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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. PGR2026-00017

U.S. Patent No. 12,268,397

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

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1001	U.S. Patent No. 12,268,397 to Dayton et al. (“the ’397 Patent”)
1002	Declaration of Steven K. Neufeld, M.D.
1003	Curriculum Vitae of Steven K. Neufeld, M.D.
1004	File History of the ’397 Patent
1005	McGlamry’s Comprehensive Textbook of Foot and Ankle Surgery, Preface and Chapters 1, 31, 34, 36, and 55, 4th Edition, 2013 (“McGlamry”)
1006	Declaration of Michelle L. Warmath for Translation of European Patent App. Publ. No. 1508316 (“Augoyard”)
1007	English Translation of Augoyard from Ex. 1006
1008	Paul W. Lapidus, <i>Operative correction of the metatarsus varus primus in hallux valgus</i> , 58 J. SURGERY GYNECOLOGY & OBSTETRICS 183–191 (1934)
1009	Mark H. Hofbauer & Jordan P. Grossman, <i>The Lapidus Procedure</i> , 13(3) CLINICS PODIATRIC MED. & SURGERY 486–496 (1996)
1010	RESERVED
1011	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)
1012	U.S. Patent No. 5,601,565 to Huebner (“Huebner”)
1013	U.S. Patent App. Publ. No. 2013/0150900 to Haddad et al. (“Haddad”)
1014	U.S. Design Patent No. D695402 to DaCosta et al. (“DaCosta”)

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1015	U.S. Patent App. Publ. No. 2007/0265634 to Weinstein (“Weinstein”)
1016	U.S. Patent No. 4,349,018 to Chambers (“Chambers”)
1017	U.S. Patent No. 9,220,518 to Neal et al. (“Neal”)
1018	U.S. Patent No. 5,935,128 to Carter et al. (“Carter”)
1019	U.S. Patent No. 6,030,391 to Brainard et al. (“Brainard”)
1020	Paul W. Lapidus, <i>The author's bunion operation from 1931 to 1959</i> , 16 CLIN. ORTHOPAEDICS 119-135 (1960).
1021	U.S. Patent No. 5,350,382 to Armstrong et al. (“Armstrong”)
1022	U.S. Patent No. 5,947,973 to Masini (“Masini”)
1023	U.S. Patent No. 5,112,334 to Alchermes et al. (“Alchermes”)
1024	Timo Schmid & Fabian Krause, <i>The modified Lapidus fusion</i> , 19(2) FOOT & ANKLE CLINICS 223–233 (June 2014)
1025	U.S. Patent App. Publ. No. 2016/0175089 to Fallin
1026	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)
1027	Bun-Yo-Matic™ Lapidus Clamp System - Surgical Technique Guide
1028	U.S. Patent No. 5,722,978 to Jenkins (“Jenkins”)
1029	U.S. Patent App. Publ. No. 2012/0078258 to Lo et al. (“Lo”)
1030	International App. Publ. No. 2015/123270 to Sachin et al. (“Sachin”)

PGR Petition – Patent 12,268,397
Paragon 28, Inc. v. Treace Medical Concepts, Inc.

Exhibit No.	Description
1031	Declaration of Sylvia Hall-Ellis, Ph.D.
1032	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)
1033	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 less than one year ago.
- The Examiner materially erred: he allowed the challenged claims of the ’397 patent in a first Office Action without issuing any rejection, failing to reject those claims under § 112 or as obvious in view of the prior art and evidence of motivation to combine.
- 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 infringement allegations implicate U.S. industry: Petitioner’s accused products are manufactured and assembled in the U.S.

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 '397 patent issued on April 8, 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 raises issues never before the Office. 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.

First, the '397 patent issued without any substantive rejection under §§ 102, 103, or 112. The Office therefore never analyzed the combinations, teachings, or motivations on which the Petition relies.

Second, the prosecution history reflects material examiner error. The Examiner allowed the claims based on his view that the prior art did not disclose the claimed cutting-guide limitations. Ex.1004, 260-262. The Petition and Dr. Neufeld's testimony show that the Examiner's rationale overlooked teachings like McGlamry's Chapter 34 and Augoyard, which expressly disclose cutting-guides and their adaptability. That is material error bearing directly on patentability.

