Paper 6
Filed: March 4, 2026

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PARAGON 28, INC.,
Petitioner,

v.

TREACE MEDICAL CONCEPTS, INC.
Patent Owner.

PGR2026-00020
Patent 12,268,428

PATENT OWNER'S REQUEST FOR DISCRETIONARY DENIAL OF INSTITUTION

TABLE OF CONTENTS

Page No.

I. INTRODUCTION 1

II. BACKGROUND 2

III. DISCRETIONARY DENIAL UNDER 35 U.S.C. § 324(a) 2

(1) Stays 2

(2) Timing 2

(3) Investment 3

(4) Issue Overlap 3

(a) Grounds/Prior Art 3

(b) Asserted Patents 3

(c) Incomplete Resolution 3

(5) Parties: PET is the defendant in the parallel proceeding 4

A. Settled Expectations Attach to the Continuity Chain, Not the Issuance Date 4

1. The Office's Double Patenting Rejection Confirms That Settled Expectations Attached No Later Than the Issuance of the '590 Patent 5

2. The '428 Patent and '590 Patent Claims 7

3. Targeted Family Disclosure 8

4. Petitioner's Notice 8

B. Evidence of Substantial Reliance and Settled Expectations 9

IV. CONCLUSION 12

TABLE OF AUTHORITIES

Page No(s).

Cases

Amgen Inc. v. Bristol-Myers Squibb Co.,
IPR2025-00601, Paper 9 (P.T.A.B. July 24, 2025) 5, 9

Apple Inc. v. Fintiv, Inc.,
IPR2020-00019, Paper 11 (P.T.A.B. Mar. 20, 2020) (Precedential).....2, 4

Dabico Airport Solutions Inc. v. AXA Power ApS,
IPR2025-00408, Paper 21 (P.T.A.B. June 18, 2025).....2, 8

Statutes

35 U.S.C. § 324..... passim

Other Authorities

Interim Processes for P.T.A.B. Workload Management Memorandum
(P.T.A.B. Mar. 26, 2025) 1

LIST OF EXHIBITS

Exhibit No.	Description
2001	*Treace Medical Concepts, Inc. v. Zimmer Biomet Holdings, Inc. and Paragon 28, Inc.,* Initial Complaint, dated May 12, 2025
2002	*Treace Medical Concepts, Inc. v. Zimmer Biomet Holdings, Inc. and Paragon 28, Inc.,* Joint Stipulation and Proposed Order to Extend Stay, dated December 1, 2025
2003	*Treace Medical Concepts, Inc. v. Zimmer Biomet Holdings, Inc. and Paragon 28, Inc.,* Joint Stipulation and Proposed Order to Stay, dated September 12, 2025
2004	*Paragon 28, Inc. and Disior Oy v. Treace Medical Concepts, Inc. and Mios Marketing, LLC,* Amended Complaint, dated December 18, 2025
2005	U.S. Patent No. 10,342,590 to Bays, *et al.* (the "'590 Patent")
2006	U.S. Patent No. 10,856,886 to Dacosta, *et al.*
2007	U.S. Patent No. 11,696,767 to Dacosta, *et al.*
2008	Treace Medical Concepts, Inc.'s SEC Form S-1 Registration Statement for Initial Public Offering, dated March 30, 2021
2009	Treace Medical Concepts, Inc.'s Initial Public Offering, dated April 22, 2021
2010	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
2011	Treace's Announcement of Grant of Additional U.S. Patent on Instrumented Bunion Correction, dated October 21, 2021

Exhibit No.	Description
2012	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
2013	Treace's Announcement of Grant of U.S. Patent on Instrumented Bunion Correction, dated January 19, 2022
2014	Treace's Announcement of Expansion of Its Global IP Portfolio with the Grant of Two New U.S. Patents, dated December 19, 2022
2015	Treace's Announcement of Expansion of Market Leading Global IP Portfolio For Bunion And Related Deformities, dated April 19, 2023
2016	Treace's Announcement of New Patent Covering Instrumented Bunion Correction Procedures and Milestone 50th U.S. Patent, dated September 14, 2023
2017	Treace's Announcement of Filing of Patent Infringement Suit Against Zimmer Biomet to Protect Lapiplasty® Bunion Technology, dated June 5, 2025
2018	Treace's Announcement of 100,000 Lapiplasty® 3D Bunion Correction® Patient Milestone Celebration, dated March 25, 2024
2019	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
2020	AlphaSense's November 12, 2024 UBS Global Healthcare Conference Transcript
2021	Treace's Announcement of Filing of Patent Infringement Suit To Protect Lapiplasty® Bunion Technology, dated March 28, 2022
2022	Treace's Announcement of Settlement of Lawsuit Against Fusion Orthopedics, dated March 3, 2023
2023	Treace's Announcement of Filing of Patent Infringement and Unfair Competition Suit to Protect Lapiplasty® Bunion Technology, dated October 14, 2024

Exhibit No.	Description
2024	J.P.Morgan's January 2023 Investor Presentation on Treace Medical Concepts, Inc.

