

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

TERUMO BCT INC.,

Petitioner

v.

HAEMONETICS CORP.,

Patent Owner

PGR2025-00078

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

PETITIONER'S AUTHORIZED PRELIMINARY SUR-REPLY

TABLE OF AUTHORITIES

Cases	Page(s)
<i>10X Genomics v. President & Fellows of Harv. Coll.</i> , IPR2023-01299, Paper 15 (Mar. 7, 2024)	2
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37 C.F.R. § 42.104(b)(3)	1

EXHIBIT LIST

Exhibit	Reference
1001	U.S. Patent No. 12,171,916 (“’916 Patent”)
1002	File History of the ’916 Patent
1003	Declaration of Dr. Gary Fletcher in Support of Petition
1004	U.S. Patent No. 4,898,675 (“Lavender”)
1005	U.S. Patent No. 7,072,769 (“Fletcher-Haynes”)
1006	U.S. Publication No. 2002/0033370 (“Bainbridge”)
1007	U.S. Patent No. 10,195,319 (“Kimura”)
1008	U.S. Patent No. 6,743,192 (“Sakota”)
1009	“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.
1010	Curriculum Vitae (“CV”) of Dr. Gary D. Fletcher
1011	Bruce C. McLeod, MD, et al., “Apheresis: Principles and Practice,” 3rd Edition, AABB Press 2010.
1012	Japanese Patent Publication No. JP 2002-282352 A and certified Japanese to English translation (“Takagi”)
1013	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
1014	Search Disclosure Declaration (Filing Party and Board Only)
1015	Redacted Search Disclosure Declaration
1016	Persona, Plasma Collection Solution Brochure
1017	U.S. Patent No. 12,186,474
1018	Full File History of U.S. Patent No. 10,758,652
1019	Full File History of U.S. Patent No. 12,377,204
1020	U.S. Patent No. 10,980,926 (“Ragusa”)
1021	PTAB Notice of Decisions on Institution, Dec. 11, 2025

Petitioner's Authorized Preliminary Sur-Reply

Patent Owner incorrectly asserts that (i) Terumo violates 37 C.F.R. § 42.104(b)(3) and (ii) takes irreconcilable claim construction positions for the terms “controller” and “control system” 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”) and in this proceeding. Terumo does not.

First, Terumo complies with 37 C.F.R. § 42.104(b)(3) because the terms “controller” and “control system” are not in controversy. 37 C.F.R. § 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).

Regarding “controller,” Terumo explains that Fletcher-Haynes’s “controller” can be a computing device. *E.g.*, Paper 1 at 24–29, 31, 33–37, 54–56. There is no dispute that these “controllers” exist in the prior art, and Patent Owner does not dispute that Fletcher-Haynes discloses a “controller.” *See generally* Paper 11. But the ’916 patent does not limit a “controller” to *only* devices, and states it could encompass a human technician. EX1001, 8:25–33, 8:62–9:4. While this scope would render the claims indefinite, Terumo’s Petition would succeed regardless of whether “controller” also encompasses humans. As there is no controversy, Terumo was not required to construe the term “controller” in its Petition.

Petitioner's Authorized Preliminary Sur-Reply

For “control system,” Patent Owner does not dispute Terumo’s mapping of the term to generic prior art features used to control apheresis procedures. Thus, it is not in controversy here. *E.g.*, Paper 1 at 30; *see also generally* Paper 11. But “control system” does not appear in the ’916 patent’s specification, and it seems Patent Owner incorporated the term in its own patent family based on a competitor’s patent by replacing “donor management system” with “control system.” *Compare, e.g.*, EX1001, Cl. 1 *with* U.S. Patent No. 11,285,251, Cl. 1. While the unbounded nature of “control system” may render it indefinite, its construction is irrelevant to the instant proceeding and it need not be construed here.

This explanation satisfies *Revvo* and its progeny. The mere fact that Terumo has raised different issues in different forums does not preclude institution. *10X Genomics v. President & Fellows of Harv. Coll.*, IPR2023-01299, Paper 15 at 11 (Mar. 7, 2024); *Revvo Techs., Inc. v. Cerebrum Sensor Techs., Inc.*, IPR2025-00632, Paper 20 at 3–4 (Nov. 3, 2025); *Tesla, Inc. v. Intell. Ventures II LLC*, IPR2025-00340, Paper 18 at 3–4 (Nov. 5, 2025). Patent Owner’s cited post-*Tesla* and post-*Revvo* decisions deny institution only where a petitioner takes irreconcilable positions. *Generac Power Sys. v. Champion Power Equip., Inc.*, IPR2025-00951, Paper 38 at 4–5 (Feb. 3, 2026). But, *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)." *Tesla*, IPR2025-00340, Paper 18, at 3–4. This is precisely what we have here.

Second, Terumo's positions have been consistent. Terumo states that a "controller" encompasses a human technician performing math and challenges the scope of the '916 patent before under § 101, consistent with its § 112(f) construction position that a controller can be a human or a computer. *See, e.g.*, Paper 1 at 72–84. Likewise, since the term "control system" lacks any specification support, Terumo maps it to generic prior art features used to control apheresis procedures, which are undisputedly found in the prior art.

Further, these positions were driven by Patent Owner's own litigation antics. Patent Owner characterizes the claims as requiring a specialized, structural "controller" and asserts the claimed operations cannot be performed mentally, ignoring the specification's express discussion of a technician being a "controller." *E.g.*, Paper 11 at 43, 50–51. Likewise, Patent Owner defines "control system" in a way to manufacture written description support despite none being present in the '916 patent. *E.g., id.* at 61–62. These antics drove the need for the District Court to assess the scope of both terms potentially under § 112(f).

For at least the foregoing reasons and for the reasons Terumo outlined in its Petition (Paper 1), institution of a trial is warranted.

Petitioner's Authorized Preliminary Sur-Reply

Respectfully submitted,

Date: February 26, 2026

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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 26, 2026 by filing a copy of this PETITIONER'S AUTHORIZED PRELIMINARY SUR-REPLY through the P-TACTS platform and served a true and correct copy of the foregoing by electronic mail on the following counsel for Patent Owner:

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