

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

TERUMO BCT INC.,

Petitioner

v.

HAEMONETICS CORP.,

Patent Owner

IPR2025-01391

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

**PETITIONER'S AUTHORIZED RESPONSE TO PATENT OWNER'S
REQUEST FOR DIRECTOR REVIEW**

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EXHIBIT LIST

Exhibit	Reference
1001	U.S. Patent No. 10,758,652 (“’652 patent”)
1002	File History of the ’652 patent
1003	Declaration of Dr. Gary D. Fletcher in Support of Petition
1004	Japanese Patent Publication No. JP 2002-282352 A including certified English translation and declaration by Japanese translator (“Takagi”)
1005	U.S. Patent No. 4,898,675 (“Lavender”)
1006	U.S. Patent No. 8,075,468 (“Min”)
1007	U.S. Patent Publication No. 2003/0125881 (“Ryan”)
1008	U.S. Patent No. 9,370,324 (“Barrett”)
1009	U.S. Patent No. 6,296,602 (“Headley”)
1010	“Membrane versus centrifuge-based therapeutic plasma exchange: a randomized prospective crossover study,” Carsten Hafer et al., Int. Urol. Nephrol (2016) 48:133-138; Springer Science+Business Media Dordrecht 2015.
1011	U.S. Patent Publication No. 2017/0029762 (“Turgut”)
1012	“Volume Limits – Automated Collection of Source Plasma,” November 4, 1992, Memorandum issued by the FDA Center for Biologics Evaluation and Research, Docket Number FDA-2013-S-0613.
1013	Bruce C. McLeod, MD, et al., “Apheresis: Principles and Practice,” 3rd Edition, AABB Press 2010.
1014	Sergent SR, Ashurst JV. Plasmapheresis. [Updated 2023 Jul 10]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK560566/?report=printable
1015	Curriculum Vitae (“CV”) of Dr. Gary D. Fletcher
1016	U.S. Patent Publication No. 2012/0175313 (“Barry”)
1017	Search Disclosure Declaration (Filing Party and Board Only)
1018	Redacted Search Disclosure Declaration
1019	Corrected Declaration of Dr. Gary D. Fletcher in Support of Petition

Petitioner Terumo BCT, Inc. ("Petitioner" or "Terumo") opposes Patent Owner's Request for Director Review to Vacate Institution regarding U.S. Patent No. 10,758,652 (the "'652 Patent"). See Paper 19, EX3100.

I. Introduction

Patent Owner incorrectly asserts that Terumo's positions for the term "controller" in this proceeding and in *Haemonetics Corp. v. Terumo BCT, Inc.*, Case No. 1:25-cv-01409-RMR-SBP (D. Colo. filed May 5, 2025) (the "District Court Litigation") are inconsistent and that this warrants vacating institution. First, the term "controller" is not in controversy, and its construction is immaterial to the prior art analysis. As Terumo explained, at least Lavender and Takagi disclose a "controller." Patent Owner does not dispute this, and the Director agreed.

Second, this remains true under any reasonable interpretation of "controller," including the interpretation advanced in the District Court Litigation months after Terumo's filing of this IPR Petition. Terumo's positions here and in District Court are not at odds with each other. As Terumo explains through its discussion of Lavender and Takagi, a "controller" can be a computing device like a microprocessor and/or control unit. There is no dispute that these "controllers" exist in the prior art. But the scope of the '652 patent does not limit a "controller" to *only* these types of devices. Instead, it states that a "controller" could encompass a human technician. While this scope would render the claims invalid as indefinite, this

argument is irrelevant to the instant proceeding as Terumo's IPR Petition would succeed regardless of whether "controller" encompasses more than computing devices. In other words, while the district court needs to determine whether "controller" is sufficiently definite for the jury to properly understand the scope of the claimed technology, this issue is irrelevant to this IPR. Accordingly, and as more fully set forth below, the Director should deny Patent Owner's request and maintain its institution decision.