I. INTRODUCTION

Patent Owner ("PO") respectfully requests that the Director exercise discretion to deny institution of post-grant review ("PGR") of US 12,268,428 (Ex. 1001, the "'428 Patent") under 35 U.S.C. § 324(a). This PGR is being litigated alongside four other AIA matters (IPR2026-00194, PGR2026-00017, PGR2026-00022, and PGR2026-00031). The '428 Patent and the patents challenged in these proceedings were all previously asserted in a co-pending district court case ("litigation"). *See* Paper 4 at 2. The complaint in that litigation was filed on May 12, 2025 (Ex. 2001) while this PGR was requested on December 23, 2025.

"Parties are encouraged to address any fact or circumstance they believe bears on the Director's discretion to institute, including reasons not discussed in current Board precedent or in the Process Memorandum." Guidance I.B (https://www.uspto.gov/patents/ptab/interim-director-discretionary-process; "Guidance"). Consistent with the Guidance, the totality of the circumstances in this proceeding supports discretionary denial as an appropriate exercise of the Director's authority. Discretionary denial is warranted under § 324(a) based on settled expectations and resource-allocation considerations. PO invented and commercialized the claimed bunion correction procedure that became the new standard of care over a decade ago. Settled expectations attach to the '428 continuity chain's longstanding public disclosure and claiming, not merely to the '428 Patent

issuance date. *Dabico*, IPR2025-00408, Paper 21 at 2–3 (PTAB June 18, 2025) (Informative).

II. BACKGROUND

The ’428 Patent is part of a chain of continuations tracing back to an initial 2015 filing. With that filing, PO disclosed instrumented bunion correction methods to correct and align the deformity and control cutting alignment, as well as to improve accuracy and reproducibility relative to preexisting techniques. The ’428 Patent describes systems and methods for instrumented bunion correction surgery. The specific claims of the ’428 Patent are directed to instrumented surgical techniques for bunion correction surgery. Earlier-issued patents in the priority chain claim instrumented surgical techniques for bunion correction surgery and related systems utilizing the same fundamental approach.

III. DISCRETIONARY DENIAL UNDER 35 U.S.C. § 324(a)

The *Fintiv* factors regarding parallel proceedings weigh in favor of denial. *See Fintiv*, IPR2020-00019, Paper 11 (PTAB Mar. 20, 2020) (Precedential):

(1) Stays: Multiple stays have been requested for ongoing settlement negotiations (*See* Exs. 2002, 2003). The case is currently progressing, but Petitioner (“PET”) filed a motion to stay in district court on March 4, 2026. Settlement discussions remain ongoing;

(2) Timing: Nine months into case but no trial date set;

(3) Investment: Nine months into case; substantial briefing; seeking to consolidate patent claims in parallel ongoing case;

(4) Issue Overlap:

(a) Grounds/Prior Art: PET has provided only a standard *Sotera* stipulation, but has not disavowed asserting the same art in different ways (Pet. 121);

(b) **Asserted Patents:** Four of the five patents currently asserted in the related litigation were challenged at PTAB with petitions filed in December and January. The fifth patent (US 12,349,941, "'941 Patent") was just challenged on March 3 (PGR2026-00031), despite it issuing almost eight months ago. That proceeding, which includes closely related subject matter, will occur months later than the four earlier filings. The first petition was filed on December 19, 2025 for PGR2026-00017. Accordingly, the delayed filing of the PGR2026-00031 proceeding, which occurred almost four months after the first petition filing, makes it impossible for the Board to put this case on the same schedule as the other proceedings, raising delay concerns; If instituted, the parties would likely have to wait almost four months after the first final written decisions issue before a final written decision in PGR2026-00031 issues; PET's delayed filing will also require separate hearings based on the inability to align trial schedules; and

(c) **Incomplete Resolution:** PET has filed its own district court suit against PO related to bunion correction products, alleging misappropriation of trade

secrets, copyright violation, and patent infringement. *See* Ex. 2004. The potential for joinder of those patent infringement claims and practical likelihood of at least parallel case management of those claims means that the parties' dispute over the same products is almost certainly moving forward;

(5) Parties: PET is the defendant in the parallel proceeding.

