Paper 9
Filed: May 5, 2026

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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PARAGON 28, INC.,
Petitioner,

v.

TREACE MEDICAL CONCEPTS, INC.
Patent Owner.

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PGR2026-00031
Patent 12,349,941

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# PATENT OWNER'S REQUEST FOR DISCRETIONARY DENIAL OF INSTITUTION

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# LIST OF EXHIBITS

| Exhibit No. | Description |
|---|---|
| 2001 | *Treace Medical Concepts, Inc. v. Zimmer Biomet Holdings, Inc. and Paragon 28, Inc.,* Initial Complaint, dated May 12, 2025 |
| 2002 | U.S. Patent Application Publication No. US 2013/0325076 A1, dated December 5, 2013 |
| 2003 | *Treace Medical Concepts, Inc. v. Zimmer Biomet Holdings, Inc. and Paragon 28, Inc.,* Joint Stipulation and Proposed Order to Extend Stay, dated December 1, 2025 |
| 2004 | *Treace Medical Concepts, Inc. v. Zimmer Biomet Holdings, Inc. and Paragon 28, Inc.,* Joint Stipulation and Proposed Order to Stay, dated September 12, 2025 |
| 2005 | *Paragon 28, Inc. and Disior Oy v. Treace Medical Concepts, Inc. and Mios Marketing, LLC,* Amended Complaint, dated December 18, 2025 |
| 2006 | U.S. Patent No. 10,945,764 to Dayton, *et al. (*the "'764 Patent") |
| 2007 | Treace Medical Concepts, Inc.'s SEC Form S-1 Registration Statement for Initial Public Offering, dated March 30, 2021 |
| 2008 | Treace Medical Concepts, Inc.'s Initial Public Offering, dated April 22, 2021 |
| 2009 | J.P. Morgan's Analyst Report entitled "A Differentiated Solution for the Large, Poorly Treated Bunion Market; Initiating at OW and $37 PT", dated May 18, 2021 |
| 2010 | Treace's Announcement of Grant of Additional U.S. Patent on Instrumented Bunion Correction, dated October 21, 2021 |
| 2011 | Treace's Announcement of Grant of U.S. Patent and Allowance of U.S. Patent Application on Bone Positioner Technology for Bunion Correction, dated November 30, 2021 |

| Exhibit No. | Description |
|---|---|
| 2012 | Treace's Announcement of Grant of U.S. Patent on Instrumented Bunion Correction, dated January 19, 2022 |
| 2013 | Treace's Announcement of Expansion of Its Global IP Portfolio with the Grant of Two New U.S. Patents, dated December 19, 2022 |
| 2014 | Treace's Announcement of Expansion of Market Leading Global IP Portfolio For Bunion And Related Deformities, dated April 19, 2023 |
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| 2016 | Treace's Announcement of Filing of Patent Infringement Suit Against Zimmer Biomet to Protect Lapiplasty® Bunion Technology, dated June 5, 2025 |
| 2017 | Treace's Announcement of 100,000 Lapiplasty® 3D Bunion Correction® Patient Milestone Celebration, dated March 25, 2024 |
| 2018 | Stephen Inc.'s Analyst Report entitled "TMCI's Device Superiority Is Winning The War on Bunions, Initiating EW/V Due To Valuation", dated April 10, 2023 |
| 2019 | AlphaSense's November 12, 2024 UBS Global Healthcare Conference Transcript |
| 2020 | Treace's Announcement of Filing of Patent Infringement Suit To Protect Lapiplasty® Bunion Technology, dated March 28, 2022 |
| 2021 | Treace's Announcement of Settlement of Lawsuit Against Fusion Orthopedics, dated March 3, 2023 |
| 2022 | Treace's Announcement of Filing of Patent Infringement and Unfair Competition Suit to Protect Lapiplasty® Bunion Technology, dated October 14, 2024 |
| 2023 | J.P. Morgan's January 2023 Investor Presentation on Treace Medical Concepts, Inc. |

| Exhibit No. | Description |
|---|---|
| 2024 | USPTO Additional Discretionary Institution Considerations – U.S. Manufacturing and Small Business Use of AIA Proceedings Memorandum, dated March 11, 2026 |
| 2025 | Zimmer Biomet Website - Company Overview |
| 2026 | Declaration of Terry Wade Lubben |

