

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 PRELIMINARY RESPONSE**

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**PATENT OWNER'S UPDATED LIST OF EXHIBITS**

| <b>Exhibit No.</b> | <b>Description</b>                                                                                                                                                      |
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| 2001               | <i>Treace Medical Concepts, Inc. v. Zimmer Biomet Holdings, Inc. and Paragon 28, Inc.</i> , Initial Complaint, dated May 12, 2025                                       |
| 2002               | U.S. Patent Application Publication No. US 2013/0325076 A1, dated December 5, 2013                                                                                      |
| 2003               | <i>Treace Medical Concepts, Inc. v. Zimmer Biomet Holdings, Inc. and Paragon 28, Inc.</i> , Joint Stipulation and Proposed Order to Extend Stay, dated December 1, 2025 |
| 2004               | <i>Treace Medical Concepts, Inc. v. Zimmer Biomet Holdings, Inc. and Paragon 28, Inc.</i> , Joint Stipulation and Proposed Order to Stay, dated September 12, 2025      |
| 2005               | <i>Paragon 28, Inc. and Disior Oy v. Treace Medical Concepts, Inc. and Mios Marketing, LLC</i> , Amended Complaint, dated December 18, 2025                             |
| 2006               | U.S. Patent No. 10,945,764 to Dayton, <i>et al.</i> (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     |

| <b>Exhibit No.</b> | <b>Description</b>                                                                                                                                       |
|--------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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                        |
| 2015               | Treace's Announcement of New Patent Covering Instrumented Bunion Correction Procedures and Milestone 50th U.S. Patent, dated September 14, 2023          |
| 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.                                                                        |

| <b>Exhibit No.</b> | <b>Description</b>                                                                                                                                        |
|--------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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                                                                                                                          |
| 2027<br>[NEW]      | Declaration of Daniel C. Farber, M.D. ("Farber Declaration")                                                                                              |
| 2028<br>[NEW]      | <i>Curriculum Vitae</i> of Daniel C. Farber, M.D.                                                                                                         |

## **I. INTRODUCTION**

### **A. Background**

Paragon 28, Inc. (“Petitioner”) filed a Petition (Paper 2, “Petition” or “Pet.”) requesting post grant review of claims 1–27 of U.S. Patent No. 12,349,941 (Ex. 1001, “’941 Patent”).

The Petition should be denied because Petitioner has not established that it is more likely than not that any challenged claim is unpatentable. The written description challenges fail because Petitioner’s own expert walks through the specification and confirms disclosure of the structural components and method context Petitioner later relies on for obviousness. The enablement challenges fail because Petitioner invokes but does not meaningfully apply the *Wands* analysis while elsewhere describing the same design choices as “routine” and “predictable” in its obviousness challenges. The obviousness challenges fail for a fundamental reason that pervades all fifteen obviousness grounds: Petitioner proposes combining an article describing a freehand Lapidus procedure (Dayton) with a percutaneous external fixator reference (Waisman, Taylor, or Orsak) and an implant-based fusion system (Palmer) or a thumb-joint osteotomy guide (Orbay), and then asks the Board to accept that a skilled surgeon would have viewed this combination as an obvious modification with a reasonable expectation of success.

The references Petitioner seeks to combine do not share a common surgical

context. Dayton is a 7-page article reporting the radiographic outcomes of 25 freehand Lapidus procedures. Ex. 1005, 348–50. Dayton describes using pins as visual references for manual rotation of the first metatarsal, not structural anchors for a positioning instrument. *Id.* Dayton describes no cutting guide, no bone positioning device, and no joint plate. Those are all features Petitioner imports from other references. Dayton instead describes temporary stabilization with smooth wires after manual correction and final internal fixation using plates and/or screws, including locking plates, screw fixation, and an anatomic locking plate with compression screw. *Id.*

Waisman, Taylor, and Orsak are, by contrast, external-fixation references directed to maintaining or adjusting bone portions in materially different treatment contexts. Waisman is a polyaxial K-wire external fixator whose device is “mounted close to the bone through the skin and other soft tissues” and “subsequently removed later, after optimal bone healing.” Ex. 1006, 2:16–19. Waisman further describes non-rigid fixation producing “[m]icromovements between fragments” to “promote and accelerate bone healing.” *Id.* at 6:21–23. Taylor discloses a spatial frame, and the operative embodiment Petitioner relies on depicts an application to a fractured tibia. Ex. 1007, Fig. 29, 9:58–59. Orsak references “attach[ment] externally to the patient’s body for the duration of the treatment, which can last from several weeks to many months.” Ex. 1008 ¶ 3.

Petitioner does not establish that any cited reference teaches or suggests the use of the claimed intraoperative joint-spanning bunion-correction instrument. Each is directed to a materially different fixation or correction paradigm from the controlled intraoperative multiplanar repositioning step the claims recite. Dr. Farber confirms that, from the perspective of a foot-and-ankle surgeon, those differences affect whether an instrument would fit the anatomy, workflow, and objective of a Lapidus bunion-correction procedure. Ex. 2027 ¶¶ 25–36, 42–57.

Palmer and Orbay do not cure that threshold defect. Petitioner relies on those references for cutting guide features, not for the claimed bone positioning device. Thus, even assuming Petitioner could show cutting guide features in Palmer or Orbay, those references do not supply the missing teaching or motivation for modifying Dayton’s freehand Lapidus procedure to use a pinned, joint-spanning, bone positioning device that adjusts alignment in multiple planes engaged to the first metatarsal and first cuneiform to adjust metatarsal alignment in multiple planes.

These mismatches go to the threshold question whether a POSA would have had any reason to replace Dayton’s manual visually guided correction with the claimed instrumented method using a pinned, joint-spanning, bone positioning device that adjusts alignment in multiple planes. Petitioner identifies no record-supported teaching or reasoned rationale for using the cited external-fixation architectures in Dayton’s Lapidus procedure as the claimed pinned, joint-spanning,

bone positioning device engaged to the first metatarsal and first cuneiform and used to adjust alignment in multiple planes. Petitioner also fails to establish that a POSA would have reasonably expected success in making its proposed modifications, which is underscored by Petitioner's § 112 challenges.

The Petition's obviousness challenges are a product of hindsight, not prior art.

**B. The '941 Patent**

The '941 Patent issued from a continuity chain tracing back to a July 15, 2014 priority date. The '941 Patent relates to “devices and methods for positioning and cutting bones,” including “temporarily fixing bones in a desired position during a surgical procedure such as a bone alignment, osteotomy, and/or fusion procedure.” Ex. 1001, 1:24–25, 2:63–66. In the bunion-correction context, the patent describes an integrated instrumented system having three coordinated components: a bone positioning device, a bone cutting guide, and a bone connector.

**C. Illustrative Claim**

Claim 1 is representative for the issues discussed in Patent Owner's Preliminary Response (“POPR”) and is reproduced below:

1. A method of performing a bunion surgery to correct an alignment between a first metatarsal and a first cuneiform, the method comprising:  
  
engaging a bone positioning device with a first metatarsal using a first fixation pin and with a first cuneiform using a second fixation pin,

the bone positioning device extending across a joint separating the first metatarsal from the first cuneiform;

aligning a bone cutting guide with the joint between the first metatarsal and the first cuneiform, the bone cutting guide comprising a joint plate offset from a guide feature of the bone cutting guide, the joint plate extending downwardly relative to the guide feature, wherein aligning the bone cutting guide with the joint comprises inserting the joint plate into the joint;

using the guide feature of the bone cutting guide to guide a cutting tool to cut a leading edge of the first metatarsal;

using the bone positioning device to adjust an alignment of the first metatarsal in multiple planes to correct a bunion;

compressing the first metatarsal and the first cuneiform together; and

fixing a position of the first metatarsal relative to the first cuneiform with a bone connector.

Ex. 1001, 6:24–48.

**D. Evidence and Asserted Grounds**

Petitioner asserts that claims 1–27 would have been unpatentable on the following grounds:

| Ground | Reference(s)                           | Claims | Basis |
|--------|----------------------------------------|--------|-------|
| 1      | N/A (Written Description & Enablement) | 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 |
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| 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 |

Petitioner submits the Declaration of Steven K. Neufeld, M.D. Ex. 1003 (“Neufeld Declaration”). Patent Owner submits the Declaration of Daniel C. Farber, M.D. Ex. 2027 (“Farber Declaration”).

## **II. ANALYSIS**

### **A. Legal Standards**

Petitioner bears the burden of persuasion to prove unpatentability, by a preponderance of the evidence, of the claims challenged in the Petition. 35 U.S.C.

§ 326(e). This burden never shifts to Patent Owner. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015). For purposes of instituting trial, Petitioner must “demonstrate that it is more likely than not that at least 1 of the claims challenged in the petition is unpatentable.” 35 U.S.C. § 324(a).

**B. Level of Ordinary Skill in the Art**

Petitioner contends that because the patent includes both surgical procedures and mechanical devices, a hypothetical person of ordinary skill in the art would have a combination of these two skill sets. Pet. 15. Accordingly, Petitioner contends that “a hypothetical person of ordinary skill in the art (“POSA”) would have had [a] medical degree and at least 3 years of surgical experience with foot surgery,” and “would have worked as part of a team and collaborated with a person having a degree in mechanical engineering or a similar engineering discipline, and experience with the design of surgical instrumentation.” *Id.*

The level of ordinary skill in the art is “a prism or lens” through which the prior art and the claimed invention are viewed. *Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001). The person of ordinary skill in the art is a hypothetical person presumed to have known the relevant art at the time of the invention. *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995). In determining the level of ordinary skill in the art, factors considered include the “type of problems encountered in the art; prior art solutions to those problems; rapidity with which innovations are made;

sophistication of the technology; and educational level of active workers in the field.” *Id.*

The level of skill in the art is a reference point for gauging what would have been obvious based on the reference disclosures. *See Okajima*, 261 F.3d at 1355. In other words, the lens of the level of ordinary skill in the art does not change a prior art’s disclosure, though it may change one’s understanding of what is disclosed. Patent Owner disagrees that a POSA would need to have worked as part of a team and collaborated with a person having a degree in mechanical engineering or a similar engineering discipline. Nevertheless, Petitioner does not explain how its definition provides a reference point that would alter the Petition’s assertion of obviousness and instead concedes it does not. *See* Pet. 15 (“Petition does not turn on this specific definition of the level of ordinary skill.”).

Accordingly, the definition of a POSA provided by Petitioner should not affect the outcome of the institution decision.

### **C. Claim Construction**

In a post-grant review, a claim “shall be construed using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. [§] 282(b).” 37 C.F.R. § 42.200(b). Under this standard, claims “are generally given their ordinary and customary meaning,” as understood by a person

of ordinary skill. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (citation omitted).

Petitioner proposes constructions for “bone positioning device,” “bone connector,” and “cutting tool.” Pet. 16–17. Patent Owner does not believe there is a need to expressly construe any particular claim term in order for the Board to deny institution. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (confirming that the Board need not construe claim terms where their construction is not material to the dispute). Petitioner agrees. *See* Pet. 16 (“Petitioner submits the Board need not specially construe any claim terms.”).

**D. Petitioner’s Written Description Challenge**

Petitioner argues that all claims lack written description on two grounds: (i) the specification allegedly fails to describe “how” the bone positioning device is used to achieve multiplanar bunion correction while pinned across the joint (Pet. 20–22); and (ii) claims 4 and 18 allegedly lack written description for reciting the specific sequence of adjusting metatarsal alignment before performing the cuneiform cut (*id.* at 22–23). Both contentions fail.