Based on the above, efficiency is best served by denying institution and allowing resolution at the district court both parties chose to litigate their disputes over bunion correction products. Nevertheless, the Director's authority under § 324(a) extends beyond *Fintiv* efficiency factors. Here, settled expectations and considerations of resource allocation conclusively tip the scales in favor of discretionary denial.

A. Settled Expectations Attach to the Continuity Chain, Not the Issuance Date

The relevant inquiry under § 324(a) is whether the public had a meaningful opportunity to evaluate, rely upon, and design around the claimed technology, not whether the challenged continuation issued recently. The core instrumented bunion correction technology was published by at least February 2017. From at least that point forward, the public could reasonably assess a stable and predictable claim trajectory directed to instrumented bunion correction, rather than facing a later-emerging or materially different claim theory. Related claims in patents issued no

later than June 2019 (US 10,342,590 (Ex. 2005, "'590 Patent"). The Director has denied institution, finding "strong settled expectations" warranting discretionary denial under § 324(a) for durations similar to the '590 Patent, which is closely related to the '428 Patent as explained below. *See Amgen Inc. v. Bristol-Myers Squibb Co.*, IPR2025-00601, Paper 9 at 3 (PTAB July 24, 2025) (Informative).

PO has relied on established rights related to the claimed technology and its continuation family. Allowing a late-stage challenge years into this continuity chain would upset those settled expectations despite the absence of claim-scope surprise or deviation from the family's established claiming direction. Specifically, earlier family patents claimed instrumented systems and techniques for bunion correction. Although claim language differs, the later claims fall within a predictable continuation trajectory that was visible to the public when the earlier claims issued.

1. The Office's Double Patenting Rejection Confirms That Settled Expectations Attached No Later Than the Issuance of the '590 Patent

Strong evidence that settled expectations attached early in this continuity chain comes from the Patent Office itself. During prosecution of the '428 Patent, the Office issued a double patenting rejection based on the claims of the '590 Patent, concluding that the two claim sets "are not patentably distinct from each other." Ex. 1002, 384–385. Specifically, the Office found that both patents "disclose a method of treating a bunion deformity that includes inserting an instrument between a first

metatarsal and a second metatarsal, wherein the first metatarsal is anatomically misaligned with respect to the second metatarsal, preparing an end of the first metatarsal, preparing an end of a medial cuneiform opposing the end of the first metatarsal, moving the first metatarsal in at least one plane to treat the bunion deformity, and after moving the first metatarsal in at least one plane to treat the bunion deformity, fixing the position of the first metatarsal with respect to the medial cuneiform using at least one bone fixation device." Ex. 1002, 384–385.

This determination by the Office has a direct and significant consequence for the settled expectations analysis. Because the Office determined the '428 claims are not patentably distinct from earlier-issued claims, the '428 Patent does not represent a late-emerging expansion of claim territory. Instead, it continues the same inventive footprint the Office already treated as substantively equivalent within the family. In those circumstances, the equity and resource-allocation rationale for instituting a post-grant challenge to "new" claim scope is substantially diminished.

The Office's non-distinctness determination confirms that the public-facing scope of the family's claims (*i.e.*, what competitors would assess, design around, and litigate) was already established by no later than the 2019 issuance of the '590 Patent.

That conclusion undermines any claim-scope "surprise" narrative. Where the Office has already found the later claims to not be patentably distinct, institution would expend Office resources re-examining claims that the Office already treated

as substantively overlapping within the family. And here, where the Office presented the double patenting rejection noted above, the general claim scope has already been considered *twice* by the Office. This is precisely the type of circumstance where discretionary denial is appropriate under § 324(a).