# I. INTRODUCTION

Patent Owner ("PO") respectfully requests that the Director exercise discretion to deny institution of post-grant review ("PGR") of U.S. 12,349,941 (Ex. 1001, the "'941 Patent") under 35 U.S.C. § 325(d) and, independently, under 35 U.S.C. § 324(a). This PGR is being litigated alongside four other AIA matters (IPR2026-00194, PGR2026-00017, PGR2026-00020, and PGR2026-00022). The '941 Patent and the patents challenged in these proceedings were all previously asserted in a co-pending district court case ("litigation"). *See* Paper 6 at 2. The complaint in that litigation was filed on May 12, 2025 (Ex. 2001) and this PGR was requested on March 3, 2026.

"Parties are encouraged to address any fact or circumstance they believe bears on the Director's discretion to institute, including reasons not discussed in current Board precedent or in the Process Memorandum." Guidance § I.B (https://www.uspto.gov/patents/ptab/interim-director-discretionary-process; "Guidance"). Consistent with the Guidance, the totality of the circumstances in this proceeding supports discretionary denial as an appropriate exercise of the Director's authority. Denial is appropriate under § 325(d) because the Petition relies on prior art previously presented to the Office and fails to identify any material error. This is the type of re-litigation § 325(d) is designed to prevent. Discretionary denial is also warranted under § 324(a) based on settled expectations and resource-allocation

considerations. Settled expectations attach to the '941 Patent continuity chain's longstanding public disclosure and claiming, not merely to the '941 Patent issuance date. *Dabico*, IPR2025-00408, Paper 21 at 2–3 (PTAB June 18, 2025) (Informative).

## II. BACKGROUND

The '941 Patent is part of a continuity chain tracing back to an initial 2014 filing. With that filing, PO disclosed bunion surgery methods to control cutting and alignment, improving accuracy and reproducibility relative to preexisting techniques. The specific claims of the '941 Patent are directed to methods for performing bunion-correction surgery that include bone alignment and bone cutting instrumentation. Earlier-issued patents in the priority chain claim bone positioning and cutting systems and methods.

## III. DISCRETIONARY DENIAL UNDER 35 U.S.C. § 325(d)

### A. Governing Framework — *Advanced Bionics*

Under *Advanced Bionics*, discretionary denial is appropriate where (1) the same or substantially the same art or arguments were previously presented, and (2) Petitioner ("PET") fails to show material error. *Advanced Bionics*, IPR2019-01469, Paper 6 at 7–8 (PTAB Feb. 13, 2020) (Precedential).

Two independent claims from the '941 Patent are challenged: claim 1 and claim 18. ***PET presents 17 challenges*** to those two claims. As explained below, the volume of challenges and reference repackaging are relevant to discretionary denial.

## B. *Advanced Bionics* Part One — Same or Substantially the Same Art

PET's table of challenges from pages 18–19 of the Petition (Paper 2, "Petition" or "Pet.") is reproduced below:

| Ground | Reference(s) | Claims | Basis |
|---|---|---|---|
| 1 | N/A | 1-27 | §112 |
| 2 | Dayton, Waisman, and Palmer | 1-27 | §103 |
| 3 | Dayton, Taylor, and Palmer | 1-27 | §103 |
| 4 | Dayton, Orsak, and Palmer | 1-27 | §103 |
| 5 | Dayton, Orsak, Palmer, and Waisman | 1-27 | §103 |
| 6 | Dayton, Orsak, Palmer, and Taylor | 1-27 | §103 |
| 7 | Dayton, Waisman, and Orbay | 1-27 | §103 |
| 8 | Dayton, Taylor, and Orbay | 1-27 | §103 |
| 9 | Dayton, Orsak, and Orbay | 1-27 | §103 |
| 10 | Dayton, Orsak, Orbay, and Waisman | 1-27 | §103 |
| 11 | Dayton, Orsak, Orbay, and Taylor | 1-27 | §103 |
| 12 | Dayton, Waisman, Palmer, and Orbay | 1-27 | §103 |
| 13 | Dayton, Taylor, Palmer, and Orbay | 1-27 | §103 |
| 14 | Dayton, Orsak, Palmer, and Orbay | 1-27 | §103 |
| 15 | Dayton, Orsak, Palmer, Waisman, and Orbay | 1-27 | §103 |
| 16 | Dayton, Orsak, Palmer, Taylor, and Orbay | 1-27 | §103 |

PO notes that there are actually ***17 challenges*** because PET includes separate Written Description and Enablement Challenges under Ground 1. *See* Pet. 20–25.