**1. “how” the bone positioning device is used — all claims**

Petitioner contends that “the specification does not describe how to perform the claimed surgical method at the level of method steps.” Pet. 21. According to

Petitioner, “[w]hat is missing is any disclosure of how a surgeon imparts and controls the forces/torques through the pinned device to achieve a desired multi-planar correction while fixed across the joint.” *Id.* Petitioner further contends: “Nor does the specification provide any description of multi-planar bunion deformities, target correction criteria, intraoperative decision criteria, any actuation/manipulation technique (e.g., where to apply force/torque on the device), or how multi-plane adjustments are selected to ‘correct a bunion.’” *Id.* at 21–22 (citing Ex. 1003 ¶¶ 70–71). Petitioner alleges that “the patent describes a vague multi-axis capability, not the claimed clinical/surgical use of that capability to accomplish multi-planar bunion correction.” *Id.* (citing 1003 ¶¶ 70–71).

Petitioner concludes:

Despite the complete lack of disclosure, the claim language (“multiple planes...to correct a bunion”) encompasses a wide range of multi-planar manipulations and endpoints implemented using a device pinned across the first metatarsal-cuneiform joint. Without disclosure tying the device’s generic multiplanar movement capability to that claimed bunion-correction objective, the specification fails to show possession across the full claim scope and instead attempts to claim beyond what is described. *See Gentry Gallery*, 134 F.3d at 1479-81; *ICU Med.*, 558 F.3d at 1378-79. Nor can Patent Owner cure the deficiency by arguing that a POSA would “know” what multi-planar bunion correction entails or how to push/pull/twist the device: importing missing methodology is

not written description. *See Ariad Pharms.*, 598 F.3d at 1352;  
*Lockwood*, 107 F.3d at 1571-72.

Pet. 22.

Patent Owner disagrees with Petitioner's conclusion regarding lack of written description. As an initial matter, Petitioner misapprehends what is required of it. As noted above, Petitioner has the burden to establish unpatentability (in this challenge based on lack of written description). But Petitioner at best provides allegations, not persuasive argument supported by evidence.

Petitioner provides a list of items purportedly missing from the specification without meaningful explanation as to why those purportedly missing items establish lack of possession of the claimed method. Petitioner fails to meaningfully engage with the specification's disclosure of the relevant structure and its multi-axis operation. *See* Ex. 1001, 3:2–5 (“the procedure can be performed to correct an alignment between a metatarsal (e.g. a first metatarsal) and a cuneiform (e.g., a first cuneiform), such as a bunion correction”), 3:37–4:33 (describing how the bone positioning device operates), 5:28–6:3 (describing “methods of temporarily fixing the orientation of a first bone with respect to a second bone, such as during a surgical procedure, using a bone positioning device.”). Petitioner identifies no claim limitation requiring the additional clinical-operation narrative it says is missing.

The level of detail required to satisfy the written description requirement

varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology. *See Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc); *see also Bilstad v. Wakalopulos*, 386 F.3d 1116, 1126 (Fed. Cir. 2004) (holding that in “the mechanical world—a fairly predictable field—it is wholly conceivable that [a disclosed species] may convey to one skilled in the art” possession of the broader claimed subject matter, and faulting the Board for failing to analyze predictability of the field before finding written description deficient). Written description requires possession of the claimed subject matter, not a how-to operative manual. *Ariad*, 598 F.3d at 1352 (“the hallmark of written description is disclosure” of the invention; *ipsis verbis* support is not required).

Petitioner’s complaint is that the specification omits clinical-operation narrative (“how a surgeon imparts and controls the forces/torques through the pinned device” (Pet. 21), “target correction criteria” (*id.*), “intraoperative decision criteria” (*id.*), and “how multi-plane adjustments are selected to correct a bunion” (*id.*)). But none of those attributes is a claim limitation. The claim recites “using the bone positioning device to adjust an alignment of the first metatarsal in multiple planes to correct a bunion.” It does not require disclosure of the clinical protocol by which a surgeon selects target correction values or chooses application forces for every possible scenario.

The Specification explains that “the procedure can be performed to correct an alignment between a metatarsal (e.g. a first metatarsal) and a cuneiform (e.g., a first cuneiform), such as a bunion correction. An example of such a procedure is a Lapidus procedure.” Ex. 1001, 3:2–6. The Specification proceeds to describe the bone positioning device’s structure and how that structure provides multiple planes of correction. *See id.* at 3:10–67.

Moreover, Petitioner itself acknowledges that the ’941 Patent demonstrates possession of what the claims recite. For example, Petitioner contends that a “positioning device like Waisman’s [can be] used to adjust first metatarsal alignment in multiple planes to correct a bunion” (Pet. 45) and that Waisman’s “positioning device is identical or at least equivalent to structures identified in the ’941 patent for the claimed positioning device” (*id.* at 32). Petitioner’s expert provides similar testimony. *See, e.g.*, Ex. 1003 ¶¶ 106, 114, 141.

For at least these reasons, Petitioner fails to establish that it is more likely than not to succeed on its written description challenge to claims 1 and 18. Petitioner does not present any separate written description contentions for the remaining dependent claims that cure these defects. Because Petitioner’s dependent claim written description challenges rest on the same asserted deficiencies in the independent claims, those challenges fail for the same reasons.

2. **the specific sequence of adjusting metatarsal alignment before performing the cuneiform cut—claims 4 and 18**

Petitioner alleges that “Claims 4 and 18 compound the defect by requiring a specific sequence: adjusting metatarsal alignment before performing the cuneiform cut.” Pet. 22. Petitioner contends:

The specification addresses timing only at a high level, stating that “cutting of bone” may occur “after a position of the bone has been fixed by the device” (Ex.1001, 4:66-5:2), but it provides no operative protocol for performing the pre-cut adjustment in practice or criteria for when that adjustment is complete or sufficient.

*Id.* at 22–23. Petitioner again relies on allegation without meaningful argument.

Petitioner itself states that “the ’941 patent indicates that step order is exemplary (‘need not be performed in the order stated’) and that cutting *may be* performed ‘after a position of the bone has been fixed.’” Pet. 49 (citing Ex. 1001, 5:52–53, 4:66–5:2). And Petitioner’s own expert testifies that “a POSA would have understood that the order of resection (including the cuneiform cut) and frontal-plane rotational correction is not critical” (Ex. 1003 ¶ 157), “[t]he ’941 patent itself confirms that the claimed step order is exemplary” (*id.* ¶ 158), and “[a] POSA would have recognized that a finite number of sequencing options exist for repositioning the first metatarsal and cutting the first metatarsal and cuneiform” (*id.* ¶ 159). Petitioner offers no persuasive explanation reconciling these statements with alleged lack of written description.

Where the same disclosed components perform the same disclosed operations, but in a different sequence, a person of ordinary skill in a mechanical field would understand the inventor to have possessed that ordered method. *See Bilstad*, 386 F.3d at 1125–26. Petitioner does not demonstrate that a person of ordinary skill would understand the specification to limit the inventors’ possession to a single, mandatory order of steps, nor does it identify any teaching that performing the cut in the claimed order is inconsistent with the disclosed system.

At most, Petitioner shows that the specification’s example proceeds in one order. That showing is insufficient. Petitioner has not carried its burden to show that the specification fails to reasonably convey to a person of ordinary skill that the inventors possessed the method recited in claims 4 and 18 and fails to establish that it is more likely than not to succeed on its written description challenge to claims 4 and 18.

**E. Petitioner’s Enablement Challenge**

Petitioner contends that the ’941 Patent: (1) “does not teach a POSA how to perform the claimed surgical method [recited in the independent claims], including how to manipulate/actuate a device pinned across the joint to achieve clinically appropriate multiplanar correction, including where and how to apply force/torque to drive the claimed adjustments” (Pet. 23–25); and (2) “provides no guidance for [claims 4 and 18 regarding] how to achieve/confirm th[e] pre-cut correction or when

it is sufficient” (*id.* at 25). Petitioner has not established either contention.

Petitioner attempts to invoke *Amgen v. Sanofi*, 598 U.S. 594 (2023) for an unduly narrow enablement requirement. *See* Pet. 23 (generally alleging that “[a] patent must enable a POSA to make and use the full scope of the claimed invention without undue experimentation”). *Amgen* stated that “[i]f a patent claims an entire class of processes, machines, manufactures, or compositions of matter, the patent’s specification must enable a person skilled in the art to make and use the entire class. In other words, the specification must enable the full scope of the invention as defined by its claims.” *Id.* at 610. But *Amgen* went on to explain: “That is not to say a specification always must describe with particularity how to make and use every single embodiment within a claimed class.” *Id.* at 610–611. “[I]t may suffice to give an example (or a few examples) if the specification also discloses ‘some general quality . . . running through’ the class that gives it ‘a peculiar fitness for the particular purpose.’” *Id.* at 611. “[A] specification may call for a reasonable amount of experimentation to make and use a patented invention. What is reasonable in any case will depend on the nature of the invention and the underlying art.” *Id.* at 612.

*Amgen* addressed functional genus claims in an unpredictable biochemical art, where the claims covered an essentially unlimited universe of antibody structures, and the specification left skilled artisans to engage in research-level “trial and error” to discover which molecules would work. *Amgen*, 598 U.S. at 600, 610–15. That

context bears no resemblance to the present claims. *See In re Vaeck*, 947 F.2d 488, 496 (Fed. Cir. 1991) (“Where, as here, a claimed genus represents a diverse and relatively poorly understood group of microorganisms, the required level of disclosure will be greater than, for example, the disclosure of an invention involving a ‘predictable’ factor such as a mechanical or electrical element.”); *In re Bowen*, 492 F.2d 859, 862 (C.C.P.A. 1974) (“In cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws.”).

The challenged claims here are in a mechanical and surgical instrumentation context, not a functional genus of unpredictable chemical species. Accordingly, enablement does not require exhaustive disclosure of every permutation within the claim scope, but only sufficient information to allow a POSA to practice the invention without undue experimentation. *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). The key word is “undue,” not experimentation.

Petitioner identifies no evidence that instrumented multi-plane bunion correction is an unpredictable art akin to antibody engineering or that practicing the claimed structural relationships would require the type of research program condemned in *Amgen*. Instead, Petitioner’s own obviousness analysis, though misplaced, characterizes cutting guide technology as adaptable across different

procedures, anatomies, and approaches, and asserts that a POSA would have had a reasonable expectation of success in modifying such systems. *See, e.g.*, Pet. 35, 71, 84. That is, Petitioner itself asserts that this field operates under predictable structural principles, further underscoring why *Amgen* does not control here. Absent proof of undue experimentation across the claim scope, Petitioner's reliance on *Amgen* is misplaced.

In determining whether undue experimentation would have been required to make and use an invention, the following factors are considered:

- (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

*Wands*, 858 F.2d at 737. Petitioner presents no meaningful *Wands* analysis and no evidence quantifying the experimentation required, identifying specific failures a POSA would encounter, or explaining why the relevant mechanical/surgical instrumentation field is unpredictable. Its failure to do so reflects that the factors do not support Petitioner's enablement challenges.

Petitioner's contentions regarding purported lack of enablement regarding claims 1, 4, and 18 are effectively its written description challenge repackaged. And as explained above, relative to the written description challenge, the '941 Patent

describes the bone positioning device's use in multi-plane bunion correction. *See* Ex. 1001, 3:2–67. Petitioner's contentions are reproduced below to make clear the lack of merit in Petitioner's positions, as they are simply cursory allegations without meaningful argument.

**1. “how” the bone positioning device is used —all claims**

According to Petitioner:

[T]he independent claims require engaging a bone positioning device across the first metatarsal-cuneiform joint using fixation pins and using the pinned device to adjust the first metatarsal alignment in multiple planes to correct a bunion. The patent, however, at most describes the mechanical capability: a “multi-axis joint” permitting movement “about the three cardinal planes (i.e., X, Y, and Z axes),” with “angulation in all directions and rotation,” and set screws to “fix[]” an achieved orientation. Ex.1001, 3:43-48, 4:1-13. That generic description does not teach a POSA how to perform the claimed surgical method, including how to manipulate/actuate a device pinned across the joint to achieve clinically appropriate multiplanar correction, including where and how to apply force/torque to drive the claimed adjustments.

