UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

TERUMO BCT, INC.,

Petitioner

v.

HAEMONETICS CORP.,

Patent Owner

Case No. IPR2026-00046

U.S. Patent No. 10,980,926

PATENT OWNER'S BRIEF REQUESTING DISCRETIONARY DENIAL

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35 U.S.C. § 103 10

35 U.S.C. § 314(a) 2, 7, 11

List of Exhibits

Exhibit No.	Description of Document
2001	Interim Processes for PTAB Workload Management, Coke Morgan Stewart (Mar. 26, 2025), *available at* https://www.uspto.gov/sites/default/files/documents/InterimProcesses-PTABWorkloadMgmt-20250326.pdf
2002	Second Amended Complaint, *Haemonetics Corp. v. Terumo BCT, Inc.*, No. 1:25-cv-01409-RMR-SBP (D. Colo. Aug. 12, 2025), D.I. 48
2003	Persona Plasma Collection Solution Brochure, Haemonetics Corporation (2020), *available at* https://plasma.haemonetics.com/-/media/files/plasma/persona_brochure.pdf
2004	510(k) Summary, Rika Plasma Donation System, Terumo Blood and Cell Technologies (2021), *available at* 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), *available at* https://www.fda.gov/media/177027/download?utm
2006	U.S. FDA Clears Terumo Blood and Cell Technologies' New Plasma Collection Technology, Terumo Global (Mar. 10, 2022), *available at* https://www.terumo.com/newsrelease/detail/20220310/683
2007	Letter from E. Milch to A. Gawin re Notice of Infringement of Haemonetics' Plasma Collection Patents (Oct. 1, 2024)
2008	Lex Machina Motion Metrics Report for Patent Cases in the District of Colorado since Jan. 1, 2000, *available at* https://law.lexmachina.com/court/cod/motion-metrics/?filed_on-from=2000-01-01&case_types-

Exhibit No.	Description of Document
	include=27&filters=true&tab=federal_motion_metrics_motion_types&view=analytics (last accessed Nov. 14, 2025)
2009	Scheduling Order in a Patent Case, *Haemonetics Corp. v. Terumo BCT, Inc.*, No. 1:25-cv-01409-RMR-SBP (D. Colo. Aug. 19, 2025), D.I. 54
2010	Lex Machina Timing for Patent Cases in the District of Colorado since Jan. 1, 2009, *available at* https://law.lexmachina.com/court/cod/cases/?status=terminated&case_types-include=27&pending-from=2009-01-01&pending (last accessed Nov. 14, 2025)
2011	Guidance on USPTO's recission of "Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation," Scott R. Boalick (Mar. 24, 2025), available at https://www.uspto.gov/sites/default/files/documents/guidance_memo_on_interim_procedure_recission_20250324.pdf
2012	Voluntary Search Disclosure Declarations as a Favorable Factor in Institution Decisions, John A. Squires (Nov. 17, 2025), available at https://www.uspto.gov/sites/default/files/documents/vsdd_as_a_favorable_factor_in_institution_decisions.pdf?utm_campaign=subscriptioncenter&utm_content=&utm_medium=email&utm_name=&utm_source=govdelivery&utm_term=

I. INTRODUCTION

Patent Owner respectfully requests that the Board exercise its discretion to deny institution. The challenged patent—U.S. Patent No. 10,980,926 (the "'926 Patent")—was issued in April of 2021, over four years before Petitioner brought its *inter partes* review petition (the "Petition"). Petitioner did not even enter the highly concentrated plasma apheresis market with its competing product until one year after the '926 Patent issued and after Patent Owner had released its commercialized and product, which Patent Owner marked with the parent patent—U.S. Patent No. 10,758,652 (the "'652 Patent"). Petitioner was well aware of Patent Owner's portfolio and patented product and even used Patent Owner's marked product as a "reference device" in Petitioner's 510(k) submissions.

Additionally, Petitioner was put on explicit notice of the '926 Patent on October 1, 2024, over a year before Petitioner filed the Petition. Nevertheless, Petitioner waited until only after the district court litigation commenced to file the instant challenge. This deliberate delay undermines efficiency, fairness, and the integrity of the PTAB's discretionary framework. Because Petitioner has been aware of the '926 Patent for over four years, and the patent portfolio for even longer, Patent Owner had settled expectations that the '926 Patent would not be subjected to collateral attack and discretionary denial is appropriate.

