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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. PGR2026-00031

U.S. Patent No. 12,349,941

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

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LIST OF EXHIBITS

Exhibit No.	Description
1001	U.S. Patent No. 12,349,941 to Dayton, et al. (“the ’941 patent”)
1002	File History of U.S. Patent Application No. 18/615,875
1003	Declaration of Steven K. Neufeld, M.D.
1004	Curriculum Vitae of Steven K. Neufeld, M.D.
1005	Dayton, Paul, Mindi Feilmeier, Merrell Kauwe, and Jordan Hirschi, “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>Journal of Foot and Ankle Surgery</i> , Vol. 52, No. 3 (May-June 2013): 348-354 (“Dayton”)
1006	International Appl. Publ. No. 2012/004798 to Waisman (“Waisman”)
1007	U.S. Patent No. 5,702,389 to Taylor et al. (“Taylor”)
1008	U.S. Publication No. 2012/0029575 to Orsak et al. (“Orsak”)
1009	International Appl. Publ. No. 2012/103335 to Palmer et al. (“Palmer”)
1010	U.S. Publication No. 2011/0288550 to Orbay et al. (“Orbay”)
1011	<i>McGlamry's Comprehensive Textbook of Foot and Ankle Surgery</i> , 4th ed. 2 vols. Edited by E. Dalton McGlamry, Joe T. Southerland, and Daniel F. Vickers. Chapters 1, 31, 34, 36, and 55. Philadelphia, PA: Wolters Kluwer Health, 2013 (“McGlamry”)
1012	U.S. Patent No. 4,349,018 to Chambers (“Chambers”)
1013	Declaration of Michelle L. Warmath for Translation of European Patent App. Publ. No. 1508316 (“Augoyard”)
1014	English Translation of Augoyard from Ex. 1013

Exhibit No.	Description
1015	U.S. Patent App. Publ. No. 2013/0150900 to Haddad et al. (“Haddad”)
1016	Cottom, James M. and Anand M. Vora. “Fixation of Lapidus Arthrodesis with a Plantar Interfragmentary Screw and Medial Locking Plate: A Report of 88 Cases.” <i>The Journal of Foot and Ankle Surgery</i> , Vol. 52, No. 4 (July-August 2013): 465-469 (“Cottom”)
1017	Baravarian, Babak, Gary B. Briskin, and Patrick Burns, “Lapidus Bunionectomy: Arthrodesis of the First Metatarsocunieiform Joint,” <i>Clinics in Podiatric Medicine and Surgery</i> , Vol. 21, No. 1, (January 2004): 97-111 (“Baravarian”)
1018	Paul W. Lapidus, <i>The author's bunion operation from 1931 to 1959</i> , 16 Clin. Orthopaedics 119-135 (1960)
1019	Paul W. Lapidus, <i>Operative correction of the metatarsus varus primus in hallux valgus</i> , 58 J. Surgery Gynecology & Obstetrics 183–191 (1934)
1020	Mark H. Hofbauer & Jordan P. Grossman, <i>The Lapidus Procedure</i> , 13(3) Clinics Podiatric Med. & Surgery 486–496 (1996)
1021	Declaration of Sylvia Hall-Ellis, Ph.D.
1022	U.S. Patent No. 5,350,382 to Armstrong et al. (“Armstrong”)
1023	U.S. Patent No. 4,988,349 to Pennig (“Pennig”)
1024	U.S. Patent App. Publ. No. 2009/0118733 to Orsak et al. (“Orsak-733”)
1025	U.S. Patent App. Publ. No. 2009/0198279 to Zhang et al. (“Zhang”)
1026	U.S. Patent App. Publ. No. 2016/0213384 to Fallin et al. (“Fallin”)
1027	Declaration of Michael Schmidt
1028	Defendants’ Opening Brief in Support of Motion to Stay, <i>Treace Medical Concepts, Inc. v. Zimmer Biomet Holdings, Inc. and Paragon 28, Inc.</i> , No. 1:25-cv-00592-GBW (D. Del. 2026)

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 Petition identifies material Office error: Applicant acknowledged that “no agreement on allowability was reached” and further examination remained, yet the Office allowed new claims without stated reasons and with no record of evaluating the Petition’s prior-art combinations or § 112 grounds.
- The Office never evaluated the Petition’s § 112 grounds, never considered Waisman or Taylor, never applied Dayton, Palmer, or Orbay, and never addressed the Petition’s combinations, mappings, or 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 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 considered key secondary references, much less considered the § 112 and 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 '941 patent issued on July 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 presents § 112 and 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 Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 at 8-10 (Director Feb. 13, 2020) (precedential). That concern is not present here.

