

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PARAGON 28, INC.,
Petitioner,

v.

TREACE MEDICAL CONCEPTS, INC.
Patent Owner.

PGR2026-00017
Patent 12,268,397

**PATENT OWNER'S 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. § 325(d).....	2
A. Governing Framework — <i>Advanced Bionics</i>	2
B. <i>Advanced Bionics</i> Part One — Same or Substantially the Same Art.....	3
C. <i>Advanced Bionics</i> Part Two — No Material Examiner Error.....	4
1. McGlamry.....	5
2. Augoyard	7
3. Other References	8
4. <i>Becton, Dickinson</i> Factors Favor Denial.....	11
(1) Similarity of Art	12
(2) Cumulative Nature	12
(3) Extent of Evaluation.....	12
(4) Overlap of Arguments.....	12
(5) Examiner Error	12
(6) Additional Evidence.....	12
IV. DISCRETIONARY DENIAL UNDER 35 U.S.C. § 324(a).....	12
A. Settled Expectations Attach to the Continuity Chain, Not the Issuance Date.....	14
1. The '397 Patent Claims and '426 Patent Claims.....	15

TABLE OF CONTENTS
(cont'd)

	Page No.
2. Targeted Family Disclosure.....	16
3. Petitioner’s Notice	16
B. Evidence of Substantial Reliance and Settled Expectations	17
C. Merits Considerations Reinforce § 324(a) Discretionary Denial.....	20
V. CONCLUSION.....	20

TABLE OF AUTHORITIES

Page No(s).

Cases

Advanced Bionics, LLC v. MED-EL Elektromedizinische,
IPR2019-01469, Paper 6 (P.T.A.B. Feb. 13, 2020)passim

Amgen Inc. v. Bristol-Myers Squibb Co.,
IPR2025-00601, Paper 9 (P.T.A.B. July 24, 2025)..... 14, 17

Apple Inc. v. Fintiv, Inc.,
IPR2020-00019, Paper 11 (P.T.A.B. Mar. 20, 2020)..... 12, 14, 20

Becton, Dickinson, and Company v. B. Braun Melsungen AG,
IPR2017-01586, Paper 8 (P.T.A.B. Dec. 15, 2017)..... 11, 12

Dabico Airport Solutions Inc. v. AXA Power ApS,
IPR2025-00408, Paper 21 (P.T.A.B. June 18, 2025)2, 16

Ecto World LLC and SV3 LLC v. Rai Strategic Holdings, Inc.,
IPR2024-01280, Paper 13 (P.T.A.B. May 19, 2025) 4

Statutes

35 U.S.C. § 112(a)..... 5

35 U.S.C. § 324passim

35 U.S.C. § 325passim

Other Authorities

Interim Processes for P.T.A.B. Workload Management Memorandum
(P.T.A.B. Mar. 26, 2025)..... 1, 9

LIST OF EXHIBITS

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

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

Exhibit No.	Description
2024	AlphaSense's November 12, 2024 UBS Global Healthcare Conference Transcript
2025	Treace's Announcement of Filing of Patent Infringement Suit To Protect Lapiplasty® Bunion Technology, dated March 28, 2022
2026	Treace's Announcement of Settlement of Lawsuit Against Fusion Orthopedics, dated March 3, 2023
2027	Treace's Announcement of Filing of Patent Infringement and Unfair Competition Suit to Protect Lapiplasty® Bunion Technology, dated October 14, 2024
2028	J.P.Morgan's January 2023 Investor Presentation on Treace Medical Concepts, Inc.

I. INTRODUCTION

Patent Owner (“PO”) respectfully requests that the Director exercise discretion to deny institution of post-grant review (“PGR”) of US 12,268,397 (Ex. 1001, the “’397 Patent”) under 35 U.S.C. § 325(d) and, independently, under 35 U.S.C. § 324(a). This PGR is being litigated alongside three other AIA matters (IPR2026-00194, PGR2026-00020, and PGR2026-00022). The ’397 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 March 12, 2025 (Ex. 2001) and this PGR was requested on December 19, 2025. A fifth patent (US 12,349,941 (Ex. 2002), “’941 Patent”) asserted in the co-pending district court litigation issued on July 8, 2025 and has not been challenged at the PTAB.

