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On behalf of **Petitioner Paragon 28, Inc.**

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PARAGON 28, INC.,

Petitioner,

v.

TREACE MEDICAL CONCEPTS, INC.,

Patent Owner.

Case No. PGR2026-00022

U.S. Patent No. 12,274,481

**PETITIONER'S RESPONSE TO PATENT OWNER'S
REQUEST FOR DISCRETIONARY DENIAL**

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1001	U.S. Patent No. 12,274,481 to Santrock et al. (“the ’481 patent”)
1002	File History of the ’481 patent
1003	Declaration of Steven K. Neufeld, M.D.
1004	McGlamry’s Comprehensive Textbook of Foot and Ankle Surgery, Preface and Chapters 1, 31, 34, 36, and 55, 4 th Edition, 2013 (“McGlamry”)
1005	U.S. Patent No. 8,882,816 to Kartalian et al. (“Kartalian”)
1006	U.S. Patent App. Publ. No. 2016/0213384 to Fallin et al. (“Fallin”)
1007	U.S. Patent No. 8,328,806 to Tyber et al. (“Tyber”)
1008	RESERVED
1009	Paul Dayton, et al., <i>Relationship of Frontal Plane Rotation of First Metatarsal to Proximal Articular Set Angle and Hallux Alignment in Patients Undergoing Tarsometatarsal Arthrodesis for Hallux Abducto Valgus: A Case Series and Critical Review of the Literature</i> , 52(3) J. Foot & Ankle Surgery 348–354 (May-June 2013)
1010	Paul W. Lapidus, <i>Operative correction of the metatarsus varus primus in hallux valgus</i> , 58 J. Surgery Gynecology & Obstetrics 183–191 (1934)
1011	Paul W. Lapidus, <i>The author's bunion operation from 1931 to 1959</i> , 16 Clin. Orthopaedics 119-135 (1960)
1012	Mark H. Hofbauer & Jordan P. Grossman, <i>The Lapidus Procedure</i> , 13(3) Clinics Podiatric Med. & Surgery 486–496 (1996)

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1013	Babak Baravarian, et al., <i>Lapidus bunionectomy: arthrodesis of the first metatarsocunieform [sic] joint</i> , 21 Clinics in Podiatric Med. & Surgery 97–111 (2004)
1014	Brian C. Toolan, <i>Surgical Strategies: The Lapidus Procedure</i> , 28 Foot & Ankle Int'l 1108-1114 (2007)
1015	Timo Schmid & Fabian Krause, <i>The modified Lapidus fusion</i> , 19(2) Foot & Ankle Clinics 223–233 (June 2014)
1016	Nathan J. Young & Charles M. Zelen, <i>New techniques and alternative fixation for the lapidus arthrodesis</i> , 30(3) Clinics Podiatric Med. & Surgery 423–434 (July 2013)
1017	Lawrence A. DiDomenico, et al., <i>Correction of Frontal Plane Rotation of Sesamoid Apparatus During the Lapidus Procedure: A Novel Approach</i> , 53 J. Foot & Ankle Surgery 248–251 (Mar.-Apr. 2014)
1018	James M. Cottom & Anand M. Vora, <i>Fixation of lapidus arthrodesis with a plantar interfragmentary screw and medial locking plate: a report of 88 cases</i> . 52(4) J. Foot & Ankle Surgery 465–469 (July-Aug. 2013)
1019	Bas B.G.M. Franssen, et al., <i>One century of Kirschner wires and Kirschner wire insertion techniques: A historical review</i> , 76 Acta Orthopedic Belgium 1–6 (2010)
1020	File History for U.S. Provisional Application No. 62/108,936 (“the ’936 application”)
1021	Curriculum Vitae of Steven K. Neufeld, M.D.
1022	U.S. Patent App. Publ. No. 2013/0150900 to Haddad et al. (“Haddad”)
1023	U.S. Patent App. Publ. No. 2007/0265634 to Weinstein (“Weinstein”)