Pet. 23–24. Petitioner further contends:

Nor does the specification explain what multi-planar components of correction are required or contemplated for bunion correction at the metatarsal-cuneiform joint once the device is pinned, how to determine target correction in each plane, how to apply and control force/torque

through the device to produce desired rotation/translation while pinned, how to sequence and coordinate multi-plane adjustments while maintaining joint congruity, or what objective intraoperative criteria indicate the bunion has been “correct[ed].” *See e.g.*, Ex.1003, ¶¶70-71. Instead, the disclosure largely reduces to hardware that can move in multiple axes coupled with the claim’s functional endpoint (“to correct a bunion”). *Id.*

*Id.* at 24. Petitioner contends that “the specification provides no instruction on actuating the device to impart controlled rotation/translation while pinned across the joint, forcing a POSA to develop actuation and control techniques through experimentation.” *Id.* at 25.

Enablement does not preclude experimentation, only undue experimentation. As seen above, Petitioner’s contentions are allegations unsupported by evidence. Paragraph 70 of the Neufeld Declaration describes Figure 4 of the ’941 Patent, and paragraph 71 alleges that “the ’941 patent does not explain how this bone positioning device is used to correct a bunion.” Dr. Neufeld does not opine on the quantity of experimentation a POSA would need to undertake, does not identify specific failures a POSA would encounter, does not address the predictability of foot and ankle surgical device design as a field, and does not compare the hypothesized experimentation to the level of skill in the art. He does not testify that a POSA would be required to engage in trial-and-error experimentation rising beyond clinical

judgment within the skill of a POSA. This is not an undue experimentation analysis.

Petitioner does not identify any embodiment within the scope of the claims that could not be practiced by a POSA or demonstrate that any such embodiment would require more than the ordinary skill level of a POSA. Petitioner's failure to apply *Wands* through competent evidence is sufficient to defeat its non-enablement challenge on this record.

Notwithstanding those fundamental failings, Dr. Neufeld later testifies that “[a] POSA would have had a reasonable expectation of success in combining Waisman’s fixator with Dayton’s [multi-plane bunion correction] procedure because the modification is consistent with the references’ disclosures and relies on predictable mechanics.” Ex. 1003 ¶ 112; *see also id.* ¶¶ 238, 274 (repeating same for other challenges). According to Petitioner, Waisman’s “positioning device is identical or at least equivalent to structures identified in the ’941 patent for the claimed positioning device.” Pet. 32. As noted above, Petitioner contends that “the positioning device like Waisman’s [can be] used to adjust first metatarsal alignment in multiple planes to correct a bunion.” Pet. 45. Dr. Neufeld provides similar testimony. *See, e.g.*, Ex. 1003 ¶¶ 106, 114, 141. Petitioner offers no explanation for the tension between its non-enablement challenge and its reasonable expectation of success contentions.

For at least these reasons, Petitioner fails to meet its burden required to show

it is more likely than not to establish lack of enablement regarding claims 1 and 18. Petitioner's enablement challenge to the dependent claims rests on the same asserted lack of guidance for using the claimed bone positioning device and therefore fails for the same reasons.

**2. the specific sequence of adjusting metatarsal alignment before performing the cuneiform cut—claims 4 and 18**

Petitioner additionally contends that “Claims 4 and 18 further compound the lack of enablement by requiring a specific operative sequence: adjusting metatarsal alignment before performing the cuneiform cut. Yet the specification provides no guidance for how to achieve/confirm that pre-cut correction or when it is sufficient.” Pet. 25. This is the extent of Petitioner's contentions.

Petitioner itself notes, however, that “the '941 patent indicates that step order is exemplary (‘need not be performed in the order stated’) and that cutting *may be* performed ‘after a position of the bone has been fixed.’” Pet. 49 (citing Ex. 1001, 5:52–53, 4:66–5:2). Petitioner's own expert testifies that “a POSA would have understood that the order of resection (including the cuneiform cut) and frontal-plane rotational correction is not critical” (Ex. 1003 ¶ 157), “[t]he '941 patent itself confirms that the claimed step order is exemplary” (*id.* ¶ 158), and “[a] POSA would have recognized that a finite number of sequencing options exist for repositioning the first metatarsal and cutting the first metatarsal and cuneiform” (*id.* ¶ 159). Again,

Petitioner offers no explanation for the tension between its non-enablement position and its own obviousness contentions regarding finite sequencing options and non-critical step order.

For at least these reasons, Petitioner fails to meet its burden required to show it is more likely than not to establish lack of enablement regarding claims 4 and 18.

**F. Petitioner's Obviousness Challenges**

A claim is unpatentable under 35 U.S.C. § 103 if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious at the time of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved based on underlying factual determinations including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) when in the record, objective evidence of non-obviousness. *Graham v. John Deere Co. of Kan. City*, 383 U.S. 1, 17–18 (1966). Obviousness requires that a petitioner establish both (1) a reason to combine or modify the prior art and (2) a reasonable expectation of success in doing so. *Intelligent Bio-Systems, Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1367–68 (Fed. Cir. 2016). Conclusory assertions are insufficient.

**1. Petitioner’s § 112 and § 103 Theories Are Internally Inconsistent**

Before addressing Petitioner’s § 103 challenge in detail, Patent Owner notes a threshold problem that runs through all of Petitioner’s grounds. For purposes of § 112, Petitioner contends that use of the claimed bone positioning device for multi-plane correction in a bunion correction surgery cannot be determined without undue experimentation. Pet. 23–25. For purposes of § 103, however, Petitioner contends that a POSA would have had a reasonable expectation of success in using the devices it characterizes as “identical or at least equivalent to structures identified in the ’941 patent” (Pet. 32, 69, 82) in Dayton’s freehand Lapidus procedure (*id.* at 35, 45, 71, 73, 84–85, 87–88). Petitioner offers no explanation reconciling these positions and does not identify record evidence showing why the same type of multi-plane use would require undue experimentation for enablement but would be predictably successful for obviousness.

**2. Background**

All of Petitioner’s fifteen obviousness grounds share the same basic structure and the same basic flaws. Each starts with Dayton (an article by Paul Dayton, the first named inventor of the ’941 Patent, describing a freehand Lapidus-style procedure) and then reconstructs the claimed instrumented method by importing an external fixator device from Waisman, Taylor, or Orsak and a cutting guide from Palmer or Orbay. That reconstruction is hindsight-driven and fails at the threshold

motivation to combine requirement and fails again on reasonable expectation of success based on Petitioner's own assertions related to its enablement challenges.

### **3. Ground 2 – Dayton/Waisman/Palmer**

The discussion below focuses on the challenge to claim 1, as the issues are similar for independent claim 18. Petitioner's challenge proposes "us[ing] a bone positioning device like Waisman's in Dayton's procedure to facilitate bone repositioning" (Pet. 28) and "us[ing] a bone cutting guide like Palmer's in Dayton's procedure to facilitate bone cutting" (*id.* at 36).

#### ***a. Dayton***

Dayton is not an instrumentation reference. It is a 7-page retrospective case-series published in the Journal of Foot and Ankle Surgery reporting the radiographic outcomes of Lapidus procedures in patients. Ex. 1005, 349. Dayton's stated scope is even narrower than a clinical outcomes study: "The determination of outcomes such as union rate and patient satisfaction were considered to be outside the scope of the present review. We studied only the radiographic changes in position resulting from the procedure." *Id.* Dayton is a paper about measuring angular changes after a freehand Lapidus procedure.

Dayton's correction and cutting steps are freehand and its pins are visual references, not components of a bone positioning device:

Initially, we simply observed the frontal plane rotation needed to

realign the joint. In later cases, before release of the tarsometatarsal joint (TMTJ) and resection of the articular surfaces, 2 smooth, 2-mm, pins were placed directly in the sagittal plane and parallel, 1 in the base of the metatarsal and 1 in the cuneiform. These pins were used as a reference to more easily visualize the rotation of the metatarsal in the frontal plane.

Ex. 1005, 349. Dayton's pins are smooth wires placed "directly in the sagittal plane and parallel." *Id.* They are visual markers "used as a reference to more easily visualize the rotation of the metatarsal in the frontal plane." *Id.* They are not structural anchors for a positioning instrument. The pins are placed before resection of the articular surfaces and have no positioning role during the cutting step. The pins are "1 in the base of the metatarsal and 1 in the cuneiform" for visualization, not structural anchoring. Dr. Farber confirms that a surgeon reading Dayton would understand those pins as visual reference markers for manual correction, not as structural anchors for a bone positioning device. Ex. 2027 ¶¶ 20–24.

Dayton's rotation step is also explicitly freehand: "[T]he rotation of the metatarsal was addressed by rotating the bone in a varus, or inverted, direction until congruous alignment of the first MTPJ and sesamoids was observed clinically and on the fluoroscopic examination. We found that using the reference pins allowed us to better note the direction of the rotation." Ex. 1005, 349. This is the surgeon's hand manipulating bone under visual and fluoroscopic guidance. No instrument is

described as performing the rotation. Dr. Neufeld agrees: “Dayton achieves its movement through a surgeon manually manipulating the first metatarsal.” Ex. 1003 ¶ 98. Dayton’s cuts are also freehand. *See* Ex. 1005, 349.

Dayton’s temporary stabilization is with “smooth wires” inserted after the bones are already positioned by hand. Ex. 1005, 349 (“The segments were next temporarily stabilized with smooth wires.”). Dayton’s fixation is internal and does not include the use of external fixators. *See id.* (“[T]he final fixation in our cases consisted of multiple methods, including 2 small, flexible, locking plates placed dorsally and medially, single- and double-screw fixation, and anatomic locking plate with compression screw.”). Although Dayton identifies an “anatomic locking plate with compression screw” as one form of final internal fixation, Dayton does not disclose a separate compression instrument or an operative compression step before final fixation. Rather, “[t]he fusion site was positioned with the dorsal and medial cortices flush in all cases.” *Id.*

Dayton’s cited disclosures do not teach the claimed bone positioning device. Petitioner relies on other references for the instrumentation.

***b. Waisman***

Waisman is a modular polyaxial external fixator (“PEF”) for “fractured or osteotomized bones.” Ex. 1006, Abstract; 28:2–3 (claim 1). Its stated field is “skeletal bone fixation . . . relate[d] to a modular polyaxial bone fixator.” Ex. 1006,

2:4–5. Waisman’s purpose is bone fixation. Its devices are “used for fixed location of two or more bone portions after fracture or after surgery with the aim to ensure healing and joining of the fractured or osteotomized bone portions or joints in their correct anatomical position.” Ex. 1006, 2:11–14.

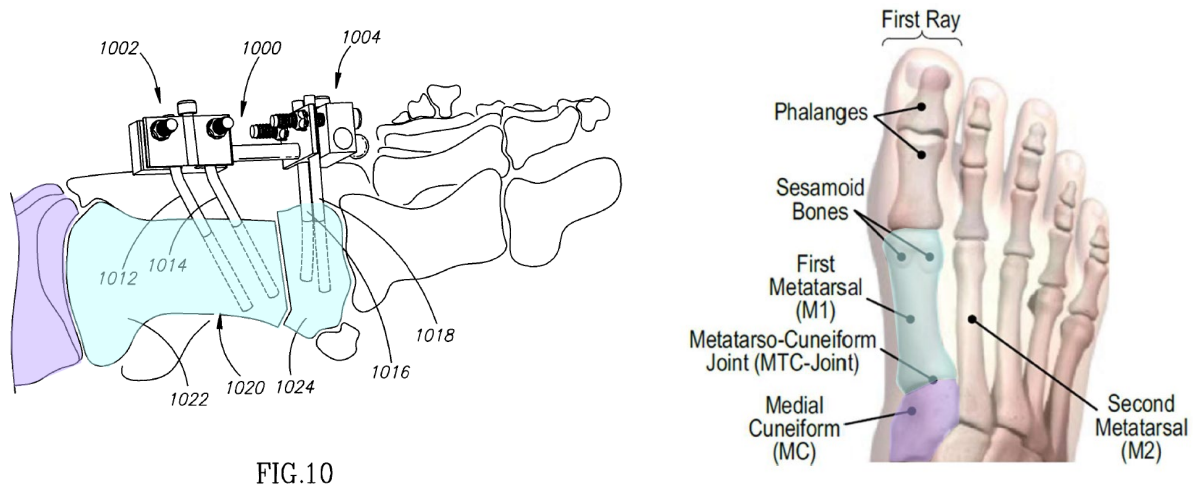
Waisman’s physical configuration is telling. The fixators are “usually mounted close to the bone through the skin and other soft tissues and are subsequently removed later, after optimal bone healing.” Ex. 1006, 2:16–19. “[W]here small bones of the hand, foot, face and skull, which are only thinly covered by skin and soft tissues, external fixators are the first choice to be used. The fixators maintain the bone parts in their correct position by pins, screws, or wires located in drilled bores in the bone, while extending outwardly through skin and other soft tissues.” *Id.* at 2:19–23.

