

Filed: April 13, 2026

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. IPR2026-00194

U.S. Patent No. 12,102,368

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

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LIST OF EXHIBITS

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1001	U.S. Patent No. 12,102,368 to Smith et al. (“the ’368 Patent”)
1002	File History of the ’368 Patent
1003	Declaration of Steven K. Neufeld, M.D.
1004	Curriculum Vitae of Steven K. Neufeld, M.D.
1005	U.S. Patent App. Publ. No. 2016/0213384 to Fallin et al. (“Fallin”)
1006	U.S. Patent No. 8,882,816 to Kartalian et al. (“Kartalian”)
1007	McGlamry’s Comprehensive Textbook of Foot and Ankle Surgery, Preface and Chapters 1, 31, 34, 36, and 55, 4 th Edition, 2013 (“McGlamry”)
1008	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)
1009	RESERVED
1010	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)
1011	Mark H. Hofbauer & Jordan P. Grossman, <i>The Lapidus Procedure</i> , 13(3) CLINICS PODIATRIC MED. & SURGERY 486–496 (1996)
1012	Paul W. Lapidus, <i>The author's bunion operation from 1931 to 1959</i> , 16 CLIN. ORTHOPAEDICS 119-135 (1960)

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1013	Paul W. Lapidus, <i>Operative correction of the metatarsus varus primus in hallux valgus</i> , 58 J. SURGERY GYNECOLOGY & OBSTETRICS 183–191 (1934)
1014	Babak Baravarian, et al., <i>Lapidus bunionectomy: arthrodesis of the first metatarsocunieform [sic] joint</i> , 21 CLINICS IN PODIATRIC MED. & SURGERY 97–111 (2004)
1015	Brian C. Toolan, <i>Surgical Strategies: The Lapidus Procedure</i> , 28 FOOT & ANKLE INT’L 1108-1114 (2007)
1016	Timo Schmid & Fabian Krause, <i>The modified Lapidus fusion</i> , 19(2) FOOT & ANKLE CLINICS 223–233 (June 2014)
1017	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)
1018	U.S. Design Patent No. D695,402 to DaCosta et al. (“DaCosta”)
1019	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)
1020	RESERVED
1021	RESERVED
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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1026	U.S. Patent No. 4,349,018 to Chambers (“Chambers”)

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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	U.S. Patent No. 5,722,978 to Jenkins (“Jenkins”)
1030	U.S. Patent No. 5,112,334 to Alchermes et al. (“Alchermes”)
1031	U.S. Patent App. Publ. No. 2012/0078258 to Lo et al. (“Lo”)
1032	International App. Publ. No. 2015/123270 to Sachin et al. (“Sachin”)
1033	U.S. Patent App. Publ. No. 2013/0030438 to Fox (“Fox”)
1034	U.S. Patent App. Publ. No. 2011/0186456 to Bertazzoni et al. (“Bertazzoni”)
1035	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)
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 314(a). The Board should deny PO’s request and institute review.

I. INTRODUCTION

The relevant considerations overwhelmingly favor institution of this IPR:

- The Office never analyzed the specific combinations, structural teachings, and motivation-to-combine analysis presented here, and the Petition directly addresses the Examiner’s erroneous rationale for allowing the claims.
- PO’s infringement allegations implicate U.S. industry: Petitioner’s accused products are manufactured and assembled in the U.S.
- There are no strong settled expectations: Petitioner filed the Petition approximately fifteen months after the ’368 patent issued.
- 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 substantially 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 some of the 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 rejected the challenged claims, 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 '368 patent issued on October 1, 2024, just 15 months before Petitioner filed the IPR 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 IPR.

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

This IPR 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 simply revisit what the Office already analyzed. *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 is not this case.

The '368 patent issued without any prior-art rejection of the challenged claims.¹ The Office never analyzed the McGlamry-Fallin 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 denial under § 325(d) is unwarranted.

A. Material Examiner Error

To the extent the Director reaches prong two of *Advanced Bionics*, the record reflects material examiner error. The Examiner's rationale for allowing the claims was that the prior art did not disclose the claimed bone-positioning-guide concepts. Ex.1002, 497. The Petition and Dr. Neufeld's testimony address that rationale directly and expose its error by identifying teachings and combinations the Office never analyzed, including McGlamry's Lapidus reduction technique, Kartalian's bunion-specific reduction instrument, and Fallin's guide-body and fixation techniques.