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1024	RESERVED
1025	U.S. Patent No. 5,350,382 to Armstrong et al. (“Armstrong”)
1026	U.S. Patent No. 4,349,018 to Chambers (“Chambers”)
1027	U.S. Patent No. 9,220,518 to Neal et al. (“Neal”)
1028	U.S. Patent App. Publ. No. 2014/0031882 to Schmuck et al. (“Schmuck”)
1029	RESERVED
1030	U.S. Patent No. 5,112,334 to Alchermes et al. (“Alchermes”)
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1035	U.S. Design Patent No. D695,402 to DaCosta et al. (“DaCosta”)
1036	Declaration of Sylvia Hall-Ellis, Ph.D.
1037	U.S. Patent App. Publ. No. 2009/0036893 to Kartalian et al.
1038	Defendants’ Opening Brief in Support of Motion to Stay, <i>Treace Medical Concepts, Inc. v. Zimmer Biomet Holdings, Inc. and Paragon 28, Inc.</i> , C.A. No. 1:25-cv-00592-GBW (Dist. Del.)
1039	Declaration of Michael Schmidt

Patent Owner (“PO”) requests discretionary denial under §§ 325(d) and 324(a). The Board should deny PO’s request and institute review.

I. INTRODUCTION

The relevant considerations overwhelmingly favor institution of this PGR:

- There are no settled expectations: this PGR proceeding challenges a patent that issued only one year ago.
- The Petition addresses—and shows material error in—the Examiner’s stated reasons for allowance, namely the perceived absence of the claimed knob-actuated bone-positioning-guide operation.
- The Office never applied McGlamry, Kartalian, or Fallin in any rejection, nor evaluated the Petition’s combinations, mappings, and motivation evidence.
- PO’s infringement allegations implicate U.S. industry: Petitioner’s accused products are manufactured and assembled in the U.S.
- The parallel district court case is in the earliest stages: there is no scheduling order, no trial date, and no meaningful party investment. PO has delayed that case and sought stays and extensions totaling more than 270 days.
- Any potential for overlapping efforts with the district court has been mitigated by Petitioner’s *Sotera* stipulation.

PO’s arguments for discretionary denial lack merit. PO argues that the Director should deny institution under § 325(d), but the fact that certain references

cited in the Petition were listed among ***hundreds*** of references submitted in IDSs does not show that those references were considered. Indeed, the Examiner never issued any rejection, much less considered the obviousness grounds in the Petition.

PO's *Fintiv* arguments fare no better. Because ***PO*** repeatedly sought stays and delays, the district court case has not progressed at all. The court has not held a scheduling conference or set any dates, and the parties have not opened discovery.

PO's "settled expectations" argument is likewise unavailing. The scope of a patent—and any resulting public expectations—is defined by the issued claims. The '481 patent issued on April 15, 2025, just eight months before Petitioner filed the PGR Petition. On these facts, PO cannot show settled expectations that weigh against institution. PO's request for discretionary denial should therefore be denied, and the Board should institute this PGR.

II. DISCRETIONARY DENIAL UNDER § 325(D) IS UNWARRANTED

This PGR presents obviousness challenges to be considered for the first time and does not duplicate the Office's prior work. Under *Advanced Bionics*, the question is not whether the art is listed on the patent's face, but whether the same or substantially the same art and arguments were previously presented such that this proceeding would merely duplicate the Office's earlier work. *Advanced Bionics, LLC v. MED-EL Electromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 at 8-10 (P.T.A.B. Feb. 13, 2020) (precedential). That concern is not present here.

The '481 patent issued without any substantive rejection by the Examiner. The Office never analyzed the McGlamry-primary or Fallin-primary combinations, never applied Kartalian in any rejection, and never evaluated the Petition's specific motivation-to-combine analysis or supporting evidence. Thus, PO fails to satisfy *Advanced Bionics* prong one and discretionary denial under § 325(d) is unwarranted.

A. Material Examiner Error

Even if *Advanced Bionics* prong two is reached, the prosecution record shows material error. The Examiner allowed the claims based on the Examiner's view that the prior art failed to disclose the claimed knob-actuated bone-positioning-guide operation, as well as related frontal-plane pin, cuneiform-preparation, compression, and fixation steps. Ex.1002, 586-587. The Petition addresses that exact rationale with prior-art combinations the Office never applied.

