Paper 7
Filed: March 12, 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.

IPR2026-00194
Patent 12,102,368

PATENT OWNER'S REQUEST FOR DISCRETIONARY DENIAL OF INSTITUTION

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Other Authorities

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(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	U.S. Patent No. 9,936,994 to Smith, *et al.* (the "'994 Patent")
2003	USPTO Examiner Interview Summary of U.S. Patent Application No. 15/210,426, dated August 16, 2017
2004	U.S. Patent No. 4,159,716 to Borchers
2005	McGlamry's Comprehensive Textbook of Foot and Ankle Surgery, Chapter 9, Vol. 1, 5th Edition, 2022 ("McGlamry")
2006	*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
2007	*Treace Medical Concepts, Inc. v. Zimmer Biomet Holdings, Inc. and Paragon 28, Inc.,* Joint Stipulation and Proposed Order to Stay, dated September 12, 2025
2008	*Paragon 28, Inc. and Disior Oy v. Treace Medical Concepts, Inc. and Mios Marketing, LLC* Amended Complaint, dated December 18, 2025
2009	U.S. Patent No. 10,856,886 to Dacosta, *et al.*
2010	U.S. Patent No. 11,696,767 to Dacosta, *et al.*
2011	Treace Medical Concepts, Inc.'s SEC Form S-1 Registration Statement for Initial Public Offering, dated March 30, 2021

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2012	Treace Medical Concepts, Inc.'s Initial Public Offering, dated April 22, 2021
2013	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
2014	Treace's Announcement of Grant of Additional U.S. Patent on Instrumented Bunion Correction, dated October 21, 2021
2015	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
2016	Treace's Announcement of Grant of U.S. Patent on Instrumented Bunion Correction, dated January 19, 2022
2017	Treace's Announcement of Expansion of Its Global IP Portfolio with the Grant of Two New U.S. Patents, dated December 19, 2022
2018	Treace's Announcement of Expansion of Market Leading Global IP Portfolio For Bunion And Related Deformities, dated April 19, 2023
2019	Treace's Announcement of New Patent Covering Instrumented Bunion Correction Procedures and Milestone 50th U.S. Patent, dated September 14, 2023
2020	Treace's Announcement of Filing of Patent Infringement Suit Against Zimmer Biomet to Protect Lapiplasty® Bunion Technology, dated June 5, 2025
2021	Treace's Announcement of 100,000 Lapiplasty® 3D Bunion Correction® Patient Milestone Celebration, dated March 25, 2024
2022	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
2023	AlphaSense's November 12, 2024 UBS Global Healthcare Conference Transcript

Exhibit No.	Description
2024	Treace's Announcement of Filing of Patent Infringement Suit To Protect Lapiplasty® Bunion Technology, dated March 28, 2022
2025	Treace's Announcement of Settlement of Lawsuit Against Fusion Orthopedics, dated March 3, 2023
2026	Treace's Announcement of Filing of Patent Infringement and Unfair Competition Suit to Protect Lapiplasty® Bunion Technology, dated October 14, 2024
2027	J.P. Morgan's January 2023 Investor Presentation on Treace Medical Concepts, Inc.
2028	USPTO Additional Discretionary Institution Considerations – U.S. Manufacturing and Small Business Use of AIA Proceedings Memorandum, dated March 11, 2026
2029	Zimmer Biomet Website - Company Overview

I. INTRODUCTION

Patent Owner ("PO") is an American company and respectfully requests that the Director exercise discretion to deny institution of *inter partes* review ("IPR") of US 12,102,368 (Ex. 1001, "'368 Patent") under 35 U.S.C. § 325(d) and, independently, under 35 U.S.C. § 314(a). This IPR is being litigated alongside four other AIA matters (PGR2026-00017, PGR2026-00020, PGR2026-00022, and PGR2026-00031). The '368 Patent and the patents challenged in these proceedings were all previously asserted in a co-pending district court case ("litigation"). *See* Paper 6 at 2. The complaint in that litigation was filed on May 12, 2025 (Ex. 2001) and this IPR was requested on December 19, 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. Denial is appropriate under § 325(d) because the Petition relies on prior art previously presented to the Office and fails to identify any material error. This is the type of re-litigation § 325(d) is designed to prevent. Discretionary denial is also warranted under § 325(a) based on settled expectations and resource-allocation