“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 '397 continuity chain's longstanding public disclosure and claiming, not merely to the '397 Patent issuance date. *Dabico*, IPR2025-00408, Paper 21 at 2–3 (PTAB June 18, 2025) (Informative).

II. BACKGROUND

The '397 Patent is part of a continuity chain tracing back to an initial 2015 filing. With that filing, PO disclosed bunion correction methods to control cutting and alignment, improving accuracy and reproducibility relative to preexisting techniques. The specific claims of the '397 Patent are directed to methods for performing bunion-correction surgery that include bone cutting instrumentation. Earlier-issued patents in the priority chain claim guided cutting systems 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

Three independent claims from the '397 Patent are challenged: claim 1; claim 20; and claim 29. Those independent claims are challenged based on McGlamry (Ex. 1005) and Augoyard (Ex. 1007). *See* Pet. 51. Both of these references were cited to the Patent Office during prosecution and are on the face of the '397 Patent.

McGlamry was previously presented (referenced twice on the face of the '397 Patent in citations that specifically reference Chapters 29 and 31). PET cites Chapter 31 of McGlamry when challenging the independent claims. *See, e.g.*, Pet. 51–52. Although PET additionally cites Chapter 34 of McGlamry to support the assertion that “in another chapter, McGlamry discloses that commercially available cutting guides ‘help the surgeon resect the proper amount of bone and at the proper angles,’ including when resecting the joint surface” (Pet. 52), this is not in connection with a bunion correction procedure. Further, this is cumulative with Augoyard, which is expressly listed on the face of the '397 Patent, establishing it was also before the Examiner. The Petition itself reinforces that McGlamry’s disclosure is cumulative by repeatedly characterizing McGlamry as reflecting “known” procedures and conventional surgical tools, rather than disclosing a bunion correction method with cutting guides. *See, e.g.*, Pet. 4. PET’s own framing confirms that McGlamry is general background knowledge, not a teaching newly brought before the Office.

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 Petition does not address any specific examiner misunderstandings or omissions with respect to the primary McGlamry and Augoyard references 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 it would not have been obvious to have modified McGlamry’s procedure “based on cutting guides from other joint replacement and arthrodesis procedures.” Pet. 55.

PET’s own statements undercut any potential allegation of examiner error regarding obviousness. For example, PET argues that compatibility between first and second cutting guides raises unresolved architectural issues (Pet. 42–44) and that altering the sequencing of cuts presents alignment and workflow concerns (*id.* at 48–

50). Accordingly, PET asserts that guide integration in this context is not plug-and-play. To the extent PET attempts to argue the Examiner's decision not to make § 112(a) rejections was material error, PO disagrees based on the POPR discussion.

1. McGlamry

The Petition does not identify any method in McGlamry meeting the claimed cutting guide approach. Rather, it asserts that it would have been obvious to use known tools in the claimed manner as functional possibility without any concrete teaching of the claimed method. This supports an inference that the Examiner reasonably treated McGlamry as background context.

The Petition relies on McGlamry for general background descriptions of bunion surgery and freehand Lapidus fusion, acknowledging that McGlamry teaches that Lapidus arthrodesis is a fusion procedure in which joint preparation and precise cutting are “extremely important” to achieve bony union and avoid complications. Pet. 52. The Petition characterizes McGlamry's Lapidus technique as involving freehand resection dependent on the surgeon's skill and judgment, identifying this freehand nature as a source of risk and variability. Pet. 52–53; *see also* Pet. 52–54 (linking freehand/imprecision framing to the asserted motivation to add guides).

Notably, however, McGlamry does not propose using cutting guides for Lapidus fusion despite recognizing the importance of accurate cuts and problems with freehand techniques. That omission is telling. As PET states, McGlamry

elsewhere discusses the use of cutting guides, but in the context of joint replacement/arthroplasty, where guides are used to resect articular surfaces for joint replacement implants. Pet. 52–53 (citing Ex. 1005, 381–83). McGlamry reflects that POSAs were aware of cutting guides and understood their benefits, yet applied them in joint replacement implant-centric procedures, not in Lapidus fusion.