McGlamry discloses the Lapidus bunion-correction process, including use of a Weber clamp to "assist, increase, or maintain the reduction." Ex.1004, 325-326; *see* Pet., 26-27. Kartalian discloses a bunion-specific instrument 100 that may act as reduction forceps to align bones or reduce the distance between them, with bone-engaging ends and the threaded knob/shaft/locking-clamp structure mapped in the Petition. Ex.1005, 9:66-10:6, 10:46-62; *see* Pet., 27-30, 33-34. Fallin discloses additional bunion-correction procedure and guide teachings, including joint-alignment, bone-preparation, and fixation-sequence steps. Ex.1006, [0055], [0058],

[0060], [0065]-[0068]; *see* Pet., 54-59, 80-88. No rejection considered those combinations, structural mappings, or Dr. Neufeld’s motivation evidence.

PO’s contrary merits position does not negate material error. Section 325(d) asks whether the Office already evaluated the same art and arguments and whether the Petition identifies error material to patentability. Here, the central McGlamry/Kartalian/Fallin teachings contradict the very reason the Examiner gave for allowance. That is material.

PO’s claim that the Petition is deficient for not briefing § 325(d) is misplaced. Request, 4. *See* FAQs for Interim Processes for PTAB Workload Management¹ (“[P]etition should not address discretionary issues.”). In any event, this Response answers PO’s § 325(d) arguments and shows discretionary denial is unwarranted.

B. McGlamry

Only limited McGlamry excerpts—Chapters 29 and 31—were submitted during prosecution, and those excerpts were among hundreds of IDS references. The Petition relies on additional McGlamry chapters (including Chapters 1, 34, 36, and 55), and no office action applied any McGlamry chapter in a rejection.

¹ <https://www.uspto.gov/patents/ptab/faqs/interim-processes-workload-management>

More importantly, the McGlamry grounds do not rely on McGlamry alone. They combine McGlamry with Kartalian and, for many claims, Fallin, using claim mappings and motivation evidence never evaluated in prosecution. Thus, even accepting PO's *Ecto* premise that listed art may satisfy *Advanced Bionics* prong one, any limited Chapter 31 overlap does not make the Petition duplicative of the Office's work.

PO's remaining McGlamry criticisms go to merits, not § 325(d) duplication. Request, 4-5. The Office never analyzed McGlamry's metatarsal-positioning teachings, never evaluated the Petition's McGlamry-primary and Fallin-primary combinations, and never addressed the supporting testimony and evidence now offered. Even if PO disputes the ultimate merits, that does not establish duplication of the Office's prior work.

C. Kartalian

Kartalian reinforces why § 325(d) denial is unwarranted. The Office never evaluated the Petition's use of Kartalian in combination with McGlamry or Fallin. The Petition does not rely on Kartalian as merely background. It relies on Kartalian as a bunion-specific reference supplying structural teachings for the obviousness combinations. Pet., 27-30, 82-84. Kartalian discloses instrument 100, which "may act as reduction forceps to align two bones [and] allow for correction of any rotational deformity when used for surgical correction of a bunion." Ex.1005, 9:66-

10:3; *see* Pet., 27-30. Kartalian further discloses specific structure for that instrument, including bone-engaging ends and the threaded knob/shaft structure mapped in the Petition. Ex.1005, 9:66-10:3, 10:46-62, Fig.1; *see* Pet., 27-30, 32-34. That disclosure is not mere “alignment concepts”; it is bunion-correction instrumentation with disclosed structure and a stated use for reduction and rotational correction.

Nothing in the prosecution record shows the Office ever analyzed Kartalian in that way—or at all. Being listed on the patent does not show that the Examiner considered Kartalian’s instrument 100, its threaded knob/shaft structure, or any asserted combination involving Kartalian. The Examiner never applied Kartalian in a rejection and never addressed whether Kartalian’s teachings combined with McGlamry or Fallin rendered the claims obvious.

PO’s focus on Kartalian’s description of element 114 as a “locking clamp” merely raises a merits dispute, not § 325(d) duplication. The Petition relies on Kartalian’s disclosed threaded knob/shaft/locking-clamp structure and Dr. Neufeld’s explanation of how a POSA would understand and use that structure in McGlamry’s procedure. Pet., 33-34; Ex.1003, ¶¶131-132. The Office never considered that analysis, and PO’s “guide” and hindsight criticisms do not answer the *Advanced Bionics* prongs. Request, 6-10.

