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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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Case PGR2026-00031  
Patent 12,349,941

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**PETITION FOR POST-GRANT REVIEW OF  
U.S. PATENT NO. 12,349,941**

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## LIST OF EXHIBITS

| <b>Exhibit No.</b> | <b>Description</b>                                                                                                                                                                                                                                                                                                                                                                                                   |
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| 1001               | U.S. Patent No. 12,349,941 to Dayton, et al. (“the ’941 patent”)                                                                                                                                                                                                                                                                                                                                                     |
| 1002               | File History of U.S. Patent Application No. 18/615,875                                                                                                                                                                                                                                                                                                                                                               |
| 1003               | Declaration of Steven K. Neufeld, M.D.                                                                                                                                                                                                                                                                                                                                                                               |
| 1004               | Curriculum Vitae of Steven K. Neufeld, M.D.                                                                                                                                                                                                                                                                                                                                                                          |
| 1005               | Dayton, Paul, Mindi Feilmeier, Merrell Kauwe, and Jordan Hirschi, “Relationship of Frontal Plane Rotation of First Metatarsal to Proximal Articular Set Angle and Hallux Alignment in Patients Undergoing Tarsometatarsal Arthrodesis for Hallux Abducto Valgus: A Case Series and Critical Review of the Literature,” <i>Journal of Foot and Ankle Surgery</i> , Vol. 52, No. 3 (May-June 2013): 348-354 (“Dayton”) |
| 1006               | International Appl. Publ. No. 2012/004798 to Waisman (“Waisman”)                                                                                                                                                                                                                                                                                                                                                     |
| 1007               | U.S. Patent No. 5,702,389 to Taylor et al. (“Taylor”)                                                                                                                                                                                                                                                                                                                                                                |
| 1008               | U.S. Publication No. 2012/0029575 to Orsak et al. (“Orsak”)                                                                                                                                                                                                                                                                                                                                                          |
| 1009               | International Appl. Publ. No. 2012/103335 to Palmer et al. (“Palmer”)                                                                                                                                                                                                                                                                                                                                                |
| 1010               | U.S. Publication No. 2011/0288550 to Orbay et al. (“Orbay”)                                                                                                                                                                                                                                                                                                                                                          |
| 1011               | <i>McGlamry's Comprehensive Textbook of Foot and Ankle Surgery</i> , 4th ed. 2 vols. Edited by E. Dalton McGlamry, Joe T. Southerland, and Daniel F. Vickers. Chapters 1, 31, 34, 36, and 55. Philadelphia, PA: Wolters Kluwer Health, 2013 (“McGlamry”)                                                                                                                                                             |
| 1012               | U.S. Patent No. 4,349,018 to Chambers (“Chambers”)                                                                                                                                                                                                                                                                                                                                                                   |
| 1013               | Declaration of Michelle L. Warmath for Translation of European Patent App. Publ. No. 1508316 (“Augoyard”)                                                                                                                                                                                                                                                                                                            |
| 1014               | English Translation of Augoyard from Ex. 1013                                                                                                                                                                                                                                                                                                                                                                        |
| 1015               | U.S. Patent App. Publ. No. 2013/0150900 to Haddad et al. (“Haddad”)                                                                                                                                                                                                                                                                                                                                                  |

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

Petitioner Paragon 28, Inc. requests post grant review (“PGR”) of claims 1-27 of U.S. Patent 12,349,941 (“the ’941 patent,” Ex.1001).

## **I. INTRODUCTION**

The ’941 patent claims instrumented methods for bunion correction surgery. But the claims extend far beyond the patent’s disclosure. Specifically, the specification fails to provide adequate written description of and enable the full scope of the claimed requirement that a bone positioning device be engaged and fixed across the first metatarsal-cuneiform joint and then used to achieve multi-planar alignment of the first metatarsal to correct a bunion.

Even apart from these §112 issues, the instrumentation and techniques recited in the claims were well known before the patent’s earliest claimed priority date in 2014. The claims of the ’941 patent recite, for example, “[a] method of performing a bunion surgery,” including: (1) engaging the first metatarsal and first cuneiform with “a bone positioning device;” (2) “aligning a bone cutting guide with the joint between the first metatarsal and the first cuneiform;” (3) “using the guide feature of the bone cutting guide to guide a cutting tool to cut a leading edge of the first metatarsal;” (4) “using the bone positioning device to adjust an alignment of the first metatarsal in multiple planes;” (5) “compressing the first metatarsal and the first cuneiform together;” and (6) “fixing a position of the first metatarsal relative to the first cuneiform with a bone connector.”

Surgeons have been performing bunion-correction procedures for more than a century. By the early 1900s, surgeons had described techniques for correcting misalignment of the first metatarsal and cuneiform, including cutting and removing bone to restore anatomic alignment and fixating the bones in the corrected position.

More than one year before the '941 patent's earliest priority date, a named inventor publicly disclosed the core concepts of the challenged claims—cutting, adjusting, compressing, and fixing the first metatarsal relative to the first cuneiform—demonstrating these steps were known before the critical date.

The prior art likewise disclosed the relevant instruments. For example, Waisman, Taylor, and Orsak describe devices for positioning bones, and Palmer and Orbay describe cutting guides for controlled bone cuts.

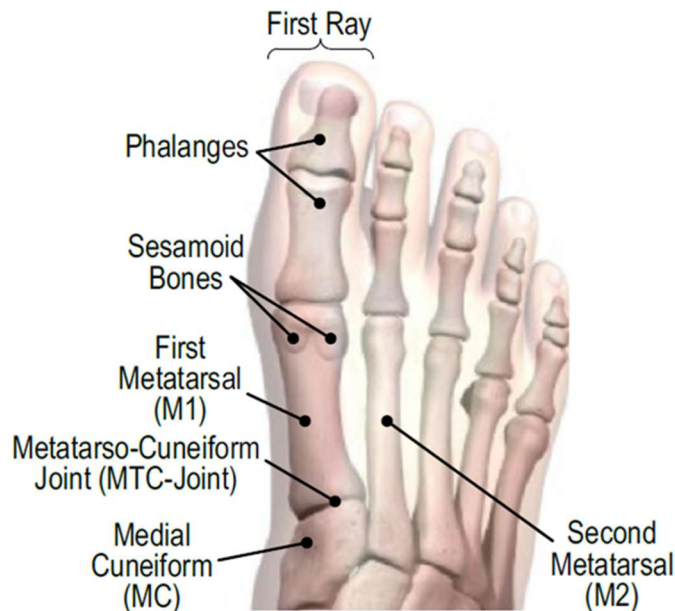
Accordingly, the claims are unpatentable as a predictable combination of known steps using known instruments, and because the specification lacks adequate written description and enablement for the full claimed scope. The Board should cancel all claims.

## **II. STATE OF THE ART**

### **A. Bunion Deformity**

In a typical foot anatomy, the first metatarsal and first/medial cuneiform<sup>1</sup> bones are positioned in three-dimensional alignment to permit normal foot function.

Ex. 1003, ¶¶40-41. These bones meet to form the metatarsal-cuneiform joint:



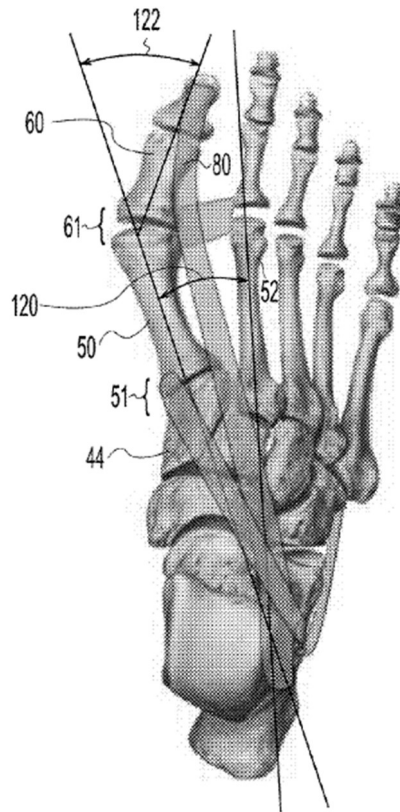
*Id.*, ¶40.

A bunion can result when the first metatarsal and first cuneiform become misaligned in one or more planes. *Id.*, ¶¶42-43. As part of this misalignment, the first metatarsal may deviate away from the second metatarsal, increasing the

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<sup>1</sup> The '941 patent refers to the medial cuneiform as the “first cuneiform.” Ex.1001, 3:2-5.

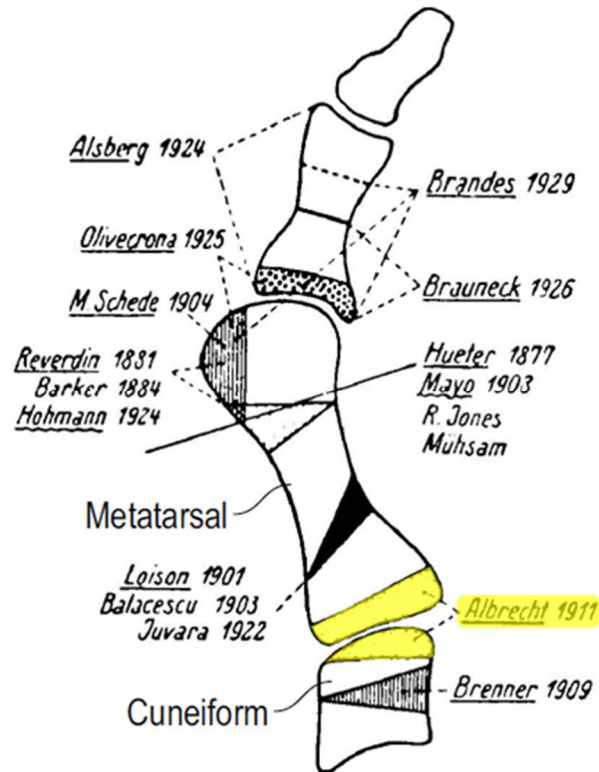
intermetatarsal angle (“IM angle” or “IMA”)—the angle 120 formed between the longitudinal axes of the first and second metatarsals:



Ex.1003, ¶43 (citing Ex.1026). Such misalignment can cause a visible bump on the foot’s inner portion, potentially impairing function and causing pain. Ex.1003 ¶¶43-44.

#### **B. Instrumented Bunion Correction**

Operative techniques for bunion correction have been known for more than a century, as illustrated in the following foot schematic that identifies various procedures by year and developer:

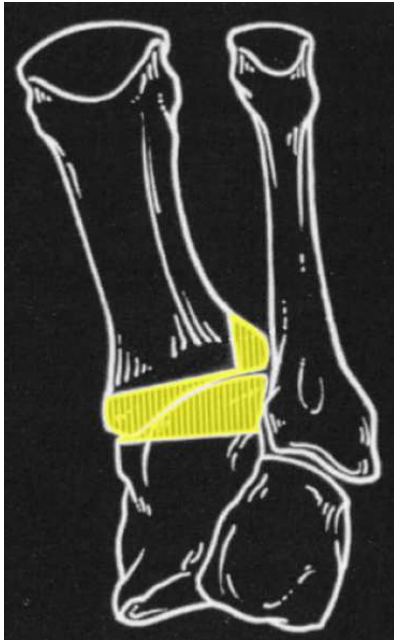


Ex.1018, 122<sup>2</sup>; Ex.1003, ¶¶45-47. One procedure involves fusing the first metatarsal and first cuneiform in the corrected position—referred to as a “Lapidus” procedure (also as metatarso-cuneiform arthrodesis)—which was developed in 1934. Ex.1003, ¶46; Ex.1011, 803; Ex.1019.

To prepare the joint, a surgeon cuts facing surfaces of the first metatarsal and cuneiform, as indicated by hatched areas below (left), creating space for repositioning the first metatarsal as shown below (right):

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<sup>2</sup> Annotations and highlighting added unless otherwise noted.



**Before Correction**

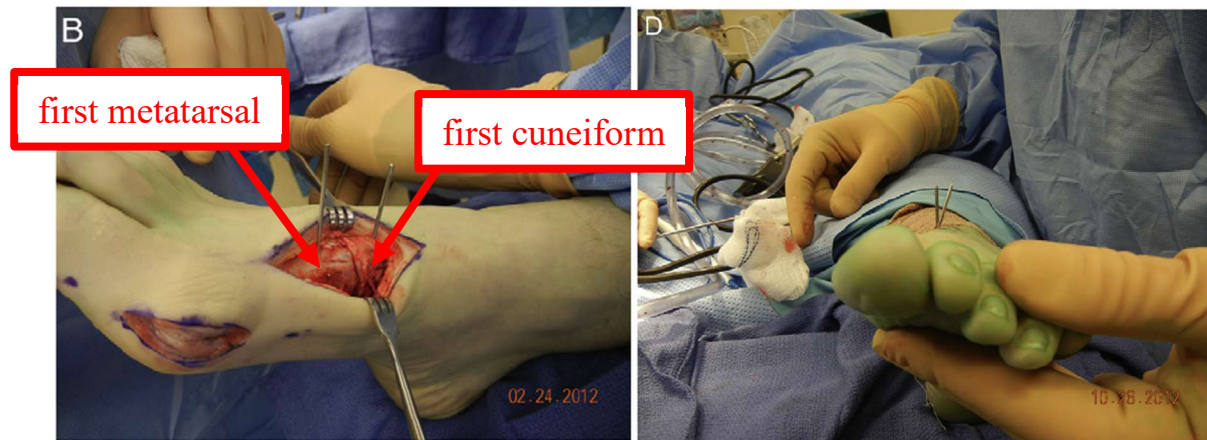


**After Correction**

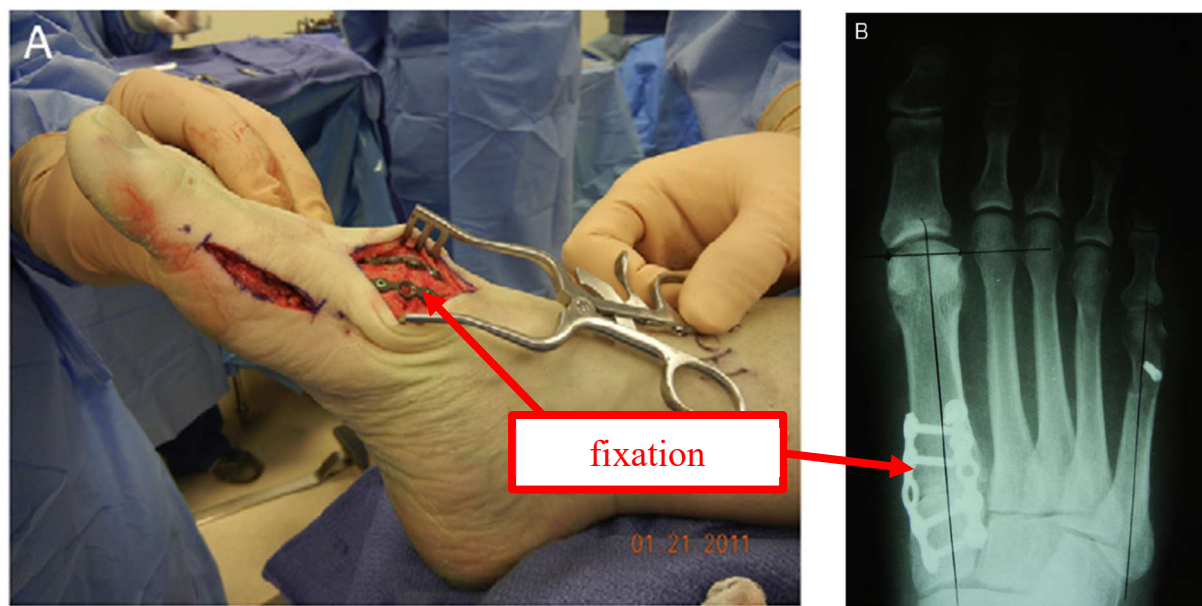
Ex.1020, Fig.1A (excerpt); Ex.1003, ¶48. The surgeon subsequently fixes the first metatarsal to the first cuneiform using fixation devices to achieve bone fusion. Ex.1003, ¶¶49-51; Ex.1019, 187-188; Ex.1020, 493; Ex.1011, 324-327; Ex.1016, 466.

**C. Known Surgical Methods For Correcting Bunion Deformities**

Dayton discloses a Lapidus procedure for bunion correction that emphasizes triplanar alignment of the first metatarsal. Ex.1005, 348-349; *see also* Ex.1003, ¶¶52-54. Dayton's procedure exposes the first metatarsal-cuneiform joint, cuts facing surfaces of the first metatarsal and cuneiform, and repositions the first metatarsal relative to the first cuneiform in multiple planes. Ex.1005, 348-349.



*Id.*, 349. The bones are temporarily stabilized and then fixed with permanent constructs (e.g., plates/screws). *Id.*



*Id.*, 349, 353.

#### **D. Known Bone Positioning Devices**

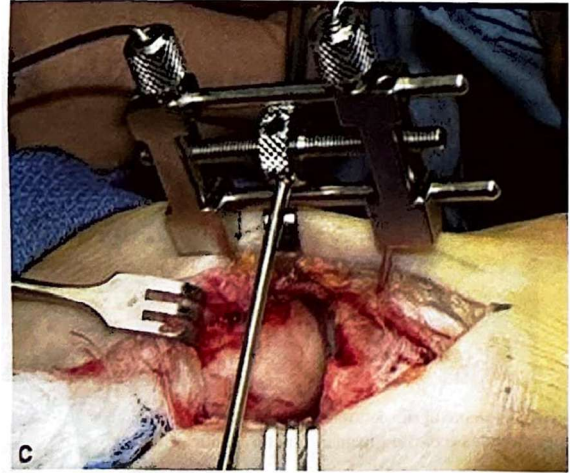
Positioning devices to reposition bone were known. Ex.1003, ¶¶55-62.