Waisman is hardware for percutaneous fixation, not an intraoperative positioning device used during an open bunion correction. Dr. Farber explains that a surgeon would understand Waisman to describe external fixation hardware used to maintain bone portions during healing, not an intraoperative positioning device used during an open Lapidus bunion-correction procedure. Ex. 2027 ¶¶ 25–29.

Waisman’s operative examples confirm its design paradigm. Figures 9A–9D show four external fixator applications: (A) a fractured distal radius; (B) a fractured finger phalanx; (C) a supracondylar humeral fracture; and (D) a distal tibio-fibular

fracture. Ex. 1006, 24:11–26:20, Figs. 9A–9D. Each application shows a single bone with two fragments fixated across a fracture (or osteotomy) site. The one application Petitioner seizes on (Fig. 10’s “foot for fixing an osteotomy (hallux valgus surgery) of first metatarsus deformity”) uses the same architecture. Ex. 1006, 26:21–30.

Petitioner’s reliance on Waisman’s single-sentence Figure 10 hallux-valgus application is misplaced. Waisman itself describes Figure 10 as a fixator “for fixing an osteotomy (hallux valgus surgery) of first metatarsus deformity.” Ex. 1006, 26:21–27, 27:1–3. Waisman’s Figure 10 is reproduced below, alongside Petitioner’s foot-anatomy illustration from page 3 of the Petition, with Patent Owner’s annotations.



The figure on the left above is Waisman’s Figure 10, along with Patent Owner’s colored annotations. The figure on the right is Petitioner’s foot anatomy illustration from page 3 of the Petition with Patent Owner’s coloring added. Fig. 10 shows “K-

wires 1012 and 1014 . . . inserted into bone portion 1022 and K-wires 1016 and 1018 . . . inserted into bone portion 1024.” Ex. 1006, 27:1–3.

As seen above, both figures are annotated with coloring (blue = first metatarsal and purple = medial cuneiform) to illustrate the difference between Waisman and the claimed “engag[ement of] a bone positioning device with a first metatarsal using a first fixation pin and with a first cuneiform using a second fixation pin, the bone positioning device extending across a joint separating the first metatarsal from the first cuneiform.”

Figure 10 of Waisman illustrates *fixation of an osteotomized first metatarsal* (the device spans two fragments of the first metatarsal after an osteotomy), not a device spanning the joint between the metatarsal and the cuneiform.

Waisman’s operative unit is also structurally different from the claimed architecture. Waisman’s “novel concept [is] of intraosseous anchoring of two or more smooth surface K-wires (basically smooth pins) into a holding-gripping fixation.” Ex. 1006, 5:25–27. Waisman uses “[a]t least one[] pair (or optionally more) preloaded K-Wires or pins . . . for polyaxial external fixation,” with “preloading at least a pair of K-wires or pins after drilling into the bone and then approximation or separation of distal ends of the K-wires or pins, in order to tighten and gripping the proximal ends of the k-wires into the bone.” Ex. 1006, 5:7–10, 5:28–6:2. Waisman includes pairs of pre-loaded K-wires per cage in each bone

fragment. The '941 Patent claims recite a different configuration: a fixation pin in the first metatarsal and a fixation pin in the first cuneiform, with the device extending across the joint between those bones. Ex. 1001, 6:27–29. Dr. Farber explains that Waisman's Figure 10 shows an external fixator spanning two portions of the first metatarsal after an osteotomy, not a device engaged to the first metatarsal and first cuneiform across the metatarsal-cuneiform joint. Ex. 2027 ¶¶ 30–33.

Waisman's fundamental design goal is further misaligned with the claimed workflow. Waisman touts “[n]on rigid fixation” as a core advantage. *See* Ex. 1006, 6:21–23 (“The PEF method of external fixation is flexible and intuitive. There is no need for strict calculation of approaching angle for K-wire drilling under fluoroscopic vision. Micromovements between fragments after non rigid fixation, promote and accelerate bone healing.”). That design objective is materially different from Petitioner's proposed use of Waisman as an intraoperative positioning device for controlled multiplanar correction across the metatarsal-cuneiform joint.

The claimed method uses the bone positioning device to drive controlled, repeatable multiplanar repositioning of the first metatarsal relative to the cuneiform intraoperatively, and then uses a compression step to bring the bones flush before final fixation with a bone connector. Ex. 1001, 6:24–48; *see also* Ex. 1001, 7:38–41 (sliding connection and screw used to compress). Dr. Farber confirms that Waisman's design objective differs materially from using an intraoperative

positioning device to perform controlled multiplanar correction before compression and final fixation. Ex. 2027 ¶¶ 34–36.

*i. Modifications to Dayton based on Waisman*

Petitioner’s motivation to combine Dayton and Waisman reduces to the observation that “Dayton discloses placing pins in the first metatarsal and cuneiform to visualize rotation” and “Waisman . . . discloses a polyaxial fixator . . . used on small bones such as those of the foot.” Pet. 33. Petitioner jumps from the general allegation that Waisman is “the same operative scale and environment as Dayton’s procedure” to a conclusion of obviousness. *Id.* Specifically, Petitioner alleges that “combining these familiar elements according to their known functions would have predictably yielded the expected benefit,” such that “a POSA would have been motivated to place pins in the first metatarsal and cuneiform to couple them to a known frame to provide controlled, maintainable triplanar correction.” Pet. 33–34. The Neufeld Declaration repeats the same formulation. *See* Ex. 1003 ¶¶ 105–113.

That is not a motivation-to-combine analysis. It is a restatement of the obviousness conclusion. Petitioner identifies no teaching in Dayton, Waisman, or the cited expert testimony that would have led a POSA to replace Dayton’s freehand Lapidus correction procedure that uses pins as a mere visual reference with Waisman’s external-fixator architecture and use that architecture at a location spanning the metatarsal-cuneiform joint. Waisman’s own explicit teaching is

materially different. Waisman’s device is for fixation with micromovement to promote healing, not for Petitioner’s proposed use as an intraoperative joint-spanning positioning device for controlled multiplanar correction. Ex. 1006, 6:21–23. Dr. Farber explains that general surgical goals such as control, stability, or repeatability do not, by themselves, tell a surgeon to use Waisman’s external fixation frame across the metatarsal-cuneiform joint during a Lapidus procedure. Ex. 2027 ¶¶ 35–36.

Petitioner’s generic “controlled correction is better than freehand” assertion does not bridge this gap. That rationale would justify replacing Dayton’s freehand technique with *any* bone-holding instrument. If generalized “precision” were sufficient, every long-known external fixator, reduction clamp, or bone-manipulating tool in the orthopedic literature would render the claimed workflow obvious. *KSR* requires more. 550 U.S. at 418.

Petitioner’s challenge is simply a recreation of the claimed method based on impermissible hindsight and is not supported by record evidence. Dr. Farber explains that fixing two portions of an osteotomized first metatarsal is not the same thing as engaging a first metatarsal and a first cuneiform with a device extending across the joint between those bones. Ex. 2027 ¶¶ 30–33.

Petitioner also invokes *KSR*’s “applying a known technique to improve a similar method” rationale (Pet. 34), but that rationale requires a *similar method*.

Dayton's freehand open Lapidus correction and Waisman's percutaneous external-fixation architecture are not similar methods. Dayton manually rotates a first metatarsal at its base and then freehand resects the articular surfaces. Waisman's PEF is applied through skin and soft tissue to bone portions or fragments of a single bone to maintain their position during healing. Indeed, Waisman describes an external fixator that is mounted through skin and soft tissue and later removed after healing, and it touts non-rigid fixation with micromovements to promote healing. Ex. 1006, 2:16–23, 6:21–24. A POSA would understand that disclosure as directed to fixation/healing (*i.e.*, a role more analogous to holding bone portions together after correction) rather than to an intraoperative instrument for performing Dayton's manual metatarsal correction before internal fixation. The procedural contexts are fundamentally different. Dr. Farber states that, without hindsight, a POSA would not read Dayton and Waisman and conclude that Waisman's external fixator should be substituted for Dayton's manual correction to perform the claimed intraoperative, joint-spanning, multiplanar bunion-correction step. Ex. 2027 ¶ 36.

***ii. Reasonable Expectation of Success***

The reasonable expectation of success inquiry “refers to the likelihood of success in combining references to meet the limitations of the claimed invention.” *Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1367 (Fed. Cir. 2016). Generalized adaptability is not enough. *In re O'Farrell*, 853 F.2d 894, 903

(Fed. Cir. 1988) (“[W]here the prior art [gives] ‘only general guidance as to the particular form of the claimed invention or how to achieve it,’ there is no reasonable expectation of success.”).

The claimed method requires the bone positioning device to engage the first metatarsal and first cuneiform with a fixation pin in each, extending across the joint and using the bone positioning device to adjust the first metatarsal alignment in multiple planes to correct the bunion. Ex. 1001, 6:27–29, 6:42–44. Petitioner does not explain how Waisman’s external-fixator architecture would be adapted to engage the first metatarsal and first cuneiform across the metatarsal-cuneiform joint during Dayton’s Lapidus procedure, rather than fixing two portions of an osteotomized first metatarsus as Waisman’s Fig. 10 describes.

Petitioner does not engage with this integration challenge to establish a reasonable expectation of success. Importantly, as noted above, Waisman’s fixator in a bunion application spans *two fragments of the first metatarsus after osteotomy* (Ex. 1006, 13:17–20, Fig. 10), not the metatarsal and the cuneiform across the metatarsal-cuneiform joint. Nor does Waisman address how its external fixator could be used as a bone positioning device intraoperatively to adjust an alignment of the first metatarsal in multiple planes to correct a bunion. Petitioner does not explain how that external-fixator architecture would be integrated into Dayton’s procedure without procedure-specific redesign. Nor does Petitioner explain why a

POSA would take a device disclosed for fixation of bone portions during healing and transform it into an intraoperative tool for performing the claimed multi-plane metatarsal adjustment before compression and final fixation. Dr. Farber explains that adapting Waisman's external fixator to Dayton's procedure would require procedure-specific design and surgical decisions, including where to place pins, how to avoid obstructing access to the metatarsal-cuneiform joint, how to perform the multiplanar correction while the device is attached, how to compress the prepared joint surfaces, and how to transition to final fixation. Ex. 2027 ¶¶ 37–41.

That gap is particularly notable because Petitioner's own § 112 theory elsewhere tells the Board that “how to sequence and coordinate multi-plane adjustments while maintaining joint congruity” is precisely the kind of clinical-operational question the specification fails to answer. Pet. 24. Petitioner cannot on the one hand contend that such coordination is not taught by the patent and requires undue experimentation, and on the other hand contend that a POSA would have had a reasonable expectation of success in coordinating Waisman's frame in Dayton's freehand procedure to produce exactly that coordinated multi-plane workflow. This internal inconsistency independently defeats Petitioner's reasonable expectation of success contentions.