The following table lists the asserted references:

| Reference | Relationship to Art Considered by Examiner |
|---|---|
| Dayton (Ex. 1005) | Listed on the face of the '941 Patent; Journal Article Written by First Named Inventor of '941 Patent |
| Waisman (Ex. 1006) | Cumulative |
| Taylor (Ex. 1007) | Cumulative |
| Orsak (Ex. 1008) | Divisional Application of US Patent App. Pub. No. 2009/0118733 (Listed on the Face of the '941 Patent and Applied by the Examiner) |
| Palmer (Ex. 1009) | PCT Application Corresponding to US Patent App. Pub. |

| | |
|---|---|
| | No. 2013/0325076 (Listed on the Face of the ’941 Patent) |
| Orbay (Ex. 1010) | Listed on the Face of the ’941 Patent |

Dayton, Orsak, Palmer, and Orbay were each previously presented to the Office. Art cited on the face of the patent constitutes previously presented art, regardless of whether it formed the basis of a rejection, and satisfies Part One of *Advanced Bionics*, even when the number of cited references is large. *See Ecto World*, IPR2024-01280, Paper 13 at 24 (PTAB May 19, 2025) (Precedential). Waisman and Taylor are cumulative, as discussed in greater detail below.

**1. References Cited During Prosecution**

PET notes: “During prosecution of the ’941 patent, the Examiner rejected claims over Pennig (Ex.1023), Orsak [2] (Ex.1024), and/or Zhang (Ex.1025). Ex.1002, 67-76; see also Ex.1003, ¶74. In response, Applicant canceled all pending claims and presented new claims. Ex.1002, 48-52. The Examiner subsequently allowed the new claims. *Id.*, 10-14.” Pet. 14.

Exhibit 1024 (“Orsak 2”) is the parent filing for Exhibit 1008 (“Orsak”). PET acknowledges that the Examiner applied Orsak 2 during prosecution, but fails to disclose that it is essentially the same reference as Orsak. PET takes a similar route with Exhibit 1009 (“Palmer”). U.S. Patent App. Pub. No. 2013/0325076 (Ex. 2002, “Palmer 2”) is cited on the face of the ’941 Patent and is the U.S. counterpart of Palmer (Ex. 1009) asserted by PET in its challenges, which PET fails to disclose.

Consistent with the Director's suggestion that "[p]arties are encouraged to address ***any fact or circumstance*** they believe bears on the Director's discretion to institute, including reasons not discussed in current Board precedent or in the Process Memorandum" (Guidance § I.B), PO requests the Director take the above considerations into account when determining whether to apply discretion to deny institution in this proceeding. Petitioner's reliance on a divisional publication (Orsak) of a reference previously applied by the examiner (Orsak 2) is not a genuine presentation of new art, nor is the reliance on a PCT counterpart (Palmer) of a US Application previously before the Office (Palmer 2). It is an attempt to repackage previously-presented art while ***intentionally obscuring the prosecution history***. Under *Advanced Bionics* and *Ecto World*, the Board should look to substance, not citation format, and deny institution under § 325(d).

PET's presentation is not merely incomplete. PET acknowledges that the Examiner applied Orsak 2 during prosecution, yet PET relies on its divisional, Orsak, without candidly disclosing that it is the same Orsak-family disclosure previously before the Office. That omission creates a materially misleading account of what the Office actually considered and, at minimum, is inconsistent with the candor expected of parties invoking the Board's discretionary review process under 37 C.F.R. § 42.11. PET takes a similar approach with Palmer and Palmer 2.

Accordingly, at a minimum, that presentation strongly favors denial under

§ 325(d), because PET seeks to repackage previously presented art while obscuring the prosecution history relevant to *Advanced Bionics* Part One and Part Two.