McGlamry discloses “bone-holding clamps and reduction forceps” for grasping and manipulating foot bones. Ex.1011, 10; Ex.1003, ¶56. McGlamry

further describes self-retaining retractors, such as with a Weintraub retractor or AO mini distractor, connectable to bone via pins. Ex.1011, 7-8, 803, 806, 809.

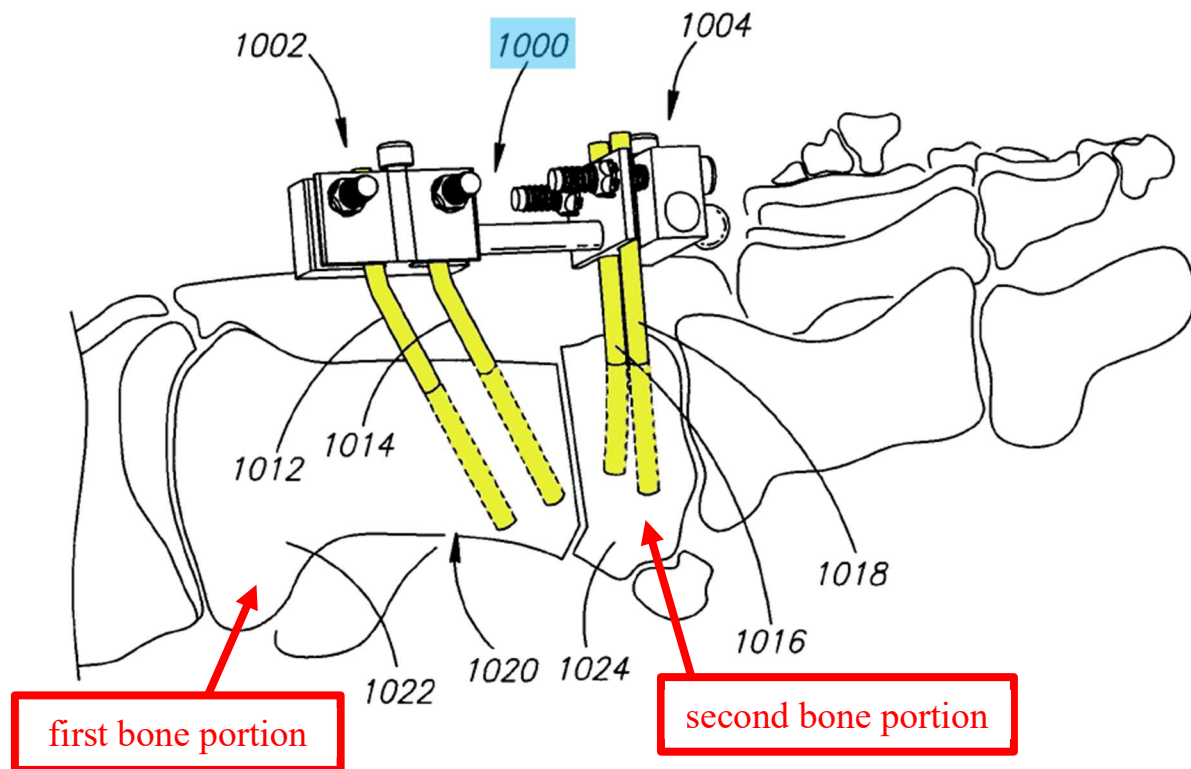


**Figure 1.20** The Weintraub retractor affixed to joint margins via 0.045-inch K-wires and used to distract the osseous segments.



*Id.*, 7-8 (Fig.1.20), 809 (Fig.55.5C). These devices “free the assistant to perform duties that may expedite the procedure” and “prepar[e] for fusion.” *Id.*, 7.

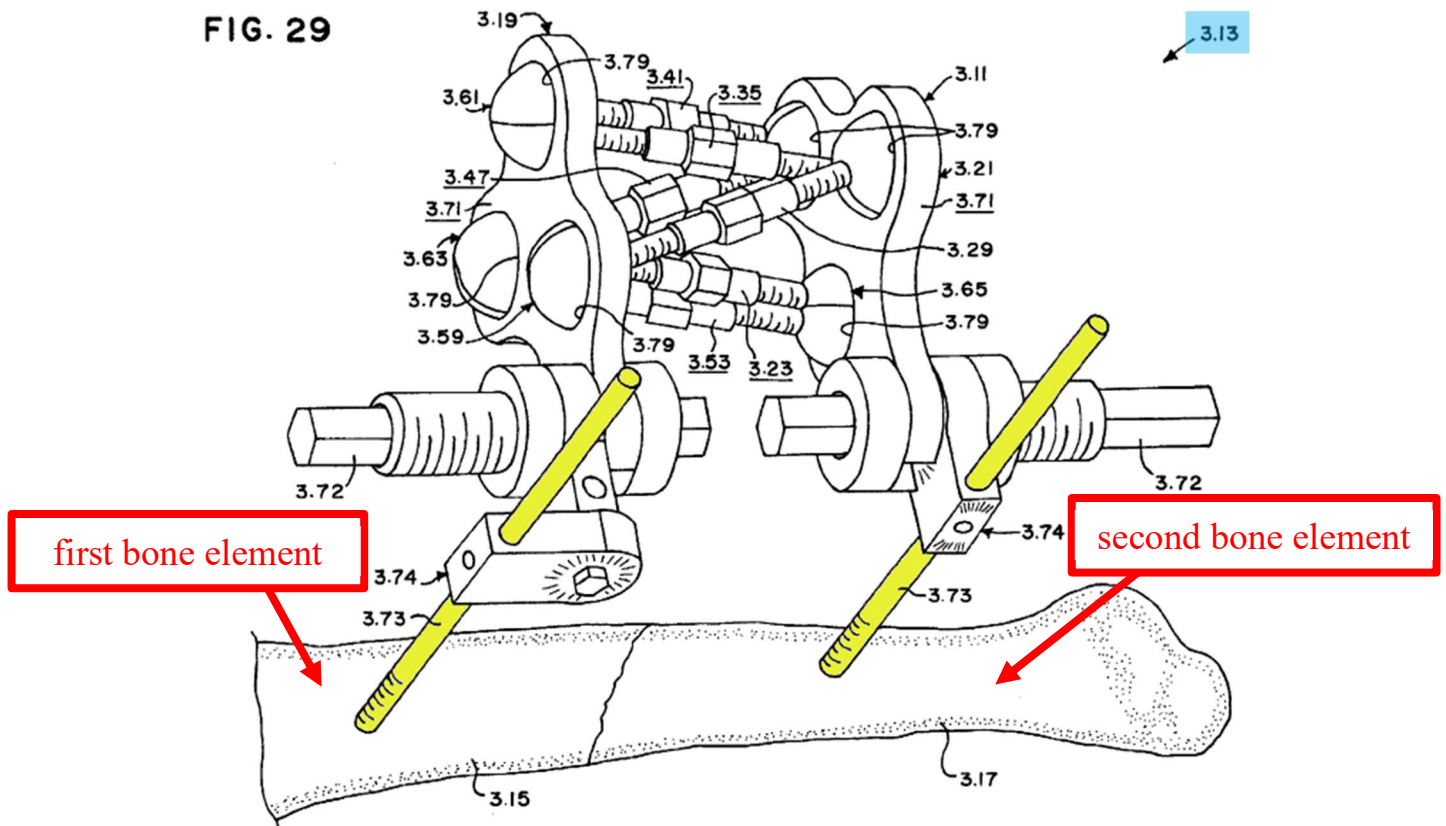
Waisman discloses a bone positioning device (blue) connected to bones via pins (yellow):



*Id.*, Fig.2F. The device may be “applied to a human foot for fixing an osteotomy (hallux valgus surgery) of first metatarsus deformity.” *Id.*, 26:21-24. It performs “holding fixation possibilities” including “compression,” “distraction,” “[c]lockwise motion,” and “translation.” Ex.1006, 6:7-13.

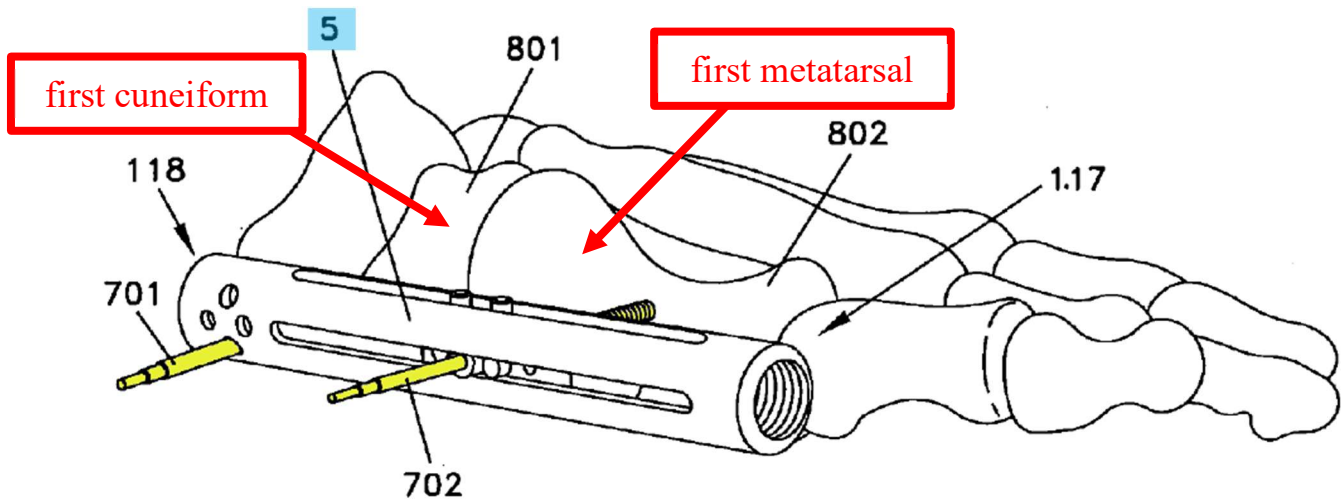
Taylor discloses a bone positioning device (blue) that is attached to bones with pins (yellow) and “can move one fragment with respect to the other in six orthogonal degrees of freedom” (Ex.1007, 5:26-33):

**FIG. 29**

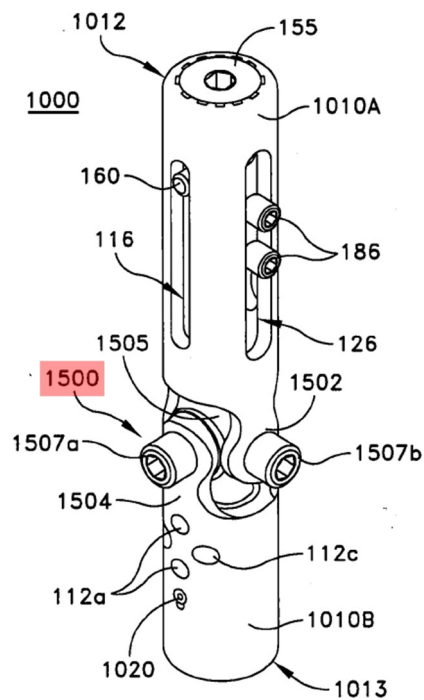


*Id.*, Fig.29. The device is “used for any situation requiring relative motion between elements including compression (shortening), distraction (lengthening), translation, angulation, or rotation and any combination of such movements.” *Id.*, 5:37-42.

Orsak discloses a bone positioning device usable to “adjust the relative orientation and spacing of the bone parts on opposing sides of a bone repair site.” Ex.1008, [0003]. Orsak illustrates a device (blue) engaged with the first metatarsal and cuneiform using pins (yellow):



*Id.*, Fig.5C; Ex.1003, ¶60. Embodiments in Orsak facilitate movement in multiple axes with a universal joint (red):

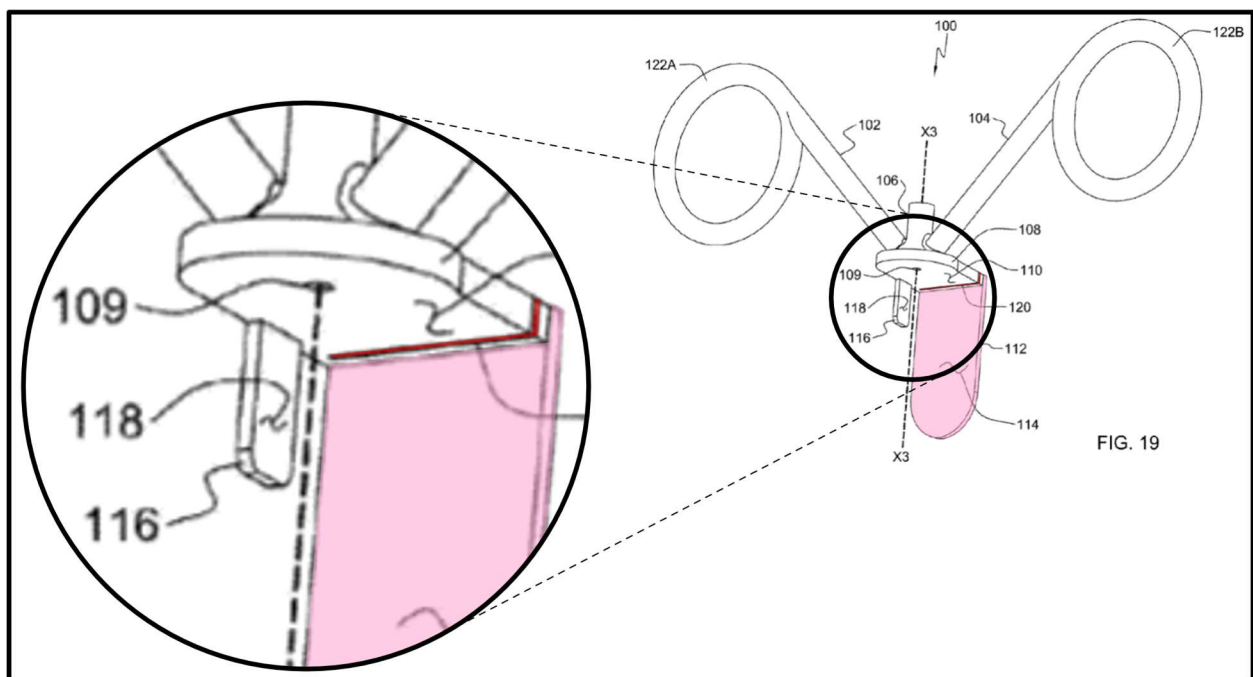


*Id.*, Fig.8A, [0094].

**E. Known Bone Cutting Guides**

Bone cutting guides, including those for corrective foot surgery, were well known. Ex.1003, ¶¶63-65.

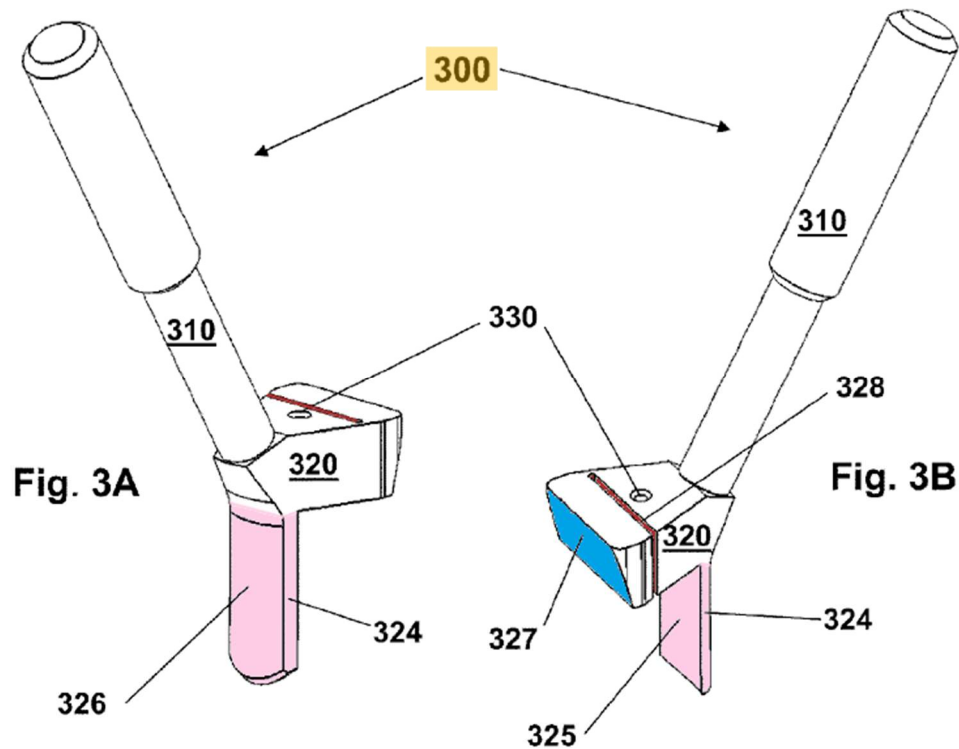
Palmer discloses a cutting guide “for preparing one of the target fusion bones for fusion thereof.” Ex.1009, Abstract. The guide includes a resection slot 120 (red) and positioning tab 112 (pink):



*Id.*, Fig.19. Palmer identifies the medial/first cuneiform as an example bone cut using its guide. *Id.*, [00139]-[00140].