***c. Palmer Does Not Cure the Deficiencies***

Palmer does not cure the defects in Petitioner's obviousness challenge

regarding the claimed bone positioning device. Petitioner relies on Palmer only for the cutting-guide limitations. Pet. 36–43; Ex. 1003 ¶¶ 117–130. Because Palmer is not relied on to supply the missing teaching or motivation regarding the bone positioning device, Palmer cannot cure the deficiencies in Petitioner’s positioning-device contentions. Thus, even accepting Petitioner’s Palmer mapping for the cutting-guide limitations, the Ground 2 combination still fails at the positioning-device step.

*d. Summary*

For at least these reasons, Petitioner fails to establish it is more likely than not to succeed on its obviousness challenge to claim 1. Petitioner relies on its contentions presented with respect to claim 1 for its challenge to claim 18, which fails for the reasons set forth above. *See* Pet. 65. Petitioner’s dependent-claim challenges under Ground 2 rely on the same deficient claim 1 and claim 18 mappings and do not identify any additional teaching or rationale that cures the missing bone positioning device teaching, motivation, or reasonable expectation of success.

**4. Ground 3 – Dayton/Taylor/Palmer**

Petitioner’s Ground 3 substitutes Taylor for Waisman as the alleged bone positioning device. Pet. 66. Petitioner expressly states that “[t]he disclosures and analysis of Dayton and Palmer set forth in Ground 2 (*supra* §VIII) are adopted and applied here for the same claims and corresponding limitations addressed in Ground

2, and are not repeated in full for brevity.” *Id.* Accordingly, Patent Owner incorporates its Dayton discussion above. As explained there, Dayton does not disclose a bone positioning device extending across the metatarsal-cuneiform joint, does not disclose fixation pins that engage such a device, and does not disclose using such a device to adjust the first metatarsal in multiple planes to correct a bunion. Dayton’s pins are visual references used to observe rotation, not structural anchors for a positioning instrument. Ex. 1005, 349.

Petitioner’s Ground 3 also adopts its Ground 2 Palmer analysis for the cutting-guide limitations. Pet. 66, 72. Thus, Palmer does not cure the threshold deficiencies in Petitioner’s bone positioning device theory for the same reason discussed in Ground 2. Even assuming Petitioner’s Palmer mapping for the cutting guide limitations, Ground 3 still fails.

***a. Taylor***

Taylor is not a bunion-correction reference. Taylor is directed to an “orthopaedic fixation device,” specifically a spatial frame for positioning one element relative to another using bases and adjustable-length struts. Ex. 1007, Abstract. Petitioner relies on Taylor because Taylor describes realigning, repositioning, and securely holding bone fragments and because its device can move one fragment relative to another in six degrees of freedom. Pet. 66–67. But Petitioner does not identify any disclosure in Taylor directed to a Lapidus procedure, bunion

correction, the metatarsal-cuneiform joint, or an intraoperative joint-spanning instrument engaged to the first metatarsal and first cuneiform using the claimed fixation-pin arrangement.

Notably, the majority of Petitioner's contentions associated with Taylor relate to its "Summary of the Invention" discussion found at columns 5–8. *See* Pet. 66–71. Those statements relate to generic purported benefits of Taylor's device. *See* Ex. 1007, 5:26–28 ("Another object of the present invention is to provide a device that can move one fragment with respect to the other in six orthogonal degrees of freedom."), 5:37–38 ("Another object of the present invention is to provide a device that is universal in that it can be used for any situation."), 5:51–53 ("Another object of the present invention is to provide a mechanism for producing a prescribed relative change in position between two bone fragments."), 6:31–33 ("Another object of the present invention is to provide a device that may be used to reposition any two bodies relative to each other."), 6:54–56 ("Another object of the present invention is to provide a device that can be used to reestablish skeletal joint motion after injury or disease."), 7:58–60 ("Another object of the present invention is to provide a device that can predictably and reproducibly cause small displacements between bone fragments.").

Even accepting Taylor's general disclosure that its frame can reposition two bodies relative to one another, that general capability does not supply the claimed

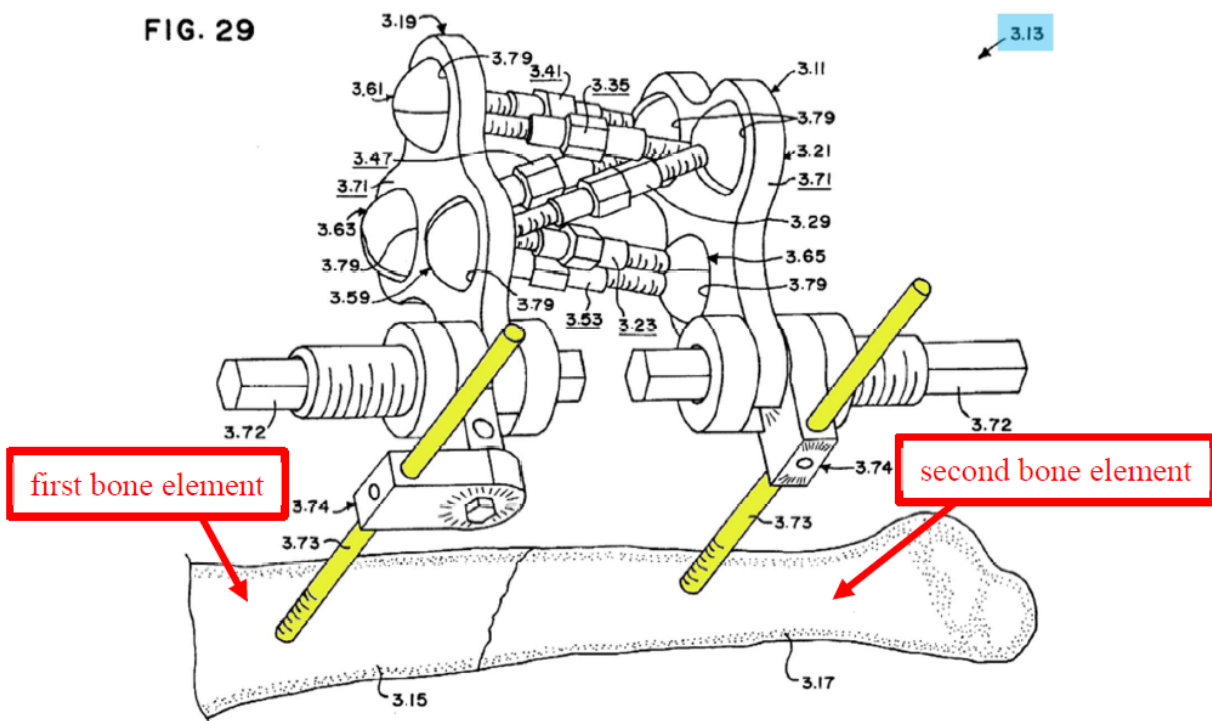
surgical architecture or the procedure-specific reason to use Taylor’s fixation device in Dayton’s Lapidus workflow. Petitioner relies on Taylor’s general disclosure that bone fragments may need to be “aligned or realigned and repositioned,” and that Taylor’s device can provide multi-axis relative movement. Pet. 66–71; Ex. 1003 ¶¶ 229–238. But that disclosure is at a much higher level of generality than the challenged claims. Claim 1 requires “engaging a bone positioning device with a first metatarsal using a first fixation pin and with a first cuneiform using a second fixation pin,” with the device “extending across a joint separating the first metatarsal from the first cuneiform,” and then “using the bone positioning device to adjust an alignment of the first metatarsal in multiple planes to correct a bunion.” Ex. 1001, 6:27–44. Taylor’s general spatial-frame disclosure does not teach or suggest that claimed surgical architecture or claimed bunion-correction use. Dr. Farber explains that Taylor’s general ability to move two bodies or bone fragments in multiple degrees of freedom does not teach or suggest using Taylor’s spatial frame intraoperatively across the first metatarsal-cuneiform joint during a Lapidus bunion-correction procedure. Ex. 2027 ¶¶ 42–49.

Petitioner’s own description confirms the breadth of its challenge. Petitioner argues that Taylor discloses a device that can “move one fragment with respect to the other in six orthogonal degrees of freedom” and that a POSA would have used “a device like Taylor’s” in Dayton’s procedure to facilitate repositioning. Pet. 66–

67. Petitioner then reasons that Taylor provides “the same degrees of freedom” a surgeon uses to correct triplanar deformity, and that engaging a Taylor-like device with metatarsal and cuneiform pins would have predictably improved intraoperative precision and retention compared to freehand manipulation. Pet. 71; Ex. 1003 ¶¶ 237–238. That is not a teaching in Taylor to use its frame in a Lapidus bunion-correction workflow. It is a claim-driven hindsight selection of a generic multi-axis external frame because the claims require a positioning device that corrects in multiple planes. Taylor’s generic statement that components may be made in various shapes and sizes does not supply a teaching to configure the frame for the first metatarsal and first cuneiform across the metatarsal-cuneiform joint during bunion surgery. Dr. Farber further explains that a surgeon would need procedure-specific support showing that Taylor’s frame could be adapted to the relevant anatomy and operative sequence; Taylor does not provide that support. Ex. 2027 ¶¶ 46–49.

Petitioner alleges that “Taylor discloses a device for repositioning one bone relative to another . . . and is used in small sizes.” Pet. 69 (citing Ex. 1007, 8:45–48). But the citation Petitioner provides for Taylor’s use in “small sizes” explains that “[a]nother object of the present invention is to provide a device that can be used in Small sizes in situations where space is at a premium, for example, in external fixation of children’s bones.” Ex. 1007, 8:45–48. Again, this is just a purported benefit listed in Taylor’s “Summary of the Invention” section.

The actual structure that Petitioner relies on in Taylor is the embodiment of the spatial frame shown in Taylor's Figure 29 and described at column 18, line 56 to column 19, line 52, which relates to securing portions of a tibia. *See* Pet. 67–70. Petitioner provides an annotated version of Taylor's Figure 29, reproduced below, to illustrate Taylor's spatial frame in use.



Taylor describes its Figure 29 as “an orthopedic external fixator and a fractured tibia.” Ex. 1007, 9:58–59. That is, Taylor depicts its fixator as securing fractured segments of a tibia to one another. Dr. Farber explains that a fractured tibia external fixation frame is a materially different surgical context from Dayton's freehand Lapidus procedure and is not the same as an intraoperative bunion-correction

positioning instrument used at the first metatarsal-cuneiform joint. Ex. 2027 ¶¶ 45–49. Taylor’s spatial frame is actually a specific type of device for post-operative care that a POSA would not expect to use in a Lapidus procedure. These devices are large and require individual strut length adjustment dictated by complex calculations that often involve a computer program. *Id.* ¶ 48; *see also* Ex. 1007, 19:31–34.

*i. Modifications to Dayton based on Taylor*

Petitioner’s motivation to combine Dayton and Taylor reduces to the same generic rationale used in Ground 2: Dayton performs manual triplanar correction, Taylor can reposition and hold bones in multiple degrees of freedom, so a POSA allegedly would have used Taylor to improve Dayton’s freehand procedure. Pet. 66–71. That rationale is insufficient.

Dayton already describes a manual surgical technique for Lapidus correction. Dayton’s pins are placed “directly in the sagittal plane and parallel” and are “used as a reference to more easily visualize the rotation of the metatarsal in the frontal plane.” Ex. 1005, 349. Dayton then describes the surgeon rotating the metatarsal until congruous alignment was observed clinically and fluoroscopically. *Id.* Petitioner identifies nothing in Dayton that suggests replacing that freehand correction with a spatial frame like Taylor’s. Petitioner does not identify any problem in Dayton’s procedure requiring a spatial frame and does not identify any teaching using any device engaged across the metatarsal-cuneiform joint to perform

the correction.