2. The ’428 Patent and ’590 Patent Claims

The claims of the ’428 and the ’590 patents are closely aligned because both recite an instrumented bunion correction technique in which a device is inserted between the first and second metatarsals, opposing ends of the first metatarsal and medial cuneiform are cut or prepared, and the first metatarsal is moved to correct the deformity as part of a coordinated surgical workflow. *Compare* Ex. 1001 (’428 Patent) claim 1, 26:12–18 (“inserting an instrument between a first metatarsal and a second metatarsal,” cutting ends of the first metatarsal and medial cuneiform, and “moving the first metatarsal in at least one plane to treat the bunion deformity”) *with* Ex. 2005 (’590 Patent) claim 1, 25:51–62 (“inserting a fulcrum between a first metatarsal and a second metatarsal,” “preparing an end of the first metatarsal,” “preparing an end of a medial cuneiform,” and “moving a distal portion of the first metatarsal . . . and reducing an intermetatarsal angle”). This alignment reinforces that the ’428 Patent continues the same core instrumented correction technique that the family has claimed for years.

3. Targeted Family Disclosure

The predictable nature of the continuation claims is reinforced by the nature of the disclosure itself. The family disclosure is not a sprawling omnibus of divergent embodiments that leaves the public guessing which direction might be pursued in continuation claims. Instead, the issued claims in the ’428 Patent have consistently tracked an instrumented bunion correction approach PO claimed since at least 2019. This targeted disclosure and consistent claiming trajectory further supports settled expectations by reducing the risk of unforeseen claim-scope shifts.

4. Petitioner’s Notice

Although notice is not required to establish settled expectations (*Dabico* at 3), the record demonstrates that PET has known about this patent family for years. PET’s own patents (*see*, *e.g.*, Ex. 2006 (US 10,856,886); Ex. 2007 (US 11,696,767)) cite PO’s patents (including the ’590 Patent discussed above), confirming long-standing technical familiarity.

This is not a case where unexpected claim scope later ensnared an unsuspecting competitor. The ’428 Patent represents predictable continuation practice: refining claims based on the original disclosure and available art. PET knew of the family, understood the scope, designed products within that scope, and proceeded with infringing products and techniques in order to compete anyway. This confirms the settled expectations that attached to this stable, publicly available patent

family. PET offers no persuasive justification for expending Office resources.

B. Evidence of Substantial Reliance and Settled Expectations

PO's commercialization activities corroborate the reliance interests discussed above. *See Amgen* at 2 (settled expectations can be established for young patents where "an explanation of how [PO's activities] correlate[]").

1. PO has invested substantial resources in commercializing products in this patent family, and investors have relied on the established patent rights to inform their continued investment in PO. *See* Ex. 2008, 27–29, 70–71, 87–88, 104–105 (March 2021 IPO prospectus identifying patents as critical business asset, warning that loss of patent protection would materially harm business, and describing "robust intellectual property portfolio" as competitive differentiator and "significant barrier to entry"); Ex. 2009 (April 2021 IPO); Ex. 2010, 1 (May 2021 J.P. Morgan analyst report stating "strong IP surrounding the Lapiplasty® kit has created high barriers to entry").

From the time the '590 patent issued in 2019 through 2025, PO made substantial investments in the claimed technology and regularly reinforced its reliance on patent protection through public announcements. *See* Ex. 2011 (October 2021 announcement of 30th granted US patent "strategically enhanc[ing] Treace's comprehensive patent coverage"); Ex. 2012 (November 2021 announcement emphasizing bone positioner technology patents); Ex. 2013 (January 2022

announcement of patent "augment[ing] Treace's extensive and growing patent portfolio"); Ex. 2014 (December 2022 announcement of expansion to 50 granted patents globally, including 40 in US, "strategically enhanc[ing]" patent coverage on instrumented bunion correction with priority dating to 2014); Ex. 2015 (April 2023 announcement of 58 granted patents including 47 in US and 84 pending applications); Ex. 2016 (September 2023 celebrating milestone 50th US patent with July 2014 priority date as demonstration of "commitment to rapid and meaningful innovation"); Ex. 2017 (June 2025 announcement identifying portfolio of 80 granted US patents, 26 granted patents worldwide, and over 150 pending applications). PO's commercial products gave rise to widespread market adoption and industry reliance. *See* Ex. 2018 (March 2024 announcement celebrating 100,000th patient treated with "patented Lapiplasty® 3D Bunion Correction® System").