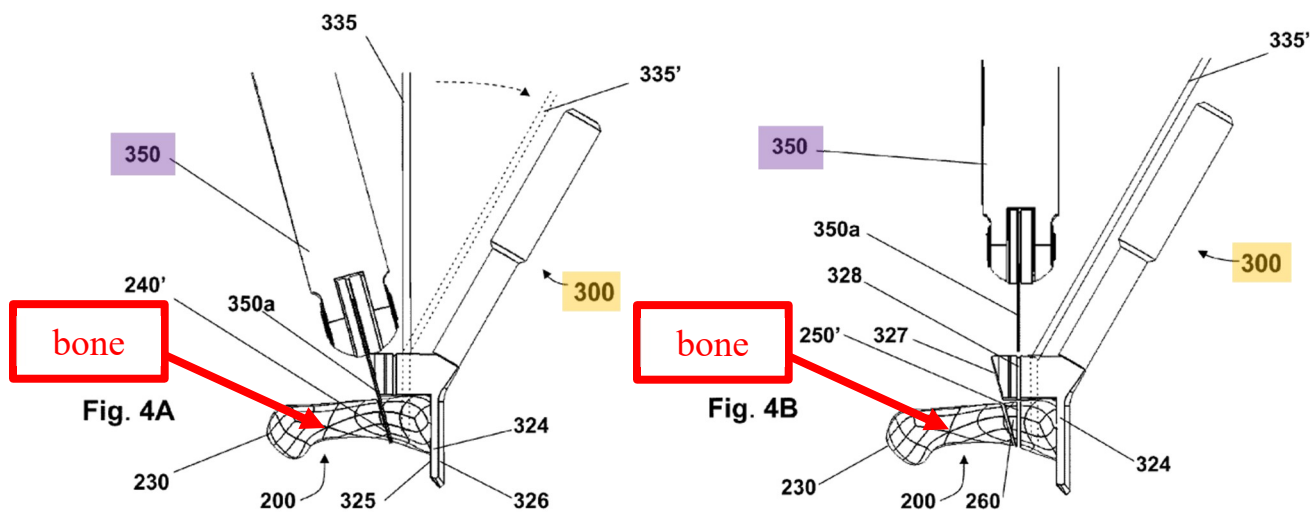
Orbay discloses “[a] cutting guide 300 for performing small bone osteotomy.” Ex.1010, [0037]. The guide’s “body portion 320 includes an angled plane surface 327 [(blue)], adapted to align a cutting blade along the angled line 240, and a vertical

guide 300 (orange) includes a divider piece 324 (pink) for placing into the joint. *Id.*



*Id.*, Figs.3A-3B. An oscillating saw 350 (purple) makes cuts with Orbay's guide.

*Id.*, [0039].



*Id.*, Figs.4A-4B.

### **III. THE '941 PATENT**

#### **A. Overview**

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; *see also* Ex.1003, ¶¶66-73.

Each '941 patent claim encompasses “[a] method of performing a bunion surgery to correct an alignment between a first metatarsal and a first cuneiform.” Ex.1001, claims 1-27. In general, the method involves: engaging a positioning device with the first metatarsal and cuneiform using fixation pins, using a cutting guide to guide a cutting tool to cut the leading edge of one or both bones, adjusting bone alignment using the positioning device, and compressing the bone ends together and fixing them with a bone connector. *Id.*

#### **B. Prosecution History**

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

#### **IV. LEVEL OF ORDINARY SKILL**

The '941 patent relates to “devices and methods for positioning and cutting bones,” specifically the first metatarsal and cuneiform. Ex.1001, 1:24-25, 3:2-5. The claims recite surgical methods performed using devices and therefore include limitations directed to both surgical techniques and medical instrumentation.

A hypothetical person of ordinary skill in the art (“POSA”) would have possessed a combination of these skill sets. Ex.1003, ¶¶29-34. A POSA would have had a medical degree and at least 3 years of surgical experience with foot surgery. *Id.*, ¶31. Such person 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.* For individuals with different engineering backgrounds, a person could still be of ordinary skill provided that person’s additional experience compensates for any differences in that person’s education. *Id.*, ¶32.

This Petition does not turn on this specific definition of the level of ordinary skill. The claims would be obvious under any reasonable POSA definition. *Id.*, ¶¶34, 37; *see also id.*, ¶¶1-37.

#### **V. CLAIM CONSTRUCTION**

In a PGR, 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. § 42.100(b). Under this standard, claims “are generally given their ordinary and customary meaning,” as understood by a POSA. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (citation omitted).

Petitioner submits the Board need not specially construe any claim terms. *Toyota Motor Corp. v. Cellport Sys., Inc.*, IPR2015-00633, Paper No. 11 at 16 (P.T.A.B. Aug. 14, 2015); *see also Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) (“[O]nly those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy.”). The claims are unpatentable under the claim language’s plain and ordinary meaning.

To the extent any limitation should be analyzed under 35 U.S.C. §112(f), Petitioner provides the function and identifies corresponding structure for completeness. Petitioner’s obviousness showings apply under any reasonable construction consistent with the record. *See* Ex.1003, ¶¶75-88.

**A. “bone positioning device”**

The term’s plain and ordinary meaning is a “device designed to move bone(s).” Ex.1003, ¶¶77-78.

To the extent it were construed under §112(f), then:

**Function:** “adjust[ing] an alignment of the first metatarsal in multiple planes to correct a bunion.” Ex.1001, claims 1, 18.

**Corresponding Structure:** The specification discloses that the structure performing the claimed function includes a multi-axis joint with ball-and-socket ends. *Id.*, 3:55-67; Ex.1003, ¶¶79-80.

**B. “bone connector”**

The term’s plain and ordinary meaning is “a device for connecting bone.” Ex.1003, ¶82.

To the extent it were construed under §112(f), then:

**Function:** “fixing a position of the first metatarsal relative to the first cuneiform.” Ex.1001, claims 1, 5, 18, 21.

**Corresponding Structure:** The specification discloses that the structure performing the claimed function includes a plate, pin, screw, wire, or staple. *Id.*, 5:62-66; Ex.1003, ¶¶83-84.

**C. “cutting tool”**

The term’s plain and ordinary meaning is “a device for cutting tissue.” Ex.1003, ¶86.

To the extent it were construed under §112(f), then:

**Function:** “cut a leading edge of the first metatarsal/cuneiform.” Ex.1001, claims 1, 5, 18, 21.

**Corresponding Structure:** The specification discloses that the structure performing the claimed function includes a saw blade. *Id.*, 5:17-21; Ex.1003, ¶¶87-88.

## **VI. RELIEF REQUESTED**

### **A. Grounds**

Petitioner requests PGR on the following grounds:

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

| Ground | Reference(s)                              | Claims | Basis |
|--------|-------------------------------------------|--------|-------|
| 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  |

In support, Petitioner submits the expert declaration of Steven Neufeld, M.D.  
*See* Ex.1003, ¶¶1-37, 368-370; *see also* Ex.1004.

**B. Asserted References**

The '941 patent's earliest claimed priority date is July 15, 2014. Ex.1001.

The references<sup>3</sup> relied on are prior art for the following reasons:

| Ex.  | Reference(s) | Date                     | Art Type        |
|------|--------------|--------------------------|-----------------|
| 1005 | Dayton       | Published: Mar. 5, 2013  | §102(a)(1)      |
| 1006 | Waisman      | Published: Jan. 12, 2012 | §§102(a)(1),(2) |
| 1007 | Taylor       | Published: Dec. 30, 1997 | §§102(a)(1),(2) |
| 1008 | Orsak        | Published: Feb. 2, 2012  | §§102(a)(1),(2) |
| 1009 | Palmer       | Published: Aug. 2, 2012  | §§102(a)(1),(2) |
| 1010 | Orbay        | Published: Nov. 24, 2011 | §§102(a)(1),(2) |

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<sup>3</sup> A librarian declaration is submitted to support the publication date and public accessibility of certain cited references. Ex.1021.

The references are analogous art because they are from the same field as the '941 patent—surgical procedures involving bone. Ex.1003, ¶¶89-90; Ex.1001, 1:24-30; *Unwired Planet, LLC v. Google Inc.*, 841 F.3d 995, 1000 (Fed. Cir. 2016). The references are pertinent to the problem addressed by the inventors, including cutting, repositioning, and fixing bone during surgical procedures. Ex.1001, claims 1, 18; Ex.1003, ¶90.

## **VII. GROUND 1: CLAIMS 1-27 ARE UNPATENTABLE UNDER §112**

### **A. All Claims Lack Written Description Support**

To satisfy §112's written-description requirement, the specification must demonstrate the inventors possessed the claimed invention at filing and “reasonably convey[]” that possession to a POSA. *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351-52 (Fed. Cir. 2010) (en banc). Accordingly, “claims may be no broader than the supporting disclosure” and are invalid if they attempt to cover subject matter not described in the specification. *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479-81 (Fed. Cir. 1998); *ICU Med., Inc. v. Alaris Med. Sys., Inc.*, 558 F.3d 1368, 1378-79 (Fed. Cir. 2009). A disclosure that merely renders an invention “obvious” does not satisfy written description. *Ariad Pharms.*, 598 F.3d at 1352 (quoting *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1571-72 (Fed. Cir. 1997)).

Independent claims 1 and 18 require (i) “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” and (ii) “using the bone positioning device to adjust an alignment of the first metatarsal in multiple planes to correct a bunion.” This operative limitation—multi-planar adjustment of the first metatarsal using a device fixed across the joint—materially defines the claimed method and what it accomplishes.

Yet, the specification does not describe how to perform the claimed surgical method at the level of method steps. At most, it provides: (i) a high-level statement that the device “can be useful” in procedures “to correct an alignment between a metatarsal...and a cuneiform...such as a bunion correction,” including a Lapidus procedure, and (ii) a mechanical description that a “multi-axis joint” permits relative 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, 2:63-3:6, 3:43-48, 4:1-13. What 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. The only concrete example is an illustrative longitudinal (single plane) skew (~15°) between generic bones. *Id.*, 3:48-54. 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.” In short, the patent describes a vague multi-axis capability, not the claimed clinical/surgical use of that capability to accomplish multi-planar bunion correction. *See* Ex.1003, ¶¶70-71.

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 multi-planar 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.

Claims 4 and 18 compound the defect by requiring a specific sequence: adjusting metatarsal alignment before performing the cuneiform cut. 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.

Written description must be found within the four corners of the specification. The absence of any disclosed methodology for achieving the claimed multi-planar bunion correction—including the missing actuation/manipulation guidance and the pre-cut sequencing requirement of claims 4 and 18—confirms that the claims lack adequate written description.

**B. All Claims Are Unpatentable For Lack Of Enablement**

A patent must enable a POSA to make and use the full scope of the claimed invention without undue experimentation. *Amgen v. Sanofi*, 598 U.S. 594, 612 (2023); *Baxalta Inc. v. Genentech, Inc.*, 81 F.4th 1362, 1365 (Fed. Cir. 2023). Whether experimentation is “undue” is assessed under the *Wands* factors. *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

As explained in Section VII.A, the 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.

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.*

Enablement must be commensurate with claim breadth. Here, the claims sweep broadly, yet the patent provides no meaningful examples or step-by-step teaching. Under *Wands*, the lack of guidance, lack of working examples, and claim breadth weigh heavily toward undue experimentation: a POSA would have to supply the missing clinical methodology through iterative trial-and-error across varying bunion presentations and desired correction endpoints, rather than following an

enabling disclosure. *See Wands*, 858 F.2d at 737. That is particularly true because 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.

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.

Accordingly, although the specification describes a bone positioning device with a joint capable of multi-axis motion, it never enables the claimed surgical methods across the full claim scope without undue experimentation. The claims therefore fail §112.

## **VIII. GROUND 2: CLAIMS 1-27 ARE OBVIOUS BASED ON DAYTON, WAISMAN, AND PALMER**

### **A. Claim 1**

Claim 1 recites a bunion-correction method that includes cutting a first metatarsal and first cuneiform using a bone cutting guide, adjusting first-metatarsal alignment in multiple planes using a bone positing device, compressing the first metatarsal and first cuneiform, and fixing them with a bone connector. Ex.1001, claim 1. Dayton discloses a similar method including cutting, adjusting,

compressing, and fixing the first metatarsal and first cuneiform with a bone connector. Ex.1005, 349.

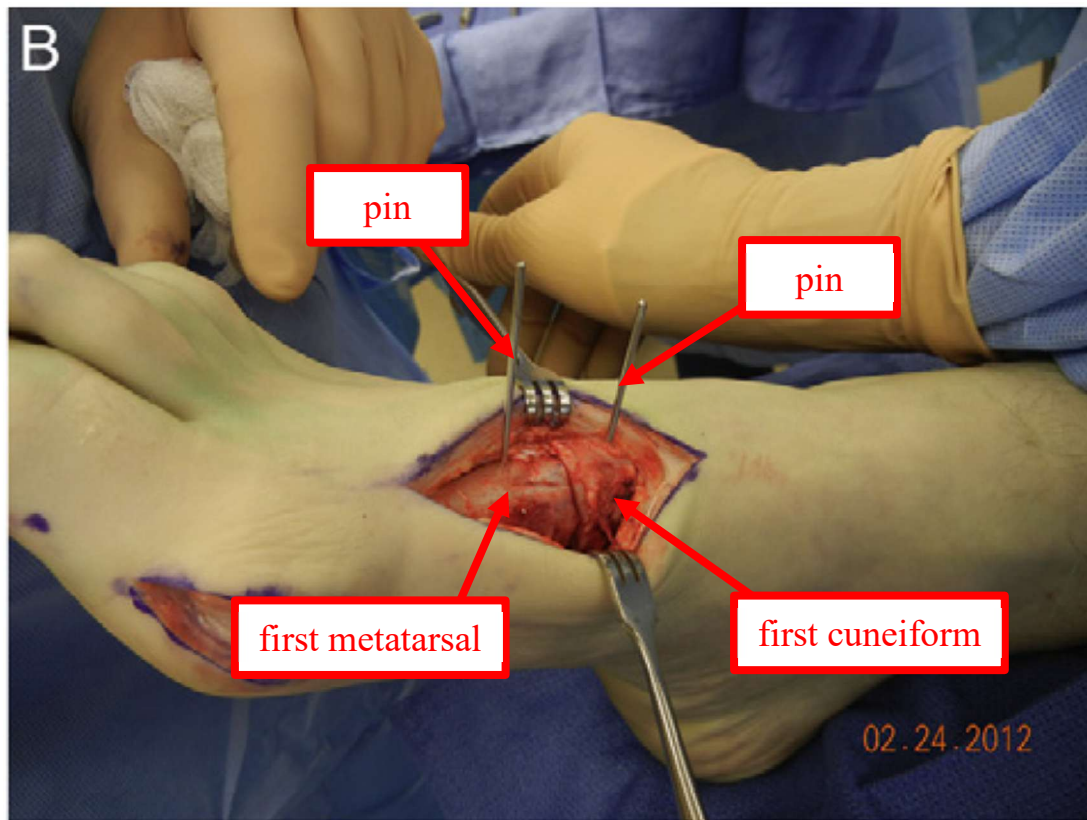
Palmer discloses bone cutting guides for foot surgery (Ex.1009, [00139]-[00140]), and Waisman discloses a bone positioning device for foot surgery and multi-planar alignment adjustment (Ex.1006, 27:4-7, 6:7-13). It would have been obvious to use these known cutting guides and positioning devices in performing Dayton's method, rendering claim 1 obvious. Ex.1003, ¶¶91-149.

# **1. Preamble**

To the extent the preamble is limiting, Dayton discloses such a method. Ex.1003, ¶¶94-96.

Dayton discloses “hallux valgus corrective procedures,” which correct a “hallux abducto valgus [HAV] deformity.” Ex.1005, Abstract. A HAV deformity is the clinical term for a bunion. Ex.1003, ¶95.

Dayton explains that, in its procedure, “pins were placed ..., 1 in the base of the metatarsal and 1 in the cuneiform,” with “[t]hese pins [being] used as a reference to more easily visualize the rotation of the metatarsal in the frontal plane.” Ex.1005, 349. Such pins are shown positioned in the first metatarsal and cuneiform:



Ex.1003, ¶96 (annotating Ex.1005, Fig.1B); *see also* Ex.1005, 348-350. According to Dayton, “the 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.” Ex.1005, 349; *see also id.*, 348, 350.

Accordingly, the combination renders the preamble obvious. Ex.1003, ¶¶94-96.