**2. Cumulative Art**

Waisman and Taylor are cumulative of the art the Examiner expressly considered. PET itself makes that showing for PO. PET represents that each of Waisman's, Taylor's, and Orsak's positioning device is "identical or at least equivalent to structures identified in the '941 patent for the claimed positioning device." *See* Pet. 32–33, 69, 82. Because Orsak is the same disclosure as Orsak 2, PET has voluntarily collapsed all three positioning-device references into a single prior art disclosure already before the Office. On PET's own theory, the Board need not treat Waisman and Taylor as materially distinct from the Orsak-family disclosure for purposes of the bone positioning device limitation. PET has already conceded they are. If PET now wishes to argue that Waisman or Taylor are materially different from Orsak for purposes of § 325(d), it would have to contradict its own obviousness theory and disavow its own expert's testimony, which would undermine PET's arguments across all ***15 obviousness challenges***.

**C. *Advanced Bionics* Part Two — No Material Examiner Error**

*Advanced Bionics* requires a showing of material Office error, not merely disagreement with prosecution outcomes or reimagined combination theories based on hindsight expert observations. *Advanced Bionics* at 9 ("If reasonable minds can

disagree regarding the purported treatment of the art or arguments, it cannot be said that the Office erred in a manner material to patentability.").

At the outset, PO notes there are written description and enablement challenges, but those challenges have no merit as will be evident in the Patent Owner Preliminary Response ("POPR"). *See* Guidance § II.C.i. ("Notwithstanding the prohibition on incorporation by reference in 37 C.F.R. § 42.6(a)(3), when filing a brief for discretionary denial, ***a patent owner may direct attention to an anticipated POPR and evidence for a discussion of the merits***.") (emphasis added).

The Petition does not address any specific examiner misunderstandings or omissions with respect to the asserted references. As noted above, after indicating that Orsak 2 was relied on during prosecution, PET proceeds to assert Orsak without noting that it is the same disclosure as Orsak 2. PET offers no persuasive basis for treating Orsak as materially new art for § 325(d) purposes. And as further explained below, PET's own statements in its § 112 allegation undercut any allegation of examiner error regarding obviousness.

It is dispositive that the bone positioning device limitation appears in every challenged independent claim, and the prior art PET identifies for that limitation is art the Examiner already expressly considered (or cumulative). Orsak 2 was not merely cited on the face of the '941 Patent. It was applied in a rejection, discussed specifically with the Examiner in a telephonic interview, and formed the precise

basis of the agreement that led to allowance of the '941 Patent. PET's choice to cite the divisional (Orsak) rather than the parent (Orsak 2) does not change the substance of the disclosure. And PET itself confirms that Waisman and Taylor add nothing new (*i.e.*, each is "identical or at least equivalent" to the structures PET identifies in Orsak). Pet. 32–33, 69, 82. Accordingly, PET identifies no materially different prior art on the bone positioning device element across its ***15 obviousness challenges***.

**1. Dayton**

No material Office error can be shown by the Examiner's decision not to expressly apply Dayton. Dayton is a Journal article written by the first named inventor of the '941 Patent and describes a freehand procedure for bunion correction employing three planes. *See*, *e.g.*, Ex. 1005, 353. PET does not rely on Dayton for the claimed ***instrumented*** bunion correction surgery recited in the claims. It is a reasonable inference that the Examiner reviewed the inventor's own prior article when examining the '941 Patent. Moreover, Dayton is directed to an improvement to existing multiple plane (*e.g.*, ***two-plane***) bunion correction surgeries. *See*, *e.g.*, Ex. 1005, 353 ("[M]ost procedures, especially sliding procedures, cannot address frontal plane rotation. However, tarsal metatarsal corrective arthrodesis can address all 3 planes of the HAV deformity."). The claims do not require three planes of correction. This is significant for *Advanced Bionics* Part Two because even if the three-plane correction was arguably unknown to the Examiner, it is reasonable to infer that the

established two-plane correction approach was known to an Examiner.

**2. Orsak, Waisman, Taylor**

As noted above, PET acknowledges that Orsak 2 was expressly considered by the Examiner during prosecution. And Orsak 2 was discussed with the Examiner (along with Pennig) in a telephonic interview that resulted in the claims of the '941 Patent. *See* Ex. 1002, 53. The Examiner expressly considered the Orsak disclosure when evaluating patentability because Orsak 2 was applied in a rejection and later discussed in the interview with PO's representative that led to allowance of the '941 Patent. *See* Ex. 1002, 53; Pet. 14. PET nevertheless (1) relies on the same Orsak-family disclosure for the recited bone positioning device features and (2) confirms that the other positioning-device references it substitutes for Orsak (Waisman and Taylor) are not materially different. *See* Pet. 32–33, 69, 82.