The *Fintiv* factors further support discretionary denial. There is no indication that the district court will stay the parallel litigation, both parties have significantly 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 in Favor of Discretionary Denial.

There is no rigid formula for assessing "settled expectations" as the inquiry is highly fact dependent from one Petition to the next. While Patent Owner recognizes the Board's decision not to discretionarily deny Petitioner's first two petitions

challenging patents within this portfolio[1], Patent Owner respectfully urges that this later-in-time Petition warrants discretionary denial.

The '926 Patent issued in 2021, over four years before the Petition was filed. EX1001. Despite its adolescence, discretionary denial has been deemed appropriate for more recently-issued patents. *See WebGroup Czech Republic, A.S. v. DISH Techs. LLC*, IPR2025-00467, Paper 14 at 2 (July 16, 2025) (discretionarily denying an IPR petition challenging a patent that issued in 2023); *Milwaukee Elec. Tool Corp. v. Klein Tools, Inc.*, IPR2025-00724, Paper 14 at 2 (Sep. 12, 2025) (same); *Samsung Elecs. Co. v. Genghiscomm Holdings LLC*, IPR2025-00793, Paper 12 at 2 (Aug. 22, 2025) (that the patent issued in 2022 does not "tip the balance against discretionary denial").

Moreover, Petitioner was aware of the patent portfolio containing the '926 Patent since, at least, 2020 when Patent Owner began marking its commercialized product[2] with the '652 Patent. *See* EX2003. Petitioner was not merely aware of

[1] Notice of Decisions on Institution (Dec. 11, 2025), IPR2025-01374, IPR2025-01391.

[2] Patent Owner has invested significant resources into commercialization of its patented technology, including $64 million in research and development in 2024 alone. EX2002 ¶ 14. *See Empower Clinic Servs., L.L.C. v. Eli Lilly & Co.*,

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). And when Petitioner entered this industry in 2022 with its accused system, the '926 Patent had been published for two years and issued for one. EX2006; EX1001. *See Dabico Airport Sols. Inc. v. AXA Power APS*, IPR2025-00408, Paper 21 at 3 (June 18, 2025) ("[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.").

Petitioner was also put on notice of the '926 Patent, and Petitioner's infringement thereof, in October of 2024, over a year before the Petition was filed. EX2007. Patent Owner then initiated the district court litigation in May 2025. Petitioner still waited until October of 2025 to mount its invalidity challenge against the '926 Patent. *See Geotab Inc. v. Fractus, S.A.*, IPR2025-00928, Paper 11 at 2-3 (Sep. 12, 2025) (discretionarily denying institution where petitioner had a patent brought to its attention but did nothing until litigation began).

IPR2025-01024, Paper 15 at 2 (Oct. 10, 2025); *Amgen Inc. v. Bristol-Myers Squibb Co.*, IPR2025-00601, Paper 9 at 2 (July 24, 2025).

In sum, Petitioner entered the plasma collection industry in 2022 fully aware that Patent Owner had commercialized a patented system since 2020. Yet Petitioner waited over four years to challenge the '926 Patent. Despite receiving a notice letter alleging infringement of that patent in 2024, Petitioner still waited a year, until five months after litigation began to file this Petition. By that time, Patent Owner had reasonable, settled expectations that the '926 Patent would not face a validity challenge in the patent office. Under these facts, discretionary denial is justified**.**

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 at 7-17 (May 13, 2020); *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. On November 7, 2025, Petitioner moved for a stay in the district court, which Patent Owner opposed. The district court has not yet ruled on that pending motion and the case is advancing on schedule. There is no reason to believe the district court will stay the litigation pre-institution of any of the nine pending IPR and PGR proceedings. The case statistics for the District of Colorado indicate that a stay

pending a Patent Office proceeding is not always granted. *See* EX2008 (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. EX2009. 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 at 2-3 (Aug. 6, 2025) (vacating a discretionary denial only after the underlying litigation was dismissed); *Mim Software Inc. v. Exini Diagnostics AB, Inc.*, IPR2025-00827, Paper 12 at 2 (Aug. 22, 2025) (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 at 2 (July 29, 2025). 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 Pharms. Ltd. v. Atossa Therapeutics, Inc.*, IPR2025-00799, Paper 12 at 2 (Aug. 29, 2025) (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 April of 2027. Although there has been a Scheduling Order entered in the district court, the Court has not yet set a trial date. EX2009. 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 at 2-3 (July 29, 2025) (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. EX2010.