The '941 patent issued after one substantive Office Action addressing the original claims. Ex.1002, 67-78. During a later interview, Applicant discussed a new claim, but Applicant's own interview summary states that "no agreement on allowability was reached" and that the Examiner would evaluate the claims during "further search and examination." *Id.*, 53. Applicant then canceled the original claims and added all new claims. *Id.*, 48-55. The Notice of Allowability issued without an Examiner's statement of reasons for allowance. *Id.*, 10-14. Thus, the record confirms that the Office did not evaluate the Petition's § 112 grounds, Waisman, Taylor, or the Petition's asserted combinations. PO therefore has not shown prong-one duplication of the Petition's grounds.

A. Material Examiner Error Defeats PO's § 325(d) Request

Even if *Advanced Bionics* prong one were satisfied for some references, PO's § 325(d) request fails at prong two. The prosecution record contains no Office analysis of the issued claims against the Petition's grounds. Applicant's own interview summary states that "no agreement on allowability was reached" and that the Examiner would evaluate the newly presented claims during further search and examination. Ex.1002, 53. But the Notice of Allowability issued without any stated

reasons for allowing those new claims. *Id.*, 10-14. That record demonstrates material error: the Office did not evaluate the Petition's § 112 grounds, Waisman, Taylor, or the asserted combinations.

That missing analysis was material. Dayton teaches the core modified Lapidus bunion procedure, including resecting the metatarsal-cuneiform joint, correcting the first metatarsal in multiple planes, using pins in the metatarsal and cuneiform to visualize frontal-plane rotation, and fixing the corrected position. Ex.1005, Abstract, 349; *see* Pet., 25-47. Waisman teaches a polyaxial bone-positioning device with pins/K-wires that can hold bone portions in desired relative positions and is expressly applied to hallux-valgus surgery of the first metatarsus. Ex.1006, Abstract, 6:7-13, 15:4-5, 24:23-25, 26:21-24; *see* Pet., 26-47. Taylor teaches a spatial-frame positioning device connected by pins/wires and adjustable to control the relative position and orientation of bone portions in six orthogonal degrees of freedom. Ex.1007, 5:26-33, 5:52-58, Fig.29; *see* Pet., 66-73. Palmer and Orbay provide cutting-guide teachings. Ex.1009, Abstract, [00131], [00137]-[00138], [00140], Fig.20; Ex.1010, [0037]-[0040], claim 1, Figs.3A-3B, 4A-4B; *see* Pet., 26, 36-42, 94-100.

Nor did the Examiner evaluate Orsak as presented. The Examiner applied a related Orsak-family reference (Ex.1024) only to canceled claims, not in a Dayton-based obviousness combination against the issued bunion-surgery method claims.

Ex.1002, 72-75; Pet., 78-88. Thus, even if PO treats Orsak and the examined Orsak-family reference as substantially the same disclosure, the Office never evaluated that disclosure in the Petition's combinations with Dayton and Palmer/Orbay, or with Dr. Neufeld's motivation and reasonable-expectation testimony.

PO's claim that the Petition was deficient for not briefing § 325(d) is misplaced. Request (Paper 9), 7. The Office's current interim process directs petitioners to raise discretionary issues, including § 325(d), in the opposition to a patent owner's discretionary-denial brief—not in the petition. Interim Director Discretionary Process Guidance §§ I.C, III.A. *Ecto* confirms that prior art listed on an IDS may satisfy *Advanced Bionics* prong one, but discretionary denial still requires the prong-two inquiry into whether the Office materially erred, informed by *Becton, Dickinson* factors (c), (e), and (f). *Ecto World, LLC & SV3, LLC v. RAI Strategic Holdings, Inc.*, IPR2024-01280, Paper 13 at 4-6 (Director May 19, 2025) (precedential as to § A); *Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 at 17-18 (Director Dec. 15, 2017) (precedential as to § III.C.5, first paragraph).