considerations. PO invented and protected technology reflected in commercialized systems and methods that became the new standard of care over a decade ago. Settled expectations attach to the '368 continuity chain's longstanding public disclosure and claiming, not merely to the '368 Patent issuance date. *Dabico*, IPR2025-00408, Paper 21 at 2–3 (PTAB June 18, 2025) (Informative).

II. BACKGROUND

The '368 Patent is part of a continuity chain tracing back to an initial 2015 filing. With that filing, PO disclosed systems and methods for guided bone cutting and positioning, particularly for bunion-correction surgery. The specific claims of the '368 Patent recite structural arrangements of bone preparation and positioning guides that control cutting and alignment to improve accuracy and reproducibility relative to freehand techniques. Earlier patents in the priority chain claim cutting/positioning guides and methods utilizing the same fundamental approach.

III. DISCRETIONARY DENIAL UNDER 35 U.S.C. § 325(d)

A. Governing Framework —*Advanced Bionics*

Under *Advanced Bionics*, discretionary denial is appropriate where (1) the same or substantially the same art or arguments were previously presented, and (2) Petitioner ("PET") fails to show material error. *Advanced Bionics*, IPR2019-01469, Paper 6 at 7–8 (PTAB Feb. 13, 2020) (Precedential).

B. *Advanced Bionics* Part One — Same or Substantially the Same Art

Two independent claims from the ’368 Patent are challenged: claim 1 and claim 21. Those independent claims are challenged based on McGlamry (Ex. 1007), Fallin (Ex. 1005), Kartalian (Ex. 1006), and Schmuck (Ex. 1028). The discussion below focuses on the bone positioning guide element of the claims. PET relies on McGlamry and Kartalian for the alleged obviousness of the bone positioning guide features, which were each cited to the Patent Office during prosecution and are on the face of the ’368 Patent. *See* Pet. 34–37, 61–65, 75–76, 81–82, 85.

McGlamry was previously presented (referenced twice on the face of the ’368 Patent in citations that specifically reference Chapters 29 and 31). PET cites Chapter 31 of McGlamry with respect to the bone positioning guide features when challenging the independent claims. *See*, *e.g.*, Pet. 34–37, 61–65.

Art cited on the face of the patent constitutes previously presented art, regardless of whether it formed the basis of a rejection, and satisfies Part One of *Advanced Bionics*, even when the number of cited references is large. *See Ecto World*, IPR2024-01280, Paper 13 at 24 (PTAB May 19, 2025) (Precedential).

C. *Advanced Bionics* Part Two — No Material Examiner Error

Advanced Bionics requires a showing of material Office error, not merely disagreement with prosecution outcomes or reimagined combination theories based on hindsight expert observations. *Advanced Bionics* at 9 (“If reasonable minds can disagree regarding the purported treatment of the art or arguments, it cannot be said

that the Office erred in a manner material to patentability."). The lack of material Office error relative to McGlamry and Kartalian is dispositive because without error relative to those references, there can be no error *material to patentability* (*i.e.*, no error regarding patentability determination of the bone position guide features).

PET misapprehends the disclosure of the '368 Patent, alleging that the '368 Patent itself discloses a "tenaculum or tong structure" as an example of the bone positioning guide. Pet. 18 (citing Ex. 1001, 7:20–34). This is not accurate.

The '368 Patent explains: "In the embodiment of FIG. 1, bone positioning guide 10 includes a main body member 20 and a shaft 30, and the bone engagement member 40 is connected to the shaft and the tip 50 is connected to the main body member." Ex. 1001, 5:38–41. The '368 Patent provides a number of actuation mechanism examples (*see id.* at 7:1–43) that are components of the bone positioning guide and that PET mischaracterizes as the recited bone positioning guide.