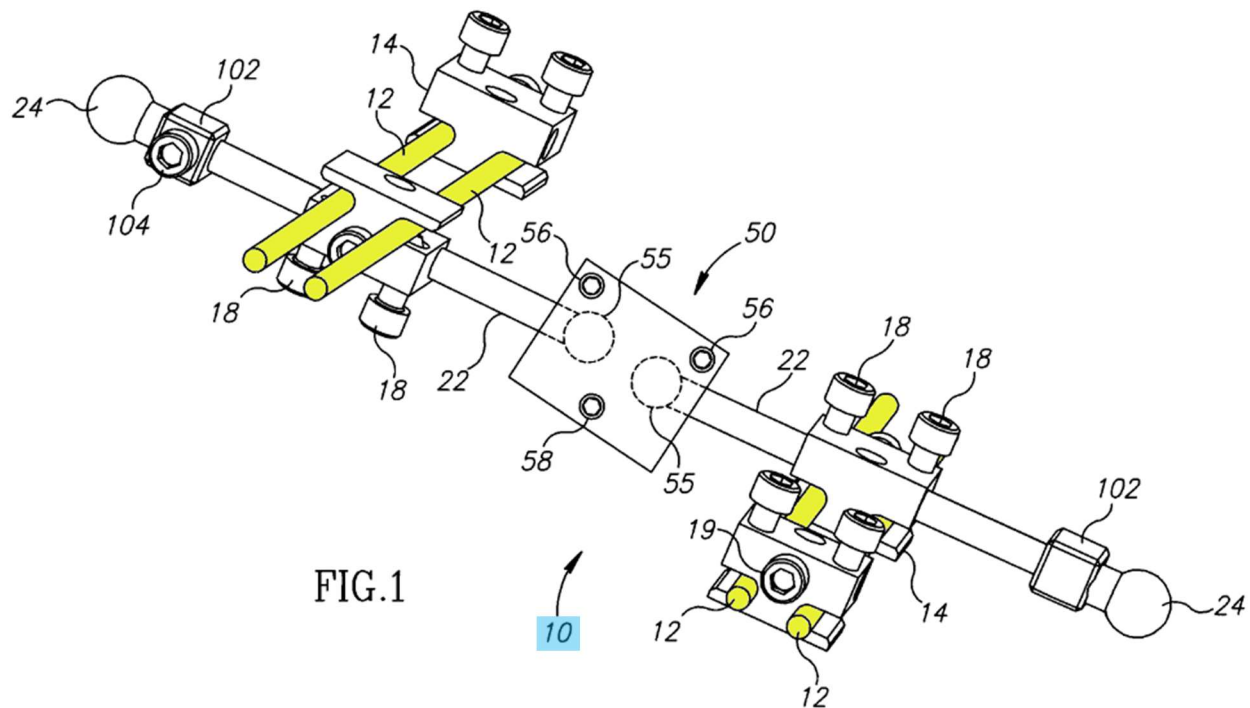
## **2. Limitation 1[a]**

This limitation recites “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.” The combination renders the limitation obvious. Ex.1003, ¶¶97-114.

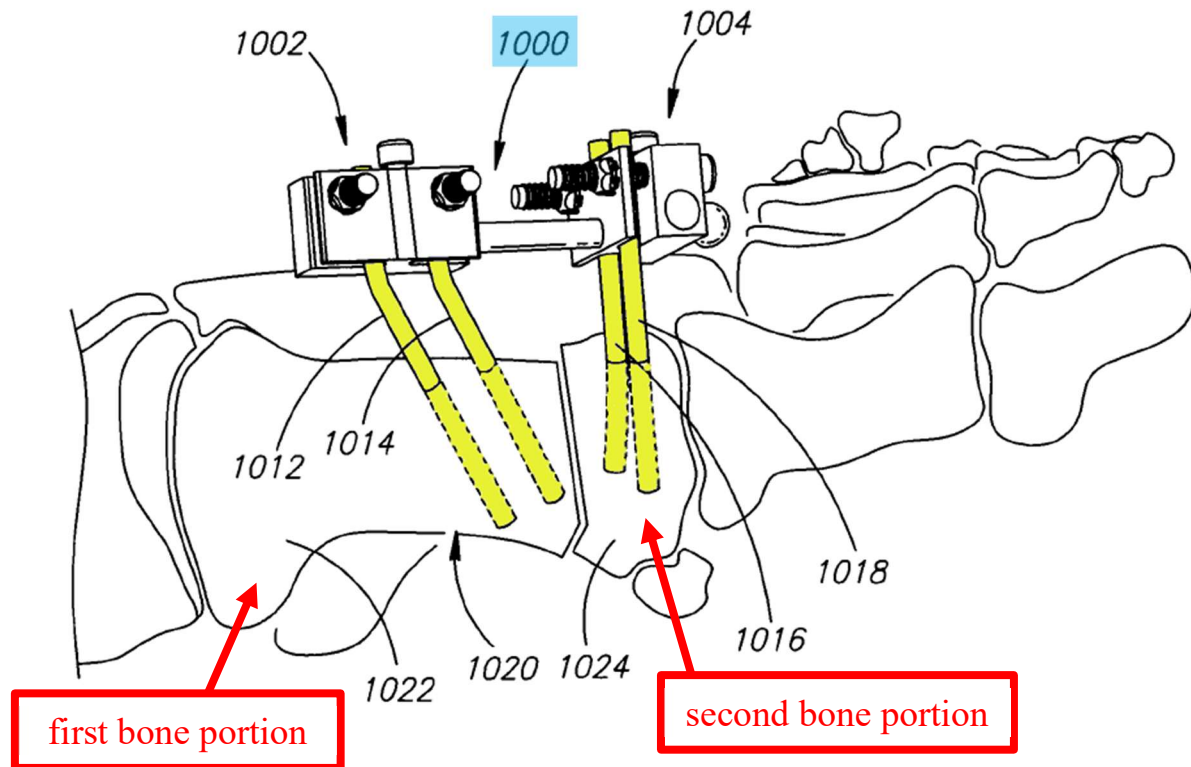
Dayton discloses repositioning the first metatarsal relative to the first cuneiform, as explained for claim 1’s preamble. *Supra* §VIII.A.1. Dayton further discloses inserting pins into the first metatarsal and cuneiform for assisting in visualizing metatarsal rotation and temporarily stabilizing the first metatarsal relative to the first cuneiform. Ex.1005, 349. Dayton achieves its movement through manual manipulation. *Id.*; Ex.1003, ¶98.

It would have been obvious to use a bone positioning device like Waisman’s in Dayton’s procedure to facilitate bone repositioning. Ex.1003, ¶¶99-113. Waisman discloses a “[p]olyaxial external fixator [(PEF)] 10 compris[ing] bone penetrating elements 12 such as K-wires, pins or screws.” Ex.1006, 15:4-5; *see also id.*, 5:10-12 (explaining “Kirschner wires (KW) [K-wires] are sterilized, sharpened, smooth stainless steel pins”). One fixator 10 (blue) with pins 12 (yellow) is shown in the following figure:

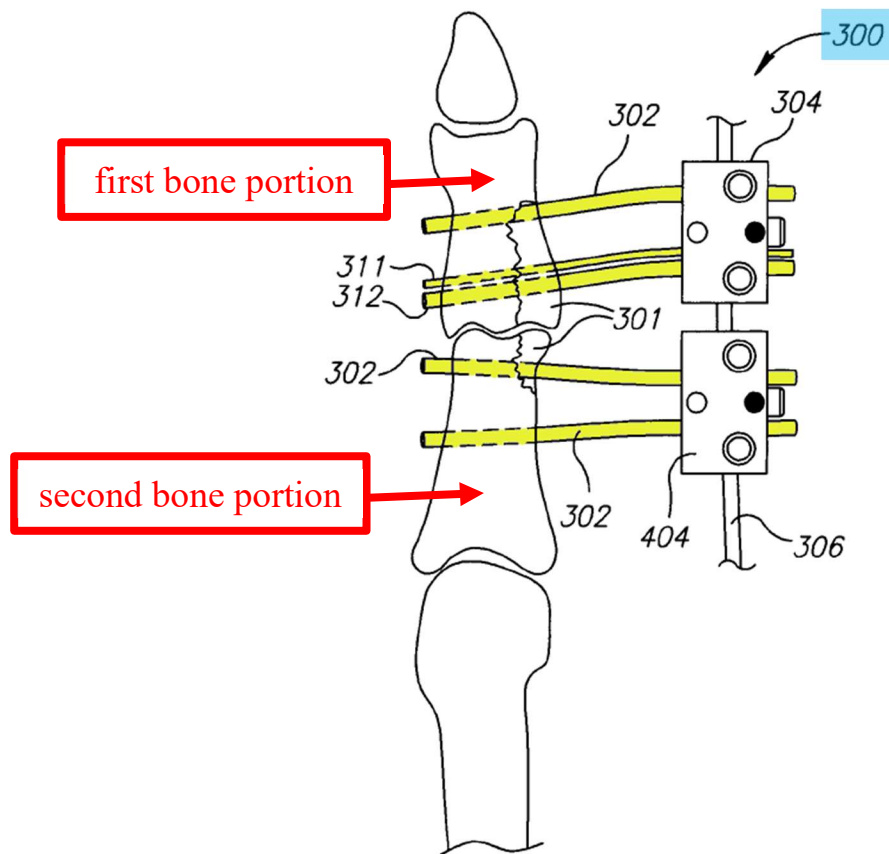


*Id.*, Fig.1. “By sliding and/or rotating the lateral cages 14 along rods 22, and by changing the relative positions of rods 22 using central cages 50, the bone fragments may be held in desired position relative to each other.” *Id.*, 24:23-25; *see also id.*, 8:15-9:12, 23:6-28.

A fixator 1000 is depicted “applied to a human foot for fixing an osteotomy (hallux valgus surgery) of first metatarsus deformity”:



*Id.*, 26:21-24, Fig.10. A fixator 300 is also illustrated applied across a joint:



*Id.*, Fig.9B; *see also* Ex.1005, 3:1-2, 4:29-5:2.

Waisman describes that its fixator performs “different holding fixation possibilities based on the polyaxial device: 1) compression 2) distraction 3) abduction 4) adduction 5) flexion 6) extension 7) Clockwise motion 8) anti-clockwise motion 9) upper translation 10) lower translation 11) All of above combinations 12) Multiple transverse connections between two or more devices, and 13) Custom modular device elongation, unilateral or bilateral frame construction.” Ex.1006, 6:7-13; *see also id.*, 2:30-3:1 (“Fixators are being used for positioning two or more bone portions.... They are often used in the course of...surgical procedures

such as reduction, realignment and correction.”), 4:25-27 (“It is an object of the present invention to provide an external fixator of different sizes for fixating bones of any size...during...reduction, realignment and correction surgery.”).

Waisman’s “inventive PEF system and method may be used in a plurality of other surgical procedures, including...orthopedic surgery such as but not limited to...foot surgeries.” *Id.*, 27:4-7. Waisman confirms “[its] invention may be used as temporary or final fixation.” *Id.*, 27:7-9. Waisman explains its fixator is used with “osteotomized bones” (*id.*, 8:7-14), which are surgically cut (Ex.1003, ¶103).

A POSA would have been motivated to use a bone positioning device like Waisman’s fixator in Dayton’s procedure and to engage the positioning device with a first metatarsal using a first fixation pin and with a first cuneiform using a second fixation pin, such that the positioning device extends across the joint separating the first metatarsal and cuneiform. Ex.1003, ¶¶105-106. Such engagement would facilitate use of the positioning device to reposition and stabilize the bones during Dayton’s procedure. *Id.* This positioning device satisfies “bone positioning device” under the plain and ordinary meaning, as it is a structure for positioning bones in multiple planes. *Id.*, ¶114 Under §112(f), this positioning device is identical or at least equivalent to structures identified in the ’941 patent for the claimed positioning device discussed in Section V.A. *Id.* The positioning device is at least an equivalent of the disclosed bone-positioning structures (multi-axis joint with ball-and-socket

ends) because it performs the same function (adjusts first metatarsal alignment in multiple planes), in substantially the same way (spheres confined in central cage joint fixing rod angles), to achieve the same result (move and hold bones in intended position). *Id.*

Dayton discloses placing pins in the first metatarsal and cuneiform to visualize rotation, rotating the metatarsal by hand until alignment is achieved, and temporarily stabilizing the bones. Ex.1005, 349; Ex.1003, ¶110. Waisman, in turn, discloses a polyaxial fixator for reduction/realignment/correction, uses K-wire/pins held by cages/rods, and is used on small bones such as those of the foot (Ex.1006, Abstract, 4:25-5:9, 27:4-7), i.e., the same operative scale and environment as Dayton's procedure. Ex.1003, ¶115. Combining these familiar elements according to their known functions would have predictably yielded the expected benefit: instead of pins serving primarily as visual references for manual manipulation or temporary stabilization (Ex.1005, 349), 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. Ex.1003, ¶107.

The combination represents a straightforward modification well within a POSA's skill. *Id.*, ¶108. Dayton discloses anchoring the first metatarsal and cuneiform with pins and relies on achieving, visualizing, and maintaining a corrected rotational relationship between those bones while subsequent steps proceed.

Ex.1005, 349. Waisman discloses a fixator “suitable for fixation using K-wires, pins or screws” (Ex.1006, 5:3-4), the type of apparatus a POSA would select for adjusting and maintaining relative alignment between adjacent bones during corrective surgery (Ex.1003, ¶108). A POSA would have been motivated to incorporate fixation like Waisman’s in Dayton’s procedure—for example, in place of, or adjunct to, manual manipulation—because the fixator affords greater precision, controlled incremental correction, and improved maintenance of alignment compared to freehand manipulation, without changing Dayton’s fundamental surgical goals or anatomical anchoring strategy. Ex.1003, ¶109; *see also* Ex.1011, 7 (The devices “free the assistant to perform duties that may expedite the procedure” and “prepar[e] for fusion.”).

A POSA would have recognized the combination as using a known technique to improve a similar method in the same way. *Id.*, ¶¶109-111. Dayton emphasizes hallux valgus is a triplanar deformity, and Dayton’s intraoperative workflow operationalizes that understanding through observing and manually correcting rotation. Ex.1005, 348-349. Waisman’s fixator supports reduction/realignment/correction and provides multiple fixation modes, including clockwise/anti-clockwise motion (rotation) and translation (Ex.1006, 6:7-13), which are the same degrees of freedom corresponding to the repositioning a surgeon performs when correcting triplanar deformity and holding the corrected relationship

(Ex.1003, ¶111). Engaging a positioning device like Waisman’s to the first metatarsal and cuneiform in Dayton’s procedure would have been an obvious way to improve intraoperative control and retention compared to manual manipulation, because it applies a known bone-repositioning technique to the same corrective alignment task and predictably achieves the expected result: controlled movement and stable maintenance of two bone portions. Ex.1003, ¶111.

A POSA would have had a reasonable expectation of success because the modification stays within reference disclosures and relies on predictable mechanics. *Id.*, ¶112. A POSA would expect that engaging a positioning device like Waisman’s to pins placed in the first metatarsal and cuneiform would provide precise repositioning and stable maintenance of the corrected alignment during the procedure. *Id.*, ¶113. Indeed, Waisman is particularly relevant because it expressly addresses small foot bones and hallux valgus-related use. Ex.1006, 5:18-20, 26:21-24. Waisman also explains its fixator “allows for optimal alignment and reduction” (*id.*, 7:9-10) and its method “may be forgiving, allowing an improved degree of freedom for K-wire insertion” (*id.*, 7:2-4). *See also id.*, 6:21-23, 7:1-2.

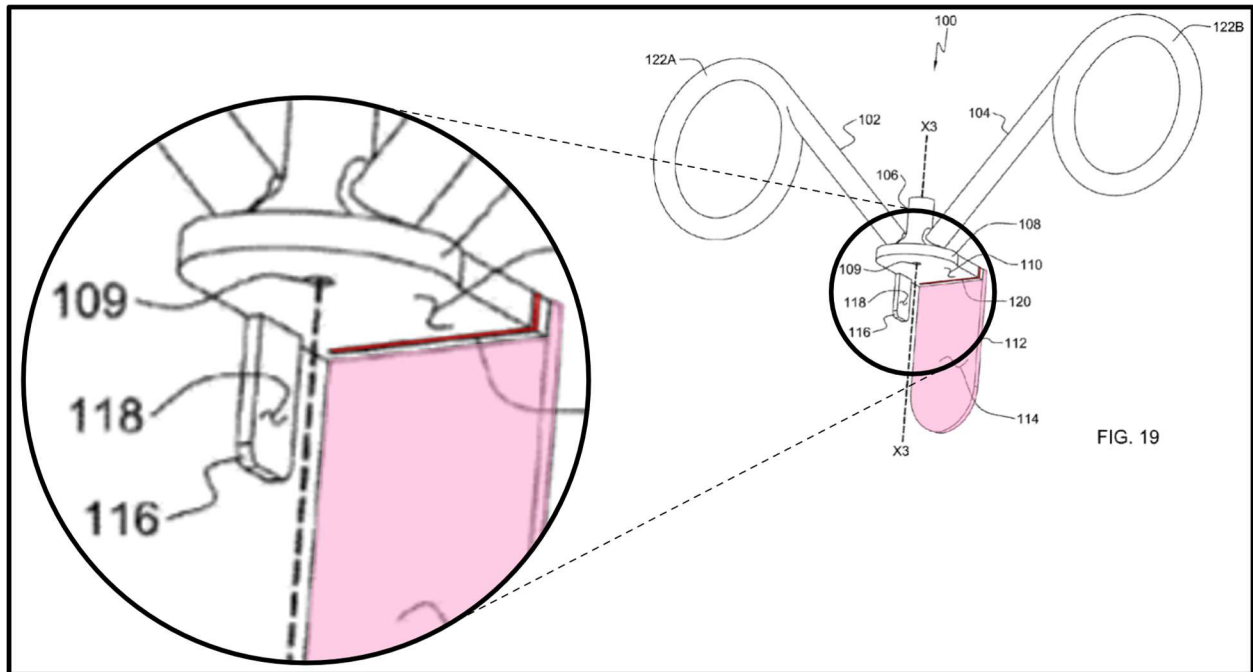
### **3. Limitation 1[b]**

This limitation recites “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.” The combination renders the limitation obvious. Ex.1003, ¶¶115-130.