PO's claim that the Petition is deficient for not briefing § 325(d) is misplaced. *See* FAQs for Interim Processes for PTAB Workload Management¹ ("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.

A. § 112 Grounds

PO's § 325(d) remarks do not meaningfully address the Petition's § 112 grounds, which independently weigh strongly against discretionary denial. The Petition challenges all claims for lack of written description and enablement. Pet., 32-51. Those grounds were neither previously presented to nor evaluated by the

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

Office. The Examiner made no § 112 rejection and allowed the claims without addressing the defects identified in the Petition. This PGR thus presents the first time those issues have been presented.

The § 112 grounds alone defeat any suggestion that this PGR merely revisits already-considered issues. PO offers only the conclusory statement that, “[t]o 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.” Request, 5. But no POPR was filed with PO’s Request, and arguments may not be incorporated by reference from one paper into another. 37 C.F.R. § 42.6(a)(3). In any event, PO identifies nothing in the prosecution relating to written description or enablement.

B. McGlamry

PO argues that McGlamry’s Chapters 29 and 31 are referenced on the face of the ’397 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 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 Augoyard 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-Augoyard combinations and arguments advanced in the Petition.

PO argues, without support, that McGlamry's Chapter 34 is "cumulative with Augoyard." Request, 3. But PO's point appears to be only that the Petition characterizes McGlamry as "reflecting 'known' procedures and conventional surgical tools, rather than disclosing a bunion correction method with cutting guides." *Id.* That attorney argument does not show that Chapter 34 is cumulative of Augoyard and does not advance the § 325(d) analysis. To the contrary, PO's characterization of McGlamry as "general background knowledge" reinforces the obviousness grounds by confirming that a POSA understood the established Lapidus procedures and the benefits of using cutting guides.

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, 4. But the Petition does not rely solely on the face-listed McGlamry excerpts; it relies on Chapter 34, combinations with Augoyard, 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). Contrary to PO's argument, Petitioner was not required to address § 325(d) in the Petition. In any event, the record makes clear that the Examiner materially erred in allowing the claims without considering the teachings and combinations on which the McGlamry grounds rely.

The prosecution history confirms as much. In the Notice of Allowance, the Examiner explained that “[t]he prior art alone or in combination fails to disclose a method of bunion correction comprising attaching a first cut guide over a metatarsal with a first and second fixation pin that are located distal of the cutting guide and cutting the bone [and] Positioning a second cut guide over a cuneiform....” Ex.1004, 261. In other words, the Examiner believed the prior art lacked the claimed cutting-guide concepts. But McGlamry Chapter 34 discloses commercially available cutting-guides to resect the proper amount of bone at the proper angles when resecting a joint surface. Pet., 52. Had the Examiner considered Chapter 34, he would have been presented with teachings directly relevant to the cutting-guide limitations he viewed as missing from the prior art.

PO assumes that the Examiner made an “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.’” Request, 4. That assumption is unsupported. There is no evidence that the Examiner considered modifying McGlamry in view of any other reference. Nor is there evidence that the

Examiner substantively analyzed McGlamry at all. *See JUUL Labs, Inc. v. NJOY, LLC*, IPR2024-00160, Paper 10 at 11–13 (PTAB May 24, 2024) (finding first prong of *Advanced Bionics* unmet where patent owner cited no evidence that the examiner substantively considered disclosed references); *Samsung Elecs. Co. v. Maxell, Ltd.*, IPR2024-00867, Paper 9 at 17, 20 (PTAB Nov. 7, 2024) (same). To the contrary, the Examiner’s stated reasons for allowance were simply that the prior art did not disclose the claimed cutting guides. The Examiner said nothing about modifying McGlamry or any motivation to combine references.

The Examiner also erred by not considering Augoyard’s disclosure of claim limitations not recited by McGlamry, or whether McGlamry and Augoyard rendered the claims obvious. Where asserted art was not substantively addressed or applied in a rejection, “the petitioner may show material error by showing that the Office failed to reject the claims over the asserted art.” *Quasar Sci. LLC v. Colt Int’l Clothing, Inc.*, IPR2023-00611, Paper 10 at 13-14 (PTAB Oct. 10, 2023).