The Examiner's error is explicit and clear from the prosecution history. Specifically, the Examiner allowed the challenged claims based on an understanding

¹ The Examiner issued an Office Action on June 4, 2024. Ex.1002, 374-381. But that Office Action addressed claims later cancelled by preliminary amendment and did not reject the challenged claims. *Id.*, 376-381.

that the prior art did not disclose the claimed bone-positioning-guide concepts. Ex.1002, 497. The Petition addresses and disproves that rationale directly. McGlamry Chapter 31 discloses a Lapidus reduction technique in which the surgeon obtains frontal-plane correction, transverse-plane reduction, and temporary fixation while a Weber clamp may be used to “assist, increase, or maintain the reduction.” Pet., 34-36. McGlamry also discloses that the corrected position is maintained while temporary fixation is placed. *Id.*, 35-36. Those teachings go directly to the concepts the Examiner viewed as missing from the prior art.

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 Management² (“The petition should not address discretionary issues.”). In any event, this Response answers PO’s § 325(d) arguments and shows why discretionary denial is unwarranted.

B. McGlamry

PO argues that McGlamry’s Chapters 29 and 31 are referenced on the face of the ’368 patent. But even if those chapters are listed, the Petition relies on additional McGlamry chapters (including Chapters 1, 34, 36, and 55) not submitted to or

² <https://www.uspto.gov/patents/ptab/faqs/interim-processes-workload-management>

considered by the Examiner. Nor did the Examiner apply McGlamry in any office action or rejection. The limited excerpts of Chapters 29 and 31 that were submitted were among hundreds of references cited in IDSs during prosecution.

Moreover, the Petition's grounds do not rely on McGlamry alone. Each ground combines McGlamry with at least Fallin and includes claim mappings, combinations, and motivation-to-combine arguments not previously before the Office. Thus, even if PO could show some overlap as to Chapters 29 and 31, that would not establish that the same or substantially the same art and arguments were presented. At a minimum, PO has not shown any overlap as to Chapter 34 or as to the McGlamry-Fallin combinations and arguments advanced in the Petition.

PO relies on *Ecto* for the proposition that art listed on the patent's face can satisfy prong one of *Advanced Bionics* even if the art was not applied during prosecution. Request, 3. But the Petition does not rely solely on the face-listed McGlamry excerpts; it relies on Chapter 34, combinations with Fallin and Kartalian, and arguments and evidence that were never applied or evaluated during prosecution.

Regarding the second *Advanced Bionics* prong, PO argues that the Petition did not address any specific examiner error and did not preemptively address § 325(d). Request, 4. Contrary to PO's argument, Petitioner was not required to address § 325(d) in the Petition. In any event, the Examiner materially erred in

allowing the claims without considering the teachings and combinations on which the McGlamry grounds rely, as explained in the previous section.

PO also responds by arguing that McGlamry discloses only background tools and that Petitioner relies on expert hindsight. Request, 5-8. But that criticism goes to the merits, not whether the Office previously considered the same record. The Office never analyzed McGlamry's reduction teachings, never evaluated the Petition's McGlamry-Fallin 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.

Thus, both *Advanced Bionics* prongs weigh against denying institution.

C. Kartalian

PO's Kartalian arguments fare no better. Request, 8-11. The Petition does not rely on Kartalian as a bare background reference or as an anticipation reference. It relies on Kartalian as a bunion-specific secondary reference supplying additional structural teachings and supporting the obviousness combinations. 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." Pet., 61-63 (citing Ex.1006, 9:66-10:3). Kartalian further discloses specific structure for that instrument, including bone-engaging ends, cannulated sleeve, and a locking/threaded mechanism for bringing the ends together

and holding the achieved alignment. Pet., 63-64, 68-69. That is not mere “alignment context”; it is bunion-reduction instrumentation with disclosed structure and stated use for rotation 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 bunion-specific rotation-correction teaching, or any McGlamry-Fallin-Kartalian combination. The Examiner never applied Kartalian in a rejection and never addressed whether Kartalian supplied limitations not recited by McGlamry or whether those references together rendered the claims obvious.