Dayton’s procedure involves preparing the metatarsal-cuneiform joint for arthrodesis by “resection of the articular surfaces” (i.e., cutting the opposing joint surfaces) of the first metatarsal and cuneiform. Ex.1005, 349; Ex.1003, ¶116; *see also* Ex.1005, 349 (explaining “[t]he joint surfaces were next resected, including the cartilage and all subchondral bone”; describing a “first metatarsal cut” and “cuneiform cut”).

It would have been obvious to use a bone cutting guide like Palmer’s in Dayton’s procedure to facilitate bone cutting. Ex.1003, ¶¶120-130. Palmer discloses “[a] guide instrument (100) for preparing one of the target fusion bones for fusion thereof.” Ex.1009, Abstract. Palmer’s instrument 100 “include[s] a resection slot 120 [(red)] extending in a medial-lateral direction from a lateral side of the base member 120.” *Id.*, [00140]. “The guide instrument 100 may also include an exemplary distal positioning tab 112 [(pink)].” *Id.*, [0135].



*Id.*, Fig.19.

Palmer explains “[t]he medial-lateral width, proximal-distal length and dorsal-plantar height of the distal positioning tab 112 should be configured such that distal abutment surface 114 of the distal positioning tab 112 can abut or engage a distal facing surface of the target bone when the dorsal abutment surface 110 abuts or engages a dorsal surface of the target bone.” *Id.*, [00137]; *see also id.*, [00138] (“the distal positioning tab 112 can be effective in positioning”). As a result, “[w]hen the bone anchor is received within the longitudinally extending aperture 109 and coupled to the target bone, the resection slot 120 can be utilized to resect a distal portion of the target bone.” *Id.*, [00140]. Palmer identifies one target bone as the medial cuneiform (*id.*, [00139]), which is the first cuneiform (Ex.1003, ¶118). *See also* Ex.1009, [00162] (explaining “the generic term ‘first target fusion bone’ or

simply ‘first target bone’ may be used hereinafter to refer to the medial or transverse cuneiform bone, or any other bone that includes similar features, positioning, orientation, function or the like”).

Palmer’s instrument 100 is a bone cutting guide. Ex.1003, ¶119. The portion of Palmer’s base member 108 that structurally defines the resection slot 120 constitutes a guide feature, and Palmer’s distal positioning tab 112 constitutes a joint plate because it extends into the joint during use. *Id.* The distal positioning tab 112 extends downwardly relative to the resection slot 120. *Id.*; *see also* Ex.1007, [00135], [00137]. Palmer explains “the resection slot 120 is preferably spaced from the distal abutment surface 114 in the proximal direction” (Ex.1009, [00140]), and thus the distal positioning tab 112 is offset from the portion of Palmer’s base member 108 that structurally defines the resection slot 120 (Ex.1003, ¶119).

A POSA would have been motivated to use a bone cutting guide like Palmer’s instrument in the procedure and to align the cutting guide with the metatarsal-cuneiform joint. Ex.1003, ¶120. In this arrangement, the cutting guide would include a joint plate (distal positioning tab) offset from a guide feature (e.g., cutting guide portion structurally defining resection slot), with the joint plate extending downwardly relative to the guide feature and being inserted into the joint during alignment. *Id.*

A POSA would have recognized—consistent with prior art from 1994—that freehand resection of bones can be “very difficult to perform and can be rather imprecise.” Ex.1003, ¶121; *see also* Ex.1022, 1:31-37. Inaccuracies during freehand resection “lead to complications such as nerve damage, poor quality bone healing, bone resorption,...increased operating time and increased blood loss.” Ex.1022, 1:45-50. Other prior art similarly warns that errors can cause complications, including “[s]ignificant shortening,” delayed unions, non-unions, and malunions. Ex.1011, 329; *see also* Ex.1005, 349 (noting the “distal medial portion of the cuneiform [is] left intact” to avoid “sacrificing the length of the first ray”). Dayton cautions to avoid damaging blood supply and unnecessary tissue disruption. Ex.1005, 349.

Using a cutting guide like Palmer’s would have been understood to reduce the risk of such complications. Ex.1003, ¶¶121-123; Ex.1022, 1:50-54 (“These significant disadvantages could be reduced or overcome with precise, quick and efficient bone cuts. It is therefore surprising that there has been no known cutting guide developed....”). The prior art confirms “[t]here are numerous prior art devices for precision cutting of bones in the appendicular skeleton,” including the feet. Ex.1022, 1:55-58. Commercially available cutting guides were known to “help the surgeon resect the proper amount of bone and at the proper angles,” including when resecting the joint surface. Ex.1011, 381-383. Cutting guides “remove the necessity

of clinical judgement and guess work.” Ex.1012, 3:1-5; *see also* Ex.1014, [0034], [0070] (describing how the cut guides “precisely determine[]” the positions of the cuts). Indeed, Palmer explains that its “instrument 100 can provide for accurate and repeatable placement.” Ex.1009, [00139]. A cutting guide like Palmer’s instrument 100 with its distal positioning tab 112 would therefore make cutting predictable and repeatable, simplifying and shortening the procedure. Ex.1003, ¶124.

Moreover, using a cutting guide like Palmer’s would specifically reduce the risk of delayed unions, non-unions, and malunions, which occur when the bones do not fuse or fuse in an undesirable manner. Ex.1003, ¶125. The prior art confirms that cutting guides were used in metatarsal-cuneiform fusion procedures to “easily and effectively achiev[ing] a union through biological healing.” Ex.1015, [0068]. Palmer’s cutting guide, with its joint plate and guide feature, promotes effective unions by “form[ing] a substantially planar prepared bone surface.” Ex.1009, [0031], [0042]. Using such a guide would have been nothing more than the use of a known technique to solve a known problem using prior art elements according to their established functions. Ex.1003, ¶126; *NuVasive, Inc. v. Hirshfeld*, 2021 WL 3661208, at \*4-5 (Fed. Cir. Aug. 18, 2021) (using known nerve-monitoring technology to avoid known surgical complication was nothing “more than the predictable use of prior art elements according to their established functions”); *see also Intel Corp. v. PACT XPP Schweiz AG*, 61 F.4th 1373, 1380 (Fed. Cir. 2023);

*KSR Intern. Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007) (claims are obvious if they apply “a known technique to a piece of prior art ready for the improvement”).

It would have been obvious to use a cutting guide like Palmer’s because doing so would apply a known technique to improve a similar method in the same way. Ex.1003, ¶127; *KSR*, 550 U.S. at 417. As explained, Palmer improves resection using a cutting guide that precisely defines cuts. A POSA would have looked to such cutting guides to improve Dayton’s procedure. Ex.1003, ¶127. Dayton and Palmer address the same metatarsal-cuneiform joint (Ex.1005, 349; Ex.1009, [00138]), and Palmer discloses that the distal abutment surface 114 of the distal positioning tab 112 can abut a distal surface of the medial cuneiform, including when positioned between the first metatarsal and cuneiform (Ex.1009, [00138]). This confirms that Palmer’s cutting guide is directly applicable to Dayton’s metatarsal-cuneiform joint. Ex.1003, ¶127.

A POSA would have had a reasonable expectation of success in using a cutting guide like Palmer’s. *Id.*, ¶128. Dayton’s cutting steps would benefit from such a cutting guide, and incorporating the cutting guide with the joint plate and guide feature would not change the device’s operational principles. *Id.* Palmer discloses inserting the joint plate into the metatarsal-cuneiform joint to align the device for subsequent cutting of a target bone like the first metatarsal or cuneiform. *Id.*; see also Ex.1009, [00162].

Modifications to dimensions or feature spacing, such as for accommodating smaller/larger feet, would have been within the POSA’s ordinary skill. Ex.1003, ¶129. The cutting guide would also operate compatibly with the positioning device, as a POSA would arrange the instruments to permit their use without interference. *Id.*, ¶130.

#### **4. Limitation 1[c]**

This limitation recites “using the guide feature of the bone cutting guide to guide a cutting tool to cut a leading edge of the first metatarsal.” The combination renders the limitation obvious. Ex.1003, ¶¶131-136.

As explained for limitation 1[b], Dayton’s procedure prepares the metatarsal-cuneiform joint for arthrodesis by resecting/cutting the opposing joint surfaces, including a “first metatarsal cut.” Ex.1005, 349; *supra* §VIII.A.3; Ex.1003, ¶132; *see also* Ex.1011, 8, 324, 803, 806-808; Ex.1010, [0039]. This metatarsal resection/cutting involves cutting the first metatarsal’s “leading edge.” Ex.1003, ¶132. Further, a POSA would understand that performing Dayton’s disclosed resections/cuts necessarily involves use of a cutting tool. *Id.*

Palmer similarly discloses its cutting guide’s “resection slot 120 can be utilized to resect a distal portion of the target bone.” Ex.1009, [00140]; *see also id.*, [0042], [00166], claim 21; *see also* Ex.1011, 382. Palmer’s “resection slot” is formed by the cutting guide’s guide feature (*supra* §VIII.A.3): by its disclosed use—

being “utilized” to perform the resection—the slot necessarily constrains and directs a cutting tool that performs resection through the slot. Ex.1003, ¶133. Palmer explains that its discussion of “first” and “second” target bones (exemplified as first cuneiform and metatarsal) is not limiting, and those terms may refer to “any other bone that includes similar features, positioning, orientation, function or the like.” *Id.*, [00162]. Thus, a POSA would have understood Palmer’s guide feature as applicable to bone resections at the fusion interface including the first metatarsal resection (Palmer’s “second target bone”). Ex.1003, ¶134.

A POSA would have been motivated to use the guide feature like Palmer’s to guide the cutting tool while performing Dayton’s first-metatarsal cut, thereby guiding the cutting tool to cut the metatarsal portion at the interface (the “leading edge”). Ex.1003, ¶135. This cutting tool satisfies the “cutting tool” limitation under its plain meaning discussed in Section V.C; and if §112(f) were applied, the tool is corresponding structure (or an equivalent) to the saw described in the ’941 patent. *Id.*, ¶136.

Accordingly, the combination renders obvious using the cutting guide’s guide feature to guide a cutting tool to cut a leading edge of the first metatarsal. *Id.*, ¶131.

## **5. Limitation 1[d]**

This limitation recites “using the bone positioning device to adjust an alignment of the first metatarsal in multiple planes to correct a bunion.” The combination renders the limitation obvious. Ex.1003, ¶¶137-141.

Dayton discloses repositioning the first metatarsal relative to the first cuneiform, as explained for claim 1’s preamble. *Supra* §VIII.A.1. Dayton further explains that HAV (bunion) deformity is “triplane” and that “each of these planes should be addressed in the corrective operation,” and describes “triplane correction” at the metatarsal-cuneiform joint. Ex.1005, 353. Dayton identifies the planes of correction (transverse, sagittal, and frontal) and “reduction that resulted from attention to frontal plane rotational correction in addition to transverse plane and sagittal plane correction.” *Id.*, 348. Dayton confirms multi-planar alignment adjustment is performed on the first metatarsal, describing placement of pins in the first metatarsal and cuneiform to visualize first metatarsal movement. Ex.1005, 349; Ex.1003, ¶139.

As explained for limitation 1[a], it would have been obvious to use a positioning device like Waisman’s to facilitate Dayton’s repositioning and correction. *Supra* §VIII.A.2. Waisman explains its device may perform “compression,” “Clockwise motion,” and “translation.” Ex.1006, 6:7-13; *see also* Ex.1006, 2:30-3:1, 4:25-27. These disclosed motions facilitate using the device to

adjust first metatarsal alignment in multiple planes, as required by Dayton’s triplanar correction. Ex.1003, ¶140.

For the reasons explained for limitations 1[a]-1[b] (*supra* §§VIII.A.2-3), a POSA would have been motivated to use a positioning device like Waisman’s and would have reasonably expected success, including for controlling Dayton’s disclosed triplanar repositioning of the first metatarsal. Ex.1003, ¶141. Thus, in the combination, the positioning device like Waisman’s is used to adjust first metatarsal alignment in multiple planes to correct a bunion, consistent with Dayton’s disclosed triplanar correction of HAV deformity. *Id.*

## **6. Limitation 1[e]**

This limitation recites “compressing the first metatarsal and the first cuneiform together.” The combination renders this limitation obvious. Ex.1003, ¶¶142-145.

Dayton discloses that, after the joint surfaces were resected and the first metatarsal was repositioned, “[t]he fusion site was positioned with the dorsal and medial cortices flush.” Ex.1005, 349. Achieving and maintaining this flush, gap-free fusion interface involves pressing the first metatarsal and cuneiform toward one another across the interface (applying compression) to close the fusion site and maintain contact. Ex.1003, ¶143; *see also* Ex.1016, 466 (“[S]urgeon was able to compress the fusion site and manipulate the base of the first metatarsal[.]”); Ex.1009,

Abstract. Dayton reports that its “final fixation” may include an “anatomic locking plate with compression screw,” further evidencing that compression is applied across the metatarsal-cuneiform fusion site to press the bones together. Ex.1005, 349. Accordingly, Dayton discloses compressing the first metatarsal and cuneiform together.

Such compression would, for example, be achieved using a bone positioning device like Waisman’s. *See* Ex.1006, 6:7-13 (performing holding/fixation possibilities including “compression”); Ex.1003, ¶145.

## **7. Limitation 1[f]**

This limitation recites “fixing a position of the first metatarsal relative to the first cuneiform with a bone connector.” The combination renders the limitation obvious. Ex.1003, ¶¶146-149.

Dayton discloses that, after repositioning the first metatarsal, “[t]he segments were [] temporarily stabilized with smooth wires.” Ex.1005, 349. Dayton further explains that “[t]he final fixation...consisted of multiple methods, including 2 small, flexible, locking plates..., single- and double-screw fixation, and anatomic locking plate with compression screw.” *Id.*

This disclosure satisfies the claimed “bone connector” under its plain and ordinary meaning discussed in Section V.B, as Dayton’s wires, plates, and screws are bone connectors that fix the first metatarsal’s position relative to the first

cuneiform. Ex.1003, ¶148. Under §112(f), these wires, plates, and/or screws are the same types of connector structures identified in the '941 patent (e.g., plate/pin/screw/wire/staple) and thus constitute the corresponding structure (or at least an equivalent) for fixing the first metatarsal's relative position. *Id.*

In the combination, the positioning device is used to manipulate and maintain the first metatarsal relative to the first cuneiform during repositioning, and then Dayton's disclosed wires and/or plates/screws are used to stabilize and maintain the achieved position. *Id.*, ¶149. Thus, Dayton's temporary and final fixation are compatible with (and complementary to) using a positioning device like Waisman's. *Id.*

Therefore, the combination renders claim 1 unpatentable. *Id.*, ¶¶146-149.

**B. Claim 2**

The combination renders claim 2 obvious. Ex.1003, ¶¶150-152.

As explained for limitation 1[f], Dayton expressly discloses a temporary fixation step prior to final fixation. *Supra* §VIII.A.7. Specifically, Dayton describes “[t]he segments were [] temporarily stabilized with smooth wires,” and then describes “final fixation” using plates and/or screws. Ex.1005, 349. Thus, Dayton discloses temporarily fixing the first metatarsal's position relative to the first cuneiform (e.g., with wires) prior to fixing that position with a bone connector (e.g., plates/screws). Ex.1003, ¶151.

Additionally, in the combination, the bone positioning device is used to temporarily hold the first metatarsal relative to the first cuneiform during repositioning before application of Dayton’s temporary wires and/or final fixation, further satisfying the “temporarily fixing...prior to fixing...with the bone connector” sequence. *Id.*, ¶152.

**C. Claim 3**

The combination renders claim 3 obvious. Ex.1003, ¶¶153-154.

As explained for limitation 1[b], Dayton discloses “resection of the articular surfaces” at the metatarsal-cuneiform joint, including resecting/cutting the first cuneiform’s opposing joint surface where it meets the first metatarsal. Ex.1005, 349; *supra* §VIII.A.3. This disclosed cuneiform resection/cutting meets the claim’s cutting-leading-edge limitation. Ex.1003, ¶154.

**D. Claim 4**

The combination renders claim 4 obvious. Ex.1003, ¶¶155-160.

Dayton explains that the surgeon achieves and confirms the intended correction intraoperatively, including clinical and fluoroscopic assessment, and positions the fusion site with the dorsal and medial cortices “flush.” Ex.1005, 349. Although Dayton’s example performs the “cuneiform cut” before addressing rotation (*id.*), a POSA would have understood that the order of joint-surface preparation (including cuneiform cut) and frontal-plane rotational correction is not

critical to achieving Dayton’s stated objective—congruent, fluoroscopically confirmed reduction and a flush fusion interface (Ex.1003, ¶156).