Thus, PET cannot identify material Office error as to the bone positioning device aspect of its obviousness theories. Without a material error regarding that aspect of the combinations, PET cannot show material error in the Office's treatment of the positioning device teachings on which its challenges depend. Nor do Palmer and Orbay cure PET's inability to identify a material Office error regarding the positioning-device teachings that form the basis of its obviousness combinations.

**3. Summary**

At best, PET's general allegations may appear to show that reasonable minds

could disagree, not material Office error. Thus, any alleged asserted error is merely disagreement. And, here, the disclosure of Orsak relied on by PET was in fact expressly considered by the Examiner.

**4. *Becton, Dickinson* Factors Favor Denial**

All *Becton, Dickinson* factors, considered in the Part Two inquiry under *Advanced Bionics*, further support discretionary denial (*See Becton, Dickinson*, IPR2017-01586, Paper 8 at 17–18 (PTAB Dec. 15, 2017) (Precedential)):

**(1) Similarity of Art:** The references relied on in the Petition to challenge the independent claims are the same as, or cumulative to, the references cited on the patent;

**(2) Cumulative Nature:** Even when substance is considered, all references in the Petition were previously considered or are cumulative, as shown above;

**(3) Extent of Evaluation:** Cited on the face of the ’941 Patent, expressly considered by the Examiner, or cumulative;

**(4) Overlap of Arguments:** All of the arguments PET now makes were available during examination as discussed above;

**(5) Examiner Error:** None identified or available, as discussed above; and

**(6) Additional Evidence:** No new technical evidence beyond an expert declaration that relies on impermissible hindsight characterizations, not disclosure in the references.

In sum, this case presents the exact re-use, swapping, and incremental repackaging concerns that § 325(d) is designed to filter out. *Id.* at 17–18.

**D. Additional Considerations**

In view of the considerable number of grounds and references asserted, PO directs the Board to its POPR for discussion of PET's characterizations in its § 112 contentions that undercut its allegations regarding reasonable expectation of success, which is expressly allowed by Guidance § II.C.i. Specifically, PET asserts that the '941 Patent does not enable the recited bone positioning device (Pet. 23–25), yet also contends that each of Waisman's, Taylor's, and Orsak's "positioning device is identical or at least equivalent to structures identified in the '941 patent for the claimed positioning device" (*id.* at 32, 69, 82). This directly contradicts PET's contention and testimony from Dr. Neufeld that "A POSA would have had a reasonable expectation of success" incorporating the purported bone positioning devices from Waisman, Taylor, and Orsak in Dayton's procedure. *Id.* at 35, 71, 84.

PET cannot simultaneously argue that the '941 Patent's bone positioning device is not enabled for purposes of § 112 while taking the position that the prior art positioning devices are "identical or at least equivalent" to that same structure and that a POSA would have had a reasonable expectation of success for purposes of obviousness. That internal contradiction further undermines PET's attempt to show material examiner error and further supports discretionary denial.

## IV. DISCRETIONARY DENIAL UNDER 35 U.S.C. § 324(a)

The *Fintiv* factors regarding parallel proceedings weigh in favor of denial. *See Fintiv*, IPR2020-00019, Paper 11 (PTAB Mar. 20, 2020) (Precedential):

**(1) Stays:** Multiple stays have been requested for ongoing settlement negotiations (*See* Exs. 2003, 2004). PET only recently filed a motion to stay in district court as of the time of this filing but the case is currently still progressing.