II. Statement of Facts

This IPR is just one part of an ever-evolving patent litigation. In its initial district court Complaint, Patent Owner asserted seven patents against Terumo. Then, within three months, Patent Owner filed two Amended Complaints that together added two additional patents, bringing the total number of asserted patents in that case to nine. Patent Owner admits that the case is too large for trial. *Id.*, Dkt. No. 67, at 2. Terumo agrees.

So, in an effort to narrow the issues between the parties, Terumo filed IPRs and PGRs on all nine asserted patents within months of Patent Owner's original May 2025 Complaint. Two of the IPRs have instituted, six survived discretionary denial considerations, and one is pending discretionary denial considerations.

A. The Petition applies a "plain and ordinary meaning" to "controller" that includes computing devices.

Claim 8 recites "a controller configured to control the operation of the blood

component separation device” and “to calculate (1) a volume of anticoagulant in the collected plasma component . . . and (2) a volume of pure plasma collected within the plasma container” EX1001, '652 Patent, Cl. 8. The '652 specification describes a computing device that performs these claimed calculations. Paper 1 at 5, 7-8 (citing EX1001, at 8:1-9:40). For example, the controller may be a device as shown in FIG. 3 coupled to a fluid pump, a blood separation device, and a user interface. EX1001, FIG. 3; 5:29-33. It is undisputed that a controller meeting the specification's “device” description falls within the scope of claim 8.

The Petition's Invalidity Grounds focus on prior art describing such a device. *See, e.g.*, Paper 1 at 10-11. For example, the Petition identifies Takagi's control unit 55 that controls fluid supply pumps 11, 12 and the operation of the centrifuge drive unit 10 and explains that control unit 55 performs the claimed functions of calculating anticoagulant volume and pure plasma volume. Paper 1 at 35 (citing EX1004 ¶[0062], 12 (annotating EX1004, FIG. 1)); 27-30 (citing EX1004 ¶¶[0119], [0126]-[0128]). Takagi's control unit 55 is also coupled to user interface components like input means 3. (EX1004, ¶[0063]). The Petition also identifies Lavender's microprocessor 301 coupled to a blood pump 308, fractionator 25, and various user inputs, and explains that microprocessor 301 calculates anticoagulant volume and pure plasma volume. Paper 1 at 16-19, 38, 51-52; 44-45 (annotating EX1005, FIG. 20 and citing, *e.g.*, EX1005, 5:42-52; 10:58-11:6; 16:5034-53; 16:60-17:2; 17:14-

16; 20:58-46; 18:27-64; 20:35-68; 22:35-46; 41:1-44:3342; FIGS. 1, 20.)

Tellingly, nowhere in its pre-institution briefing or even its Request for Director Review does Patent Owner argue that Takagi and Lavender do not recite a “controller.” Similarly, the Director found that Terumo’s arguments had merit, instituting this IPR on January 27, 2026. Thus, there is no controversy as to the meaning of “controller” for the purposes of this proceeding.

B. While Patent Owner injected ambiguity into the outer bounds of the scope of “controller,” it is not relevant here.

Patent Owner drafted the '652 patent to stretch the scope of “controller” to include not only devices, like those in the prior art, but also “technician/system 100” that calculates the claimed anticoagulant volume and pure plasma volume. *See* EX1001, 8:9-10 (defining “technician or the system 100” as a “controller”); 8:37-56 (describing “technician/system 100” determining a volume of anticoagulant and calculating volume of pure plasma); *see also id.* at 1:31-38 (describing historical plasma limits, which were calculated manually). By grouping “technician” and “system” together and denoting both as numeral “100,” Patent Owner created ambiguity about whether the claimed “controller” encompasses devices, like those in the prior art, as well as human technicians. Terumo explained this to the District Court in its Motion to Dismiss. *See generally* District Court Litigation, Dkt. 58. Terumo similarly raised this argument in PGRs on related patents (PGR2025-00077, PGR2025-00078, PGR2026-00006, and PGR2026-00009). *E.g.*, PGR2025-00077,

Paper 1, at 82–86.