PO also argues that statements in the Petition undercut any showing of examiner error because they suggest that “guide integration in this context is not plug-and-play.” Request, 4-5. That mischaracterizes the Petition. The cited statements concern deficiencies in the ’397 patent specification that support the Petition’s lack-of-enablement grounds. They do not concede or suggest the absence of examiner error with respect to the obviousness grounds.

PO further argues that the Petition failed to identify the claimed methods in McGlamry's disclosure and instead treated McGlamry as mere "background context." Request, 5-6. That is incorrect. The Petition maps McGlamry's disclosures to the challenged claims and explains where McGlamry teaches the relevant claim limitations. Pet., 51-97. To the extent McGlamry does not itself disclose a particular step or tool, the Petition identifies that feature in a secondary reference and explains why a POSA would have found it obvious to incorporate. PO's characterization of McGlamry as "background" does not undermine the Petition; if anything, it reinforces that McGlamry reflects well-established surgical knowledge predating the '397 patent's priority date.

Specifically, PO argues that McGlamry "does not propose using cutting guides for Lapidus fusion despite recognizing the importance of accurate cuts and problems with freehand techniques." Request, 5. That framing overstates the point. Chapter 31 explains that, in Lapidus bunionectomy, joint preparation is "extremely important" to achieving a boney union and avoiding delayed union and nonunion, and describes conventional, unguided preparation. Chapter 34 separately discloses a cutting guide to direct bone resection in the first metatarsophalangeal joint surgery. McGlamry thus shows both the importance of precise bone preparation in bunion-related foot surgery and the known use of guides to control bone resection. A POSA

would therefore have been motivated to use such guides to improve accuracy in procedures like Lapidus fusion.

PO's own characterization of McGlamry also supports, rather than defeats, obviousness. PO asserts that "McGlamry reflects that POSAs were aware of cutting guides and understood their benefits." Request, 6. That concession confirms that cutting guides and their benefits were already known to POSAs. And where, as here, McGlamry emphasizes the importance of accurate joint preparation in bunion correction surgery, those admitted background facts support the Petition's grounds.

PO's argument regarding the "next edition of McGlamry" fails to support denial. Even if a later edition discloses using cutting guides in Lapidus fusion, that does not suggest nonobviousness. If anything, it reinforces the known motivations.

PO further argues that the Petition's McGlamry grounds depend on "expert-driven impermissible hindsight reconstruction." Request, 6-7. But PO offers only attorney argument. PO does not dispute the benefits identified by Dr. Neufeld and offers no evidence to the contrary. Nor does the Petition's obviousness theory rest on expert opinion alone. Dr. Neufeld provided extensive testimony and supporting evidence explaining why a POSA would have been motivated to use cutting guides in a fusion procedure like McGlamry's. Ex.1002, ¶¶82-99. His analysis relied on McGlamry chapters the Examiner did not consider, as well as other references

showing the known motivations for using cutting guides in Lapidus-type fusion surgeries. *Id.* That is not hindsight reconstruction.

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

C. Augoyard

PO merely states that Augoyard “is expressly listed on the face of the ’397 Patent, establishing it was also before the Examiner.” Request, 3. Even if true, that does not show that the same or substantially the same Augoyard-based arguments were previously presented to the Office. The Examiner allowed the claims without any prior-art rejection and did not apply Augoyard, alone or with McGlamry.

PO’s arguments also fail because the Petition does not rely on Augoyard as an anticipation reference. Instead, it relies on Augoyard as a secondary reference supplying teachings for limitations not expressly disclosed in McGlamry and supporting the obviousness combinations. Thus, PO’s arguments miss the point.

Regarding the second *Advanced Bionics* prong, PO argues “an inference that Augoyard was understood by the Examiner to be background joint replacement teachings rather than disclosing the claimed method.” Request, 7. But nothing supports that inference. The prosecution history includes no analysis of Augoyard.

PO further argues that Augoyard’s cutting guide was not intended for the tarsometatarsal joint and using it therein would be “hindsight reconstruction.” *Id.*

PO likewise dismisses Dr. Neufeld's testimony as hindsight without meaningful analysis. *Id.*, 8. PO's attorney argument is not evidence and cannot rebut the record.