**(2) Timing:** Eleven months into case but no trial date set;

**(3) Investment:** Eleven months into case; substantial briefing; seeking to consolidate patent claims in parallel ongoing case;

**(4) Issue Overlap:**

**(a) Grounds/Prior Art:** PET has provided only a standard *Sotera* stipulation, but has not disavowed asserting the same art in different ways (Pet. 112);

**(b) Asserted Patents:** The timing of this proceeding is months later than the four related proceedings, raising delay concerns; and

**(c) Incomplete Resolution:** PET has filed its own district court suit against PO related to bunion correction products, alleging misappropriation of trade secrets, copyright violation, and patent infringement. *See* Ex. 2005. The potential for joinder of those patent infringement claims and the practical likelihood of at least parallel case management of those claims mean that the parties' dispute over the same products is almost certainly moving forward; and

**(5) Parties:** PET is the defendant in the parallel proceeding.

Based on the above, efficiency is best served by denying institution and allowing resolution at the district court both parties chose to litigate their disputes over bunion correction products. Nevertheless, the Director's authority under § 324(a) extends beyond *Fintiv* efficiency factors. Here, settled expectations and considerations of resource allocation conclusively tip the scales in favor of discretionary denial.

## A. Number of Challenges

As indicated above, ***PET presents 17 challenges***. Even if the Board finds merit for challenges not including Orsak, institution should still be denied for efficiency purposes because ***Orsak infects the majority of PET's prior art challenges*** (Orsak is applied in 9 out of 15). *See Chevron*, IPR2018-00923, Paper 9 at 10–11 (PTAB Nov. 7, 2018) (Informative); *Deeper*, IPR2018-01310, Paper 7 at 27–28 (PTAB Jan. 24, 2019) (Informative).

## B. Settled Expectations Attach to Continuity Chain, Not Issuance Date

The relevant inquiry under § 324(a) is whether the public had a meaningful opportunity to evaluate, rely upon, and design around the claimed technology, not whether the challenged continuation issued recently. The core technology was published by January 2016. From that point forward, the public could reasonably assess a stable and predictable claim trajectory directed to the method of bunion

correction surgery, rather than facing a later-emerging or materially different claim theory. Related claims in patents issued by March 2021 (U.S. Patent No. 10,945,764 (Ex. 2006, "the '764 Patent")). The Director has denied institution, finding "strong settled expectations" warranting discretionary denial under § 324(a) for durations similar to the '764 Patent. *See Amgen Inc. v. Bristol-Myers Squibb Co.*, IPR2025-00601, Paper 9 at 3 (PTAB July 24, 2025) (Informative).

PO has relied on established rights related to the claimed technology and its continuation family. Allowing a late-stage challenge years into this continuity chain would upset those settled expectations despite the absence of claim-scope surprise or deviation from the family's established claiming direction. Specifically, earlier family patents claimed instrumented techniques for bunion correction surgery. Although claim language differs, the later claims fall within a predictable continuation trajectory that was visible to the public when the earlier claims issued.

**1. The '941 Patent Claims and '764 Patent Claims**

The '941 and '764 Patent claims are closely aligned, both reciting a method using a bone positioning device and bone cutting guide to (i) adjust the alignment of the first metatarsal relative to the first cuneiform using the bone positioning device, (ii) align a bone cutting guide with the joint between the first metatarsal and the first cuneiform, (iii) use the guide feature of the bone cutting guide to guide a cutting tool to remove at least a portion of the metatarsal, and (iv) fix the moved position of the

first metatarsal relative to the first cuneiform with a bone connector. *Compare* Ex. 1001 (’941 Patent claim 1), 6:24–7:5 *with* Ex. 2006 (’764 Patent claim 1), 6:14–27. Moreover, the ’941 Patent tracks the core operative steps of the ’764 patent (alignment adjustment using a bone positioning device, cutting guide use, and bone connector fixation), while the ’941 Patent recites additional limitations not found in ’764 Patent’s claim 1.

**2. Targeted Family Disclosure**

The predictability is reinforced by the nature of the disclosure itself. The family disclosure is not a sprawling omnibus of divergent embodiments that leaves the public guessing which direction might be pursued in continuation claims. Instead, the issued claims have consistently tracked the same core surgical bunion correction method since at least 2021. This targeted disclosure and consistent claiming trajectory further supports settled expectations by reducing the risk of unforeseen claim-scope shifts.

**3. Petitioner’s Notice**

This is not a case where unexpected claim scope later ensnared an unsuspecting competitor. The ’941 Patent represents predictable continuation practice: refining claims based on the original disclosure and available art. PET knew the family, understood the scope, designed products within that scope, and proceeded anyway. This confirms the settled expectations that attached to this stable,

publicly available patent family. PET offers no persuasive justification for expending Office resources.