The Petition does not address any specific examiner misunderstandings or omissions with respect to McGlamry or Kartalian and, indeed, does not even address that both references were before the Examiner during prosecution. PET ultimately disagrees with the Examiner's implicit conclusion that the claimed bone positioning guide would not have been obvious in view of McGlamry and Kartalian.

The record supports an inference that the prosecution of the '368 Patent represents "examiner choice" rather than "examiner error." Indeed, the prosecution

history of related US 9,936,994 (Ex. 2002, "'994 Patent"), a family member sharing the same specification and similar claims (explained below), supports that inference. *See* Ex. 2003 (Examiner Interview Summary: Examiner considered a bone compression and realignment jig from US 4,159,716 (Ex. 2004) and allowed the claims after finding the references lacked teachings of a bone positioning guide that was configured to treat a bunion deformity by guiding multi-planar alignment).

1. McGlamry

The Petition does not identify any structure in McGlamry meeting the claimed positioning guide. Rather, it asserts that it would have been obvious to use known tools in the claimed manner, alleging functional possibility rather than any teachings.

The Petition relies on McGlamry for general background descriptions of bunion surgery and use of conventional surgical tools, characterizing it as disclosing an "instrumented technique for bunion correction surgery" including cutting bone unguided/freehand and using "Weber clamps and/or K-wires to reposition and/or stabilize the first metatarsal prior to fixation." Pet. 23–24; *see also* Ex. 1007 at 325–326 (explaining that "the surgeon must be sure not to change the sagittal plane relationship between the first and lesser metatarsals," which appears to teach against using the Weber clamp to correct in the sagittal plane entirely). The Petition addresses general surgical steps and tools and fails to identify any actual disclosure of a guide designed to guide bone positioning. In fact, the next edition of McGlamry,

unavailable as prior art, was revised to include the new standard of care established by PO's patented product. *See* Ex. 2005, 300 (describing prior difficulties and that "[t]hree-dimensional correction can be made easier . . . with specialized guides and jigs"), 303 (FIG. 13.8 depicting a commercial embodiment of the claimed bone positioning guide). PET's inability to point to disclosure of the recited bone positioning guide in McGlamry is a core reason why it cannot show material error. Because McGlamry discloses only general known tools and conventional techniques, PET is necessarily asking the Board to supply the missing structure through a paid expert-reimagined interpretation of art that was previously before the Office, not the reference itself. That is not an error-correction exercise under § 325(d). *Advanced Bionics* at 8. PET's treatment of McGlamry further confirms this.

The Petition's claim construction approach reinforces this gap. The Petition states the Board "need not specially construe any claim terms" and the claims are unpatentable under their "plain and ordinary meaning." Pet. 17–18. The Petition then defines a "bone positioning guide" as merely "a device that is designed to move bone(s)." Pet. 18. Treating the ability to position a bone during surgery as sufficient, PET effectively asks the Board to believe that the Examiner failed to consider any device designed to move bones when examining the '368 patent. Of course, the Examiner did consider devices that move foot bones during prosecution, and McGlamry brings nothing new to this inquiry whatever claim construction is used.

The Petition effectively admits as much, asserting that "McGlamry discloses that a Weber clamp ***can*** be used to move the metatarsal in the transverse plane and rotate it in the frontal plane" to support its conclusion that a "Weber clamp is a bone positioning guide." Pet. 34–35 (emphasis added). The Petition then states: "[e]ven if McGlamry did not disclose that the Weber clamp rotates the metatarsal in the frontal plane, it would have been obvious to employ the Weber clamp to rotate the metatarsal in the frontal plane." Pet. 36. PET provides no evidence-based support for this assertion, nor does it provide any evidence-based support for the proposition that a surgeon could or would manipulate the clamp as alleged.

This deficiency extends to the asserted combinations. The Petition asserts that substituting another instrument for McGlamry's Weber clamp would be "nothing more than the substitution of one known element for another with predictable results." Pet. 64. PET's own characterization confirms McGlamry does not disclose a specialized guide as claimed. The Weber clamp is a generic background tool in McGlamry, not a specific guide with features the Examiner failed to recognize.