2. Third-party analysts and competitors recognized PO's patent position as creating settled expectations and barriers to entry. *See* Ex. 2010, 5, 11 (May 2021 J.P. Morgan report concluding "Treace has a competitive advantage over peers given its broad intellectual property (IP) portfolio covering key methods of 3D bunion surgery" and noting that "Treace's . . . patent protected methodology forces" competitors to "make tradeoffs to work around Treace's IP"); Ex. 2019 (April 2023 Stephens analyst report identifying "strong IP" as basis for continued market penetration); Ex. 2020, 3 (November 2024 investor conference identifying

65 US-issued patents with "active defense" as key competitive advantage). PO's enforcement actions further demonstrate reliance on its patent portfolio and the industry's recognition of patent strength. See Ex. 2021 (March 2022 announcement of patent infringement suit); Ex. 2022 (March 2023 settlement with competitor); Ex. 2023 (October 2024 announcement of suit against Stryker alleging infringement of 9 patents (with no challenges to those patents at PTAB) and unfair competition); Ex. 2017 (June 2025 announcement of patent infringement suit against Zimmer Biomet).

3. Prior techniques were imprecise and variable, underscoring the significance of the claimed advance. The prior approaches required significant surgical skill and were prone to variability in outcome. *See* Ex. 2008, 27–28 (explaining need for patent protection against prior art problems); Ex. 2010, 1, 11 (May 2021 analyst report addressing the Lapiplasty® system and noting competitive products "make tradeoffs to work around Treace's IP"). PO's technology directly addressed these shortcomings by enabling consistent alignment and controlled cutting, reducing dependence on subjective judgment and free-hand variability. See Ex. 2018 (noting the Lapiplasty® Procedure benefits including "quick return to bearing weight" and "low recurrence rate of only 0.9% to 3.2%"); Ex. 2024, 3–4, 8 (January 2023 investor presentation emphasizing patents). This alignment between PO's technology and the long-recognized problem explains why reliance interests reasonably formed. The technology patented has been widely accepted as a way of

improving surgical outcomes, so PO reasonably expected that the patents issuing from this continuity chain would not be disturbed.

Taken together, the duration of public disclosure and claiming, the reliance interests reflected in adoption and investment, and the absence of any identified examination error support discretionary denial under § 324(a). Allowing institution at this stage would disrupt PO's settled expectations and undermine the balance Congress intended.

IV. CONCLUSION

Considering the totality of the circumstances, including: (1) the duration of public disclosure dating to at least 2017; (2) the Office's own double patenting determination that the '428 Patent's claims are not patentably distinct from the '590 Patent's claims that issued in 2019; (3) the consistent and targeted claiming trajectory across the family; (4) PO's substantial commercial and financial reliance on the established patent portfolio; (5) PET's long-standing actual notice of the family's scope; and (6) the efficiency interests served by directing all validity disputes to the district court, discretionary denial is warranted.

Dated: March 4, 2026

Respectfully Submitted,

/Joshua Van Hoven/

Joshua Van Hoven (Reg. No. 56,786)

VAN HOVEN PC
3001 Bishop Dr, Suite 300
San Ramon, CA 94583
Tel.: 925.302.5941
josh@vhiplaw.com

Counsel for Patent Owner

CERTIFICATE OF SERVICE

The undersigned certifies that on the 4th of March 2026, a complete and entire copy of the foregoing "PATENT OWNER'S REQUEST FOR DISCRETIONARY DENIAL OF INSTITUTION," including any exhibits, was electronically served via email to MLB-P28-PGR-428@morganlewis.com to the below counsel of record for Petitioner per Petitioner's consent for electronic service (*see* Paper 1 at 123).

Lead Counsel	**Back-up Counsel**
Ali S. Razai (Reg. No. 60,771) ali.razai@morganlewis.com Postal and Hand-Delivery Address: MORGAN, LEWIS & BOCKIUS LLP 600 Anton Boulevard, Suite 1800 Costa Mesa, CA 92626-7653 Tel.: (714) 830-0600 Fax: (714) 830-0700	Benjamin J. Everton (Reg. No. 60,659) ben.everton@morganlewis.com Jacob L. Peterson (Reg. No. 65,096) jacob.peterson@morganlewis.com Zachary Messick (Reg. No. 77,839) zachary.messick@morganlewis.com Postal and Hand-Delivery Address: MORGAN, LEWIS & BOCKIUS LLP 600 Anton Boulevard, Suite 1800 Costa Mesa, CA 92626-7653 Tel.: (714) 830-0600 Fax: (714) 830-0700

Dated: March 4, 2026

/Joshua Van Hoven/
Joshua Van Hoven (Reg. No. 56,786)

Counsel for Patent Owner