## C. Evidence of Substantial Reliance and Settled Expectations

PO's commercialization activities corroborate the reliance interests discussed above. *See Amgen* at 2 (settled expectations can be established for young patents where "an explanation of how [PO's activities] correlate[]").

**1. PO has invested substantial resources in commercializing products in this patent family, and investors have relied on the established patent rights to inform their continued investment in PO**. *See* Ex. 2007, 27–29, 70–71, 87–88, 104–105 (March 2021 IPO prospectus identifying patents as critical business asset, warning that loss of patent protection would materially harm business, and describing "robust intellectual property portfolio" as competitive differentiator and "significant barrier to entry"); Ex. 2008 (April 2021 IPO); Ex. 2009, 1 (May 2021 J.P. Morgan analyst report stating "strong IP surrounding the Lapiplasty kit has created high barriers to entry").

From the time the '764 patent issued in 2021 through 2025, PO made substantial investments in the claimed technology and regularly reinforced its reliance on patent protection through public announcements. *See* Ex. 2010 (October 2021 announcement of 30th granted US patent "strategically enhanc[ing] Treace's comprehensive patent coverage"); Ex. 2011 (November 2021 announcement

emphasizing bone positioner technology patents); Ex. 2012 (January 2022 announcement of patent "augment[ing] Treace's extensive and growing patent portfolio"); Ex. 2013 (December 2022 announcement of expansion to 50 granted patents globally, including 40 in US, "strategically enhanc[ing]" patent coverage on instrumented bunion correction with priority dating to 2014); Ex. 2014 (April 2023 announcement of 58 granted patents including 47 in US and 84 pending applications); Ex. 2015 (September 2023 celebrating milestone 50th US patent with July 2014 priority date as demonstration of "commitment to rapid and meaningful innovation"); Ex. 2016 (June 2025 announcement identifying portfolio of 80 granted US patents, 26 granted patents worldwide, and over 150 pending applications). PO's commercial products gave rise to widespread market adoption and industry reliance. *See* Ex. 2017 (March 2024 announcement celebrating 100,000th patient treated with "patented Lapiplasty® 3D Bunion Correction® System").

**2. Third-party analysts and competitors recognized PO's patent position as creating settled expectations and barriers to entry**. *See* Ex. 2009, 5, 11 (May 2021 J.P. Morgan report concluding "Treace has a competitive advantage over peers given its broad intellectual property (IP) portfolio covering key methods of 3D bunion surgery" and noting that "Treace's . . . patent protected methodology forces" competitors to "make tradeoffs to work around Treace's IP"); Ex. 2018 (April 2023 Stephens analyst report identifying "strong IP" as basis for continued market

penetration); Ex. 2019, 3 (November 2024 investor conference identifying 65 US-issued patents with "active defense" as key competitive advantage). PO's enforcement actions further demonstrate reliance on its patent portfolio and the industry's recognition of patent strength. *See* Ex. 2020 (March 2022 announcement of patent infringement suit); Ex. 2021 (March 2023 settlement with competitor); Ex. 2022 (October 2024 announcement of suit against Stryker alleging infringement of 9 patents (with no challenges to those patents at PTAB) and unfair competition); Ex. 2016 (June 2025 announcement of patent infringement suit against Zimmer Biomet).

**3. The Petition acknowledges that prior techniques were imprecise and variable, underscoring the significance of the claimed advance**. *See*, *e.g.*, Pet. 39 (discussing "freehand" resection and imprecision concerns). The prior approaches required significant surgical skill and were prone to variability in outcome. *See* Ex. 2007, 27–28 (explaining need for patent protection against prior art problems); Ex. 2009, 1, 11 (May 2021 analyst report addressing Lapiplasty and noting competitive products "make tradeoffs to work around Treace's IP"). PO's technology directly addressed these shortcomings by enabling consistent alignment and controlled cutting, reducing dependence on subjective judgment and free-hand variability. *See* Ex. 2017 (noting Lapiplasty Procedure benefits including "quick return to bearing weight" and "low recurrence rate of only 0.9% to 3.2%"); Ex. 2023, 3–4, 8 (January 2023 investor presentation emphasizing patents). This alignment between PO's

technology and the long-recognized problem explains why reliance interests reasonably formed. The technology patented has been widely accepted as a way of improving surgical outcomes, so PO reasonably expected that the patents issuing from this continuity chain would not be disturbed, particularly using the old devices that caused these difficulties.