It would have been an obvious and predictable variation to first use the bone positioning device to adjust the first metatarsal in the intended corrected alignment and then perform the leading-edge cut of the first cuneiform after that alignment is established. Ex.1003, ¶¶156-159. Finalizing the cuneiform cut after establishing the intended reduction promotes the “flush” cortices Dayton seeks and reduces the likelihood of recuts or rework that can result if the cut is finalized before the intended alignment is established. *Id.* Consistent with that understanding, 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” (Ex.1001, 5:52-53, 4:66-5:2), confirming that claim 4’s ordering reflects a routine sequencing alternative.

A POSA would have reasonably expected success because Dayton teaches achieving and confirming the desired reduction and then stabilizing the segments to obtain flush cortices at the fusion site; performing the cuneiform cut after establishing the intended reduction is expected to yield the flush apposition Dayton seeks. Ex.1003, ¶160.

**E. Claim 5**

The combination renders claim 5 obvious. Ex.1003, ¶¶161-166. As explained for limitation 1[b] and claim 3, Dayton’s procedure prepares the metatarsal-cuneiform joint by resecting/cutting the opposing joint surfaces, and Dayton expressly identifies a “cuneiform cut.” Ex.1005, 349; *supra* §§VIII.A.3, VIII.C.

As explained for limitations 1[b]-1[c], Palmer discloses a cutting guide having a guide feature (e.g., cutting guide portion structurally defining resection slot) used to guide a cutting tool during resection. *Supra* §§VIII.A.3-4. Palmer explains that an “illustrated embodiment of the guide instrument 100 is particularly well suited for use with the medial or transverse cuneiform bone.” Ex.1009, [00136]; *see also id.*, [00135], [00138]-[00139], [00162].

It would have been obvious to use a cutting guide like Palmer’s and its guide feature to guide the cutting tool while performing Dayton’s disclosed “cuneiform cut” at the metatarsal-cuneiform interface. Ex.1003, ¶164. It would have been a predictable, routine design choice to use the same cutting guide (and its guide feature) to guide the cutting tool during resections of each of the two bones forming the fusion interface—the first metatarsal and cuneiform—rather than requiring separate guides for different bones, because doing so reduces instruments changes and inventory, simplifies operative workflow, and promotes consistent preparation of complementary planar bone surfaces for apposition at the fusion interface. *Id.*,

¶165. A POSA would have had a reasonable expectation of success in doing so because a guide feature like Palmer’s is intended to guide resection to create a prepared surface for fusion with another bone, which is the same objective of the metatarsal-cuneiform joint preparation in Dayton. *Id.*, ¶166.

**F. Claim 6**

The combination renders claim 6 obvious. Ex.1003, ¶¶167-170.

As explained for limitation 1[a], Waisman discloses using fixation pins/K-wires to engage its positioning device with the first metatarsal and cuneiform during reduction/realignment/correction and explains that “[its] invention may be used as temporary...fixation.” Ex.1006, 15:4-5, 4:25-27, 27:7-9; *supra* §VIII.A.2. Waisman further explains that its pins/K-wires are easily removable (e.g., by “just pull[ing] out applying a gentle rotation”). Ex.1006, 7:5.

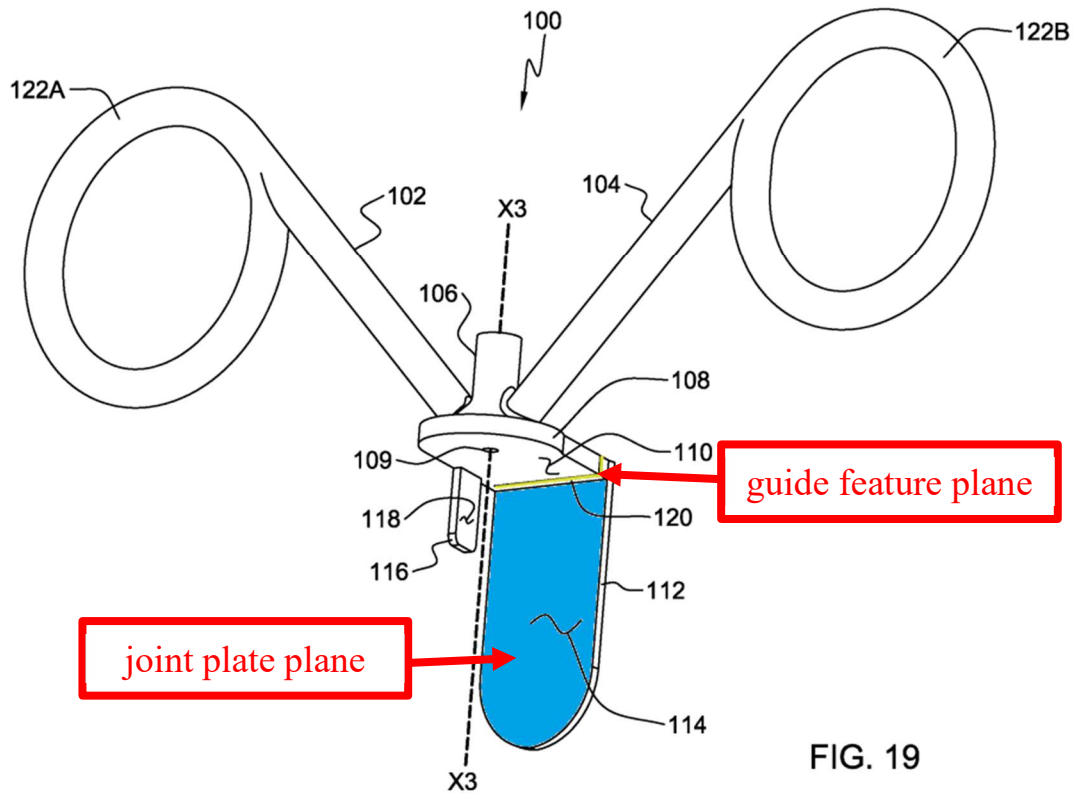
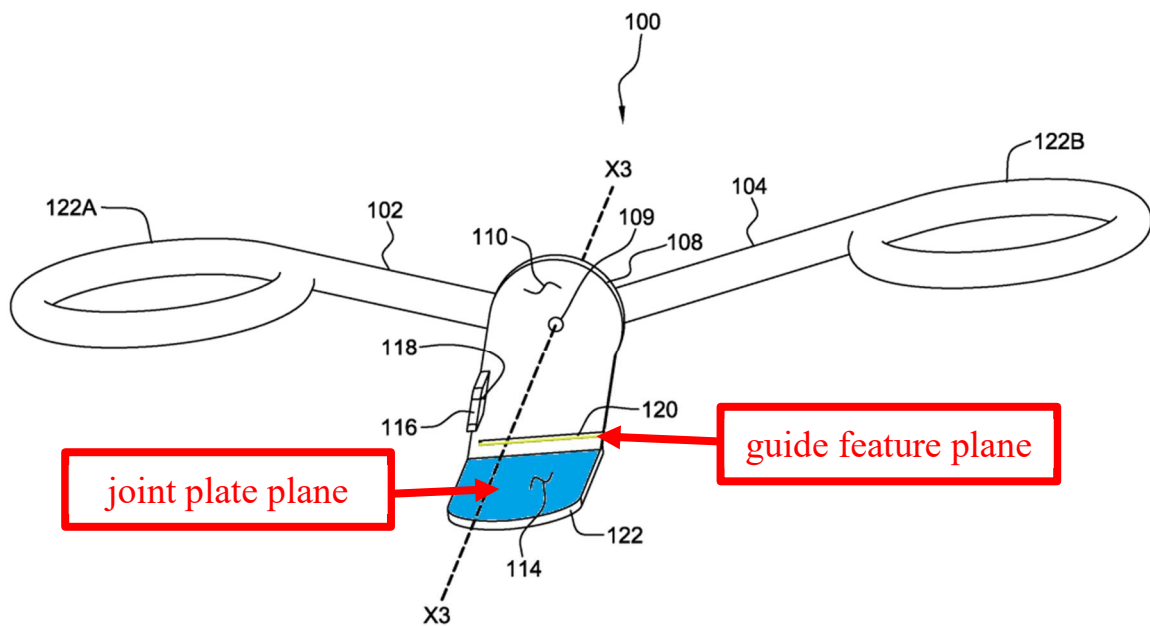
In the combination, fixation pins like Waisman’s are used to achieve and maintain the desired repositioning during the correction steps, as explained for limitations 1[a] and 1[d]. *Supra* §§VIII.A.2, VIII.A.5. After the corrected relationship between the first metatarsal and cuneiform is fixed with the bone connector—e.g., Dayton’s disclosed fixation using wires and/or plates/screws as explained for limitation 1[f] (*supra* §VIII.A.7)—the fixation maintains the corrected alignment independently of the fixation pins. Ex.1003, ¶169. The pins therefore are no longer needed to maintain alignment. *Id.*

It would have been obvious—and consistent with Waisman’s disclosure that the pins are removable and used for temporary fixation—to remove the first and second fixation pins after the position is fixed with the bone connector. *Id.*, ¶170. This is a predictable, routine step because leaving temporary fixation pins in place after fixation would be unnecessary and could interfere with placement or function of the bone connector or leave unnecessary hardware at the operative site. *Id.*

**G. Claim 7**

The combination renders claim 7 obvious. Ex.1003, ¶¶171-172.

Palmer discloses its joint plate (distal positioning tab) “may define a substantially planar member.” Ex.1009, [00137]; *see also id.*, Figs.19-20. A POSA would understand that a “substantially planar” tab defines a plane, and that Palmer’s resection slot—by virtue of its slot walls/slot-defining structure that guides the cutting tool—likewise defines a plane corresponding to the guided cutting direction. Ex.1003, ¶172; Ex.1009, Figs.19-20, [00140]. Consistent with the configuration shown in Palmer’s Figures 19-20, it would have been obvious to orient the slot-defined cutting plane (yellow below) parallel to the tab-defined plane (blue below) so that the guided resection is aligned to the reference plane established by the tab, yielding predictable and repeatable planar bone preparation. Ex.1003, ¶172.

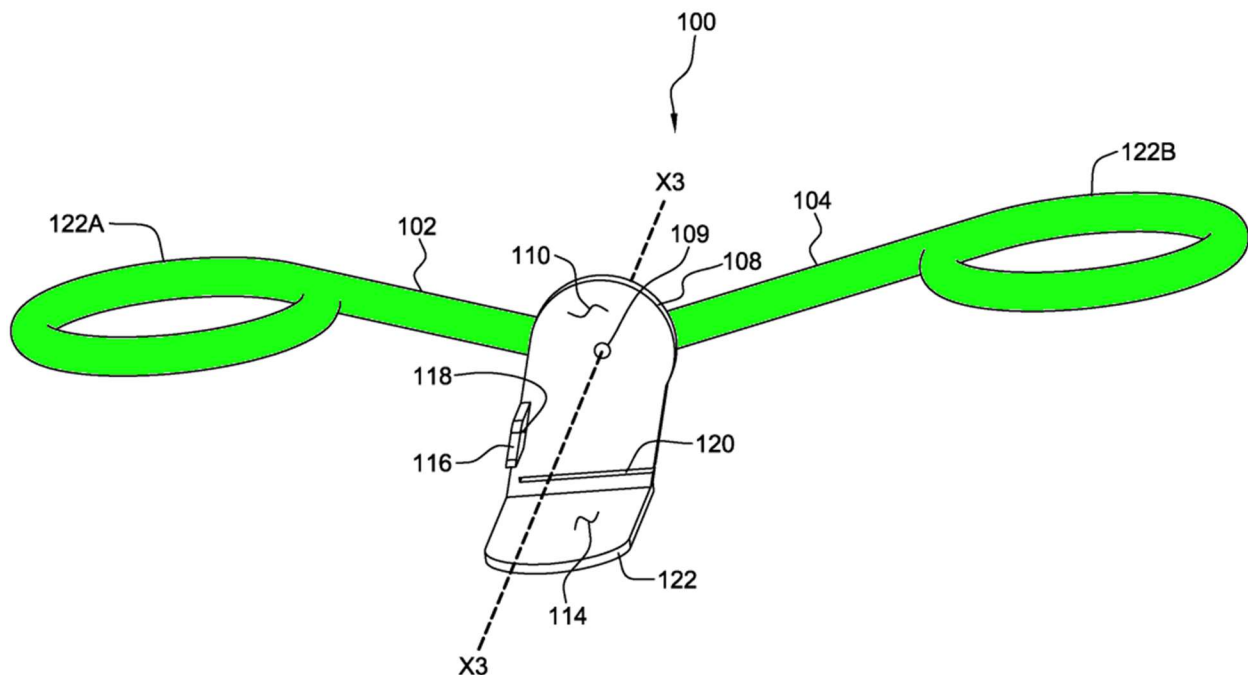


Ex.1009, Figs.19-20; Ex.1003, ¶172.

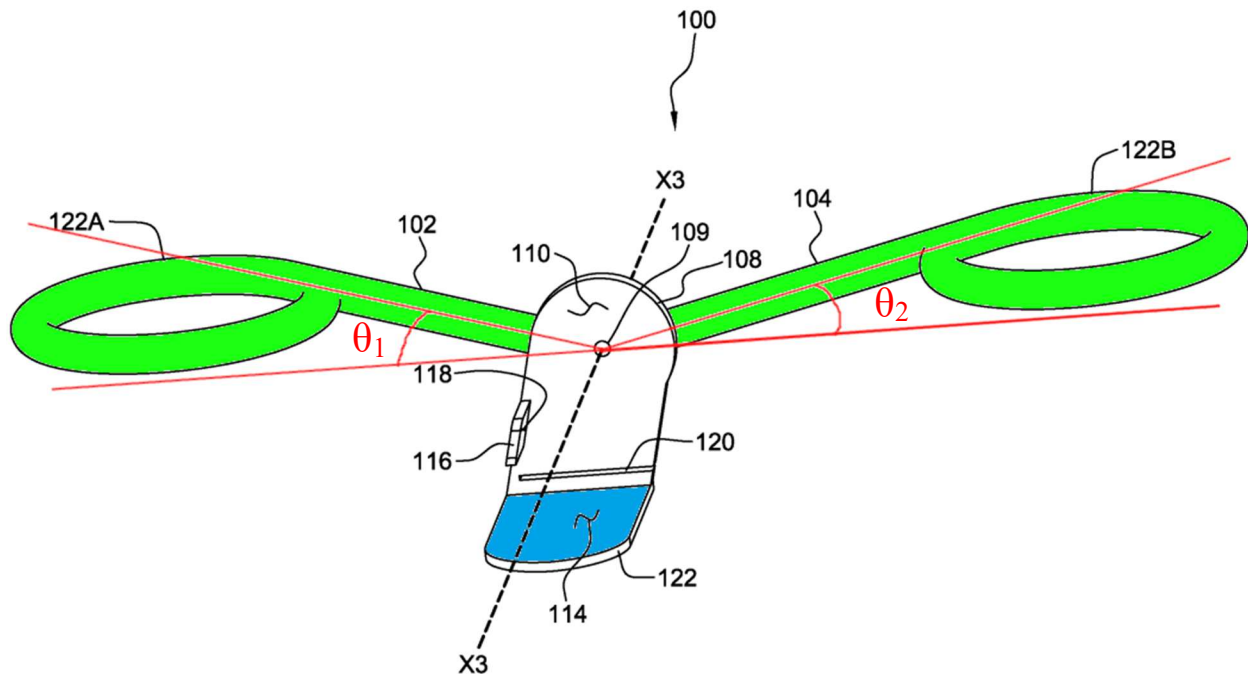
## H. Claim 8

The combination renders claim 8 obvious. Ex.1003, ¶¶173-177.

Palmer discloses its guide having first and second arms 102, 104 that terminate in manually engageable members 122A, 122B (green), which function as a handle for guide manipulation. Ex.1009, [00131].



Ex.1009, Fig.20. Palmer’s arms extend “vertically” from the guide’s top surface—away from the body/joint-plate rather than remaining coplanar with it. *Id.*; *see also id.*, [00137]. In Palmer’s illustration, the members 122A, 122B do not extend parallel to one another, but instead extend away from a line parallel to the joint plate (blue) by acute “away” angles ( $\theta_1$ ,  $\theta_2$ ):



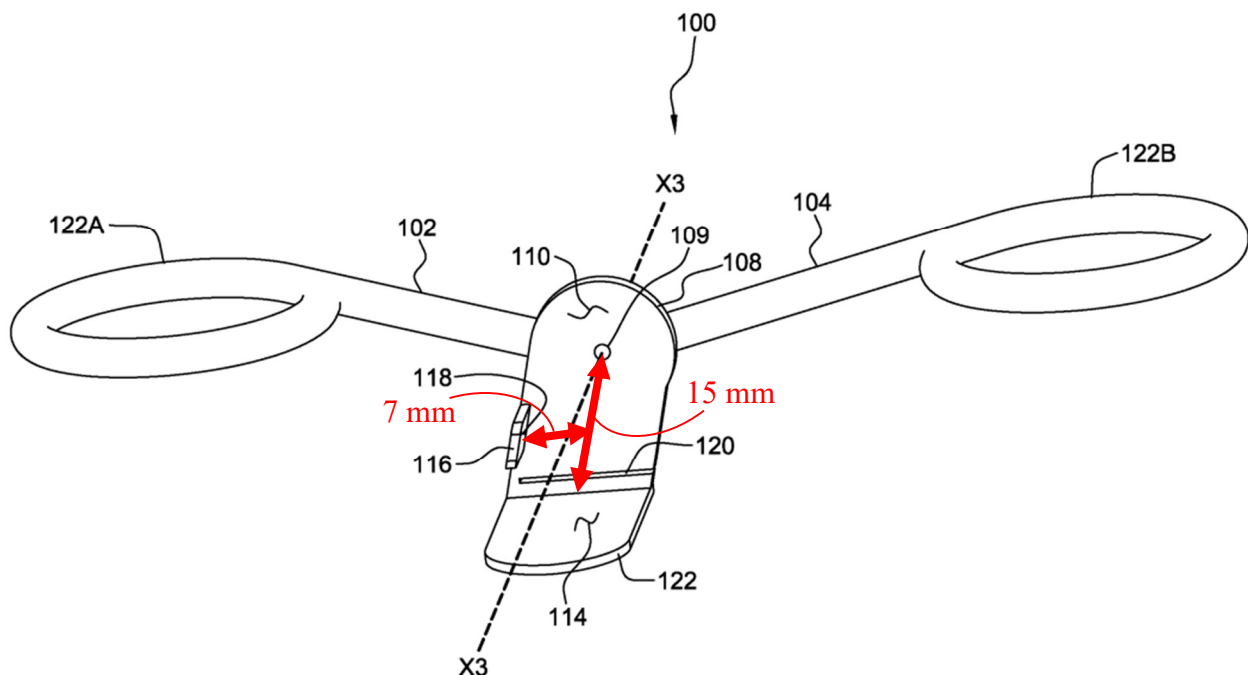
Ex.1003, ¶175 (annotating Ex.1009, Fig.20).