More telling is that the next edition of McGlamry, unavailable as prior art, included PO’s patented approach and expressly discussed cutting guides with respect to Lapidus fusion. *See* Ex. 2003, 300 (describing prior difficulties and instructing to “make precise cuts utilizing a cutting jig (preferred by authors)”). This validates the Examiner’s reasonable implicit conclusion that McGlamry did not disclose the claimed method and demonstrates industry recognition that PO’s approach represented a novel advance over conventional techniques.

In view of the lack of relevant or new disclosure over what was considered by the Examiner, PET relies upon expert-driven reconstruction through Dr. Neufeld’s testimony. Rather than pointing to any passage in McGlamry describing cutting guides for Lapidus fusion, he baldly states that cutting guides would “improve precision, reduce complications, and simplify procedures” without tying those assertions to Lapidus fusion surgery specifically. Ex. 1002 ¶¶ 82–92. His testimony relies on generalized assertions about cutting guide benefits, absent any support from McGlamry regarding their application to fusion procedures. Ex. 1002 ¶¶ 84–99,

120–131, 145. This conclusory testimony is the basis for PET’s “obvious to use cutting guides” rationale in McGlamry’s Lapidus procedure. In sum, the declaration confirms that PET’s theory relying on McGlamry depends on expert-driven impermissible hindsight reconstruction, not on teachings in McGlamry that were overlooked or misunderstood. This is what § 325(d) aims to avoid.

2. Augoyard

Augoyard discusses joint replacement concepts but does not disclose a method using a cutting guide for joint fusion. The Petition again relies on adaptation and expert reasoning rather than disclosed teachings. Pet. 12–14, 56–58, 63–68. Augoyard adds nothing beyond the prior art presented and available to the Examiner. The record supports an inference that Augoyard was understood by the Examiner to be background joint replacement teachings rather than disclosing the claimed method. PET expresses disagreement, not material error. *Advanced Bionics* at 8.

As PET repeatedly admits, Augoyard is directed to metatarsophalangeal joint replacement, not fusion at the tarsometatarsal joint, with its guide system designed around a surgical workflow where geometry is dictated by the implant, not by intraoperative alignment decisions required in fusion. Pet. 12–14. The Petition acknowledges Augoyard’s guides cut both sides of the metatarsophalangeal joint to create articular surfaces for prosthetic replacement, with the purpose of the interlocking guide structure for implant fit. Pet. 12–13. Nothing suggests

Augoyard's guide system was intended for, or naturally applicable to, procedures requiring intraoperative alignment decisions and relative bone movement for a fusion procedure, much less those occurring at an anatomically different joint. The Petition concedes that Augoyard's second cutting guide is used on the phalanx, but attempts to cure this deficiency by saying that "modifications would largely be limited to changes in the orientation" and "placement on the cuneiform instead of the phalanx." Pet. 58. This is hindsight reconstruction.

Dr. Neufeld's testimony does not help. He supplies the alleged fusion methodology through expert assertion, concluding Augoyard's joint replacement-focused guides could be adapted to fusion "because Augoyard's cutting guides would have been nothing more than the use of a known technique for cutting bones to improve McGlamry's known technique in the same way that the guides improved Augoyard's technique." Ex. 1002 ¶ 89. This testimony, too, is based on impermissible hindsight.

3. Other References

PET's reconstruction is further illustrated by PET's reliance on Haddad (Ex. 1013). The Petition invokes Haddad not as a disclosure of a Lapidus procedure, but for the generalized proposition that complementary planar bone surfaces created by a cutting guide may promote union. Pet. 54 (citing Ex. 1013 ¶ 68). It then links that general principle to McGlamry's discussion of union risks and concludes that a

POSA would have replaced McGlamry's disclosed freehand joint-preparation technique with Augoyard's dual-slot, interconnected guide structure.

