

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PARAGON 28, INC.,
Petitioner,

v.

TREACE MEDICAL CONCEPTS, INC.
Patent Owner.

PGR2026-00022
Patent 12,274,481

**PATENT OWNER'S REQUEST FOR DISCRETIONARY DENIAL OF
INSTITUTION**

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LIST OF EXHIBITS

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2001	<i>Treace Medical Concepts, Inc. v. Zimmer Biomet Holdings, Inc. and Paragon 28, Inc.</i> , Initial Complaint, dated May 12, 2025
2002	<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
2003	<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
2004	<i>Paragon 28, Inc. and Disior Oy v. Treace Medical Concepts, Inc. and Mios Marketing, LLC</i> Amended Complaint, dated December 18, 2025
2005	U.S. Patent No. 10,849,670 to Santrock, <i>et al.</i> (the “’670 Patent”)
2006	U.S. Patent No. 10,856,886 to Dacosta, <i>et al.</i>
2007	U.S. Patent No. 11,696,767 to Dacosta, <i>et al.</i>
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.
2025	USPTO Additional Discretionary Institution Considerations – U.S. Manufacturing and Small Business Use of AIA Proceedings Memorandum, dated March 11, 2026
2026	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 post-grant review (“PGR”) of US 12,274,481 (Ex. 1001, the “’481 Patent”) under 35 U.S.C. § 325(d) and, independently, under 35 U.S.C. § 324(a). This PGR is being litigated alongside four other AIA matters (IPR2026-00194, PGR2026-00017, PGR2026-00020, and PGR2026-00031). The ’481 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) while this PGR was requested on January 13, 2026.

“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 § 324(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 '481 Patent continuity chain's longstanding public disclosure and claiming, not merely to the '481 Patent issuance date. *Dabico*, IPR2025-00408, Paper 21 at 2–3 (PTAB June 18, 2025) (Informative).

II. BACKGROUND

The '481 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 bone alignment and control cutting alignment, as well as to improve accuracy and reproducibility relative to preexisting techniques. The '481 Patent describes systems and methods for instrumented bunion correction surgery. The specific claims of the '481 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. § 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

Four independent claims from the '481 Patent are challenged: claims 1, 14, 27, and 30. Those independent claims are challenged based on McGlamry (Ex. 1004), Kartalian (Ex. 1005), and Fallin (Ex. 1006). The discussion below focuses on the operation of the bone positioning guide of the claims, and specifically bunion correction through the knob rotation actuation of the bone positioning guide. Of the references listed above, PET relies on McGlamry and Kartalian for the alleged obviousness of the bone positioning guide in a similar manner for all independent claims. *See* Pet. 26–34, 48, 50, 64–66, 74–79, 82–85, 93–95, 99–100, 103–104.

McGlamry, Kartalian, and Fallin were each cited to the Patent Office during prosecution and are listed on the face of the '481 Patent. McGlamry is referenced twice on the face of the '481 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. 26, 30–31.

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 operation).

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 operation would not have been obvious in view of McGlamry and Kartalian. The Petition itself reinforces that disclosures in McGlamry and Kartalian are cumulative by repeatedly characterizing them as reflecting “known” procedures and conventional variations of forceps, rather than disclosing a positioning guide operated to treat a bunion deformity in the manner claimed. *See, e.g.*, Pet. 10–15.

As part of the “bone positioning guide operation,” each claim requires “rotating a knob connected to a threaded shaft of the bone positioning guide to cause the bone engagement member to push the first metatarsal laterally toward the second

metatarsal and thereby reduce the intermetatarsal angle between the first metatarsal and the second metatarsal to correct the bunion deformity.” Ex. 1001, 18:17–22, 19:63–20:2, 21:55–60, 22:42–47. The record supports an inference that the prosecution of the ’481 Patent represents “examiner choice” rather than “examiner error.” The Examiner reasonably treated the now-asserted references as background or general knowledge rather than as disclosing the claimed method.

1. McGlamry

The Petition does not identify any structure in McGlamry meeting the claimed “rotating a knob” operation of the bone positioning guide. Rather, it asserts that “McGlamry discloses using a Weber clamp to engage the first metatarsal for moving the first metatarsal in the transverse plane.” Pet. 26. PET contends that “[i]t would have been obvious to use Kartalian’s instrument in McGlamry’s procedure.” Pet. 27.

Initially, PO notes that a clamp is not a guide. Nevertheless, the “rotating a knob” operation of the recited bone positioning guide is itself fatal to any allegation of material Office error. Even if one skilled in the art would have used Kartalian’s clamp in McGlamry’s procedure, there is still no material Office error because as explained below, PET is necessarily asking the Board to supply the missing operation recited in the claims through expert-reimagined interpretation of Kartalian. That is not a proper error-correction under § 325(d). *Advanced Bionics* at 8.