Instead of addressing the *Advanced Bionics* prong, PO again attacks the merits, arguing that Kartalian does not disclose sufficient “guide” structure and dismissing Dr. Neufeld’s opinions as hindsight. Request, 10-11. But those arguments do not answer the § 325(d) question. The Office never previously evaluated the Kartalian-based analysis advanced here. To the extent *Advanced Bionics* prong two is reached, the record reflects material error because the claims were allowed based on a perceived absence of the claimed bone-positioning-guide concepts, while Kartalian provides additional bone-positioning-guide teachings the Office never applied. This proceeding is therefore the first time the Office will consider those Kartalian-based obviousness theories on a developed record.

Thus, the *Becton Dickinson* factors favor institution. The Examiner did not consider the same art and arguments presented here: he did not evaluate the additional McGlamry chapters, did not apply Kartalian in any rejection, or 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 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 § 314(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. 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, Petitioner filed a motion to dismiss at the same time it filed this IPR 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, 12. 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 significant has occurred on the merits. The court has not invested substantial resources, and the parties have not advanced the case to a stage of duplication with this IPR. PO relies on elapsed time, but time alone is not investment. This factor weighs against discretionary denial.

4. Issue Overlap

Petitioner’s *Sotera* stipulation materially reduces overlap concerns. Pet., 89-90. If review is instituted, Petitioner will not pursue in district court any ground raised, or that reasonably could have been raised, in this IPR. PO argues that the stipulation “has not disavowed asserting the same art in different ways.” Request, 12. That assertion 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 and scheduling concerns. It does not. All petitions were filed within 3 months,

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. Request, 13. That argument is speculative at best. The parties have not met and conferred on consolidation, and Petitioner will oppose consolidation or parallel case management because the separate action involves trade secret and copyright claims, different parties and subject matter, 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.

C. There are No Settled Expectations

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 '368 patent claims, not the age of the earliest family disclosure.

The '368 patent issued on October 1, 2024, and Petitioner filed its Petition on January 5, 2026—roughly fifteen months later. On those facts, PO cannot show strong settled expectations.

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 '368 patent had been in force for only fifteen months when the Petition was filed, placing this case much closer to *Embodiment* and the three-year patent in *Amgen* than to the eight-year patent in *Dabico* or the other patents in *Amgen*.

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

PO's continuity-chain theory is unpersuasive. A continuation disclosure does not itself create settled expectation in later-issued claims that did not yet exist. Patent

scope and preclusive effect arise from issued claims, not from the underlying disclosure alone. Petitioner could not have filed an IPR against the '368 patent before it issued. PO's theory would require the public to predict every claim that might someday issue from a family disclosure. That is not the Office's framework and is not a workable one.

2. The '368 and '994 Patent Claims are Different

Settled expectations cannot be borrowed from earlier family members; the inquiry is claim-specific. Although PO identifies similarities between the '368 patent and earlier '994 patent, the claims are very different. Request, 14-15. For example, claim 1 of the '368 patent recites a “bone preparation guide comprising a body defining guide surface” and “at least one fixation device positionable across a tarsal-metatarsal joint,” among other limitations. Ex.1001, claim 1. The '994 patent claims do not include these features and instead include different features. *See* Ex.2002, 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 the inquiry must focus on the challenged claims, not family disclosures.

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.

3. 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 an IPR before the '368 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 '368 patent's recent issuance and prompt petition filing, PO's notice argument carries little weight.

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

PO's evidence is insufficient. Nearly all evidence predates issuance of the '368 patent and concerns commercialization efforts, investor messaging, adoption, or portfolio size. Request, 16-20 (citing Exs.2011-2027). That evidence may show recognition of PO's business, but not strong settled expectations in the '368 patent's claims, which had been in force fifteen 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 '368 patent's in-force period.

PO's reliance theory is overstated. The Petition was filed soon after the patent's issuance. 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. 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 § 314(a), asserting that the Petition's "weak merits will be evident after review of the POPR."

Request, 20. But arguments for discretionary denial must be presented in the Request itself, 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.”). And here, most of PO’s actual merits criticisms appear elsewhere in the Request, 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. 21-90; Ex.1003.