In response, Patent Owner acknowledged that a technician can perform the claimed functions. But it went on to argue, without citation, that the technician could not do it alone, but needed equipment to perform certain other claim limitations, like separating plasma. District Court Litigation, Dkt. 63, at 24-25; PGR2025-00077, Paper 9 at 51-58. To this day, it appears Patent Owner maintains that the claims are directed to a machine that performed all claimed functions, and not a human. District Court Litigation, Dkt. 63, at 28–30; PGR2025-00077, Paper 9 at 51-58. This position, however, not only departs from the specification but is internally inconsistent—acknowledging that a technician can perform certain claimed calculations while simultaneously insisting that the claims are directed solely to a device performing all claimed functions.

In light of the specification Patent Owner drafted, and positions that Patent Owner has taken in the District Court, Terumo informed the Court that the scope of the claimed “controller” in the ’652 patent is indefinite, including under § 112(f) (EX2021) because the scope of “controller” is broad enough to encompass computing devices (like a microprocessor) and *also* humans. If the District Court agrees, then the patent would be invalid. *See Lone Star Tech. Innovations, LLC v. Asustek Comput. Inc.*, No. 6:19-CV-00059-RWS, 2020 WL 6811484, at *14 (E.D. Tex. July 31, 2020) (finding claim indefinite because “viewer” meant “a user or

person”); *CytoLogix Corp. v. Ventana Med. Sys., Inc.*, 424 F.3d 1168 (Fed. Cir. 2005) (finding “temperature controller” indefinite under § 112, ¶ 6); *Dionex Softron GmbH v. Agilent Techs., Inc.*, 811 F. App'x 630 (Fed. Cir. 2020) (similar).

Regardless, Terumo's proposed District Court construction of “controller” is not inconsistent with how it is interpreted here. Here, Terumo alleges, and Patent Owner and the Director agree, that the claimed “controller” includes computing devices, like those in Takagi and Lavender. Whether “controller” is broader, and also encompasses humans, need not, and in fact, cannot be resolved by the PTAB. Instead, this argument, raised to specifically clarify the scope of the '652 patent in view of Patent Owner's positions, must be resolved by the District Court.

III. Argument

The issues Patent Owner raises share the same misplaced premise: that Terumo is attempting to game the system. It is not. Terumo has complied with regulatory requirements, *Revvo*, and *Tesla* by interpreting “controller” to include at least a microprocessor or control unit. No party disagrees that “controller” should include at least those devices. And no party has asserted that this is a disputed claim term. If anything, it is Patent Owner that is using its Request to take another bite at already-decided issues and to force a bright line rule—that petitioners cannot, in any circumstances, advance **any** legal theories in District Court that are not identical to those raised in post-grant proceedings. Terumo respectfully requests that the

Director decline Patent Owner's invitation to create such a bright line rule.

A. The term “controller” is not in dispute here and Terumo's positions here and in the District Court Litigation are consistent.

Patent Owner does not dispute that a “controller” is a device. Patent Owner also does not dispute that the prior art discloses this device. Therefore, this term, and its application to the prior art, is not in controversy here. As such, Terumo was not required to construe the term “controller” in its Petition. Whether “controller” encompasses more than just the types of devices disclosed in the prior art, however, is at issue in the District Court Litigation. But because the Board can assess whether the prior art discloses a “controller” without resolving the ambiguity that Patent Owner injected into its scope, assessing the full scope of “controller” is irrelevant to this proceeding.

1. There is no controversy regarding whether a “controller” is disclosed in the prior art.

Patent Owner's Request attempts to manufacture a controversy that does not exist here. Patent Owner does not dispute that the Petition's prior art identifies devices that fall squarely within the scope of a “controller.” That alone resolves the 37 CFR § 42.104(b)(3) issue, because while 37 CFR § 42.104(b)(3) requires “a statement of the precise relief,” including “[h]ow the challenged claim is to be construed,” that applies to “only those terms . . . that are in controversy, and only to the extent necessary to resolve the controversy.” *Realtime Data, LLC v. Iancu*, 912

F.3d 1368, 1375 (Fed. Cir. 2019). To be clear, and as explained below, the term would *still* be undisputed *even if* the PTAB were to apply the District Court construction, because whether “controller” *also* encompasses humans is irrelevant here—the Petition’s prior art involves devices (not humans) that fall within any reasonable interpretation of controller. The question for the District Court of whether this stretched scope renders “controller” indefinite does not create a controversy here.