Petitioner relies upon expert-driven reconstruction through Dr. Neufeld's declaration. Without evidentiary support, Dr. Neufeld baldly states that "McGlamry's Weber clamp is a bone positioning guide." Ex. 1003 ¶¶ 140, 192. He then selectively maps portions of the clamp to claim elements. *See*, *e.g.*, Ex. 1003 ¶¶ 194–196. These identifications are merely expert characterizations based on the

expert's hindsight beliefs that lack any direction from McGlamry regarding how they form the claimed guide components. Dr. Neufeld again substitutes his bare opinions for non-existent disclosure of McGlamry with his conclusion that "[e]ven if McGlamry does not disclose that the Weber clamp rotates the metatarsal in the frontal plane, it would have been obvious to use the Weber clamp to rotate the metatarsal in the frontal plane" and that "[a] POSA would have recognized that a Weber clamp engaged across adjacent metatarsals (as shown by McGlamry) not only transmits compressive forces (for transverse plane correction) but also torsional movement (frontal plane derotation) as part of a controlled reduction." Ex. 1003 ¶ 143. No evidence supports this allegation.

Dr. Neufeld further concludes the Weber clamp is "identical to or at least equivalent" to the claimed guide because it allegedly "performs the same function, in the same way (opposing jaws that apply/maintain a corrective clamping force), to achieve the same result of controlling the repositioning and maintenance of the correction during fixation." Ex. 1003 ¶¶ 141, 197. The declaration confirms the Petition's McGlamry theory depends on unsupported paid expert testimony, not on structural teachings in McGlamry that the Examiner overlooked or misunderstood. This is the expert-driven re-imagination that § 325(d) aims to avoid.

2. <u>Kartalian</u>

Kartalian discusses orthopedic alignment concepts but does not disclose a

bone positioning guide having the claimed features. The Petition again relies on general allegations and expert reasoning rather than disclosed structure. Pet. 61–65. This absence of structural disclosure reinforces that Kartalian adds nothing beyond the prior art presented and available to the Examiner. The record supports an inference that during prosecution Kartalian was used as and only discloses background alignment context. PET's disagreement with that discretionary judgment is not "material error" under *Advanced Bionics*. *Advanced Bionics* at 8.

PET's treatment of Kartalian parallels its approach to McGlamry. The Petition does not identify any examiner error grounded in Kartalian's disclosure of a bone clamp. Instead, it asserts that Kartalian's instrument "functions to position the bones by moving the metatarsal in the transverse plane and rotating it in the frontal plane" and therefore "satisfies 'bone positioning guide' under the plain and ordinary meaning." Pet. 63. This conclusion is based on the PET's abstract definition of a guide as "any device designed to move bone(s)." Pet. 18. This is not identification of guide-specific structure disclosed in Kartalian. PET does not cite any passage in Kartalian describing a mechanism for guiding rotational realignment but instead relies on the unsupported assertion that Kartalian's instrument can be used by a surgeon for guiding rotational realignment during surgery. PET again treats Kartalian as a functionally interchangeable tool, asserting that using Kartalian's instrument in place of McGlamry's Weber clamp would be "nothing more than the

substitution of one known element for another with predictable results." Pet. 64. This does not identify any structural teachings missed during prosecution.

Dr. Neufeld's testimony does not help. He supplies the alleged guide functionality through allegations of equivalence and conclusory modifications, asserting that Kartalian's instrument is "identical or at least equivalent" to the claimed bone positioning guide because it performs the positioning and rotational functions "in substantially the same way." Ex. 1003 ¶ 220. He alleges that a POSA would have been motivated to use Kartalian's instrument in bunion surgery because it includes features "specifically designed for bunion correction procedures" and would have been "desirable." Ex. 1003 ¶ 222. Dr. Neufeld does not identify any guide-specific mechanism disclosed in Kartalian for controlling or constraining bone rotation but instead characterizes Kartalian's instrument as "identical or at least equivalent" based on its use by a surgeon to position and rotate bone during a procedure and purported performance of similar functions "in substantially the same way." Ex. 1003 ¶¶ 216–228. This testimony rests on allegations, unsupported by any evidence, regarding user manipulation purportedly providing the recited functionality, not on any disclosed structural features in Kartalian corresponding to the claimed guide arrangement. There is no evidence-based support that the alleged functional outcome could even be achieved based on user manipulation.