2. Kartalian

Kartalian discusses orthopedic alignment concepts but does not disclose a bone positioning guide operated in the claimed manner. As PET itself states: “Kartalian’s instrument is a tenaculum (forceps).” Pet. 27. PO initially notes that PET attempts to equate Kartalian’s tenaculum with the examples of the bone positioning guide in the ’481 Patent. PET contends, for example, that Kartalian’s “instrument is identical or at least equivalent to structures identified in the ’481 patent for the claimed bone positioning guide discussed in Section V.A.” Pet. 29. PET misapprehends the disclosure of the ’481 Patent, alleging that the ’481 Patent itself discloses a “tenaculum or tong structure” as an example of the bone positioning guide. Pet. 20 (citing Ex. 1001, 6:44–58). This is not accurate.

The ’481 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, 4:63–66. The ’481 Patent provides a number of example actuation mechanisms. *See, e.g., id.* at 5:11–24 (“In some embodiments, the shaft 30 includes threads 80 . . . In other embodiments, the shaft can slide within the main body member . . . In yet other embodiments, the shaft can be moved with respect to the main body by a ratchet mechanism.”). The ’481 Patent further explains that “bone positioning guide 10 can also include an actuator (e.g., a knob or a handle)

120 to actuate the mechanism.” *Id.* at 6:26–28.

PET selectively cites the ’481 Patent, obfuscating the actual disclosure of the patent. Their cited portion of the ’481 Patent explains: “In other embodiments, the mechanism to urge the bone engagement member and the tip towards each other can include a tenaculum or tong structure.” Ex. 1001, 6:44–46. Contrary to PET’s characterization, this language does not state that “a tenaculum or tong” is itself the bone positioning guide. *See* Pet. 20 (citing Ex. 1001, 6:44–58). It is merely a component, and does not establish material Office error.

PET further contends that “Kartalian’s instrument 100 includes a rotatable knob connected to a threaded shaft.” Pet. 33. PET further alleges that “[w]hen the instrument is used in McGlamry’s procedure and engaged with the first and second metatarsals, a surgeon would rotate the threaded knob to bring the handles toward each other, thereby causing the arm 106 (bone engagement member) to move toward the end 102.” Pet. 33 (citing Ex. 1003 ¶ 131). But neither PET nor Dr. Neufeld cites any actual disclosure related to that purported operation. Dr. Neufeld testifies:

A POSA would understand that rotation of the knob would cause the knob to move down the threaded shaft, thereby causing a reduction of the distance between the first end 102 and the second end 106. This would move the bone engagement member and the tip relative to one another. Accordingly, Kartalian’s IMA reduction mechanism includes a knob connected to a threaded shaft.

Ex. 1003 ¶ 131. Without discussing the knob, the Petition similarly contends:

Kartalian explains that movement of the arm 106 (bone engagement member) toward the end 102 pushes the first metatarsal laterally toward the second metatarsal, reducing the intermetatarsal angle between the two metatarsals: “[t]he instrument 100 may act as reduction forceps to align two bones or reduce the distance between the bones, as desired.” Ex.1005, 9:66-10:3, *see also id.*, 10:46-62 (“After the instrument 100 is placed on the bones and the bone is set in the desired orientation, the reduction or realignment may occur to the desired angle as estimated by angle indicator 116.”); Ex.1003, ¶132.

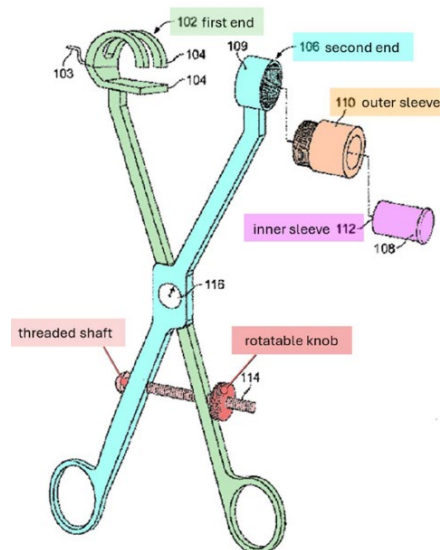
Pet. 34. The cited portion of Dr. Neufeld’s testimony parrots the Petition:

When Kartalian’s instrument is used in McGlamry’s procedure and engaged with the first and second metatarsals, the surgeon would rotate the threaded [k]nob to bring the handles toward each other, thereby causing the arm 106 (bone engagement member) to move toward the end 102. Kartalian explains that the movement of the arm 106 toward end 102 pushes the first metatarsal laterally toward the second metatarsal, reducing the IMA between the two metatarsals. Ex.1005, 9:66-67 (“The instrument 100 may act as reduction forceps to align two bones or reduce the distance between the bones, as desired.”), 10:8-18 (describing operation of the “automatic angle indicator 116” for estimating the IMA between the “bones requiring correction” (the first and second metatarsals)), 10:46-62 (“After the instrument 100 is placed on the bones and the bone is set in the desired orientation, the reduction or realignment may occur to the desired angle as estimated by angle

indicator 116.”). This IMA reduction corrects the bunion deformity.

Ex. 1003 ¶ 132. Dr. Neufeld’s testimony is not credible. Both PET and Dr. Neufeld fail to provide any evidence to support the purported operation of Kartalian’s knob and are *directly contradicted by the express disclosure of Kartalian*.