Thus, the *Becton Dickinson* factors favor institution. The Examiner did not evaluate the additional McGlamry chapters, did not apply Kartalian in any rejection, and did not address the Petition's specific obviousness combinations or supporting motivation evidence. The extent-of-evaluation factor also favors institution because the Examiner did not apply any prior art to reject the claims. This proceeding is the first time the Office will consider these obviousness grounds on a developed record.

For these reasons, PO's § 325(d) arguments lack merit.

III. PATENT OWNER'S § 324(A) ARGUMENTS FAIL

A. Petitioner Manufactures the Accused Products in the United States

The Director's March 11, 2026 Memorandum directs consideration of U.S. manufacturing and related investments. Ex.2025. The devices PO alleges practice the asserted method claims are assembled in the United States as final products. Ex.1039. Most components are also made in the United States and not sent abroad for additional processing. *Id.* For example, the clamp component is manufactured in Michigan, and the wedge component is manufactured in Florida. *Id.* These considerations weigh against discretionary denial and in favor of institution.

The Request asserts that PO's business is "entirely American," but it offers no evidence to support that assertion. Request, 20. Unsupported attorney argument cannot establish a factual basis for discretionary denial.

B. The *Fintiv* Factors Weigh in Favor of Institution

1. A Stay in the District Court Is Likely

Petitioner moved to stay the district court case on March 4, 2026. Now that Petitioner has filed PGR/IPR petitions challenging all asserted patents, a stay is likely. In any event, the case has not progressed: there is no schedule, no trial date, and not even a deadline for the parties to discuss a schedule. Although PO represented that it would request a Rule 16 conference, it has not done so. Instead, PO has repeatedly sought stays and extensions in the district court, delaying the case and minimizing investment. Ex.1038, 1-2.

After filing its Amended Complaint on August 13, 2025, PO stipulated to a forty-five-day stay, then an additional thirty-day stay, and then a further nine-day extension of that stay. *Id.* After the case had been stayed for nearly three months, PO filed a motion to dismiss at the same time Petitioner filed this PGR Petition. Rather than promptly responding to that motion, PO requested, and the parties stipulated to, yet another extension, extending Plaintiff's deadline to respond by forty-six days. *Id.* As a result of those stays and extensions, the case remains at an early stage: the pleadings are still open, the parties have not conducted a Rule 26(f) conference, discovery has not begun, and the court has not set a schedule. This factor therefore weighs against discretionary denial, or at most is neutral.

2. There Is No Trial Date

As PO admits, there is no trial date. Request, 11. PO argues the case is “[n]ine months in[],” but it has not meaningfully progressed and remains in its infancy, with no scheduling order. This factor weighs against discretionary denial.

3. Minimal Investment by the Parties and the Court

Without a schedule, nothing has occurred on the merits. The court has not invested substantial resources, and the case has not reached a stage of duplication. Time alone is not investment. This factor weighs against discretionary denial.

4. Issue Overlap

Petitioner’s *Sotera* stipulation materially reduces overlap concerns. Pet., 109-110. If review is instituted, Petitioner will not pursue in district court any ground raised, or that reasonably could have been raised, in this PGR. PO argues that the stipulation “has not disavowed asserting the same art in different ways.” Request, 12. That assertion is unsupported and misses the point: the stipulation substantially mitigates concerns about duplicative efforts and inconsistent results.

Petitioner has filed PGR/IPR petitions challenging all five asserted patents. PO asserts, without support, that the later-filed petition on the ’941 patent creates

delay concerns. *Id.* It does not. All petitions were filed within 3 months², and the '941 patent is from a different family with different subject matter. There is no delay, and having separate schedules/hearings is irrelevant.

PO also argues that the parties' dispute will proceed because Petitioner filed a separate district court case against PO and joinder is possible. *Id.*, 12-13. That argument is speculative at best. Although PO has moved to sever and join certain portions of a second offensive action brought by Petitioner, Petitioner has opposed consolidation on the grounds that the separate action involves trade secret and copyright claims, different parties and subject matter, different patents, and different accused products. Factor 4 therefore weighs strongly against discretionary denial.

5. The Parties are the Same

Petitioner is the district court defendant. This factor carries little weight given the absence of a schedule, the minimal investment, and the *Sotera* stipulation.