Selecting an acute handle-extension angle ( $\theta_1/\theta_2$ ) within the claimed 30°-60° range would have been an obvious design choice. *Id.*, ¶176. A POSA would have viewed the handle angle relative to the joint-plate plane as a routine ergonomic/clearance parameter chosen to improve access, visibility, and control while reducing interference—without altering the guide’s cutting function. *Id.* The claimed range reflects a finite set of predictable acute-angle configurations balancing access and clearance, and a moderate “away” angle within 30°-60° would predictably preserve or improve access to the resection slot rather than obstruct it. *Id.* A POSA would have had a reasonable expectation of success because selecting an angle within 30°-60° does not change the guiding relationship among the guide feature, cutting tool, and cut plane, but merely relocates the grasp point. *Id.*, ¶177.

**I. Claim 9**

The combination renders claim 9 obvious. Ex.1003, ¶¶178-182.

Palmer discloses that its guide has millimeter-scale geometric offsets between functional locating/abutment features and other structures, including disclosing that “the distal abutment surface 114 of the distal positioning tab 112 is spaced from the longitudinal X3-X3 of the longitudinally extending aperture 109 about 15 millimeters” and “the lateral abutment surface 118 of the lateral positioning tab 116 is spaced from the longitudinal X3-X3 of the longitudinally extending aperture 109 about 7 millimeters” in an illustrative embodiment. Ex.1009, [00136]-[00138].



Ex.1003, ¶179 (annotating Ex.1009, Fig.20). These disclosures confirm Palmer teaches millimeter-scale dimensional offsets (on the order of 1-20 mm) between locating structures and guide structures on the cutting guide. *Id.*, ¶180. Palmer’s

positioning tabs are joint-locating structures that are positioned between adjacent bones at the target joint (e.g., between first cuneiform and metatarsal, or between first and intermediate cuneiform). *Id.* Palmer’s disclosed 15 and 7 mm spacings from the tab abutment surfaces to the X3-X3 axis of aperture 109 exemplify the type of millimeter-scale offset between the joint-inserted locating structure and the guide structure that defines the guiding surface/slot required by claim 9. *Id.*

It would have been obvious to select a lateral spacing between the joint plate that locates the cutting guide at the joint and the guiding surface of the guide feature within the claimed range of 1-20 mm. *Id.*, ¶181. That spacing is a predictable, result-effective design parameter that a POSA would choose based on routine considerations (e.g., anatomical clearance, stable seating of joint plate, allowing cutting tool passage and constraint by guide feature, and achieving intended resection location). *Id.* Where the general conditions are disclosed in the prior art, optimizing workable ranges through routine experimentation is not inventive. *In re Aller*, 220 F.2d 454, 456 (C.C.P.A. 1955). A POSA would have had a reasonable expectation of success because varying the offset or selecting it to be within the claimed millimeter scale range does not change the guide feature’s fundamental guiding function; it positions the guided cut relative to the locating/abutment structure used to position the guide on the bone. Ex.1003, ¶182.

**J. Claim 10**

The combination renders claim 10 obvious. Ex.1003, ¶¶183-185.

Palmer discloses its guide includes a distal positioning tab 112 that may define a “substantially planar member” and “extend[] from the dorsal abutment surface 110 of the base member 108.” Ex.1009, [00137]. Palmer further discloses the same guide may include “a resection slot 120 extending...from a lateral side of the base member.” *Id.*, [00140]. Thus, Palmer describes the distal positioning tab 112 (joint plate) and structure defining the resection slot 120 (guide feature) as portions of the same guide/body, evidencing they are integral with one another. Ex.1003, ¶184. It would have been obvious to use such an integral cutting device like Palmer’s. *Id.*

To the extent Patent Owner contends “integral” requires a particular construction beyond Palmer’s disclosure that both features are portions of the same guide/body, it would have been obvious to implement the distal positioning tab and slot-defining guide feature as integral in the cutting guide. Ex.1003, ¶185. Palmer expressly discloses that “particular aspects or features described or illustrated herein as individual separate components may be combined into an integral unit.” Ex.1009, [00177]. A POSA would have understood this as a predictable implementation choice that maintains rigidity and repeatable cut guidance (and avoids unnecessary interfaces/assembly) while leaving the guiding and positioning functions unchanged.

Ex.1003, ¶185. A POSA would therefore also have had a reasonable expectation of success in implementing the joint plate and guide feature integrally. *Id.*

**K. Claim 11**

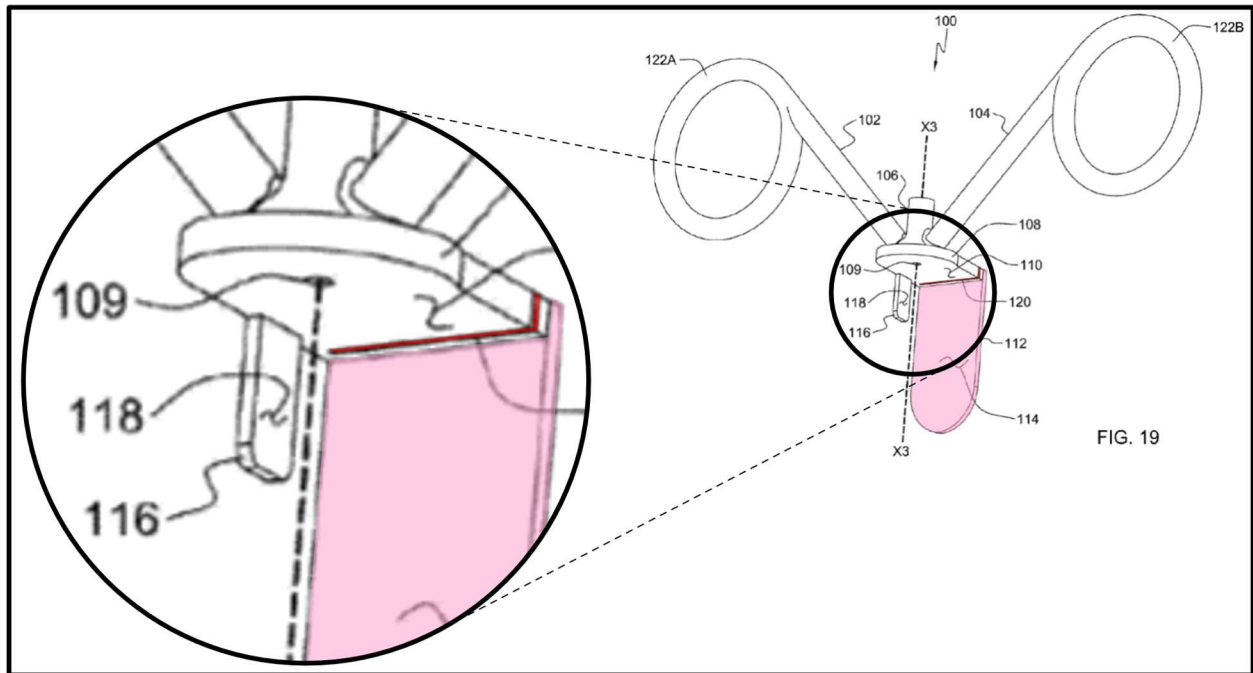
The combination renders claim 11 obvious. Ex.1003, ¶¶186-188.

As explained for limitation 1[c], it would have been obvious to use the cutting guide like Palmer’s—with its guide feature (e.g., resection slot)—to guide the cutting tool while performing Dayton’s first-metatarsal cut. *Supra* §VIII.A.4. In that context, the “guide surface defined by the guide feature” corresponds to a surface that defines the slot and provides the guiding constraint (e.g., interior wall surface forming the slot). Ex.1003, ¶187; *see also* Ex.1009, [00140]; Ex.1011, 382. Using the guide feature to guide the cutting tool therefore comprises placing the cutting tool in apposition to that guide surface (i.e., positioned against the slot’s guiding surface) by positioning the cutting tool through and along the slot such that, as used, the tool is guided by the slot-defining guiding surface with the guide surface constraining and directing the tool’s movement during the resection. Ex.1003, ¶188. This is a routine, predictable manner in which slot-based cutting guides operate and would have been implemented in ordinary course. *Id.*

**L. Claim 12**

The combination renders claim 12 obvious. Ex.1003, ¶¶189-191.

Palmer explains its cutting guide includes the resection slot (red) that “extend[s] in a medial-lateral direction” and is “utilized to resect a distal portion of the target bone.” Ex.1009, [00140].



*Id.*, Fig.19. Because the slot extends in a defined direction and is used to perform a resection, the slot-defining wall surface presents a straight guiding surface over that extent, such that the tool path during resection remains in a plane parallel to that surface. Ex.1003, ¶190.

In the combination, when the cutting tool is placed in apposition to the slot’s guide surface, that surface guides the tool’s movement in a plane parallel to the surface because the tool’s permitted motion during resection is constrained to slide/translate along that surface. *Id.*, ¶191.

**M. Claim 13**

The combination renders claim 13 obvious. Ex.1003, ¶¶192-193.

As explained for claim 11, it would have been obvious to place the cutting tool in apposition to a guide surface defined by the guide feature. *Supra* §VIII.K. Using the guide feature to guide the cutting tool requires the tool to contact that slot-wall guide surface during movement through the slot, thereby constraining and directing the tool along the intended resection path. Ex.1003, ¶193.

**N. Claim 14**

The combination renders claim 14 obvious. Ex.1003, ¶¶194-197.

As explained for limitation 1[c], it would have been obvious to use the cutting guide like Palmer’s—with its guide feature (e.g., resection slot)—to guide the cutting tool while performing Dayton’s first-metatarsal cut. *Supra* §VIII.A.4. A saw blade is a conventional “cutting tool” for performing controlled planar bone resections of the type described in Dayton and guided by a slot-type guide as described in Palmer. Ex.1003, ¶195; *see also* Ex.1017, 99 (“It is the surgeon’s choice as to joint resection technique, though a saw is commonly used.”); Ex.1011, 382. Using a saw blade with a guide slot is a predictable, routine choice because the flat blade geometry is well-suited to the guide’s planar constraint, enabling repeatable cuts while maintaining the intended resection plane. Ex.1003, ¶196.

In the combination, a POSA would have implemented the guided cutting using a saw blade, with a reasonable expectation of success because substituting one known bone-cutting implement (saw blade) for another generic cutting tool does not change the guide’s function and yields the predictable result of a guided resection. *Id.*, ¶197.

**O. Claim 15**

The combination renders claim 15 obvious because, as explained for limitation 1[f], Dayton discloses a bone connector comprising a plate, screw, or pin. *Supra* §VIII.A.7; Ex.1003, ¶¶198-199.

**P. Claim 16**

The combination renders claim 16 obvious. Ex.1003, ¶¶200-204.

As explained for limitation 1[e], it would have been obvious in the combination to compress the first metatarsal and cuneiform together. *Supra* §VIII.A.6. Further, as explained for limitation 1[a], Waisman discloses engaging a positioning device with bones using fixation pins/K-wires and explains its invention may be used as “temporary or final fixation” during reduction/realignment/correction. *Supra* §VIII.A.2. Waisman further discloses its positioning device “may perform” various holding/fixation possibilities, including “compression.” Ex.1006, 6:7-13. Waisman’s compression function thus applies a compressive force through the device to the pins anchored in the bones to drive those

pins toward one another, reducing the inter-bone gap and pressing the bones together. Ex.1003, ¶202.

In the combination, it would have been obvious to use a positioning device like Waisman’s with the first pin inserted into the first metatarsal and the second pin inserted into the first cuneiform not only to achieve/hold Dayton’s corrected alignment, but also—consistent with Waisman’s disclosure of “compression”—to apply a force that presses the metatarsal and cuneiform pins toward one another, compressing the first metatarsal and cuneiform together at the fusion site. *Id.*, ¶203. This is a predictable, routine use of Waisman’s compression capability in Dayton’s procedure because compression across opposing joint surfaces is a known, expected objective at a fusion site, and implementing compression by actuating a pin-based positioning device does not require changes to Dayton’s surgical goal or to Waisman’s disclosed mode of operation. *Id.*, ¶204.

**Q. Claim 17**

The combination renders claim 17 obvious. Ex.1003, ¶¶205-208.

As explained for limitation 1[e], it would have been obvious to compress the first metatarsal and cuneiform together. *Supra* §VIII.A.6. Further, as explained for claim 16, it would have been obvious to use a positioning device like Waisman’s to apply a force pressing the first metatarsal and cuneiform toward one another, compressing them together. *Supra* §VIII.P.

Waisman discloses a positioning device in which fixation pins are secured to “cages,” and the cages are mounted to connecting rods via rod-receiving holes sized to fit the rods, such that the cages can be positioned relative to the rod(s) before being locked/clamped in a selected position. Ex.1006, 16:15-17:8, 20:23-28. Waisman further discloses the cages’ relative positioning on the rods can be maintained by screw(s) (e.g., screws in tapped cage holes) that are tightened to fix (clamp/lock) the cage relative to the rod. *Id.*

It would have been obvious to use a structure like Waisman’s disclosed sliding cage/rod interface together with its disclosed screw-based locking to implement compression across Dayton’s metatarsal-cuneiform fusion site. Ex.1003, ¶208. A POSA would achieve the desired “compression” identified by Waisman by (i) sliding one or both cages along the rod(s) to reduce the spacing between the bone-anchored pins (thereby bringing the first metatarsal and cuneiform together) and then (ii) operating the screw (e.g., tightening the cage lock screw) to lock the cage(s) and thereby maintain the compressive force at the fusion site while fixation completes. *Id.* This meets the requirement that “compressing...comprises operating the screw” because the compression step in Waisman’s screw/slide mechanism is carried out by setting the cage position via the slidable connection and then operating the screw to secure the compression-setting configuration. *Id.* This is a predictable, routine use of Waisman’s screw-actuated locking of a slidable connection to achieve and

maintain compression for Dayton’s procedure, with a reasonable expectation of success. *Id.*

**R. Claim 18**

**1. Preamble and Limitations 18[a]-18[d]**

For reasons explained for claim 1’s preamble and 1[a]-1[d], the combination renders claim 18’s preamble and limitations 18[a]-18[d] obvious. *Supra* §§VIII.A.1-5; Ex.1003, ¶¶210-214.

**2. Limitation 18[e]**

For reasons explained for claims 3-4, the combination renders limitation 18[e] obvious. *Supra* §§VIII.C-D; Ex.1003, ¶215.

**3. Limitations 18[f]-18[g]**

For reasons explained for limitations 1[e]-1[f], the combination renders limitations 18[f]-18[g] obvious. *Supra* §§VIII.A.6-7; Ex.1003, ¶¶216-217.

Therefore, the combination renders claim 18 unpatentable. *Id.*, ¶¶209-217.

**S. Claims 19-27**

For reasons explained for claims 2, 6, 5, 7, 8, 12, 15, 16, and 17 in this ground, respectively, the combination renders claims 19-27 obvious. *Supra* §§VIII.B, VIII.E-H, VIII.L, VIII.O-Q; Ex.1003, ¶¶218-226.

**IX. GROUND 3: CLAIMS 1-27 ARE OBVIOUS BASED ON DAYTON,  
TAYLOR, AND PALMER**

A POSA would have substituted a positioning device like Taylor’s for one like Waisman’s in the Ground 2 combination. Ex.1003, ¶227. Taylor, like Waisman, provides positioning-device disclosures that satisfy the positioning-device claim limitations, and substituting Taylor for Waisman in the combination likewise renders claims 1-27 unpatentable. *Id.*, ¶¶227-260.

The 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.

**A. Claim 1**

**1. Preamble**

To the extent the preamble is limiting, Dayton discloses it for the reasons explained in Ground 2. *Supra* §VIII.A.1; Ex.1003, ¶228.