By relying on alleged equivalence and unsupported functional similarity

rather than pointing to missed structural teachings in Kartalian, PET confirms that Kartalian does not disclose the claimed bone positioning guide and that any asserted error is merely disagreement with the Examiner's implicit treatment of Kartalian.

3. *Becton, Dickinson* Factors Favor Denial

All *Becton, Dickinson* factors, considered in the Part Two inquiry under *Advanced Bionics*, further support discretionary denial (*See Becton, Dickinson*, IPR2017-01586, Paper 8 at 17–18 (PTAB Dec. 15, 2017) (Precedential)):

(1) Similarity of Art: The relevant references relied on in the Petition to challenge the independent claims are the same as the references cited on the patent;

(2) Cumulative Nature: Even when substance is considered, McGlamry and Kartalian are generalized background knowledge, as discussed above;

(3) Extent of Evaluation: Cited on the face of the '368 Patent;

(4) Overlap of Arguments: All of the arguments PET now makes were available during examination as discussed above;

(5) Examiner Error: None identified or available, as discussed above; and

(6) Additional Evidence: No new technical evidence beyond an expert declaration that relies on hindsight characterizations, not disclosure in the references.

In sum, this case presents the exact reference swapping and incremental repackaging concerns that § 325(d) is designed to filter out. *Id.* at 17–18.

IV. DISCRETIONARY DENIAL UNDER 35 U.S.C. § 314(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. 2006, 2007). The case is currently progressing, but 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 provides only a standard *Sotera* stipulation, but has not disavowed asserting the same art in different ways (Pet. 98–99);

(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. 2008. 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 § 314(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 Continuity Chain, Not the Issuance Date

The relevant inquiry under § 314(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 technology was published by February 2017. From that point forward, the public could reasonably assess a stable and predictable claim trajectory directed to bone positioning and cutting guides for bunion correction, rather than facing a later-emerging or materially different claim theory. Related claims in patents issued by April 2018 (the '994 Patent). The Director has denied institution, finding "strong settled expectations" warranting discretionary denial under § 314(a) for durations similar to the '994 Patent. *See Amgen*, 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 bone positioning guides 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. <u>The '368 Patent Claims and '994 Patent Claims</u>

The '368 and '994 patent claims are closely aligned, both reciting a bone

positioning guide. *Compare* Ex. 1001 ('368 Patent) claim 1, 18:51–55 ("a bone positioning guide configured to . . . treat a bunion deformity by at least: moving the first metatarsal in a transverse plane to reduce an intermetatarsal angle . . . and rotating the first metatarsal in a frontal plane") with Ex. 2002 ('994 Patent) claim 1, 18:31–41 ("[a] bone positioning guide . . . configured to . . . correct an alignment of the first bone in more than one plane with respect to a second bone . . . including about an axis in a frontal plane").

2. Targeted Family Disclosure

The predictability 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 have consistently tracked the same core guided approach since at least 2018. This targeted disclosure and consistent claiming trajectory supports settled expectations by reducing the risk of unforeseen claim-scope shifts.

3. 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. 2009 (US 10,856,886); Ex. 2010 (US 11,696,767)) cite PO's patents (including the '994 Patent discussed above), confirming long-standing technical familiarity.