On balance, the *Fintiv* factors favor institution.

² PO asserts that the '941 petition was filed "almost four months after the first petition filing," but that same paragraph identifies December 19, 2025 as the first petition date and March 3, 2026 as the '941 petition date—a 74-day interval, about two and a half months. Request, 12.

C. There are No Settled Expectations Here

The relevant inquiry is how long the challenged claims have been in force, not the earliest publication in the family. The USPTO's Interim Director Discretionary Process identifies "[s]ettled expectations of the parties, such as the length of time the claims have been in force," as the relevant consideration. Process Memorandum at 2. Consistent with that framework, the question here is the age of the challenged '481 patent claims, not the age of the earliest family disclosure.

1. PGRs are Preferred

Petitions for PGR are favored. PGR petitions must be filed within nine months of grant, are close in time to examination, and occur before patent-rights expectations are strongly settled. *Multi-Color Corp. v. Brook & Whittle Ltd.*, PGR2025-00025, Paper 10 (P.T.A.B. July 16, 2025) (precedential). That principle applies here. The '481 patent issued on April 15, 2025, and Petitioner filed its Petition on January 13, 2026, within the nine-month window. The timing weighs strongly against any settled-expectations claim.

The age of the '481 patent likewise weighs against discretionary denial. The Office has declined to find strong settled expectations even for much older patents, including those issued in 2021-2023. *Apple Inc. v. Apex Beam Techs. LLC*, IPR2025-00896, Paper 10 (P.T.A.B. Sept. 3, 2025). The same is true for patents issued in 2019-2020. *See, e.g., Cambridge Indus. USA, Inc. v. Applied*

Optoelectronics, Inc., IPR2025-00434, Paper 11, 2-3 (P.T.A.B. June 26, 2025). If patents in force for years did not create strong settled expectations, a patent challenged within nine months of issuance plainly does not.

Recent decisions reinforce the point. In *Dabico*, the Board found strong settled expectations where a patent had been in force for eight years. *Dabico Airport Sols. Inc. v. AXA Power ApS*, IPR2025-00408, Paper 21 (P.T.A.B. June 18, 2025) (informative). In *Amgen*, the Board distinguished patents that had been in force for seven and six years from one that had been in force for only three years. *Amgen Inc. v. Bristol-Myers Squibb Co.*, IPR2025-00601, Paper 9 (P.T.A.B. July 24, 2025) (informative). And in *Embodiment*, although one challenged patent issued in 2022 and a related parent patent issued in 2018, the Board held that the patent owner had not developed strong settled expectations as to the younger patent and that it was an efficient use of Board resources to address the related parent patent. *Embodiment, Inc. v. Lifenet Health*, IPR2025-00248, Paper 13 (P.T.A.B. June 26, 2025). Here, the '481 patent had been in force for less than nine months when the Petition was filed, placing this case well below established years necessary for settled expectations.

2. **The Relevant Period is How Long the Challenged Patent Claims Have Been in Force—Not the Earliest Publication in the Family**

Recognizing that the recently issued '481 patent cannot support settled expectations, PO argues that the settled expectations period should instead run from the earliest publication in the family. Request, 13-14. That is not the Office's

framework. Consistent with the Director's guidance, PTAB decisions measure settled expectations by how long the challenged patent has been in force—not the earliest publication or filing date in the family. *Dabico* found strong settled expectations where the patent was in force for eight years. *Dabico Airport Sols. Inc. v. AXA Power ApS*, IPR2025-00408, Paper 21 (P.T.A.B. June 18, 2025) (informative). *Amgen* distinguished patents in force for seven and six years from a patent in force for three years. *Amgen Inc. v. Bristol-Myers Squibb Co.*, IPR2025-00601, Paper 9 (July 24, 2025) (informative).

Embodiment is especially instructive because it rejects the very move PO attempts here. *Embodiment, Inc. v. Lifenet Health*, IPR2025-00248, Paper 13 (P.T.A.B. June 26, 2025). There, one challenged patent issued in 2022 and another, related parent patent issued in 2018. Even so, the Acting Director held that the patent owner had not developed strong settled expectations as to the younger patent and that it was an efficient use of Board resources to address the related parent patent as well. *Id.* The existence of an older related patent, or an older family publication, thus does not transplant settled expectations onto a newly issued challenged patent.