Petitioner does not identify anything in Taylor suggesting its use in a bunion correction procedure spanning a joint. Taylor's general ability to reposition two elements relative to each other does not explain why a POSA would have selected Taylor's spatial-frame architecture for Dayton's open Lapidus procedure. Petitioner identifies no teaching in Taylor that its frame should be temporarily attached to the first metatarsal and first cuneiform during bunion surgery, no teaching that Taylor's frame should span the metatarsal-cuneiform joint during joint preparation, and no teaching that Taylor's device should be used as the claimed intraoperative positioning device before final fixation. That omission is important because Dayton's workflow proceeds to temporary wires and final internal fixation with plates and/or screws, whereas Taylor is an external spatial-frame fixation system. Petitioner does not explain why a POSA would replace Dayton's manual correction and internal-fixation workflow with Taylor's external-frame architecture.

Petitioner's "controlled movement" rationale is too generic. If the desire for improved precision and retention were enough, then any orthopedic reduction frame, external fixator, clamp, or holding device capable of moving bone could be substituted into Dayton. That is not a reasoned motivation to make the specific claimed combination. It is hindsight reconstruction from the claim requirement for a pinned joint-spanning bone positioning device that adjusts alignment in multiple

planes.

Petitioner also invokes *KSR*'s "known technique to improve a similar method" rationale. Pet. 71. But Dayton's freehand Lapidus procedure and Taylor's spatial-frame fixation system are not shown to be similar methods in the relevant respect. Dayton concerns manual correction of a first metatarsal during bunion surgery. Taylor provides a post-operative orthopedic spatial frame for moving and holding bone fragments or bodies relative to one another. The Petition does not identify record evidence that a POSA would have viewed Taylor's spatial frame as a suitable intraoperative substitute for Dayton's manual metatarsal repositioning at the metatarsal-cuneiform joint.

***ii. Reasonable Expectation of Success***

Petitioner's reasonable expectation contentions are likewise conclusory. Petitioner asserts that a POSA would have had a reasonable expectation of success because the modification "stays within the references' disclosures and relies on predictable mechanics," and because Taylor discloses repositioning "any two bodies relative to each other" and constructing components in "various shapes and sizes." Pet. 71; Ex. 1003 ¶ 238. Those statements do not address the claimed surgical integration.

The issue is not whether Taylor can reposition two bodies in the abstract. The issue is whether Petitioner has shown a reasonable expectation of success in

modifying Dayton's freehand Lapidus procedure to use a spatial frame like Taylor's as a pinned, joint-spanning bone positioning device engaged to the first metatarsal and first cuneiform and used to adjust metatarsal alignment in multiple planes to correct a bunion. Petitioner does not provide that explanation.

Petitioner does not explain how Taylor's spatial frame architecture would be scaled, configured, and attached to the first metatarsal and first cuneiform during Dayton's procedure. Petitioner does not explain how the frame would be placed across the metatarsal-cuneiform joint without interfering with joint preparation, cutting, compression, and final fixation. Petitioner does not identify any Taylor embodiment used in a foot joint or in a Lapidus-type bunion procedure. And Petitioner does not explain why a surgeon performing Dayton's manual correction would reasonably expect Taylor's spatial frame to provide the claimed intraoperative correction workflow rather than a different external-fixation arrangement inconsistent with Dayton's disclosed manual correction followed by internal fixation.

Notwithstanding the wholly different use and purpose of Taylor's spatial frame, the individual strut adjustment based on complex calculations and its size make it unrealistic for use in a Lapidus procedure. For example, Taylor explains: "The exact change in length for each strut to move one fragment relative to the other a prescribed amount can be accomplished by coordinate transformation by hand

calculation, calculator, or computer.” Ex. 1007, 19:31–34. Taylor itself underscores the point by describing a six-strut external fixator designed to provide controlled six-degree-of-freedom motion, biologically compatible relative velocities “on the order of one millimeter per day,” and coordinate transformation based on mathematical computation of points on an end plate and resulting changes in six strut lengths. *Id.* at 7:50–8:5. Those disclosures are consistent with a spatial-frame correction arrangement, not Dayton’s rapid, manual intraoperative rotation of the first metatarsal under visual and fluoroscopic confirmation. Dr. Farber confirms this understanding, explaining that adapting Taylor’s spatial frame to a small, first metatarsal-cuneiform surgical field would require procedure-specific design decisions about scale, pin placement, access to the joint, correction, compression, and final fixation, and Taylor does not provide those details. Ex. 2027 ¶¶ 48–49.

That gap is especially significant because Petitioner’s own § 112 contentions allege that “how to sequence and coordinate multi-plane adjustments while maintaining joint congruity” is not adequately taught by the ’941 Patent and would require undue experimentation (Pet. 24), while also alleging that Taylor’s “positioning device is identical or at least equivalent to structures identified in the ’941 patent for the claimed bone positioning device” (*id.* at 69). Petitioner offers no explanation for why that same coordination would be predictably successful when reconstructed from Dayton and Taylor. Petitioner’s unexplained tension between its

non-enablement contentions and its Taylor reasonable expectation contentions further undermines Ground 3.

***b. Palmer Does Not Cure the Deficiencies***

Palmer does not cure the defects in Ground 3 regarding the claimed bone positioning device. Petitioner relies on Taylor, not Palmer, for the alleged bone positioning device. Pet. 66–72. Petitioner relies on Palmer only for the cutting-guide limitations and expressly states that the Ground 2 Palmer analysis is adopted in Ground 3. Pet. 66, 72; Ex. 1003 ¶¶ 239–240. Because Palmer is not relied on to supply the missing teaching, motivation, or reasonable expectation of success for modifying Dayton’s freehand Lapidus procedure to use a pinned, joint-spanning, bone positioning device that adjusts alignment in multiple planes, Palmer cannot cure the deficiencies in Petitioner’s positioning-device contentions. Thus, even accepting Petitioner’s Palmer mapping for the cutting-guide limitations, the Ground 3 combination still fails.

***c. Summary***

For at least these reasons, Petitioner fails to establish it is more likely than not to succeed on its obviousness challenge to claim 1. Petitioner relies on its contentions presented with respect to claim 1 for its challenge to claim 18, which fails for the reasons set forth above. *See* Pet. 77. Petitioner’s dependent-claim challenges under Ground 3 rely on the same deficient claim 1 and claim 18 mappings and do not

identify any additional teaching or rationale that cures the missing bone positioning device teaching, motivation, or reasonable expectation of success.

**5. Ground 4 – Dayton/Orsak/Palmer**

Petitioner’s Ground 4 substitutes Orsak for Waisman as the alleged bone positioning device. Pet. 78. Petitioner states that “[a] POSA would have substituted a positioning device like Orsak’s for one like Waisman’s in the Ground 2 combination” and that Orsak, like Waisman, allegedly “provides positioning-device disclosures that satisfy the positioning-device claim limitations.” *Id.*; Ex. 1003 ¶ 261. Petitioner further states that the “disclosures and analysis of Dayton and Palmer set forth in Ground 2” are “adopted and applied” in Ground 4 for the same claims and corresponding limitations. Pet. 78. Accordingly, Patent Owner incorporates its Dayton discussion above. As explained there, Dayton does not disclose a bone positioning device extending across the metatarsal-cuneiform joint, does not disclose fixation pins that engage such a device, and does not disclose using such a device to adjust the first metatarsal in multiple planes to correct a bunion. Dayton’s pins are visual references used to observe rotation, not structural anchors for a positioning instrument. Ex. 1005, 349.

Petitioner’s Ground 4 also adopts its Ground 2 Palmer analysis for the cutting-guide limitations. Pet. 78, 85–88. Thus, Palmer does not cure the threshold deficiencies in Petitioner’s bone positioning device theory for the same reason

discussed in Ground 2: Petitioner relies on Palmer for cutting-guide features, not for the claimed bone positioning device. Pet. 78, 85–88; Ex. 1003 ¶¶ 278–286. Even accepting Petitioner’s Palmer mapping for the cutting-guide limitations, Ground 4 still fails at the positioning-device step.

*a. Orsak*

Orsak is an external orthopedic external fixation device, not an instrumented union-correction method. Orsak states that “[e]xternal orthopedic devices are used in many orthopedic treatments to fixate, distract, or reduce bone segments” and to “adjust the relative orientation and spacing of the bone parts on opposing sides of a bone repair site.” Ex. 1008 ¶ 3. Orsak further describes “an external fixator device for fixating bone parts,” including use in treating “osteotomies.” Ex. 1008 ¶ 5. Petitioner relies on those general disclosures, and on Orsak embodiments involving fixation pins and compression/distraction, to argue that a POSA would have used “a bone positioning device like Orsak’s in Dayton’s procedure to facilitate bone repositioning.” Pet. 78–85; Ex. 1003 ¶¶ 263–277. But Orsak explains that “external devices are attached externally to the patient’s body for the duration of the treatment, which can last from several weeks to many months, the bulkiness of the [existing] external fixator devices are important features in the market acceptance of any particular design.” Ex. 1008 ¶ 3. Orsak explains that it addresses “a continuing need for an improved external fixator that is adaptable to a variety of configurations while

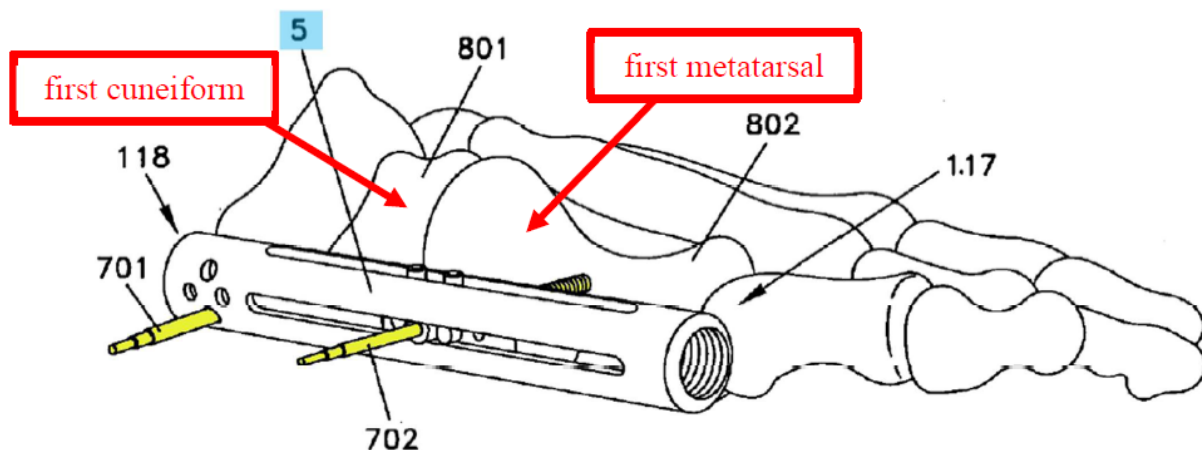
maintaining a low profile for physical compactness.” *Id.*

Claim 1 does not merely require any device capable of moving or compressing bone parts. It requires “engaging a bone positioning device with a first metatarsal using a first fixation pin and with a first cuneiform using a second fixation pin,” the device “extending across a joint separating the first metatarsal from the first cuneiform,” and then “using the bone positioning device to adjust an alignment of the first metatarsal in multiple planes to correct a bunion.” Ex. 1001, 6:24–48. Petitioner identifies no disclosure in Dayton or Orsak that teaches using an external fixation device like Orsak’s as an intraoperative joint-spanning bunion-correction instrument to perform Dayton’s manual metatarsal rotation. Dr. Farber explains that Orsak’s disclosure of external fixation, compression, distraction, and relative positioning does not teach using Orsak’s device intraoperatively to perform multiplanar bunion correction of the first metatarsal relative to the cuneiform in Dayton’s Lapidus procedure. Ex. 2027 ¶¶ 50–57.