This is not a case where unexpected claim scope later ensnared an unsuspecting competitor. The '368 Patent represents predictable continuation practice: refining claims based on the original disclosure and available art. PET knew the family, understood the scope, designed products within that scope, and proceeded 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. 2011, 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. 2012 (April 2021 IPO); Ex. 2013, 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 ’994 Patent issued in 2018 through 2025, PO made substantial investments in the claimed technology and regularly reinforced its reliance on patent protection through public announcements. *See* Ex. 2014 (October 2021 announcement of 30th granted US patent “strategically enhanc[ing] Treace’s comprehensive patent coverage”); Ex. 2015 (November 2021 announcement emphasizing bone positioner technology patents); Ex. 2016 (January 2022 announcement of patent “augment[ing] Treace’s extensive and growing patent portfolio”); Ex. 2017 (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. 2018 (April 2023 announcement of 58 granted patents including 47 in US and 84 pending applications); Ex. 2019 (September 2023 celebrating milestone 50th US patent with July 2014 priority date as demonstration of “commitment to rapid and meaningful innovation”); Ex. 2020 (June 2025 announcement identifying portfolio of 80 granted US patents, 26 granted patents worldwide, and over 150 pending applications).

PO’s commercial products that gave rise to widespread market adoption and industry reliance practice bone positioning guide features recited in claims of the ’368 Patent. *See* Ex. 2021 (March 2024 announcement celebrating 100,000th patient treated with “patented Lapiplasty® 3D Bunion Correction® System,” representing substantial market penetration and clinical reliance on patented technology since

2015). In fact, many of the products *are* the claimed product (as will be discussed in more detail) in connection with the nexus in the POPR. This shows that reliance developed around the claimed features.

2. Third-party analysts and competitors recognized PO's patent position as creating settled expectations and barriers to entry. *See* Ex. 2013, 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. 2022 (April 2023 Stephens analyst report identifying "strong IP" as basis for continued market penetration); Ex. 2023, 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. 2024 (March 2022 announcement of patent infringement suit); Ex. 2025 (March 2023 settlement with competitor); Ex. 2026 (October 2024 announcement of suit against Stryker alleging infringement of 9 patents (with no challenges to those patents at PTAB) and unfair competition); Ex. 2020 (June 2025 announcement of patent infringement suit against Zimmer Biomet).

3. The Petition acknowledges that prior techniques were imprecise and variable, underscoring the significance of the claimed advance. *See*, *e.g.*, Pet. 25

(discussing "freehand" resection and imprecision concerns). The prior approaches required significant surgical skill and were prone to variability in outcome. *See* Ex. 2011, 27–28 (explaining need for patent protection against prior art problems); Ex. 2013, 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. 2022 (noting Lapiplasty® Procedure benefits including "quick return to bearing weight" and "low recurrence rate of only 0.9% to 3.2%"); Ex. 2027, 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, particularly using the old devices that caused these difficulties.

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 § 314(a). Allowing institution at this stage, based on cumulative art and a petition that relies materially on expert-based reimagination narratives over previously presented references, would disrupt

those expectations and undermine the balance Congress intended.

C. Merits Considerations Reinforce § 314(a) Discretionary Denial

The Director considers "other circumstances . . . including the merits," confirming that the Petition's strength is a relevant § 314(a) consideration. *Fintiv* at 6. The challenges rely on cumulative art and expert-driven hindsight, not disclosures newly brought before the Office. The weak merits will be evident after review of the POPR. Even crediting the Petition's merits theories at a high level, those theories lack the character or strength to justify institution.

D. PO's U.S. Based Operations vs PET's Large Multi-National Operations

In view of the Director's March 11, 2026 Memorandum (Ex. 2028), PO notes that PET is owned by a large multinational corporation with approximately 17,000 employees spread across 31 offices globally and numerous foreign subsidiaries (Ex. 2029; Paper 1 at 90). PO is a U.S. based company with U.S. manufacturing and all 437 employees located domestically. 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 places this growing American company at risk.

V. CONCLUSION

Considering all circumstances together, discretionary denial is warranted.

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Respectfully Submitted,

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CERTIFICATE OF SERVICE

The undersigned certifies that on the 12th 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-IPR-368@morganlewis.com to the below counsel of record for Petitioner per Petitioner's consent for electronic service (*see* Paper 1 at 91).

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