PO’s principal merits theme is that the Petition supposedly defines “bone positioning guide” so broadly that any device capable of moving bone qualifies. Request, 6-10. That mischaracterizes the Petition. It does not rely on abstraction alone. With respect to McGlamry, it identifies the specific reduction instrument shown and used in the disclosed Lapidus procedure—a Weber clamp—and cites McGlamry’s teaching that the clamp may be used to “assist, increase, or maintain the reduction” while the first metatarsal is being repositioned and temporarily fixed. Pet., 34-36 (discussing and citing Ex.1007, 325-326). The Petition likewise cites McGlamry’s discussion that correction must be maintained “in all three planes,” and that a K-wire may be used “as a rotation device” where additional frontal-plane correction is needed. *Id.*, 36 (discussing and citing Ex.1007, 326, 328-329).

Whether PO agrees with Petitioner's reading is a merits dispute, but it is not a showing that the Petition lacks evidentiary support or analytical substance.

PO likewise overstates its criticism that the Petition offers no support for frontal-plane rotation and instead relies on hindsight expert say-so. Request, 7-8. The Petition expressly explains why a POSA would have understood a Weber clamp engaged across adjacent metatarsals to transmit controlled corrective forces, including a rotational component, in the disclosed bunion-correction context. Pet., 35-37. The Petition also cites evidence that screw-adjustable Weber-clamp configurations were known and were capable of incremental movement and stable retention during fixation. *Id.*, 51-52. PO may disagree with that analysis, but disagreement over what the art would have conveyed to a POSA is ordinary merits territory, not proof of a weak petition.

PO's "generic background tool" criticism of McGlamry fares no better. Request, 5-8. McGlamry does not merely mention clamps in the abstract; it describes a triplanar bunion-correction procedure, discusses reduction of the first metatarsal in multiple planes, and shows the Weber clamp in use during reduction of a large intermetatarsal angle. Pet., 34-36 (discussing Ex.1007, 322-327, Fig.31.5). PO's reliance on the later, non-prior-art McGlamry edition likewise does not render the Petition weak. At most, PO uses the later edition to argue for its preferred reading of the earlier record. But the Petition's obviousness analysis is grounded in

the prior-art McGlamry disclosure itself, together with contemporaneous evidence and Dr. Neufeld's explanation of how a POSA would have understood familiar reduction instrumentation used in bunion surgery. Pet., 34-37, 51-52. That is a conventional obviousness dispute for the Board, not a basis for discretionary denial.

The same is true of Kartalian. PO characterizes Kartalian as mere "background alignment context" and contends that the Petition identifies no guide-specific structure. Request, 9-11. But the Petition cites Kartalian's express disclosure of "instrument 100," which "may act as reduction forceps to align may act as reduction forceps to align two bones" and "may allow for correction of any rotational deformity (pronation) when used for surgical correction of a bunion." Pet., 62-64 (discussing and citing Ex.1006, 9:66-10:3). The Petition also identifies specific structural features of instrument 100—including first and second bone-engaging ends, a locking/threaded mechanism, and related components used to engage and reposition the metatarsals—and explains why those bunion-specific features would have made Kartalian's instrument a desirable option in McGlamry's procedure. Pet., 63-65, 68-69. Nor does the Petition rise and fall solely with PO's characterization of McGlamry. Ground 2 expressly argues that, even if McGlamry alone were deemed insufficient for limitation 1[b], Kartalian separately supplies that limitation. Pet., 61-64.

PO further argues that the Petition misreads the '368 patent by treating tong/tenaculum-type structures as the recited bone positioning guide. Request, 4-6. But that too is a conventional merits dispute about claim scope and how the prior art compares to the challenged claims and disclosed corresponding structures. It does not show that the Petition is facially weak. At most, PO identifies issues the Board can resolve in the ordinary institution analysis after considering the Petition and POPR.

In short, even if merits are considered as part of the totality under § 314(a), PO has not shown the type of facially deficient petition that could justify discretionary denial. PO's criticisms dispute Petitioner's claim-scope position, its reading of McGlamry and Kartalian, and the inferences a POSA would draw from the record. Those are ordinary merits issues. They do not warrant discretionarily denying institution.

Respectfully submitted,

Dated: April 13, 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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