Orsak’s disclosure is directed to external fixation, compression, distraction, and relative positioning of bone parts at a repair site. That is materially different from Dayton’s freehand Lapidus workflow. Dayton places two smooth pins “directly in the sagittal plane and parallel” so they can be “used as a reference to more easily visualize the rotation of the metatarsal in the frontal plane.” Ex. 1005, 349. Dayton then manually rotates the metatarsal until congruous alignment is observed clinically

and fluoroscopically. *Id.*; Ex. 1003 ¶ 98. Dayton does not teach attaching those reference pins to an external fixator, does not teach using an external compression-distraction device during the correction, and does not teach that a device like Orsak's should replace the surgeon's manual manipulation. To the contrary, coupling an external fixator to Dayton's visual reference pins would undermine the very function Dayton assigns to those pins (*i.e.*, allowing the surgeon to observe the direction and extent of metatarsal rotation). The added fixator structure would alter the pins from unobstructed visual reference markers into load-bearing components of a frame, creating a physical and visual obstruction for the manual rotation Dayton describes.

Petitioner's reliance on Orsak's first metatarsal/cuneiform embodiment does not cure the problem. Petitioner provides an annotated version of Orsak's Figure 5C, reproduced below.



Pet. 79. The fixator 5 shown above is described as providing compression or distraction. *See* Ex. 1008 ¶ 92. Petitioner points to Orsak as disclosing fixation pins

in the first metatarsal and first cuneiform and as disclosing compression by turning a screw. Pet. 80–85, 88–92; Ex. 1003 ¶¶ 272–277, 294–300. But a device that can compress or distract bone parts using pins and a screw does not, without more, teach or suggest the claimed use of a bone positioning device to adjust first-metatarsal alignment in multiple planes to correct a bunion in Dayton’s procedure.

Petitioner relies on Orsak’s later embodiments as teaching “bone movement in multiple axes.” Pet. 80. For example, Petitioner cites the arrangements shown in Orsak’s Figures 8A, 11A–F, and 12A–B for movement in multiple axes. *Id.* at 80–81. Petitioner does not identify anything Orsak teaching use of those alternate embodiments in the application shown in Orsak’s Figure 5C related to the metatarsal-cuneiform joint. Although the later embodiments reference fixator 5, Orsak prefaces the alternate embodiment discussion by stating that those “embodiments of the external fixator device described herein can be used in treating other bones,” and provides examples including treatment of the spine and long bones. Ex. 1008 ¶ 93. And even accepting those combinations of embodiments, there is no reason to believe that any of the combinations would even be capable of providing Dayton’s tri-plane correction, specifically the frontal plane rotation that Dayton describes as a key aspect of its procedure.

As explained below, Petitioner does not provide a reasonable basis as to why a POSA would have selected various ones of Orsak’s external fixation architecture

features for use in Dayton's freehand Lapidus method as the claimed pinned, joint-spanning, bone positioning device that adjusts alignment in multiple planes. Dr. Farber explains that compression or distraction of bone parts is not the same surgical act as using a bone positioning device to drive multiplanar correction of the first metatarsal to correct a bunion. Ex. 2027 ¶¶ 52–56. Dr. Farber specifically notes the inability of Orsak's device to achieve tri-planar correction, specifically frontal plane rotation. *Id.* ¶ 56.

***i. Modifications to Dayton based on Orsak***

Petitioner's motivation to combine Dayton and Orsak rests on the same generic rationale used in Ground 2: Dayton performs manual correction using pins for visualization, Orsak discloses an external fixator that can hold, compress, distract, or orient bone parts, so a POSA allegedly would have used Orsak to improve Dayton's freehand correction. Pet. 78–85; Ex. 1003 ¶¶ 263–277. That rationale is insufficient.

Dayton already describes how the correction is performed: the surgeon manually rotates the first metatarsal and uses the pins only to better visualize the direction of rotation. Ex. 1005, 349. Dayton does not identify a need for an external fixator, does not suggest coupling the pins to any frame, and does not disclose using a device to perform multi-plane correction. Dayton instead describes final internal fixation using plates and/or screws after the surgeon has manually positioned the

bone. The fact that Orsak discloses an external orthopedic device that may be *capable of* fixation, compression, or distraction does not explain *why* a POSA would have modified Dayton's manual Lapidus procedure to include Orsak's external-fixation architecture across the metatarsal-cuneiform joint and then use that device intraoperatively to adjust alignment of the first metatarsal in multiple planes to correct a bunion.

Petitioner's proposed rationale is also too broad. If the general desire for controlled repositioning or maintaining alignment were enough, then virtually any orthopedic fixator, clamp, reduction tool, or compression-distraction device could be imported into Dayton.

*KSR* permits reliance on common sense and known techniques, but it still requires a reasoned explanation for why the POSA would have made the specific claimed combination. Petitioner's assertion that Orsak could provide controlled positioning merely restates the desired result of the claims. Dr. Farber explains that a surgeon may value controlled positioning generally, but that general goal would not itself lead the surgeon to select Orsak's external fixation device for Dayton's intraoperative Lapidus correction. Ex. 2027 ¶¶ 55–57.

Nor does Orsak's compression capability solve the missing positioning-device problem. Compression after correction is not the same limitation as using the bone positioning device to adjust first-metatarsal alignment in multiple planes to

correct a bunion. The distinction matters because claim 1 separately recites both “using the bone positioning device to adjust an alignment of the first metatarsal in multiple planes to correct a bunion” and “compressing the first metatarsal and the first cuneiform together.” Ex. 1001, 6:42–45. Petitioner cannot satisfy the former limitation merely by pointing to Orsak’s alleged ability to compress or distract bone parts. Even if Orsak could provide compression, Petitioner still must show why a POSA would have used Orsak to perform the claimed multi-plane bunion correction in Dayton’s procedure. It does not.

Petitioner’s presentation of Grounds 5 and 6 further illustrates the gap in Ground 4. There, Petitioner states that “[e]ven if the Ground 4 combination does not disclose or render obvious using the positioning device to adjust the first metatarsal alignment in multiple planes to correct a bunion,” Waisman or Taylor allegedly would supply that use. Pet. 93–94; Ex. 1003 ¶¶ 305–308. That fallback confirms that Petitioner’s Ground 4 Orsak challenge does not stand on a clear teaching in Orsak to use the device for the claimed multi-plane bunion-correction adjustment. At minimum, Petitioner’s need for additional grounds highlights the gap in Ground 4’s bone positioning device rationale.

***ii. Reasonable Expectation of Success***

Petitioner’s reasonable expectation of success contentions are likewise conclusory. Petitioner asserts that using Orsak’s device in Dayton’s procedure would

be predictable because Orsak's device can position, compress, distract, and hold bone parts. Pet. 78–85, 88–92; Ex. 1003 ¶¶ 263–300. But Petitioner does not address the claimed surgical integration.

The question is not whether Orsak can move or compress bone parts in the abstract. The question is whether Petitioner has shown a reasonable expectation of success in modifying Dayton's freehand Lapidus procedure to use Orsak's external fixation device as a pinned, joint-spanning bone positioning device engaged to the first metatarsal and first cuneiform and used to adjust metatarsal alignment in multiple planes to correct a bunion. Petitioner does not provide that showing.

Petitioner does not explain how Orsak's device would be adapted and positioned during Dayton's open Lapidus procedure so that it could perform the claimed multi-plane metatarsal correction while the metatarsal-cuneiform joint is prepared, compressed, and finally fixed. Petitioner does not explain how Orsak's external-fixator components would be arranged without interfering with Dayton's manual correction, articular-surface resection, or fixation.

Petitioner also does not identify any Orsak teaching that its external fixator should be used as an intraoperative bunion-correction instrument rather than as an external device for fixation, compression, or distraction at a repair site. Dr. Farber explains that using Orsak in Dayton would require procedure-specific decisions about where to place pins, how to preserve access to the metatarsal-cuneiform joint,

how to perform correction while the device is attached, and how to transition to compression and final fixation. Ex. 2027 ¶¶ 56–57.

That gap is particularly notable because Petitioner’s own § 112 contentions allege that “how to sequence and coordinate multi-plane adjustments while maintaining joint congruity” is not adequately taught by the ’941 Patent and would require undue experimentation (Pet. 24), while also alleging that Orsak’s “positioning device is identical or at least equivalent to structures identified in the ’941 patent for the claimed bone positioning device” (*id.* at 82). Petitioner offers no explanation for why that same coordination would be predictably successful when reconstructed from Dayton and Orsak. Petitioner’s unexplained tension between its non-enablement theory and its Orsak reasonable expectation of success contentions further undermines Ground 4.

***b. Palmer Does Not Cure the Deficiencies***

Palmer does not cure the defects in Ground 4 regarding the claimed bone positioning device. Petitioner relies on Orsak, not Palmer, for the alleged bone positioning device. Pet. 78–85; Ex. 1003 ¶¶ 263–277. Petitioner relies on Palmer only for the cutting-guide limitations and expressly states that the Ground 2 Palmer analysis is adopted in Ground 4. Pet. 78, 85–88; Ex. 1003 ¶¶ 278–286. Because Palmer is not relied on to supply the missing teaching, motivation, or reasonable expectation of success for modifying Dayton’s freehand Lapidus procedure to use a

pinned, joint-spanning, bone positioning device that adjusts alignment in multiple planes, Palmer cannot cure the deficiencies in Petitioner's positioning-device contentions. Thus, even accepting Petitioner's Palmer mapping for the cutting-guide limitations, the Ground 4 combination still fails at the positioning-device step.

*c. Summary*

For at least these reasons, Petitioner fails to establish it is more likely than not to succeed on its obviousness challenge to claim 1. Petitioner relies on its contentions presented with respect to claim 1 for its challenge to claim 18, which fails for the reasons set forth above. *See* Pet. 92. Petitioner's dependent-claim challenges under Ground 4 rely on the same deficient claim 1 and claim 18 mappings and do not identify any additional teaching or rationale that cures the missing bone positioning device teaching, motivation, or reasonable expectation of success.

**6. Grounds 5–16**

Grounds 5–16 do not cure the threshold defects discussed above. Grounds 5–16 are cumulative combinations that add or substitute references without curing the same threshold defect. They add more references, but they do not address the dispositive failure in Grounds 2–4. Petitioner has not shown why a POSA would have modified Dayton's freehand Lapidus procedure to use the claimed pinned, joint-spanning, bone positioning device that adjusts first-metatarsal alignment in multiple planes.

Grounds 5 and 6 add Waisman or Taylor to the Dayton/Orsak/Palmer combination. Pet. 93–94. Grounds 7–11 substitute Orbay for Palmer as the cutting-guide reference. *Id.* at 94–100. Grounds 12–16 add both Palmer and Orbay to the same Dayton-based combinations. *Id.* at 111. But none of those additional combinations supplies what the Petition lacks: a reasoned teaching or motivation to modify Dayton’s freehand Lapidus procedure to use a pinned, joint-spanning, bone positioning device engaged with the first metatarsal and first cuneiform and used to adjust first-metatarsal alignment in multiple planes to correct a bunion.

Grounds 5–6 depend on the same Orsak theory addressed in Ground 4, with Waisman or Taylor added as cumulative positioning-device references. Grounds 7–11 mirror Grounds 2–6 but replace Palmer with Orbay for cutting-guide features. Grounds 12–16 add Palmer and Orbay together, but still rely on Waisman, Taylor, or Orsak as allegedly teaching the bone positioning device.

The additional grounds confirm, rather than cure, the hindsight-driven nature of Petitioner’s challenges. Petitioner begins with Dayton, whose pins are visual references for manual rotation, not fixation pins that engage a bone positioning device. Petitioner then imports an alleged bone positioning device architecture from Waisman, Taylor, or Orsak, and separately imports cutting-guide features from Palmer or Orbay. Adding more references does not supply the missing reason to make that combination or the missing reasonable expectation of success in using the

resulting assembly in Dayton's procedure. Dr. Farber explains that Grounds 5–16 do not cure the same technical deficiency because adding another external fixation reference or another cutting-guide reference does not provide a teaching or surgical reason to replace Dayton's manual Lapidus correction with a pinned, joint-spanning positioning device used to perform multiplanar correction of the first metatarsal relative to the cuneiform. Ex. 2027 ¶¶ 61–63.