Nor do PO's criticisms address examiner error. The Notice of Allowance reflects that the Examiner believed the prior art did not disclose the claimed cutting-guide concepts. Ex.1004, 260-262. The Petition's Augoyard-based arguments directly address that rationale by showing how Augoyard supplies relevant teachings and why a POSA would have combined them with McGlamry. Because the Examiner did not apply Augoyard in that way—or at all—the prosecution record reflects material examiner error, not prior consideration of the same arguments.

D. Other References

PO challenges the Petition's reliance on Haddad as evidence that cutting guides promote union by forming complementary planar bone surfaces. Request, 8. But citing Haddad as evidence of a known motivation to incorporate a cut-guide system like Augoyard's is not hindsight. *See* Pet., 54; Ex.1002, ¶67. That argument highlights additional evidence the Examiner never considered.

Dr. Neufeld's testimony that a POSA would have understood Augoyard's cutting guide to be adaptable for use with McGlamry's procedure with only minor modifications is supported by record evidence, not attorney argument. PO identifies no contrary evidence. The Petition cites Alchermes and Weinstein as evidence that using a cut guide like Augoyard's in McGlamry's procedure would have reflected

routine adaptability. Pet., 56-57. Even if listed in IDSs, the Examiner did not apply those references or consider them as relied on in the Petition.

PO concedes the basic point: cutting guides can be adapted across procedures and anatomies. Request, 9. Nothing suggests the Examiner considered whether McGlamry's procedure could be adapted to include a cutting guide like Augoyard's, or evaluated Alchermes/Weinstein in that context. PO's assertion that these principles were generally known only reinforces obviousness and confirms examiner error. PO also acknowledges that Weinstein identifies a Lapidus-type procedure as one that may benefit from a cutting-guide, further confirming that error. *Id.*, 10.

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, apply Augoyard in any rejection, or 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. The prosecution history thus reflects material examiner error, including failure to reject the claims under § 112 or over the McGlamry-Augoyard grounds and failure to consider the additional supporting teachings and motivation evidence addressed above.

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

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

A. 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.1032, 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, 13. 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 PGR. 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., 98. 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, 13. 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 and roadmapping 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 meaningful delay, and PO's roadmapping assertion lacks merit.

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.

B. There are No Settled Expectations Here

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 '397 patent issued on April 8, 2025, and Petitioner filed its Petition

on December 19, 2025, within the nine-month window. The timing weighs strongly against any settled-expectations claim.

The age of the '397 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. September 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.

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 '397 patent cannot support settled expectations, PO argues that the settled expectations period should instead run from the earliest publication in the family. Request, 14-16. That is not the Office's framework. 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 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).

Embody is especially instructive because it rejects the very move PO attempts here. *Embody, 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 '397 patent before it issued.

3. The '397 and '426 Patent Claims are Different

Settled expectations cannot be borrowed from earlier family members; the inquiry is claim-specific. Although PO identifies similarities between the '397 and earlier '426 patents, the claims differ. For example, claim 1 of the '397 patent recites attaching the first guide slot with first and second fixation pins positioned distal to the slot and reusing them when positioning the second guide slot. 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.

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. That does not materially 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 '397 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. September 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 '397 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 evidence is insufficient. Nearly all evidence predates issuance of the '397 patent and concerns commercialization efforts, investor messaging, adoption, or portfolio size. Request, 17-19 (citing Exs.2021-2024). That evidence may show recognition of PO's business, but not strong settled expectations in the '397 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 '397 patent's in-force period.

PO's reliance theory is overstated. The Petition was filed at the first opportunity for PGR 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.

C. 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.1033. 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 thus weigh against discretionary denial and in favor of institution.

D. PO Identifies No Merits-Based Basis for Discretionary Denial

PO's assertion that the Petition has "weak merits" provides no basis for discretionary denial. Request, 20. PO made no merits showing with its Request, and arguments cannot be incorporated by reference. *See* 37 C.F.R. § 42.6(a)(3).

PGR2026-00017

Paragon 28 v. Treace Medical Concepts

Respectfully submitted,

Dated: April 2, 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 1032-1033** 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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