Kartalian explains: “The instrument 100 may act as reduction forceps to align two bones or reduce the distance between the bones, as desired.” Ex. 1005, 9:66–67. Although the Petition and Dr. Neufeld both identify Kartalian’s element 114 as the “rotatable knob,” neither address Kartalian’s discussion of element 114. PET’s annotated version of Kartalian’s Figure 1 is reproduced below.



Pet. 33; Ex. 1003 ¶ 130. Kartalian discusses element 114 at column 10, lines 4–6. PO reproduced PET’s contentions and Dr. Neufeld’s testimony above to make clear that PET skips over this most relevant portion of Kartalian.

With respect to knob functionality, Kartalian states: “instrument 100 may

include a locking clamp 114 to hold the instrument 100 in position *once the final alignment of the bones has been achieved.*” Ex. 1005, 10:4–6. This is significant to any allegation of material Office error. Kartalian expressly states that its clamp is a “locking clamp” used *after* the bones are positioned, not that it is rotated to position the bones as recited in the claims (*i.e.*, “rotat[ed] . . . to cause the bone engagement member to push the first metatarsal laterally toward the second metatarsal”).

Moreover, it is not even clear if Kartalian’s instrument 100 could be operated as claimed. Nor does PET provide any evidence regarding such capability. For example, the friction between the knob on locking clamp and the handle may prohibit such operation from being practical without Kartalian’s instrument 100 first being closed by a surgeon’s hand (*i.e.*, via the typical actuation of forceps by engaging the finger holes at the bottom of the device shown above). We are left only with Dr. Neufeld’s conclusory testimony that contradicts the disclosure of Kartalian.

PET is effectively asking the Board to consider its allegations and conclusory paid expert testimony (which both directly contradict the teachings of Kartalian itself), which is not sufficient basis for a determination of material Office error.

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 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 '481 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. § 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 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. 109–110);

(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 December 2020 (US Patent No. 10,849,670 (Ex. 2005, “the ’670 Patent”)). The Director has denied institution, finding “strong settled expectations” warranting discretionary denial under § 324(a) for durations similar to the ’670 Patent, which is closely related to the ’481 Patent as explained below. *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 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 ’481 Patent and ’670 Patent Claims

The claims of the ’481 and the ’670 patents are closely aligned because both recite accessing a tarsal-metatarsal joint, multi-planar repositioning of the first metatarsal relative to the medial cuneiform, preparation of opposing bone ends, and fixation for fusion. *Compare* Ex. 1001 (’481 Patent) claim 1, 18:8–32 (“making an incision on a foot to provide access to a tarsal-metatarsal joint,” “rotating a knob . . . to cause the bone engagement member to push the first metatarsal laterally toward the second metatarsal,” “imparting a force . . . to adjust an alignment of the first

metatarsal in a frontal plane,” “cutting an end of a medial cuneiform,” “cutting an end of the first metatarsal,” and “fixating a moved position of the first metatarsal relative to the medial cuneiform for fusion”) *with* Ex. 2005 (’670 Patent) claim 1, 17:56–18:3 (“making an incision on a foot to provide access to a tarsal-metatarsal joint,” “moving a first metatarsal relative to a medial cuneiform in at least two planes, including a frontal plane and a transverse plane,” “after moving the first metatarsal . . . preparing an end of the first metatarsal” and “preparing an end of the medial cuneiform,” and “fixing the moved position of the first metatarsal relative to the medial cuneiform”). This reinforces that the ’481 Patent continues the same core technique that the family has claimed for years.

2. 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 ’481 Patent have consistently tracked an instrumented bunion correction approach PO claimed since at least 2020. This targeted disclosure and consistent claiming trajectory further 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. 2006 (US 10,856,886); Ex. 2007 (US 11,696,767)) cite PO's patents (including the publication (US 2018/0317992) corresponding to the '670 Patent discussed above), confirming long-standing technical familiarity.

This is not a case where unexpected claim scope later ensnared an unsuspecting competitor. The '481 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 with "an explanation of how [PO's activities] correlate[]" to settled expectations).

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 '670 patent issued in 2020 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, 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 § 324(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 § 324(a) Discretionary Denial

The Director considers “other circumstances . . . including the merits,” confirming that the Petition’s strength is a relevant § 324(a) consideration. *Fintiv* at 6. The challenges rely on cumulative art and expert-driven hindsight allegations that directly contradict the asserted reference, not disclosures newly brought before the Office. Moreover, the contradictions significantly undermine the credibility of the Petition and Dr. Neufeld as explained above. The weak merits will be further evident after review of the POPR. Nevertheless, 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. 2025), 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. 2026; Paper 1 at 110). 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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Patent 12,274,481

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Respectfully Submitted,

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CERTIFICATE OF SERVICE

The undersigned certifies that on the 20th 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-481@morganlewis.com to the below counsel of record for Petitioner per Petitioner’s consent for electronic service (*see* Paper 1 at 111).

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