Patent Owner’s cases asserting otherwise are distinguishable. For example, in *Orthopediatrics* the Board was forced to construe the term “grasping members” under a means-plus function interpretation because its “construction [was] necessary to resolve the controversy” as Patent Owner argued the prior art did not disclose “grasping members.” *Orthopediatrics Corp. v. K2M, Inc.*, IPR2018-01546, Paper 10 at 6–7, 9–10 (Feb. 14, 2019). That is not the case here. Here, the facts are much more similar to two related proceedings, where the PTAB did not construe the same term “because it was not in controversy.” *Id.*; see *Orthopediatrics Corp. v. K2M, Inc.*, IPR2018-00429, Paper 8 at 6 (Jun. 28, 2018); *Orthopediatrics Corp. v. K2M, Inc.*, IPR2018-00521, Paper 8 at 8 (Jun. 28, 2018). Like those cases, it is not disputed that the prior art includes a “controller” and there is thus no controversy regarding the interpretation of this term.

Further, while the 2019 Consolidated Trial Practice Guide (CTPG) instructs

petitioners to provide a construction where language may be construed under § 112(f), the Federal Circuit has reinforced that this applies only when the limitation “necessitates” construction and has found compliance even where no specific construction was provided despite a presumption that § 112(f) applied. *See Masimo Corp. v. Sotera Wireless, Inc.*, 2023 WL 6990542, at *4 (Fed. Cir. Oct. 24, 2023). Similarly, where a petitioner sufficiently identified the structure and function when discussing the challenged patent, the petition was found to comply with § 42.104(b)(3) even without proposing a construction. *Am. Nat'l Mfg. Inc. v. Sleep No. Corp.*, 52 F.4th 1371, 1385 (Fed. Cir. 2022); *Am. Nat'l Mfg. Inc. v. Sleep No. Corp.*, IPR2019-00500, Paper 114, at 18–19, 22–26 (Sep. 30, 2020).

In fact, the cases applying the CTPG to deny institution concern situations where the term is “case dispositive,” where petitioner takes “opposite positions” and advances a narrower construction in district court, and/or where petitioner knew “by the time it filed its Petition” that the term would be in dispute. *See Cambridge Mobile Telematics, Inc. v. SFARA, Inc.*, IPR2024-00952, Paper 12 at 7–8 (Dec. 13, 2024) (claim term was a “case dispositive” issue); *10X Genomics v. President and Fellows of Harvard Coll.*, IPR2023-01299, Paper 15 at 9, 11 (Mar. 7, 2024). None of those facts exists here. The term “controller” is not in dispute, there is a presumption that §112(f) does *not* apply, Terumo has sufficiently described the “controller” in the background section of its Petition, and has (indisputably) identified devices that meet

this limitation. Further, Terumo's district court construction is broader, not narrower, than the meaning used in this proceeding, meaning it is not "logically impossible" for the Board to assess the prior art. *See* Paper 1 at 7-11, 16, 27-35, 44-52.

Again, the issue here is whether "controller" includes a device. All parties agree that it does, and that this device is in the prior art. The question for the District Court lies at the "outer bounds" of the scope of the claim term. *Intel Corp. v. Qualcomm Inc.*, 21 F.4th 801, 813 (Fed. Cir. 2021) ("The indefiniteness of a limitation (here, a means-plus-function limitation) precludes a patentability determination only when the indefiniteness renders it logically impossible for the Board to reach such a decision."); *see Tesla, Inc. v. Intellectual Ventures II LLC*, IPR2025-00340, Paper 18, at 3–4 (Nov. 5, 2025) (different constructions may be permitted "if the limitation prescribed a range and only the outer bounds of the range were unclear"). Neither Patent Owner, Terumo, nor the PTAB need to reach this question to decide if "controller" is in the prior art. The Parties all agree that it is.