This layered reasoning ((1) complementary planar cuts can promote union (Haddad); (2) McGlamry discusses union concerns; therefore (3) a POSA would have modified McGlamry by incorporating Augoyard's specific guide system) does not identify any teaching the Examiner overlooked in McGlamry or Augoyard. Rather, it reflects a reassembly of generalized principles across references through expert hindsight and cannot establish material Office error under *Advanced Bionics*.

"The extent of the petition's reliance on expert testimony" is a discretionary consideration. Guidance § I.B. PET alleges that "[a] POSA would have recognized that Augoyard's cut guide would have been adaptable for use with McGlamry's procedure with only minor modifications." Pet. 56. By relying on PET's expert-driven reconstruction, PET is not asking the Office to correct examiner error, but rather, to substitute a paid expert's hindsight opinions for those of the Examiner.

PET recasts this as "routine adaptability," citing Alchermes (Ex. 1023) and Weinstein (Ex. 1015), for example. This does not identify material error. Pet. 57. Those exhibits support only the general notion that cutting guides can be "adapted across procedures and anatomies," not that the Examiner overlooked a fusion-specific disclosure teaching the claimed workflow (first metatarsal cut; alignment adjustment; second cuneiform cut; fusion in the moved position). Pet. 57–58.

PET cites Alchermes for the broad statement that a wedge osteotomy cutting guide is “applicable to such cutting as related to any skeletal elements of the body.” Pet. 56 (quoting Ex. 1023, 7:41–48). But Alchermes addresses “acute angle osteotomy cuts,” not metatarso-cuneiform fusion requiring complementary joint preparation, intraoperative alignment adjustment, and arthrodesis. The quoted language is a generic assertion about potential applicability. Likewise, PET cites Weinstein, asserting that “its cut guides were known for use in Lapidus procedures.” Pet. 56. While Weinstein identifies a “Lapidus-type procedure” as one procedure that “may benefit” from its osteotomy guide apparatus (Ex. 1015 ¶ 51), it fails to disclose the claimed method using its osteotomy guide apparatus. Weinstein provides no sequential cut workflow, no intraoperative alignment step, and no fusion-specific protocol. It discloses a single pivoting guide threaded onto a guide wire at the apex of a wedge (*i.e.*, an apparatus architecturally distinct from the claimed arrangement and directed to angular wedge resection, not tarsometatarsal joint preparation and arthrodesis). PET does not explain how Weinstein supplies any teachings missed by the Examiner. PET cites Weinstein only as secondary support for the general proposition that cut guides could be used in a Lapidus-type procedure. PET does not map any claim limitation to Weinstein nor does PET contend that Weinstein discloses the claimed steps, guide relationships, or fusion workflow.

The structural role of Weinstein and Alchermes in the Petition further

confirms that they cannot support the finding of material error. Both references appear in the Petition's reasonable expectation of success analysis for the specific proposition that cutting guides are adaptable across procedures and anatomies. Pet. 56–57. This placement is significant. Reasonable expectation of success requires an objectively reasonable basis to expect that adapting Augoyard's joint replacement guide system to a Lapidus fusion, where the joint is fused and not replaced, would actually have succeeded. Yet the references PET uses are, as discussed above, a wedge osteotomy instrument directed to acute-angle cuts with no fusion disclosure (Alchermes), and an osteotomy guide that identifies Lapidus-type procedures as potentially beneficial in a single sentence without disclosing any fusion methodology (Weinstein). Neither reference teaches how cutting guides would be configured, positioned, or used in a metatarso-cuneiform fusion workflow, what the expected outcome of such use would be, or why a POSA would have anticipated success rather than merely possibility. PET relies on expert-driven gap-filling using references that were available to the Examiner. This is precisely what § 325(d) is intended to prevent. At most, PET's expert speculation shows reasonable minds could disagree, not material error.

Thus, any alleged asserted error is merely disagreement.