PO's continuity-chain theory is also inconsistent with PGR. If settled expectations could attach before a continuation patent issued, continuation patents could be insulated from PGR before the statutory window opened. The scope of a patent and its preclusive effect are created by the claims, not the disclosure. There

can be no expectation without an understanding of what claims are actually patentable. Under PO's theory, it would be the public's burden to either undertake or predict all claims that may issue from a particular disclosure. That is simply untenable. Moreover, PO's argument cannot be reconciled with Congress's decision to permit PGR challenges during the first nine months after issuance, or with *Multi-Color*'s recognition that PGR petitions are favored precisely because they are filed before patent-right expectations are strongly settled. Petitioner could not have filed a PGR against the '481 patent before it issued.

3. The '481 and '670 Patent Claims are Different

Settled expectations cannot be borrowed from earlier family members; the inquiry is claim-specific. Although PO identifies similarities between the '481 patent and earlier '670 patent, the claims are very different. Request, 14-15. For example, claim 1 of the '481 patent recites a "engaging the bone positioning guide with a second metatarsal separated from the first metatarsal by an intermetatarsal angle," "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," and "imparting a force to a pin inserted into the first metatarsal," among other limitations. Ex.1001, claim 1. The '670 patent claims do not include these features and instead include different features. See Ex.2005, claim 1. Even where related patents share

the same disclosure, expectations about validity, scope, and infringement turn on the claims in force. PO's comparison of claim sets confirms that principle.

PO's arguments regarding the predictability of the patent family further undermine PO's deviation from the established settled expectations framework. Request, 15. PO acknowledges that claim scope changes, even among patent family members. There is no dispute that any settled expectations would require an understanding of the claim scope and its patentability.

4. Petitioner's Notice does Not Establish Settled Expectations

PO also argues that Petitioner had notice of the family for years because Petitioner's patents cite earlier PO publications. Request, 15-16. That does not advance PO's settled-expectations theory. *Dabico* explains that actual notice of a patent or possible infringement theory is not required to create settled expectations, but it does not suggest that awareness of an earlier family publication creates settled expectations in later-issued claims not yet in force. To the contrary, the Office's framework focuses on how long the challenged claims have been in force. Here, Petitioner could not have filed a PGR before the '481 patent issued. Pre-issuance awareness of the family does not show that strong settled expectations had formed.

Nor is notice dispositive even in older-patent cases. In *Apple Inc. v. Ferid Allani*, the Office declined discretionary denial despite years of awareness because surrounding circumstances undercut any expectation of enforcement. *Apple Inc. v.*

Ferid Allani, IPR2025-00857, Paper 11 (P.T.A.B. Sept. 5, 2025). Notice is only one factor in a broader inquiry and cannot substitute for showing that strong settled expectations formed around the challenged claims. Given the '481 patent's recent issuance and prompt petition filing, PO's notice argument carries little weight.

5. **PO has Not Shown Substantial Reliance Giving Rise to Strong Settled Expectations**

PO's reliance evidence is insufficient. Nearly all evidence predates issuance of the '481 patent and concerns commercialization efforts, investor messaging, adoption, or portfolio size. Request, 16-19 (citing Exs.2008-2024). That evidence may show recognition of PO's business, but not strong settled expectations in the '481 patent's claims, which had been in force less than nine months when challenged. *Amgen* indicates that a patent owner may establish strong settled expectations for a younger patent by showing extraordinary investment tied to the ***challenged patent***. But *Amgen* did not find strong settled expectations even for a patent in force for about three years. PO's showing is weaker: its evidence is pre-issuance and portfolio-level, not claim-specific or tied to the '481 patent's in-force period.

PO's reliance theory is overstated. Request, 16-19. The Petition was filed within the nine-month PGR window Congress created for prompt post-issuance review. Institution would not upset long-accrued expectations present in decisions like *Dabico*, where the patent had been in force almost eight years. Instead,

institution would allow the Office to evaluate a newly issued patent within the review window Congress created. On this record, PO has not shown the type of strong, claim-specific reliance needed to support discretionary denial.