Taken together, the duration of public disclosure and claiming, the reliance interests reflected in adoption and investment, and the absence of any identified examination error support discretionary denial under § 324(a). Allowing institution at this stage, based on cumulative art and a petition that relies materially on expert-based reimagination narratives over previously presented references, would disrupt those expectations and undermine the balance Congress intended.

**D. Merits Considerations Reinforce § 324(a) Discretionary Denial**

The Director considers "other circumstances . . . including the merits," confirming that the Petition's strength is a relevant § 324(a) consideration. *Fintiv* at 6. The challenges rely on cumulative art and expert-driven hindsight, not disclosures newly brought before the Office. The weak merits will be evident after review of the POPR. *See* Guidance § II.C.i. ("Notwithstanding the prohibition on incorporation by reference in 37 C.F.R. § 42.6(a)(3), when filing a brief for discretionary denial, ***a patent owner may direct attention to an anticipated POPR and evidence for a discussion of the merits***.") (emphasis added).

### E. PO's U.S. Based Operations vs PET's Large Multinational Operations

In view of the Director's March 11, 2026 Memorandum (Ex. 2024), PO notes that PET is owned by a large multinational corporation with approximately 17,000 employees spread across 31 offices globally and numerous foreign subsidiaries (Ex. 2025; Paper 1 at 112–113). For example, PET identifies numerous foreign entities that have a financial interest and/or that would be affected by the outcome of the proceeding, including German, Finnish, South Africa, German, Japanese, and Italian entities. *See* Paper 1 at 112–113.

PO is a U.S. based company with U.S. manufacturing. PO is significantly smaller than PET, at just over 400 employees compared to 17,000 employees. But unlike PET, all of PO's employees are located domestically. Ex. 2026 ¶ 5. All of PO's research and development activities take place in the United States. *Id.* ¶ 4. And over 85% of PO's current manufacturing operations for all of PO's products are located in the United States, primarily in Florida, Massachusetts, Michigan, and Indiana. *Id.* ¶ 6. Unlike PET, PO's business is entirely American, investing in U.S. jobs and innovation. Forcing PO to defend its patents in this additional forum would consume disproportionate resources while imposing comparatively little burden on a global enterprise of PET's scale. That imbalance warrants discretionary denial.

## V. CONCLUSION

Considering all circumstances together, discretionary denial is warranted.

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Respectfully Submitted,

/Jeremy Plenzler/

Jeremy Plenzler (Reg. No. 56,432)

VAN HOVEN PC
280 N. Old Woodward Ave., Suite 100
Birmingham, MI 48009
248.289.5464
jeremy@vhiplaw.com

Counsel for Patent Owner

## CERTIFICATE OF SERVICE

The undersigned certifies that on the 5th of May 2026, a complete and entire copy of the foregoing "PATENT OWNER'S REQUEST FOR DISCRETIONARY DENIAL OF INSTITUTION," including any exhibits, was electronically served via email to MLB-P28-PGR-941@morganlewis.com to the below counsel of record for Petitioner per Petitioner's consent for electronic service (*see* Paper 2 at 114).

| **Lead Counsel** | **Back-up Counsel** |
|---|---|
| Ali S. Razai (Reg. No. 60,771)<br>ali.razai@morganlewis.com<br><br>Postal and Hand-Delivery Address:<br>MORGAN, LEWIS & BOCKIUS LLP<br>600 Anton Boulevard, Suite 1800<br>Costa Mesa, CA 92626-7653<br>Tel.: (714) 830-0600<br>Fax: (714) 830-0700 | Jacob L. Peterson (Reg. No. 65,096)<br>jacob.peterson@morganlewis.com<br><br>Brandon G. Smith (provisionally recognized PTAB attorney)<br>brandon.g.smith@morganlewis.com<br><br>Postal and Hand-Delivery Address:<br>MORGAN, LEWIS & BOCKIUS LLP<br>600 Anton Boulevard, Suite 1800<br>Costa Mesa, CA 92626-7653<br>Tel.: (714) 830-0600<br>Fax: (714) 830-0700 |

Dated: May 5, 2026

/Jeremy Plenzler/
Jeremy Plenzler (Reg. No. 56,432)

Counsel for Patent Owner