercialized a patented system and marked its products with the '652 Patent since 2020. Since then, Petitioner analyzed and referenced Patent Owner's product marked with the '652 Patent, monitored Patent Owner's portfolio, cited a patent within this family in its own patent prosecution, and received a notice letter alleging infringement of the '652 Patent. Nevertheless, it intentionally waited until after litigation began to file this Petition. By that time, Patent Owner had long-established and reasonable settled expectations that the '652 Patent would not face a validity challenge in the patent office. Under these facts, discretionary denial is not only justified, but warranted.

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

In addition to the Patent Owner's settled expectations, the *Fintiv* factors 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 evidence a stay will be granted.

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. Petitioner has not moved for a stay and there are nine asserted patents in the district court litigation. EX2002. As of this filing, seven of those patents have been challenged via *inter partes* review or post-grant review. See IPR2025-01374, IPR2025-01420, IPR2026-00046, PGR2025-00077, PGR2025-00078, PGR2026-0006². Thus, there is no reason to believe the district court will stay the litigation where only some patents are subject to parallel proceedings. See *Samsung Elecs. Co. v. VB Assets, LLC*, IPR2025-00870, Paper 11 (Oct. 10, 2025) at 3 (discretionary denial was warranted where not all patents asserted in district court would be resolved by the Patent Office and “addressing all of the challenged patents in the district court proceeding would be the fastest and most efficient resolution of the Parties’ many disputes.”) (citation modified). Moreover, the case statistics for the District of Colorado indicate that a stay pending a Patent Office proceeding is not

² Patent Owner filed a request for a discretionary denial regarding IPR2025-01374. Patent Owner intends to file requests for discretionary denials in the other proceedings as well.

always granted. *See* EX2011 (stating a stay pending a PTO proceeding was granted in only 69% of cases).

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. The district court has given no indication that a stay will be granted (nor has one been requested); therefore, allowing both proceedings to proceed in parallel risks significant duplication of efforts and inconsistent outcomes. 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 February of 2027. Although there has been a Scheduling

Order entered in the district court, the Court has not yet set a trial date. EX2012. 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 (discretionarily denying the petition where no trial date was set). 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. EX2013.

“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, Inc.*, 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).

Moreover, even if the final written decision were to precede the district court trial, that would not necessarily reduce duplication of issues or eliminate the risk of inconsistent decisions. As explained above, Petitioner has only filed challenges against some of the asserted patents which are directed to similar plasma apheresis

systems. Thus, even if each challenge is instituted and disposed of prior to trial, the district court will still consider similar arguments and potentially the same prior art. And Patent Owner expects the issue of secondary considerations to be prominent in both forums. Given the risk of duplication and inconsistencies, this factor should not be given heavy weight against discretionary denial.

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 its infringement contentions and Petitioner's responses to those contentions are due next week. EX2012. Discovery has also begun, including written discovery and document productions. Prior to the expected institution decision in February 2026, the parties will have served invalidity contentions and responses, continued collecting and producing documents, and filed a joint disputed claim terms chart in preparation for the *Markman* hearing. *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 asserted patents and claims from a validity perspective. Accordingly, the parties and

the court have already invested in the parallel district court proceeding and this factor weighs in favor of discretionary denial.

4. Petitioner's *Sotera* stipulation is not dispositive.

On September 24, 2025, Petitioner submitted a Notice of Petitioner's *Sotera* Stipulation. *See* Paper 6. While Petitioner's *Sotera* stipulation is relevant to the *Fintiv* analysis, it is not dispositive. *See* EX2014; *see also Ericsson Inc. v. Procomm Int'l Pte. Ltd.*, IPR2024-01455, Paper 15 (May 16, 2025) (discretionarily denying institution despite a *Sotera* stipulation); *Arm Ltd. v. Daedalus Prime LLC*, IPR2025-00207, Paper 10 (May 16, 2025) (same).

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's primary references for all Grounds are the Takagi or the Lavender reference. *See generally* Pet. Both primary references fail to anticipate and/or render obvious the '652 Patent.

First, Petitioner argues the Takagi reference discloses a “true current plasma collection amount (Z)” which corresponds to the claimed volume of pure plasma. Pet. at 31. And, Petitioner argues that Takagi discloses a “true target plasma collection amount (D)” which corresponds to the claimed target volume of pure plasma. *Id.* Lastly, Petitioner avers that Takagi discloses continuing the collection and processing steps in claim 1(d)-(i) “until a target volume of pure plasma is collected within the plasma collection container” as required by claim 1 of the '652 Patent. *Id.* at 30-31. The plain language of Takagi—even as quoted in the Petition—undermines Petitioner's argument.

Takagi states that its control unit “determines whether the plasma collection has been completed” based on one of two options:

- (1)[Whether] the actual current plasma collection amount Z (ml) has reached $M(\%)$ of the actual target plasma collection amount D (mL), or
- (2)[W]hether the plasma collection operation has been performed over a certain number of cycles E (iterations)

EX1004 at [0130]-[0131] (citation modified). Takagi also states that the “ $M\%$ ” is “preferably 70 to 100%[.]” EX1004 at [0132]. Takagi, thus, discloses determining if a plasma collection is complete based on determining whether a *percentage* of the target amount has been reached or whether a certain number of cycles have been completed. Determining a collection is complete where 70% of the target plasma volume has been collected does not equate to continuing the process until the target

volume is collected. Petitioner fails to make this showing and fails to argue these teachings render this claim limitation obvious.

