

Patent Owner's Brief Requesting Discretionary Denial
U.S. Patent No. 12,377,204

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

TERUMO BCT, INC.,

Petitioner

v.

HAEMONETICS CORP.,

Patent Owner

Case No. PGR2026-00006

U.S. Patent No. 12,377,204

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

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35 U.S.C. § 314(a) 1, 4, 11

List of Exhibits

Exhibit No.	Description of Document
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	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 Nov. 14, 2025)
2003	Scheduling Order in a Patent Case, <i>Haemonetics Corp. v. Terumo BCT, Inc.</i> , No. 1:25-cv-01409-RMR-SBP (D. Colo. Aug. 19, 2025), D.I. 54
2004	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 Nov. 14, 2025)
2005	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), <i>available at</i> https://www.uspto.gov/sites/default/files/documents/guidance_memo_on_interim_procedure_recission_20250324.pdf
2006	Voluntary Search Disclosure Declarations as a Favorable Factor in Institution Decisions, John A. Squires (Nov. 17, 2025), <i>available at</i> 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=go_vdelivery&utm_term=

I. INTRODUCTION

Patent Owner respectfully requests that the Board exercise its discretion to deny institution. The challenged patent—U.S. Patent No. 12,377,204 (the “’204 Patent”)—is one of nine patents asserted in the co-pending district court litigation.

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

The *Fintiv* factors¹ 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* EX2002 (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

¹ The Board routinely 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).

held a claim construction hearing and advanced even deeper into discovery. EX2003. 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); *see also Milwaukee Elec. Tool Corp. v. Klein Tools, Inc.*, PGR2025-00048, Paper 14 at 3 (Sept. 12, 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.*, PGR2025-00043, 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. EX2003. 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. EX2004.

“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).

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. EX2003. 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. Colo. May 5, 2025), D.I. 58, 63, 64. In considering this motion, the Court is currently substantively engaging with the ’204 Patent from a validity perspective, performing the exact analysis that Petitioner seeks from the Board in Ground V of its Petition. Pet. at 59-72. 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 Elecs. Corp. v. Vervain, LLC*, PGR2025-00010, Paper 14 at 3 (July 10, 2025). Moreover, Petitioner has already raised a duplicative invalidity theory before the district court—Section 101 invalidity—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* EX2005; *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 '204 Patent under eight 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 independent claims are invalid under 35 U.S.C. §§ 102, 103 over Fletcher-Haynes alone and/or in view of Lavender (Grounds I-II). Fletcher-Haynes and Lavender are also used as the primary references to render additional dependent claims invalid in Grounds I-IV. Petitioner supports Grounds I-IV with a declaration of its expert, Dr. Gary Fletcher, and cites Dr. Fletcher's declaration (EX1003) for support throughout. *See generally* Pet. at

19-58. 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 20-40 with EX1003 at ¶¶ 71-123 (the entirety of Ground I). 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.").

Petitioner's primary reference for Grounds I-IV—Fletcher-Haynes—also does not provide a strong basis for institution. Fletcher-Haynes is directed to a platelet collection system that uses "prediction algorithms" to "predetermine donor eligibility". EX1005 at 5:32-34. While Petitioner broadly concludes these algorithms are used to optimize plasma product (i.e., an optimized target value as claimed in the '204 Patent's independent claims), Fletcher-Haynes does not teach using prediction algorithms for this purpose. *See* Pet. at 28; EX1005 at 59:36-38 (referring to an "optimizer model" separate and apart from a prediction model).

Second, Petitioner argues that the challenged claims are invalid under 35 U.S.C. § 101 (Ground V). Petitioner already mounted this challenge against the '204 Patent in the co-pending district court litigation. As in the district court litigation, Petitioner has oversimplified the patented invention to “pen and paper calculations.” Pet. at 62. Petitioner, thus, ignores all the hardware elements of the claimed system in purportedly-representative claim 8. The challenged claims are directed to an 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. *See, e.g., CardioNet, LLC v. InfoBionic, Inc.*, 955 F.3d 1358, 1371 (Fed. Cir. 2020) (improved cardiac monitoring device); *EcoServices, LLC v. Certified Aviation Serv., LLC*, 830 F. App'x 634, 642 (Fed. Cir. 2020) (improved system for washing jet engines).

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 '204 Patent itself acknowledges. *See* EX1001 at 17:4-7 (noting “prior art systems . . . collect a volume of plasma product (e.g., anticoagulant and plasma mixed together) based solely on the weight of the donor”). 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 Glob. 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 (Grounds VI-VIII). 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, however, Petitioner argues there is no support in the '204 written description for the claimed “anticoagulated plasma target volume”. Pet. at 76-78. In making its argument, Petitioner repeatedly refers to the term “plasma product” instead of the claim term, “anticoagulated plasma target volume.” *Id.* Even still, Petitioner acknowledges that: (1) the term “plasma product” appears in multiple places in the patent specification; and (2) Petitioner understands the meaning of “plasma product” within the context of the '204 Patent. *Id.* As such, there is no meaningful challenge that this term, or the term “anticoagulated plasma target volume,” 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 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).

B. 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.*” EX2006 (emphasis added). In the Petition, however, all Grounds rely upon U.S. patents and publications which were

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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,

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Dated: December 22, 2025

Attorney for Patent Owner

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. 12,377,204 and all exhibits, to be served on the Petitioner as follows:

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