2. Terumo's positions are not "opposite" nor do they reflect gamesmanship; thus *Revvo* and *Tesla* permit institution.

Patent Owner seeks to transform *Revvo* and *Tesla* into a bright-line prohibition that unless the positions in district court are identical to those at the PTAB, institution should be denied. The Director has never endorsed such a rule. And while *Revvo* and *Tesla* arguably reflect increased Board scrutiny where petitioners raise different issues in these forums, "the mere fact that Petitioner has done so" does not preclude

institution. *10X Genomics*, IPR2023-01299, Paper 15 at 11; *Revvo Techs., Inc. v. Cerebrum Sensor Techs., Inc.*, IPR2025-00632, Paper 20 at 3–4 (Nov. 3, 2025) (noting the Board's trial rules "do not necessarily prohibit petitioners from taking inconsistent" positions); *Tesla*, IPR2025-00340, Paper 18 at 3–4 (recognizing different positions may be warranted).

Revvo's primary concern is gamesmanship where petitioners are "seeking broader constructions at the Board to support a patentability challenge while seeking narrower constructions in litigation to avoid infringement liability." *Revvo*, IPR2025-00632, Paper 20 at 4. *Tesla* extends this reasoning where an indefiniteness position is raised and cautions that the fact that indefiniteness cannot be raised in IPRs does not **alone** justify taking different positions in different venues. *Tesla*, IPR2025-00340, Paper 18 at 3–4; *see also Cochlear Bone Anchored Sols. AB v. Oticon Med. AB*, 958 F.3d 1348, 1360 (Fed. Cir. 2020)).

Patent owner's cited post-*Tesla* and post-*Revvo* decisions apply the above-discussed rationales, denying institution only where a petitioner takes opposite or irreconcilable positions. *Generac Power Sys. v. Champion Power Equip., Inc.*, IPR2025-00805, IPR2025-00951, Paper 40 at 4–5 (Feb. 3, 2026); *Orca Security Ltd., v. Wiz, Inc.*, IPR2025-01086, Paper 13 at 9 (Dec. 15, 2025) (arguing construction "*arguendo*" for "the sake of this Petition only"). For example, in *Generac* the Director faulted petitioner for arguing both that the terms at issue had

specific definitions in the specification and were also indefinite. *See Generac Power Systems*, IPR2025-00805, IPR2025-00951, Paper 40 at 4–5. That is not the case here. Terumo's positions are not opposite, and in fact can be explained. Here, Terumo is arguing that Patent Owner invoked §112(f) functional claiming and, in doing so, injected uncertainty as to whether the structure for performing the claimed functions includes humans.

Additionally, while Patent Owner casts aspersions of “gamesmanship” and argues that Terumo asserts “the exact opposite claim construction argument” in the District Court Litigation, it does not, nor can it, support these arguments. *See* Paper 19 at 3, n.1; 5. That is because Terumo's positions are not opposite, and Terumo is not gaming the system. Terumo's IPR position is *narrower* because it limits the prior art analysis to typical controller devices, which are not excluded from the District Court Litigation scope. This is thus the exact opposite of the concern in *Revvo* and post-*Revvo* cases. *Revvo*, IPR2025-00632, Paper 20 at 4. To be clear, Terumo's approach reflects one of caution and promotes efficient use of Board resources. Terumo has limited its prior art universe to those references disclosing devices. Both the Patent Owner and the PTAB agree that the cited references disclose a controller.

Critically, if the scope advanced in the District Court Litigation were advanced here (i.e. that the “controller” includes both devices and humans), that would not change the analysis as it pertains to Lavender and Takagi, rendering any

indefiniteness analysis of the outer bounds of the scope a waste of resources.

Moreover, given that IPRs do not concern indefiniteness, the District Court is in a better position to assess whether Patent Owner is entitled to a narrower plain and ordinary “device” meaning or has instead invoked generic functional claiming with a broader scope that includes humans. By construing this term in the District Court Litigation, that Court can clarify the scope and resolve ambiguities for the jury.