Even where Takagi acknowledges that M% may equal 100% of the target amount, Petitioner fails to connect the dots between a determination that the collection has been completed with a controller that stops the pump once that determination is made as required by claim 11[g]. EX1001 at cl. 11. Petitioner's sole argument regarding this limitation points back to its argument and citations regarding claim 1[j]. Pet. at 36. Petitioner fails to argue that, after the controller determines a certain volume has been reached, the controller then stops the pump.

Second, the Lavender reference is narrowly focused on solving an anticoagulant problem inherent in the prior art. EX1005. Specifically:

Because the plasma volume of whole blood varies with hematocrit, basing anticoagulant volume on the whole blood volume is, of necessity, inaccurate. Blood from donors with low hematocrits may receive too little anticoagulant and blood from donors with high hematocrits may receive too much.

Id. at 3:2-7. On the other hand, the '652 Patent improves upon "[p]rior art plasma collection systems [that] are unable to determine the total volume of plasma that has been collected (e.g., because the product collected is a mixture of plasma and anticoagulant) and, therefore collect based on the total collection volume[.]" EX1001 at 1:38-42. While the purpose of a patent is not necessarily coextensive with

everything it discloses, the juxtaposition of Lavender's and the '652 Patent's stated purposes underscores the differences between them.

In-line with its goal of collecting based on total plasma volume, the '652 Patent claims "the controller configured to calculate. . . a volume of pure plasma collected within the plasma container" and "configured to stop the blood draw pump when a target volume of pure plasma is collected within the plasma container." EX1001 at cl. 11³. Petitioner's argument concerning this limitation relies purely on an acronym in a calculation recited in Lavender. Pet. at 43; EX1005 at 43 (reciting "TPF (total plasma filtered, ml)"). The calculation refers to "total plasma filtered," which Petitioner argues corresponds with total plasma volume. Pet. at 43. This term—"TPF" or "total plasma filtered"—is not used in the other parts of Lavender's disclosure that explain when the system stops the blood draw. *See, e.g.*, EX1005 at 21:62-63 ("the program determines whether the desired weight of plasma has been collected.").

Contrary to Petitioner's suggestion and given the specific reference to "TPF" elsewhere in Lavender, a person of ordinary skill in the art ("POSITA") would not have understood the "volume of plasma" to correspond to TPF. The state of the art

³ This limitation is similar across both independent claims and treated the same in the Petition.

at the time of Lavender, as the '652 Patent explains, involved “prior art plasmapheresis devices [that] end plasma collection based on a total volume of anticoagulated plasma (e.g., pure plasma plus the added anticoagulant).” EX1001 at 9:55-58. Lavender, which is focused on identifying and adjusting the anticoagulant volume added to drawn donor blood, does not teach targeting and stopping a collection based on the volume of pure plasma alone. Considering Lavender and the state of the art, a POSITA would have understood Lavender's disclosures referring to stopping the collection based on an amount of plasma collected to mean the anticoagulated plasma volume. This is especially true where references to “TPF” to describe pure plasma are not used elsewhere in the reference.

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 as well as explaining 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 where factors 1, 3, 5, and 6 all support exercising discretion to deny the Petition under 35 U.S.C. § 314(a).

C. The Patent Office Has Already Adjudicated the Validity of the '652 Patent Based on Substantially the Same Art.

The validity of the '652 Patent was already adjudicated by the Patent Office. During the prosecution of the '652 Patent, the examiner considered similar references to those relied upon by Petitioner and determined the claims were valid. *See* EX1002.

For example, U.S. Patent App. Pub. No. 2003/0125881 to Ryan was analyzed by the examiner during prosecution of the '652 Patent. *Id.* at 46-53, 65-71. Both Takagi and Lavender, relied on by Petitioner, are “substantially the same art” as Ryan. *Advanced Bionics, LLC v. Med-el Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 (Feb. 13, 2020) at 13-14 (presenting “substantially the same art” as was previously considered by the Patent Office provides another basis for discretionary denial under 35 U.S.C. § 325(d)). During prosecution, applicant acknowledged that Ryan taught a similar system with similar hardware components to the patented invention; however, Ryan “calculates and stops based on a volume that includes both plasma and anticoagulant, not just pure plasma.” EX1002 at 39.

As explained above, Takagi and Lavender function the exact same way. Lavender's disclosed system targets total collection volume and stops when “the program determines whether the desired weight of plasma has been collected.” EX1005 at 21:62-63. A POSITA would have understood this “weight of plasma” to

correspond to the total weight of the plasma container (i.e., plasma and anticoagulant) and not simply the pure plasma component. As such, "Petitioner relies on [Lavender] in substantially the same manner as the Examiner cited [Ryan] during prosecution such that [Lavender] discloses substantially the same information as [Ryan] in relevant part." *Advanced Bionics*, IPR2019-01469, Paper 6 at 15. As explained above, Takagi does not even disclose that a pump is stopped when the pure plasma target volume is reached.

III. CONCLUSION

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

Respectfully submitted,

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Dated: October 24, 2025

Attorney for Petitioner

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§ 42.6(e) and 42.105, I hereby certify that on October 24, 2025, I caused a complete copy of Patent Owner's Brief Requesting Discretionary Denial of the Petition regarding U.S. Patent No. 10,758,652 and all exhibits, to be served on the Petitioner as follows:

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