

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PARAGON 28, INC.,
Petitioner,

v.

TREACE MEDICAL CONCEPTS, INC.
Patent Owner.

PGR2026-00017
Patent 12,268,397

**PATENT OWNER'S REPLY TO PETITIONER'S DISCRETIONARY
DENIAL OPPOSITION**

PATENT OWNER'S UPDATED LIST OF EXHIBITS

Exhibit No.	Description
2001	<i>Treace Medical Concepts, Inc. v. Zimmer Biomet Holdings, Inc. and Paragon 28, Inc.</i> Initial Complaint, dated May 12, 2025
2002	U.S. Patent No. 12,349,941 to Dayton, <i>et al.</i> (the “’941 Patent”)
2003	McGlamry’s Comprehensive Textbook of Foot and Ankle Surgery, Chapters 1 and 13, Vol. 1, 5th Edition, 2022 (“McGlamry”)
2004	<i>Treace Medical Concepts, Inc. v. Zimmer Biomet Holdings, Inc. and Paragon 28, Inc.</i> Joint Stipulation and Proposed Order to Extend Stay, dated December 1, 2025
2005	<i>Treace Medical Concepts, Inc. v. Zimmer Biomet Holdings, Inc. and Paragon 28, Inc.</i> Joint Stipulation and Proposed Order to Stay, dated September 12, 2025
2006	<i>Paragon 28, Inc. and Disior Oy v. Treace Medical Concepts, Inc. and Mios Marketing, LLC</i> Amended Complaint, dated December 18, 2025
2007	U.S. Patent No. 10,561,426 to Dayton, <i>et al.</i> (the “’426 Patent”)
2008	Notice of Allowance of U.S. Application No. 18/645,205 (U.S. Patent No. 12,268,397 to Dayton, <i>et al.</i>)
2009	Notice of Allowance of U.S. Application No. 16/593,153 (U.S. Patent No. 10,561,426 to Dayton, <i>et al.</i>)
2010	U.S. Patent No. 10,856,886 to Dacosta, <i>et al.</i>
2011	U.S. Patent No. 11,696,767 to Dacosta, <i>et al.</i>

Exhibit No.	Description
2012	Treace Medical Concepts, Inc.'s SEC Form S-1 Registration Statement for Initial Public Offering, dated March 30, 2021
2013	Treace Medical Concepts, Inc.'s Initial Public Offering, dated April 22, 2021
2014	J.P. Morgan's Analyst Report entitled "A Differentiated Solution for the Large, Poorly Treated Bunion Market; Initiating at OW and \$37 PT", dated May 18, 2021
2015	Treace's Announcement of Grant of Additional U.S. Patent on Instrumented Bunion Correction, dated October 21, 2021
2016	Treace's Announcement of Grant of U.S. Patent and Allowance of U.S. Patent Application on Bone Positioner Technology for Bunion Correction, dated November 30, 2021
2017	Treace's Announcement of Grant of U.S. Patent on Instrumented Bunion Correction, dated January 19, 2022
2018	Treace's Announcement of Expansion of Its Global IP Portfolio with the Grant of Two New U.S. Patents, dated December 19, 2022
2019	Treace's Announcement of Expansion of Market Leading Global IP Portfolio For Bunion And Related Deformities, dated April 19, 2023
2020	Treace's Announcement of New Patent Covering Instrumented Bunion Correction Procedures and Milestone 50th U.S. Patent, dated September 14, 2023
2021	Treace's Announcement of Filing of Patent Infringement Suit Against Zimmer Biomet to Protect Lapiplasty® Bunion Technology, dated June 5, 2025
2022	Treace's Announcement of 100,000 Lapiplasty® 3D Bunion Correction® Patient Milestone Celebration, dated March 25, 2024
2023	Stephen Inc.'s Analyst Report entitled "TMCI's Device Superiority Is Winning The War on Bunions, Initiating EW/V Due To Valuation", dated April 10, 2023

Exhibit No.	Description
2024	AlphaSense's November 12, 2024 UBS Global Healthcare Conference Transcript
2025	Treace's Announcement of Filing of Patent Infringement Suit To Protect Lapiplasty® Bunion Technology, dated March 28, 2022
2026	Treace's Announcement of Settlement of Lawsuit Against Fusion Orthopedics, dated March 3, 2023
2027	Treace's Announcement of Filing of Patent Infringement and Unfair Competition Suit to Protect Lapiplasty® Bunion Technology, dated October 14, 2024
2028	J.P. Morgan's January 2023 Investor Presentation on Treace Medical Concepts, Inc.
2029	Declaration of Daniel C. Farber, M.D. ("Farber Declaration")
2030	<i>Curriculum Vitae</i> of Daniel C. Farber, M.D.
2031 [NEW]	USPTO Additional Discretionary Institution Considerations – U.S. Manufacturing and Small Business Use of AIA Proceedings Memorandum, dated March 11, 2026
2032 [NEW]	Zimmer Biomet Website - Company Overview
2033 [NEW]	Declaration of Terry Wade Lubben

As authorized on April 23, 2026 (Ex. 3101), Patent Owner (“PO”) submits this reply. In view of the Director’s March 11, 2026 Memorandum (Ex. 2031), PO notes that Petitioner (“PET”) is owned by a large multinational corporation with approximately 17,000 employees spread across 31 offices globally and numerous foreign subsidiaries (Ex. 2032; Paper 1 at 98–99). For example, PET identifies numerous foreign entities that have a financial interest and/or that would be affected by the outcome of the proceeding, including German, Finnish, South Africa, German, Japanese, and Italian entities. *See* Paper 1 at 98–99.

PO is a U.S. based company with U.S. manufacturing. PO is significantly smaller than PET, at just over 400 employees compared to 17,000 employees. But unlike PET, all of PO’s employees are located domestically. Ex. 2033 ¶ 5. All of PO’s research and development activities take place in the United States. *Id.* ¶ 4. And over 85% of PO’s current manufacturing operations for all of PO’s products are located in the United States, primarily in Florida, Massachusetts, Michigan, and Indiana. *Id.* ¶ 6.

Unlike PET, PO’s business is entirely American, investing in U.S. jobs and innovation. Forcing PO to defend its patents in this additional forum would consume disproportionate resources while imposing comparatively little burden on a global enterprise of PET’s scale. That imbalance warrants discretionary denial.

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Dated: April 28, 2026

Respectfully Submitted,

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CERTIFICATE OF SERVICE

The undersigned certifies that on the 28th of April 2026, a complete and entire copy of the foregoing “PATENT OWNER’S REPLY TO PETITIONER’S DISCRETIONARY DENIAL OPPOSITION,” including any exhibits, was electronically served via email to MLB-P28-PGR-397@morganlewis.com to the below counsel of record for Petitioner per Petitioner’s consent for electronic service (see Paper 1 at 100).

Lead Counsel	Back-up Counsel
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Dated: April 28, 2026

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