In fact, the Director in *Tesla* contemplated this exact situation. *Tesla* recognizes that different positions would be permitted “if Petitioner had shown that, notwithstanding the alleged indefiniteness of the claim term, an ordinarily skilled artisan would understand that the asserted art satisfies the claim limitation (such as if the limitation prescribed a range and only the outer bounds of the range were unclear).” *Id.* at 3–4. This is precisely what we have here. By arguing a narrower “device” interpretation at the PTAB, and by grounding indefiniteness in whether the “outer bounds” of its scope includes a human, Terumo is arguing that “an ordinarily skilled artisan would understand that the asserted art satisfies the claim limitation such as if the limitation prescribed a range” while “only the outer bounds of the range [is] unclear.” *Tesla* at 3–4. Moreover, because both Parties understand the devices of the prior art meet the limitation, this is not a case where indefiniteness at the outer edges renders it “logically impossible” to apply prior art. *Revvo* and *Tesla* thus permit different positions and the Director should maintain institution.

B. Patent Owner attempts to re-hash their flawed arguments regarding the Petition's merits that the Director already rejected.

The Director has already reviewed and rejected Patent Owner's arguments regarding purported deficiencies with the Petition. *See* Paper 19 at 13-14; Paper 8 at 9-28; Paper 7 at 14-18; Paper 15 at 2. These arguments still lack merit.

Patent Owner again alleges that Dr. Fletcher's declaration duplicates the Petition. Paper 19 at 13; Paper 7 at Paper 8 at 10. This argument was, and still is, unconvincing. Dr. Fletcher provides a reasoned analysis highlighting how a person of ordinary skill would recognize that nothing new or novel is claimed. While the Petition cites the same disclosures, the textual overlap reflects that Terumo relied on Dr. Fletcher's analysis in preparing the Petition, not that it is improper or conclusory.

Patent Owner similarly repeats its allegation that the Petition "provid[es] only conclusory assertions with no analysis." Paper 19 at 14. This too is false and has already been rejected. Terumo provided numerous reasons why the claims of the '652 patent are either anticipated or obvious over the Takagi or Lavender references alone, and further why a POSITA would be motivated to combine Takagi or Lavender with Min or the other relied-upon prior art references. *See generally* Paper 1 at 23-73; *see also* Paper 9 at 16-19. For example, the Petition explains that "a POSITA would have been motivated to combine Takagi with Min's teachings of using weigh sensors 246 to track weight changes and derive fluid processing volumes, including volume changes of anticoagulant container 276 and plasma

collection container 304. . . it would have been an obvious design choice to use Min's anticoagulant monitoring scale in Takagi's blood component collection device to improve the accuracy of determining pure plasma volume based on the added anticoagulant volume." See Paper 2 at 58-59.

As the Petition describes, Takagi and Min "each relate to the well-known technologies of separating blood components . . . That is, combining Takagi and Min entails the use of known solutions to improve similar systems and methods in the same way, i.e., to use Min's technique of monitoring the weight of an anticoagulant bag to determine a volume of added anticoagulant to whole blood before separating blood components." Paper 1 at 58. This detailed analysis bears no resemblance to the situation in *Xerox Corp. v. Bytemark, Inc.*, where the petitioner failed to cite evidence to support obviousness and raised new arguments when it requested rehearing, highlighting its failure to raise sufficient arguments in the Petition. IPR2022-00624, Paper 12 (Feb. 10, 2023). That is not the situation here.

Contrary to Patent Owner's suppositions, Terumo's articulated reasoning for why the claims of the '652 patent are invalid is not only legally sufficient, but compelling and goes preciously to the legislative purpose of *inter partes* review proceedings – to eliminate patents that never should have been granted.

IV. Conclusion

For the foregoing reasons, Terumo asks the Director to maintain institution.

Date: February 18, 2026

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned certifies service pursuant to 37 C.F.R. §§ 42.6(e) and 42.105(b) on the Patent Owner on February 18, 2026 by filing a copy of this
AUTHORIZED RESPONSE TO PATENT OWNER'S REQUEST FOR
DIRECTOR REVIEW through the P-TACTS platform and served a true and correct
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