4. *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, all references in the Petition are generalized background knowledge, as discussed above;

(3) Extent of Evaluation: Cited on the face of the '397 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. 2004, 2005*). PET has not filed a motion to stay in district court as of the time of this filing and the case is currently progressing. 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. 98);

(b) Asserted Patents: Four of the five patents currently asserted in the related litigation have been challenged at PTAB, but the fifth patent (the '941 Patent) has not been challenged despite it issuing more than seven months ago. If challenged, that proceeding on closely related subject matter to the present proceeding will occur months later, raising both delay and roadmapping concerns. If not challenged, the litigation and PTAB proceedings will be decided piecemeal; 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. 2006*. 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 guided cutting technology was published by July 2016. From that point forward, the public could reasonably assess a stable and predictable claim trajectory directed to cutting guides for bunion correction, rather than facing a later-emerging or materially different claim theory. Related claims in patents issued by February 2020 (US Patent No. 10,561,426 (Ex. 2007, “the ’426 Patent”)). The Director has denied institution, finding “strong settled expectations” warranting discretionary denial under § 324(a) for durations similar to the ’426 Patent. *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 guided cutting systems for bunion correction that control the orientation and placement of bone cuts through structural guide elements. 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 '397 Patent Claims and '426 Patent Claims

The '397 and '426 patent claims are closely aligned, both reciting a bunion-correction method using a cutting guide to (i) make a first cut on the metatarsal via a first cutting slot, (ii) adjust metatarsal alignment relative to a cuneiform, (iii) make a second cut on the cuneiform via a second cutting slot, and (iv) fuse the metatarsal to the cuneiform in the moved position. *Compare* Ex. 1001 ('397 Patent claim 1), 10:61–11:17 *with* Ex. 2007 ('426 Patent claim 1), 10:53–65. Thus, the '397 patent tracks the core operative steps of the '426 patent (use of two guide slots, alignment adjustment, and fusion), while the '397 patent recites an additional step of “attaching the first bone cutting guide slot to the metatarsal.” Ex. 1001, 10:63–67.

This similarity is confirmed by the reasons for allowance in both applications. *Compare* Ex. 2008 ('397 Patent NOA), 6 *with* Ex. 2009 ('426 Patent NOA), 6.

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 cutting approach 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. 2010 (US 10,856,886); Ex. 2011 (US 11,696,767)) cite PO's patents (including the publication of the parent filing for this continuation family: US 2016/0192950), confirming long-standing technical familiarity.

This is not a case where unexpected claim scope later ensnared an unsuspecting competitor. The '397 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. 2012, 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. 2013* (April 2021 IPO); *Ex. 2014, 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 '426 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. 2015* (October 2021 announcement of 30th granted US patent "strategically enhanc[ing] Treace's comprehensive patent coverage"); *Ex. 2016* (November 2021 announcement emphasizing bone positioner technology patents); *Ex. 2017* (January 2022

PGR2026-00017
Patent 12,268,397

announcement of patent “augment[ing] Treace’s extensive and growing patent portfolio”); Ex. 2018 (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. 2019 (April 2023 announcement of 58 granted patents including 47 in US and 84 pending applications); Ex. 2020 (September 2023 celebrating milestone 50th US patent with July 2014 priority date as demonstration of “commitment to rapid and meaningful innovation”); Ex. 2021 (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. 2022 (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. 2014, 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. 2023 (April 2023 Stephens analyst report identifying “strong IP” as basis for continued market penetration); Ex. 2024, 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. 2025 (March 2022 announcement of patent infringement suit); Ex. 2026 (March 2023 settlement with competitor); Ex. 2027 (October 2024 announcement of suit against Stryker alleging infringement of 9 patents (with no challenges to those patents at PTAB) and unfair competition); Ex. 2021 (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. 52–54 (discussing “freehand” resection and imprecision concerns). The prior approaches required significant surgical skill and were prone to variability in outcome. *See* Ex. 2012, 27–28 (explaining need for patent protection against prior art problems); Ex. 2014, 1, 11 (May 2021 analyst report addressing Lapiplasty 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. 2028, 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, 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.

V. CONCLUSION

Considering all circumstances together, discretionary denial is warranted.

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Patent 12,268,397

Dated: February 27, 2026

Respectfully Submitted,

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CERTIFICATE OF SERVICE

The undersigned certifies that on the 27 of February 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-397@morganlewis.com to the below counsel of record for Petitioner per Petitioner’s consent for electronic service (see Paper 1 at 100).

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