B. The Petition's § 112 Grounds Were Never Presented or Evaluated During Prosecution

The Petition's Ground 1 independently defeats PO's premise that the Petition repackages examination. That ground challenges every issued claim for lack of written description and enablement under § 112. Pet., 20-25. During prosecution,

the only recorded § 112 issue was an antecedent-basis rejection of original claim 11, and Applicant later canceled that claim. Ex.1002, 68, 48-55. The record contains no § 112 rejection, no written-description or enablement analysis, and no indication that the Office considered the specific Ground 1 issues now before the Board.

PO's assertion that the § 112 grounds "have no merit as will be evident in the POPR" is not a § 325(d) showing. Request, 7. Ground 1 was not previously presented or evaluated, which weighs strongly against discretionary denial.

C. Dayton Was Listed, But Its Bunion-Correction Teachings Were Never Applied

Dayton's mere appearance on an IDS does not make the Petition duplicative. The Examiner never applied Dayton in a rejection and never addressed Dayton's modified Lapidus bunion-correction procedure. Ex.1002, 67-78. Dayton is significant because it teaches preparing and resecting the metatarsal-cuneiform joint, correcting the first metatarsal in the transverse, sagittal, and frontal planes, using pins in the metatarsal and cuneiform to visualize frontal-plane rotation, temporarily stabilizing with wires, and finally fixing the corrected position. Ex.1005, Abstract, 349; *see* Pet., 25-47.

PO's assertion that the Examiner likely appreciated Dayton because the article was written by an inventor lacks any evidentiary support. Request, 8-9. The record shows no application or discussion of Dayton, no rejection using Dayton, and no evaluation of the Petition's Dayton-based combinations. Nor does PO's "three-

plane” point help. Request, 8-9. The challenged claims recite using the bone positioning device to adjust first-metatarsal alignment “in multiple planes,” and Dayton’s triplanar correction teachings are directly relevant. Ex.1001, claim 1; Ex.1005, 349. Dayton therefore confirms that the Petition raises a materially different challenge, not a repeat of examination.

D. Waisman and Taylor Are New, Material Positioning-Device References

Waisman and Taylor were not considered during prosecution, and PO’s argument that the references are cumulative fails under the references’ actual teachings. Waisman expressly teaches a polyaxial bone-positioning device with K-wires, pins, or screws, discloses compression, distraction, rotation, and translation, and expressly illustrates use in a human foot for hallux-valgus surgery of the first metatarsus. Ex.1006, Abstract, 6:7-13, 15:4-5, 24:23-25, 26:21-24; *see* Pet., 26-47. Taylor likewise supplies claim-relevant teachings the Examiner never evaluated: a spatial-frame positioning device connected by pins/wires and adjustable struts to control bone portions in six orthogonal degrees of freedom. Ex.1007, 5:26-33, 5:52-58, Fig.29; *see* Pet., 66-73. These teachings are material, not cumulative.

PO focuses on the Petition’s statement that Waisman, Taylor, and Orsak disclose structures “identical or at least equivalent” to structures identified in the ’941 patent. Request, 6. That claim-mapping point does not collapse three distinct references into one cumulative disclosure. It shows that each reference

independently satisfies the claimed positioning-device limitation, while the Petition separately relies on each reference's own structure, surgical context, and teachings in different grounds. Pet., 28-47, 66-73, 78-88. The Examiner never considered Waisman, Taylor, those alternative grounds, or Dr. Neufeld's testimony explaining why a POSA would have used those devices in Dayton's procedure (Ex.1003, ¶¶105-114, 231-238, 265-274).

E. The Examiner's Limited Use of a Related Orsak-Family Reference Does Not Duplicate the Petition's Orsak Grounds

Orsak does not justify § 325(d) denial. The Examiner applied a related Orsak-family reference (Ex.1024) only as an anticipation reference against original claims that Applicant later canceled. Ex.1002, 72-75, 48-55. The Petition relies on Orsak as an alternative secondary reference in selected obviousness grounds, combined with Dayton and cutting-guide references, to address issued method claims that never faced any rejections by the Examiner. Pet., 14, 18-19, 78-88. Many obviousness grounds do not rely on Orsak at all. *Id.*, 18-19.