***a. Grounds 5 and 6***

Grounds 5 and 6 do not save Ground 4. Those grounds add Waisman or Taylor to the Dayton/Orsak/Palmer combination. But as explained above, Waisman and Taylor do not teach or suggest modifying Dayton's freehand Lapidus procedure to use the claimed pinned, joint-spanning bone positioning device. Waisman is directed to an external fixator architecture materially different from the claimed metatarsal-cuneiform positioning device, and Taylor is a spatial-frame fixation system whose general multi-axis capabilities do not supply the claimed bunion-correction workflow. Combining those references with Orsak merely aggregates additional positioning-device concepts; it does not provide the missing reasoned rationale for the claimed method.

***b. Grounds 7–11***

Grounds 7–11 fare no better. Those grounds substitute Orbay for Palmer as the cutting-guide reference. But Petitioner does not rely on Orbay to cure the

deficiencies in its bone positioning device theory. As with Palmer, Orbay is added for cutting-guide features. Thus, even assuming Petitioner's Orbay mapping for the cutting-guide limitations, Grounds 7–11 still fail because Dayton, Waisman, Taylor, and Orsak do not teach or render obvious the claimed use of a pinned, joint-spanning, bone positioning device that adjusts alignment in multiple planes in Dayton's bunion-correction procedure.

***c. Grounds 12–16***

Grounds 12–16 likewise fail. Those grounds add both Palmer and Orbay to the same Dayton-based positioning-device combinations. But adding a second cutting-guide reference does not address the threshold positioning-device failure. Petitioner still relies on Waisman, Taylor, or Orsak for the alleged bone positioning device, and those theories fail for the reasons explained above. Palmer and Orbay are not relied on to supply the missing teaching, motivation, or reasonable expectation of success for the claimed bone positioning device.

**7. Non-Analogous Art**

Petitioner's obviousness challenges also fail because Waisman, Taylor, and Orsak are not analogous art. A reference qualifies as prior art for an obviousness determination when it is analogous to the claimed invention. *Innovation Toys, LLC v. MGA Ent., Inc.*, 637 F.3d 1314, 1321 (Fed. Cir. 2011). “Two separate tests define the scope of analogous art: (1) whether the art is from the same field of endeavor,

regardless of the problem addressed, and (2) if the reference is not within the field of the inventor's endeavor, whether the reference still is reasonably pertinent to the particular problem with which the inventor is involved.” *In re Bigio*, 381 F.3d 1320, 1325 (Fed. Cir. 2004).

Before reaching the substance, Patent Owner notes that Petitioner's analogous-art showing is itself inadequate. The Petition devotes a single sentence to the issue, asserting that the cited references are “from the same field as the '941 patent—surgical procedures involving bone” and are “pertinent to the problem addressed by the inventors, including cutting, repositioning, and fixing bone during surgical procedures.” Pet. 20 (citing Ex. 1001, 1:24–30; Ex. 1003 ¶¶ 89–90). Petitioner does not define the field of endeavor with reference to the structure and function of the claimed invention as disclosed in the '941 Patent. *See In re Bigio*, 381 F.3d 1320, 1325–26 (Fed. Cir. 2004). And it does not identify the particular problem the inventors confronted with reference to anything specific in the patent. *See In re Clay*, 966 F.2d 656, 658–59 (Fed. Cir. 1992).

Defining the field as “surgical procedures involving bone” and the problem as “cutting, repositioning, and fixing bone during surgical procedures” is not analysis. It is a restatement of the same broad characterizations Petitioner uses throughout the Petition to bridge the gap between Dayton's freehand Lapidus procedure and the external-fixation references it seeks to combine. Petitioner's failure to engage with

the analogous-art inquiry on the actual record is itself a basis to deny institution on the obviousness grounds. The substantive analysis that follows confirms that, even if Petitioner had attempted the analysis, the cited external-fixation references would not qualify as analogous art under either prong of the analogous art test.

***a. Different Field of Endeavor***

The “field of endeavor” test asks if the structure and function of the prior art is such that it would be considered by a person of ordinary skill in the art because of similarity to the structure and function of the claimed invention as disclosed in the application.” *In re Bigio*, 381 F.3d at 1325–26. The ’941 Patent’s field of endeavor is not generic orthopedic fixation or generic movement of bone fragments. The specification states that the invention relates to “devices and methods for positioning and cutting bones,” including temporarily fixing bones in a desired position during a surgical procedure such as “bone alignment, osteotomy, and/or fusion.” Ex. 1001, 1:24–25, 2:63–66. In the context of the challenged claims, that field is coordinated intraoperative bone positioning and bone cutting for bunion correction, including use of a bone positioning device, bone cutting guide, compression, and bone connector at the first metatarsal-cuneiform joint. Ex. 1001, 6:24–48.

Waisman, Taylor, and Orsak are outside that field. Waisman is directed to polyaxial external fixation for fractured or osteotomized bone portions, mounted through skin and soft tissue and later removed after healing. Ex. 1006, 2:16–23.

Taylor is directed to a spatial external fixation frame, and the operative embodiment Petitioner relies on depicts an external fixator applied to a fractured tibia. Ex. 1007, Fig. 29, 9:58–59. Orsak is likewise external-fixation hardware attached externally to the patient’s body for the duration of treatment, which “can last from several weeks to many months.” Ex. 1008 ¶ 3. Those references are fixation/healing references, not coordinated intraoperative positioning-and-cutting systems for bunion correction at the metatarsal-cuneiform joint.

***b. Not Reasonably Pertinent to the Same Particular Problem***

“A reference is reasonably pertinent . . . if it is one which, because of the matter with which it deals, logically would have commended itself to an inventor’s attention in considering his problem.” *In re Clay*, 966 F.2d 656, 659 (Fed. Cir. 1992). Waisman, Taylor, and Orsak are not reasonably pertinent to the problem addressed by the ’941 Patent. The problem addressed is not simply moving or holding bone in the abstract. The challenged claims address the problem of performing bunion surgery by engaging the first metatarsal and first cuneiform with a bone positioning device extending across the metatarsal-cuneiform joint, using that device to adjust first-metatarsal alignment in multiple planes, aligning and using a bone cutting guide at the joint, compressing the first metatarsal and first cuneiform together, and fixing their relative position with a bone connector. Ex. 1001, 6:24–48.

Waisman is not reasonably pertinent to that problem. Even Waisman's foot example fixes an osteotomy of a first metatarsus deformity using K-wires in two portions of the first metatarsus, not a device engaged to the first metatarsal and first cuneiform across the metatarsal-cuneiform joint. Ex. 1006, 26:21–27:3. Waisman's fixation/healing paradigm does not address the problem of coordinated intraoperative multiplanar correction, cutting, compression, and fixation in a Lapidus bunion procedure.

Taylor is not reasonably pertinent either. Petitioner relies on Taylor's generic ability to move bodies or fragments relative to one another in multiple degrees of freedom. But Taylor's spatial-frame fixation disclosure does not address bunion correction, the first metatarsal-cuneiform joint, bone cutting at that joint, compression of prepared joint surfaces, or final fixation with a bone connector. Taylor's generic external-frame movement capability does not make it reasonably pertinent to the specific intraoperative problem addressed by the '941 Patent.

Orsak also is not reasonably pertinent to the claimed problem. Although Petitioner points to Orsak's first-metatarsal/cuneiform and compression/distraction disclosures, Orsak describes a long-term external-fixation hardware arrangement for treatment and healing over weeks or months. Ex. 1008 ¶ 3. Compression or distraction of bone parts at a repair site is not the same problem as intraoperatively correcting first-metatarsal alignment in multiple planes during bunion surgery while

coordinating bone positioning, joint cutting, compression, and final fixation.

Petitioner has not shown that Waisman, Taylor, or Orsak is analogous art under either test. They are outside the '941 Patent's field of coordinated intraoperative bone positioning and cutting. They are not reasonably pertinent to the claimed problem of instrumented metatarsal-cuneiform bunion correction. This independently reinforces Petitioner's failure to establish a motivation to combine or reasonable expectation of success for Grounds 2–16.

## **8. Summary**

Petitioner's obviousness challenges fail for the same threshold reason across Grounds 2–16. Petitioner does not identify a record-supported teaching, motivation, or reasonable expectation of success for modifying Dayton's freehand Lapidus procedure to use the claimed pinned, joint-spanning, bone positioning device engaged with the first metatarsal and first cuneiform and used to adjust first-metatarsal alignment in multiple planes to correct a bunion.

Dayton's pins are visual references for manual rotation, not structural anchors for a bone positioning instrument. The Petition fails to provide a reasoned basis for replacing Dayton's manual correction with the claimed instrumented positioning workflow based on the teachings of Waisman, Taylor, or Orsak. Palmer and Orbay are relied on for cutting-guide features, not to cure the deficiencies in the bone positioning device allegations.

For the reasons discussed above for the independent claims, Petitioner has not shown that claims 1 or 18 would have been obvious, and Petitioner's dependent-claim challenges fail as well because they rely on the same deficient independent-claim mappings and do not supply any additional teaching or rationale that cures those threshold defects. Dr. Farber's testimony confirms the same point from a surgeon's perspective: Dayton describes manual Lapidus correction using visual reference pins, while Waisman, Taylor, and Orsak do not provide a procedure-specific reason to replace that workflow with the claimed pinned, joint-spanning, bone positioning device that adjusts alignment in multiple planes. Ex. 2027 ¶¶ 20–63.

Notably, the volume and structure of Petitioner's grounds further confirm why institution should be denied. Petitioner asserts fifteen obviousness grounds against all twenty-seven claims, but those grounds are not materially distinct theories. They recycle the same Dayton-based reconstruction while swapping or stacking Waisman, Taylor, Orsak, Palmer, and Orbay. The additional grounds merely add cumulative references or substitute cutting-guide references that do not cure the bone positioning device deficiency. The Board has denied institution where a petitioner's showing, at most, supported only a narrow subset of claims or grounds because instituting trial on all challenged claims and grounds would not be an efficient use of Board resources. *See Chevron Oronite Co. LLC v. Infineum USA L.P.*, IPR2018-

00923, Paper 9 at 10–11 (PTAB Nov. 7, 2018) (Informative); *Deeper, UAB v. Vexilar, Inc.*, IPR2018-01310, Paper 7 at 42–43 (PTAB Jan. 24, 2019) (Informative).

The same efficiency concern applies here because Petitioner’s numerous grounds are cumulative and rise or fall on the same deficient bone positioning device theory.

Accordingly, the Petition fails to establish that it is more likely than not that any claim would have been obvious.

### **III. CONCLUSION**

For the foregoing reasons, Petitioner has not shown that it is more likely than not to prevail on any challenged claim. Ground 1 fails because Petitioner has not shown lack of written description or non-enablement. Grounds 2–16 fail because Petitioner’s obviousness theories depend on hindsight reconstruction of Dayton’s freehand Lapidus procedure and do not supply a reasoned basis or reasonable expectation of success for using the claimed pinned, joint-spanning, bone positioning device that adjusts alignment in multiple planes. Accordingly, institution should be denied.

PGR2026-00031  
Patent 12,349,941

Dated: June 5, 2026

Respectfully Submitted,

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**CERTIFICATE OF WORD COUNT**

Pursuant to 37 C.F.R. § 42.24(d), the undersigned certifies that this Patent Owner's Preliminary Response complies with the type-volume limitation of 18,700 words provided in 37 C.F.R. § 42.24(a)(1)(ii), (b)(1). The word processing program used to prepare Patent Owner's Preliminary Response indicates that it contains 15,275 words, excluding the parts of the brief exempted by 37 C.F.R. § 42.24(a), (that is, the word count does not include the table of contents, table of authorities, the exhibit list, the certificate of service, or the certificate of compliance).

Dated: June 5, 2026

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**CERTIFICATE OF SERVICE**

The undersigned certifies that on the 5<sup>th</sup> of June 2026, a complete and entire copy of the foregoing “PATENT OWNER’S PRELIMINARY RESPONSE,” 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).

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