D. PO's Merits Arguments Do Not Support Discretionary Denial

PO devotes only a brief paragraph to “Merits Considerations” under § 324(a), asserting that the Petition’s “weak merits will be evident after review of the POPR.” Request, 19-20. But discretionary-denial arguments must be presented in the Request, not deferred to a later filing. *See* 37 C.F.R. § 42.6(a)(3) (“Arguments must not be incorporated by reference from one document into another document.”). Most of PO’s actual merits criticisms appear elsewhere, principally in PO’s § 325(d) discussion. For completeness, Petitioner addresses the principal merits points here. None shows the kind of facially weak petition that could justify discretionary denial. The Petition sets forth six grounds with detailed claim mappings, citations to the prior art, and supporting expert testimony. Pet. 24-109; Ex.1003.

PO principally argues that the Petition failed to identify the claimed rotating-knob operation and relied on hindsight. Request, 5, 7-10. That mischaracterizes the Petition’s asserted combinations. McGlamry discloses a Lapidus procedure in which a Weber clamp may “assist, increase, or maintain reduction.” Ex.1004, 325-326; *see* Pet., 26-27. Kartalian discloses a bunion-specific reduction instrument 100 that aligns bones or reduces distance, includes bone-engaging ends 102/106, and has

the threaded knob/shaft/locking-clamp structure the Petition maps to the claimed rotating-knob/threaded-shaft limitation. Ex.1005, 9:66-10:6, 10:46-62; *see* Pet., 27-30, 33-34. Dr. Neufeld explains that, when used in McGlamry’s procedure, a surgeon would rotate that threaded knob to bring the handles together and move arm 106 toward end 102, thereby pushing the first metatarsal laterally toward the second metatarsal. Ex.1003, ¶¶131-132; *see* Pet., 33-34. That is evidence-based obviousness, not hindsight.

Kartalian’s description of element 114 as a “locking clamp” does not defeat the Petition’s grounds. PO reads Kartalian’s “hold” capability to exclude knob-actuated reduction (Request, 9-10), but Kartalian does not suggest that the threaded knob is inoperable during reduction or incapable of moving the arms. The Petition relies on the disclosed threaded knob/shaft/locking-clamp structure and Dr. Neufeld’s explanation of how a POSA would understand that structure. Pet., 33-34; Ex.1003, ¶¶131-132. Kartalian separately states that instrument 100 “may act as reduction forceps” and that, after placement on the bones, “reduction or realignment may occur” to the desired angle. Ex.1005, 9:66-10:6, 10:46-62; *see* Pet., 27, 34. At most, PO raises a different reading of Kartalian and challenges Dr. Neufeld’s supporting testimony. That is an ordinary merits dispute, not a basis for discretionary denial.

PO also argues that Kartalian's instrument is merely a tenaculum and not a bone positioning guide. Request, 6. But the Petition cites Kartalian's reduction-forceps disclosure, maps the first and second bone-engaging ends, sleeve, threaded mechanism, and related components, and explains why a POSA would use those bunion-specific features in McGlamry's procedure. Pet., 27-34. Whether those mapped structures satisfy the claimed guide is a claim-scope and prior-art-comparison dispute; it does not show that the Petition lacks evidentiary support or analytical substance.

PO's cumulative/background criticisms fare no better. Request, 5-8. McGlamry is not used for generic clamps in the abstract; it describes a triplanar bunion-correction procedure and shows a Weber clamp used during reduction. Pet., 26-27 (discussing Ex.1004, 325-326, Fig.31.5). Kartalian is not background either; it supplies the bone-engaging and threaded-actuation features. *Id.*, 27-34 (discussing Ex.1005, 9:66-10:6, 10:46-62). PO's criticisms dispute Petitioner's claim-scope position, its reading of McGlamry and Kartalian, and the POSA inferences drawn from the record. Those are ordinary merits issues and do not warrant discretionary denial.

Respectfully submitted,

Dated: April 22, 2026

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CERTIFICATE OF SERVICE

I hereby certify that on the date below, true and correct copies of **PETITIONER'S RESPONSE TO PATENT OWNER'S REQUEST FOR DISCRETIONARY DENIAL AND EXHIBITS 1038-1039** are being served via email pursuant to 37 C.F.R. § 42.6(e), to counsel for Patent Owner as addressed below:

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