PO's accusation that Petitioner obscured prosecution is wrong. Request, 4-6. The Petition disclosed that the Examiner rejected claims over the related Orsak-family reference and submitted that reference as Ex.1024. Pet., 14. Nor was Petitioner's reliance on Orsak (Ex.1008) misleading. The Petition and Dr. Neufeld relied on Ex.1008 as the asserted prior-art publication, including its own published claim language, such as claims 1 and 7, for positioning-device teachings relevant to

the Petition's combinations. *See* Pet., 78-88 (citing Ex.1008, claims 1, 7); Ex.1003, ¶266 (citing Ex.1008, claims 1, 7). That express claim language does not appear verbatim in the Examiner-applied Orsak-family reference. Compare Ex.1008, claims 1, 7, with Ex.1024. Even assuming substantial overlap between the Orsak-family publications, the Office never evaluated Orsak in any obviousness combination with Dayton or Palmer/Orbay, nor did it have Dr. Neufeld's testimony on motivation to combine and reasonable expectation of success. That is the relevant § 325(d) inquiry.

F. No Inconsistency Exists Between the § 112 and Obviousness Grounds

PO argues that the Petition's § 112 grounds undercut obviousness because the Petition also maps Waisman, Taylor, or Orsak to the claimed bone positioning device. Request, 11. That argument confuses distinct inquiries. Written description and enablement ask whether the '941 patent's own specification supports and enables the issued claims. Obviousness asks whether the prior art would have taught or suggested the claimed method to a POSA with a reasonable expectation of success. The Petition may therefore show that the specification lacks adequate § 112 support while also showing that prior-art references supply positioning-device teachings in obviousness combinations.

PO's reliance on the Petition's "identical or at least equivalent" claim-mapping language does not change that analysis. *Id.*, 11. The Petition uses that

language to show that Waisman, Taylor, and Orsak disclose structures satisfying the claimed positioning-device limitations. It does not concede that the '941 patent's specification provides written description or enablement for the issued claims, nor does it equate the references' full disclosures, surgical contexts, motivations to combine, or reasonable-expectation evidence. PO's asserted inconsistency therefore provides no basis for discretionary denial.

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.2024. The devices PO alleges practice the asserted method claims are assembled in the United States as final products. Ex.1027. Most components are also made in the U.S. 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.

PO's manufacturing assertions do not support denial. Although PO claims to be "entirely American," it acknowledges that up to 15% of its current manufacturing operations are outside the United States. Request, 20. At most, this shows domestic

activity on both sides; it does not negate Petitioner's U.S. final assembly, U.S.-made components, or lack of foreign post-processing.

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.1028, 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. 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, 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 “[e]leven 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., 112. 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 Petition on the ’941 patent creates delay concerns. *Id.* 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. *Id.*, 12. 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.

C. The Petition's Alternative Grounds Promote Efficient Review

PO's "number of challenges" argument is overstated. Request, 13. The informative decisions PO cites involved petitions where the Board found threshold merits only for a narrow subset of the challenged claims or grounds. *See Chevron Oronite Company LLC v. Infineum USA L.P.*, IPR2018-00923, Paper 9 at 10-11 (Director Nov. 7, 2018) (informative) (finding, at most, a reasonable likelihood as to two dependent claims out of twenty challenged claims); *Deeper, UAB v. Vexilar, Inc.*, IPR2018-01310, Paper 7 at 42-43 (Director Jan. 24, 2019) (informative) (finding a reasonable likelihood as to only two of twenty-three challenged claims

and only one of four asserted grounds). This Petition presents alternative grounds to address PO's broad claims and foreseeable disputes over secondary references, and it provides detailed claim-by-claim mappings and expert support for every challenged claim. Pet., 25-111; Ex.1003, ¶¶91-367.

Nor does Orsak "infect" the Petition. Request, 13. Six of the Petition's obviousness grounds do not rely on Orsak at all; instead, they rely on Waisman or Taylor as independent alternative positioning-device references that were never before the Examiner during prosecution. Pet., 18-19. The number of grounds reflects reasonable, transparent alternatives; it is not a reason to deny review of a recently issued PGR-eligible patent.

D. There Are No Settled Expectations Here

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 (emphasis added). Consistent with that framework, the question here is the age of the challenged '941 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 (Director July 16, 2025) (precedential). That principle applies here. The '941 patent issued on July 8, 2025, and the Petition was filed on March 3, 2026, within nine months. The timing weighs strongly against any settled-expectations claim.