"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 at 5 (Mar. 20, 2020). 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 at 2-3 (Oct. 10, 2025) (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 its infringement contentions, Petitioner has served its responses to those contentions, and Petitioner has served its invalidity contentions. EX2009. Patent Owner's response to Petitioner's invalidity contentions will be served the day after this filing, on December 23, 2025. *Id.* In its response, Patent Owner has poured through the over 33,000 pages of Petitioner's invalidity contentions, responding to overlapping prior art arguments that Petitioner advances in its Petition and the other nine IPR and PGR proceedings.

Discovery has also begun, including written discovery and document productions. Prior to the expected institution decision in April 2026, the parties will have continued collecting and producing documents as part of discovery. Importantly, prior to the expected institution decision in April 2026, the parties will

have completed all *Markman* briefing and will be preparing for the claim construction hearing in May of 2026. *Id.*

Additionally, Petitioner filed a partial 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), D.I. 58, 63, 64. In considering this motion, the Court is currently substantively engaging with the '926 Patent from a validity perspective and with the specific patented technology at-issue. Accordingly, this factor weighs in favor of discretionary denial.

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

On December 2, 2025, Petitioner submitted a Notice of Petitioner's *Sotera* Stipulation. *See* Paper 8. While Petitioner's *Sotera* stipulation is relevant to the *Fintiv* analysis, it is not dispositive. *See* EX2011; *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 has challenged the '926 Patent under two Grounds, both of which rely on a combination of references. The primary reference for both Grounds is U.S. Patent No. 4,898,675 to Lavender ("Lavender"). Both of Petitioner's challenges fail to demonstrate a reasonable likelihood that any challenged claims are unpatentable.

First, Petitioner argues the challenged claims are invalid under 35 U.S.C. § 103 over Lavender in view of Fletcher-Haynes. Petitioner supports its obviousness arguments and motivation to combine Lavender and Fletcher-Haynes with a declaration of its expert, Dr. Gary Fletcher, and cites Dr. Fletcher's declaration (EX1003) for support throughout. *See generally* Pet. at 23-70. Dr. Fletcher's declaration, however, is nearly identical to the Petition itself, repeating Petitioner's argument verbatim in many instances. *See id.*; EX1003 ¶¶ 65-189. For example, despite repeatedly citing Dr. Fletcher's declaration for support and with the exception of a few extraneous and non-substantive words, the motivation to combine sections of the Petition and Dr. Fletcher's declaration are identical. *Compare* Pet. at 23-26 *with* EX1003 ¶¶ 65-73.

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) ("This court's opinions have repeatedly recognized that conclusory expert testimony is inadequate to support an obviousness determination on substantial evidence review.").

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—which Petitioner ignored in the Petition—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).

C. Petitioner's Search Disclosure Declaration Does Not Weigh Against Discretionary Denial.

On November 25, 2025, Petitioner filed a Search Disclosure Declaration ("SDD") pertaining to its Petition. Petitioner's SDD is neutral and does not weigh for or against discretionary denial.

The Director's SDD Memo states: "The voluntary submission of an SDD will be considered as a non-exclusive, non-dispositive favorable discretionary factor supporting institution, ***particularly where the SDD reveals new or underutilized pathways relevant to Office search practice***." EX2012 (emphasis added). In the Petition, however, all Grounds rely upon U.S. patents and publications which were equally available pathways to the Office during prosecution. *See* EX1004-1006. Accordingly, Petitioner's SDD does not weigh against discretionary denial.

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,

/Erik B. Milch/ Dated: December 22, 2025

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), I hereby certify that on December 22, 2025, I caused a complete copy of Patent Owner's Brief Requesting Discretionary Denial of the Petition regarding U.S. Patent No. 10,980,926 and all exhibits, to be served on the Petitioner as follows:

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

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