The age of the '941 patent likewise weighs against discretionary denial. The Office has declined to find strong settled expectations even for much older patents, including patents issued in 2021-2023. *Apple Inc. v. Apex Beam Techs. LLC*, IPR2025-00896, Paper 10 (Director 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 (Director June 26, 2025).

Recent decisions reinforce the point. In *Dabico*, the Office 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 (Director June 18, 2025) (informative). In *Amgen*, the Office 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 (Director July 24, 2025) (informative). And in *Embodiment*, although one challenged patent issued in 2022 and a related parent patent issued in 2018, the Office 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 (Director June 26, 2025). Here, the '941 patent had been in force for less than nine months when the Petition was filed, placing this case well below the time periods that have supported settled expectations in those decisions.

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

PO invents a rule of its own when it argues that settled expectations should be measured 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 (Director 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 (Director July 24, 2025) (informative).

Embody is especially instructive because it rejects the very premise that PO relies on in its argument. *Embody*, Paper 13. 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 family-based settled-expectations 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 issue from that disclosure. Under PO's theory, the public would need to anticipate 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 '941 patent before it issued.

3. **The '941 Patent's Claims Create New, Claim-Specific Issues Not Settled by the '764 Patent**

PO cannot borrow settled expectations from the '764 patent. Request, 14-15. Settled expectations, if any, must attach to claims in force, and PO's own comparison confirms that the claims changed. For example, claim 1 of the '941 patent recites, among other things, a bone cutting guide with a "joint plate offset from a guide

feature,” the joint plate “extending downwardly” and being inserted “into the joint,” and using the bone positioning device to adjust first-metatarsal alignment “in multiple planes.” Ex.1001, claim 1. The ’764 patent claims do not include those same limitations. *See* Ex.2006, claim 1.

Those differences matter. Validity, scope, infringement, and public reliance turn on claim language, not merely a shared specification or a generalized “core operative” theme. PO’s predictability argument only underscores that point: claim scope can and did change across family members, so settled expectations cannot be transferred wholesale from the ’764 patent to materially different claims of the ’941 patent. The ’941 patent must be assessed on its own claims and record.

4. Petitioner’s Notice Does Not Establish Settled Expectations

PO also argues, without evidentiary support, that Petitioner “knew the family, understood the scope, [and] designed products within that scope.” Request, 15-16. But that assertion does not establish settled expectations. *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 ’941 patent issued. Pre-issuance awareness of the family is irrelevant.

Nor is notice dispositive even in older-patent cases. In *Apple Inc. v. Ferid Allani*, the Office declined discretionary denial despite petitioner's prior awareness because the petitioner had informed the patent owner years earlier that it did not need a license, the patent owner waited eleven years to assert the patent, and the patents were not asserted until after expiration. *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.

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 '941 patent and concerns commercialization efforts, investor messaging, adoption, or portfolio size. Request, 16-19 (citing Exs.2008-2023). That evidence may show commercial recognition of PO's products or business, but it does not show settled expectations in the protections afforded by the '941 patent, which had been in force for less than nine months when Petitioner filed its Petition. *Amgen* indicates that a patent owner may establish settled expectations for a younger patent by showing extraordinary investment tied to the ***challenged patent***. *Amgen*, Paper 9 at 2. But even in *Amgen*, the Board found no settled expectations for a patent that had been in force for about three years. PO falls far short of the showing found insufficient there. Unlike in *Amgen*, PO's alleged evidence is limited to investments

made before the '941 patent issued, and those investments are tied only to PO's broader patent portfolio, not the '941 patent specifically. Nor does PO tie those investments to the challenged claims. And the '941 patent had been in force for less than nine months when Petitioner filed its Petition for PGR.

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 expectations present in decisions like *Dabico*, where the patent had been in force almost eight years. On this record, PO has not shown the type of claim-specific reliance needed to support discretionary denial.

E. PO's Undeveloped Merits Arguments Do Not Support Denial

PO's merits argument consists of a promise that the Petition's "weak merits will be evident after review of the POPR." Request, 19. That is not a developed discretionary-denial showing. The Petition presents detailed § 112 and obviousness grounds with claim-by-claim mappings, prior-art citations, and expert testimony. Pet., 20-111; Ex.1003, ¶¶91-367. PO identifies no facial defect that would warrant discretionary denial on the merits. The merits should be addressed through the ordinary institution process, not used as a basis for discretionary denial.

Respectfully submitted,

Dated: June 5, 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 1027-1028** 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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