**2. Limitation 1[a]**

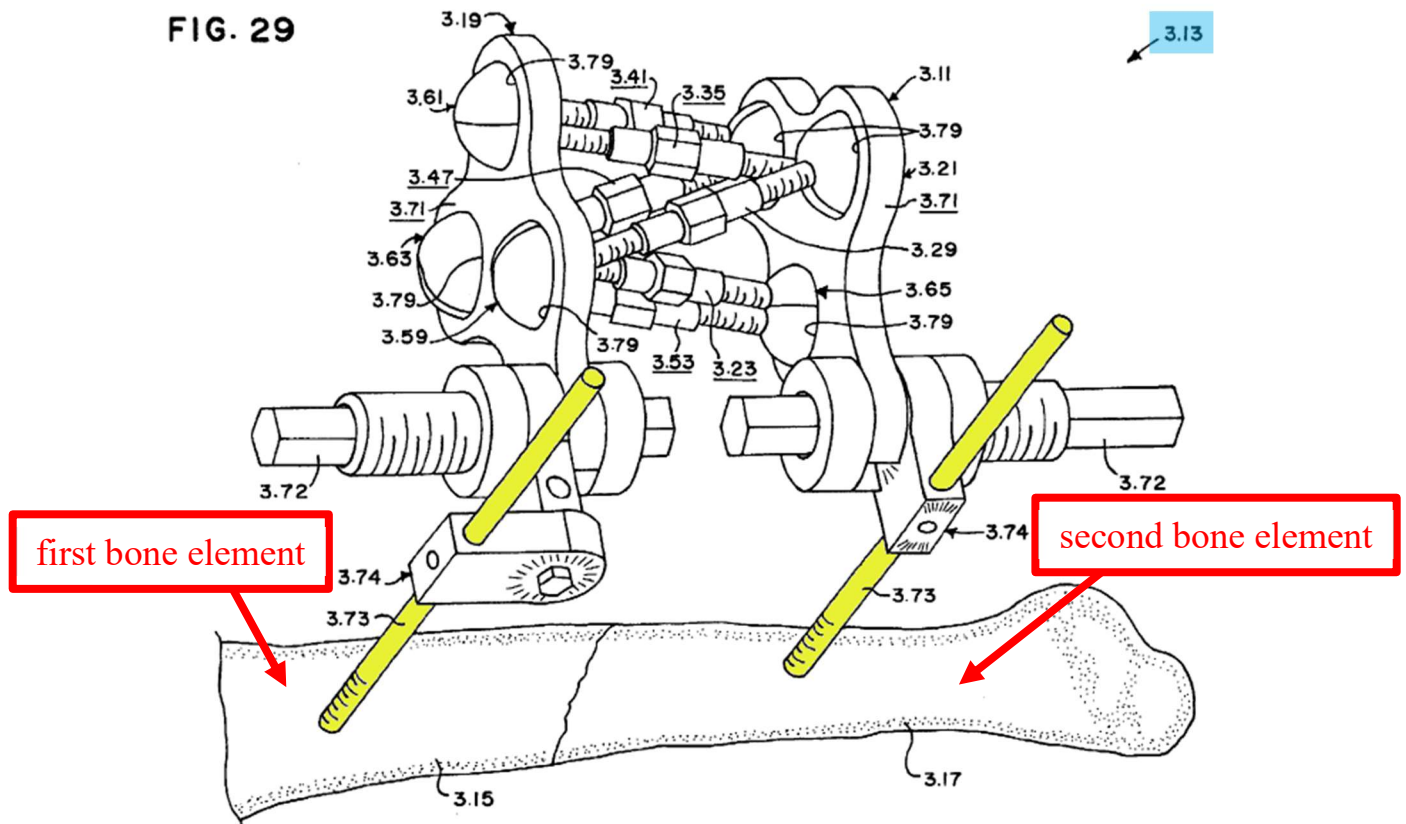
The combination renders this limitation obvious. Ex.1003, ¶¶229-238.

It would have been obvious to use a bone positioning device like Taylor’s in Dayton’s procedure to facilitate bone repositioning. Ex.1003, ¶¶231-238. Taylor explains “[i]t is often necessary to realign, reposition and/or securely hold two elements relative to one another,” and that “bone fragments and the like must sometimes be aligned or realigned and repositioned to restore boney continuity and

skeletal function.” Ex.1007, 1:17-24. Taylor thus discloses a device that “can move one fragment with respect to the other in six orthogonal degrees of freedom, a combination of three orthogonal translational axes (e.g., typical ‘X,’ ‘Y’ and ‘Z’ axes) and three orthogonal rotational axes (e.g., rotation about such typical ‘X,’ ‘Y’ and ‘Z’ axes).” *Id.*, 5:26-33; *see also id.*, 5:52-58 (explaining its device provides “a mechanism for producing a prescribed relative change in position between two bone fragments in conjunction with external fixation of the bone fragments for correction of angular and translational displacements of acutely fractured fragments, correction of angular and translational deformities in nonunion and malunion, etc.”).

Taylor illustrates one such device 3.13 (blue) engaging a first bone element 3.15 with a pin 3.73 (yellow) and a second bone element 3.17 with a pin 3.73 (yellow):

FIG. 29



*Id.*, Fig.29; *see also id.*, 18:56-19:52, Fig.28 (illustrating similar structure), 17:60-18:55. The device's spatial frame 3.11 spans the space between the engaged bone elements and provides a mechanism for controlled relative movement and stabilization between them. *Id.* The device may be “universal” because “it can be used for any situation requiring relative motion between elements including compression (shortening), distraction (lengthening), translation, angulation, or rotation and any combination of such movements.” *Id.*, 5:37-42. The device can “be[] attached to either side of a skeletal joint” (*id.*, 6:54-62), “predictably and reproducibly cause small displacements between bone fragments” (*id.*, 7:58-60), and

“be used in small sizes in situations where space is at a premium, for example, in external fixation of children’s bones” (*id.*, 8:45-48).

A POSA would have been motivated to use a bone positioning device like Taylor’s in Dayton’s procedure and to engage it with a first metatarsal using a first fixation pin and with a first cuneiform using a second fixation pin, such that the positioning device extends across the joint separating the first metatarsal and cuneiform. Ex.1003, ¶233. Such engagement would permit using the positioning device to achieve bone repositioning and stabilizing during Dayton’s procedure. *Id.* This satisfies “bone positioning device” under the plain and ordinary meaning, as the structure positions bones in multiple planes. *Id.*, ¶234. Under §112(f), this positioning device is identical or at least equivalent to structures identified in the ’941 patent for the claimed bone positioning device discussed in Section V.A. *Id.* The positioning device is at least an equivalent of the disclosed bone-positioning structures (multi-axis joint with ball-and-socket ends) because it performs the same function (adjusts first metatarsal alignment in multiple planes), in substantially the same way (split-ball joints in spherical cavities), to achieve the same result (move and hold bones in intended position). *Id.*

Taylor discloses a device for repositioning one bone relative to another, uses pins held by an adjustable spatial frame, and is used in small sizes (Ex.1007, 5:26-33, 18:56-19:52, 8:45-48), the same operative scale and environment as Dayton’s

procedure. Ex.1003, ¶¶232, 238. Combining elements from Dayton and Taylor according to their known functions would have predictably yielded the expected benefit: instead of pins serving primarily as visual references for manual manipulation (Ex.1005, 349), a POSA would have been motivated to place the pins in the first metatarsal and cuneiform to couple them to a known external device to provide controlled, maintainable correction. Ex.1003, ¶235.

The combination represents a straightforward modification. *Id.*, ¶236. Taylor discloses a device “securely attached to the bone fragments with skeletal pins or wires” (Ex.1007, 20:54-56), exactly the type of known apparatus a POSA would select when the problem is adjusting and maintaining relative alignment between adjacent bones during corrective surgery (Ex.1003, ¶236). A POSA would have been motivated to incorporate external fixation engagement like Taylor’s in Dayton’s procedure because the repositioning device predictability provides improved control and stability of the achieved alignment compared to manual manipulation without changing Dayton’s goals or strategy. Ex.1003, ¶236. That Taylor’s device is described as an external fixation does not undermine the combination. Taylor discloses known multi-axis repositioning and stabilization mechanics, which a POSA would have predictably used intraoperatively and temporarily to achieve/hold Dayton’s triplanar correction before Dayton’s separate final fixation. *Id.*

A POSA would have recognized the combination as using a known fixation-and-adjustment technique to improve a similar method. *Id.*, ¶237. Taylor’s device provides the same degrees of freedom (Ex.1007, 5:37-42) a surgeon uses to correct triplanar deformity (Ex.1003, ¶237). Engaging a device like Taylor’s with pins in the first metatarsal and cunieform in Dayton’s procedure would have predictably improved intraoperative precision and retention compared to freehand manipulation by providing controlled movement and stable maintenance of corrected alignment. Ex.1003, ¶237.

A POSA would have had a reasonable expectation of success because the modification stays within the references’ disclosures and relies on predictable mechanics. *Id.*, ¶238; *see also* Ex.1006, 26:21-24. Engaging a device like Taylor’s with metatarsal and cuneiform pins would have provided controlled repositioning and stable maintenance of the corrected alignment. Ex.1003, ¶238. Taylor discloses “reposition[ing] any two bodies relative to each other” (Ex.1007, 6:31-33) and constructing components in “various shapes and sizes” (Ex.1007, 19:24-26), supporting use at Dayton’s operative scale. Ex.1003, ¶238. Because the same pin-coupled mechanics are used to move and hold bone segments, a POSA would have reasonably expected Taylor’s adjustment framework to operate successfully in Dayton’s procedure at the time of correction. *Id.*

**3. Limitation 1[b]**

The combination renders this limitation obvious for the reasons given in Ground 2: a POSA would use a cutting guide like Palmer's in Dayton's procedure (with Taylor substituted for Waisman) and align it with the metatarsal-cuneiform joint. *Supra* §VIII.A.3; Ex.1003, ¶¶239-240. The guide includes a joint plate/tab offset from the resection-slot guide feature, extending downward and inserted into the joint during the alignment. Ex.1003, ¶240. Taylor's substitution would not change motivation or expectation of success. *Id.*

**4. Limitation 1[c]**

The combination renders this limitation obvious for the reasons explained in Ground 2. *Supra* §VIII.A.4; Ex.1003, ¶241. Taylor's substitution would not change motivation or expectation of success. Ex.1003, ¶241.

**5. Limitation 1[d]**

The combination renders this limitation obvious. Ex.1003, ¶¶242-243.

As explained for limitations 1[a]-1[b] in this ground, it would have been obvious to use a positioning device like Taylor's to facilitate Dayton's manual repositioning and correction. *Supra* §§VIII.A.2-3. Taylor discloses multi-axis relative motion like compression, translation, and rotation (Ex.1007, 5:37-42) corresponding to multi-plane adjustments required for Dayton's triplanar correction.

Ex.1003, ¶243. Taylor further explains that such controlled positioning may precede stabilization. Ex.1007, 5:4-9.

For the same reasons, a POSA would have been motivated to use a positioning device like Taylor’s to control triplanar repositioning of the first metatarsal and would have reasonably expected success. Ex.1003, ¶243. Thus, the positioning device adjusts the first metatarsal in multiple planes consistent with Dayton’s HAV correction. *Id.*

**6. Limitation 1[e]**

The combination renders this limitation obvious for the reasons explained in Ground 2. *Supra* §VIII.A.6; Ex.1003, ¶244. Taylor’s substitution would not change motivation or expectation of success. Ex.1003, ¶244. Moreover, such compression would, for example, be achieved using a bone positioning device like Taylor’s. *See* Ex.1007, 5:37-42 (relative motion including “compression (shortening)”; Ex.1003, ¶244.

**7. Limitation 1[f]**

The combination renders this limitation obvious for the reasons explained in Ground 2. *Supra* §VIII.A.7; Ex.1003, ¶245. Taylor’s substitution would not change motivation or expectation of success. Ex.1003, ¶245. Dayton’s fixation steps remain compatible. *Id.*

Claim 1 is therefore unpatentable. *Id.*, ¶¶228-245.

**B. Claims 2-5**

These claims are obvious for the reasons explained in Ground 2. *Supra* §§VIII.B-E; Ex.1003, ¶246. Taylor’s substitution would not change motivation or expectation of success. Ex.1003, ¶246.

**C. Claim 6**

The combination renders claim 6 obvious. Ex.1003, ¶¶247-248.

As explained for limitations 1[a] and 1[d] in this ground, Taylor discloses using pins to engage its positioning device with the first and second bone elements (Ex.1007, 20:54-56) and that, after controlled positioning is performed, the device may be “replaced by other means of stabilization” (Ex.1007, 5:4-9). *Supra* §§IX.A.2, IX.A.5. In the combination, pins are used to achieve and maintain the desired repositioning during correction, and once the corrected metatarsal-cuneiform relationship is fixed with the bone connector (e.g., Dayton’s wires/plates/screws as explained for limitation 1[f] in this ground (*supra* §IX.A.7)), that fixation maintains alignment independently of the pins. Ex.1003, ¶248.

Accordingly, a POSA would have removed the first and second fixation pins after fixation with the bone connector, consistent with Taylor’s disclosure and as a predictable, routine step—leaving temporary pins in place would be unnecessary and could interfere with connector placement/function or leave unnecessary hardware at the operative site. *Id.*, ¶248.

**D. Claims 7-15**

These claims are obvious for the reasons explained in Ground 2. *Supra* §§VIII.G-O; Ex.1003, ¶249. Taylor’s substitution would not change motivation or expectation of success. Ex.1003, ¶249.

**E. Claim 16**

The combination renders claim 16 obvious. Ex.1003, ¶¶250-252.

As explained for limitation 1[a] in this ground, Taylor discloses engaging a pin-based positioning device with bone elements and explains relative motion including “compression (shortening).” *Supra* §IX.A.2; Ex.1007, 5:37-42. A POSA would understand Taylor’s compression to apply force through the device to the bone-anchor pins, drawing the pins toward one another and thereby reducing the inter-bone gap and pressing the bones together. Ex.1003, ¶251.

Accordingly, it would have been obvious to use the positioning device like Taylor’s with the first pin in the first metatarsal and the second pin in the first cuneiform to hold Dayton’s correction and apply compressive force that presses the pins (and thus the metatarsal and cuneiform). *Id.*, ¶252. This is a predictable, routine use of disclosed compression capability like Taylor’s in Dayton’s procedure because compression across opposing joint surfaces is a known objective at a fusion site and uses the device according to its intended function without changing Dayton’s surgical goal or Taylor’s mode of operation. *Id.*

**F. Claim 17**

The combination renders claim 17 obvious. Ex.1003, ¶¶253-256.

As explained for limitation 1[e] and claim 16 in this ground, it would have been obvious to compress the first metatarsal and cuneiform using a positioning device like Taylor's. *Supra* §§IX.A.6, IX.E. Taylor achieves "compression (shortening)" by changing struts (Ex.1007, 5:21-25, 5:37-42), including with a screw-based strut adjuster (*id.*, 6:1-9 ("screw and nut" configuration)) in which operating (e.g., rotating) a threaded coupling produces axial sliding/translation of rod components to change (including shorten) strut length. Ex.1003, ¶254; *see also* Ex.1007, 10:64-12:7, 18:39-49, 19:36-46. That axial translation is a sliding connection between rod components and the coupling, and the threaded coupling functions as a screw that drives the sliding movement. Ex.1003, ¶254.

It would have been obvious to use a structure like Taylor's screw-actuated, axially slidable strut structure to compress Dayton's metatarsal-cuneiform fusion site by operating the screw to shorten the strut and draw the bone-mounted components together, thereby applying and maintaining compression. Ex.1003, ¶255. This meets the requirement that "compressing...comprises operating the screw" because the positioning device includes a sliding connection and screw, and the compression step is carried out by operating the screw to produce the sliding

movement that shortens the strut and generates compression. *Id.*, ¶256. This is a predictable, routine use with a reasonable expectation of success. *Id.*

**G. Claim 18**

**1. Preamble and Limitations 18[a]-18[d]**

For reasons explained for claim 1's preamble and limitations 1[a]-1[d] in this ground, claim 18's preamble and limitations 18[a]-18[d] are obvious. *Supra* §§IX.A.1-5; Ex.1003, ¶257.

**2. Limitation 18[e]**

For reasons explained for claims 3-4 in this ground, this limitation is obvious. *Supra* §IX.B; Ex.1003, ¶258.

**3. Limitations 18[f]-18[g]**

For reasons explained for limitations 1[e]-1[f] in this ground, limitations 18[f]-18[g] are obvious. *Supra* §§IX.A.6-7; Ex.1003, ¶259.

Therefore, claim 18 is unpatentable. *Id.*, ¶¶257-259.

**H. Claims 19-27**

For reasons explained for claims 2, 6, 5, 7, 8, 12, 15, 16, and 17 in this ground, respectively, the combination renders claims 19-27 obvious. *Supra* §§IX.B-F; Ex.1003, ¶260.

**X. GROUND 4: CLAIMS 1-27 ARE OBVIOUS BASED ON DAYTON, ORSAK, AND PALMER**

A POSA would have substituted a positioning device like Orsak’s for one like Waisman’s in the Ground 2 combination. Ex.1003, ¶261. Orsak, like Waisman, provides positioning-device disclosures that satisfy the positioning-device claim limitations, and substituting Orsak for Waisman in the combination likewise renders claims 1-27 unpatentable. *Id.*, ¶¶261-304.

The 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.

**A. Claim 1**

**1. Preamble**

To the extent the preamble is limiting, Dayton discloses it for the reasons explained in Ground 2. *Supra* §VIII.A.1; Ex.1003, ¶262.

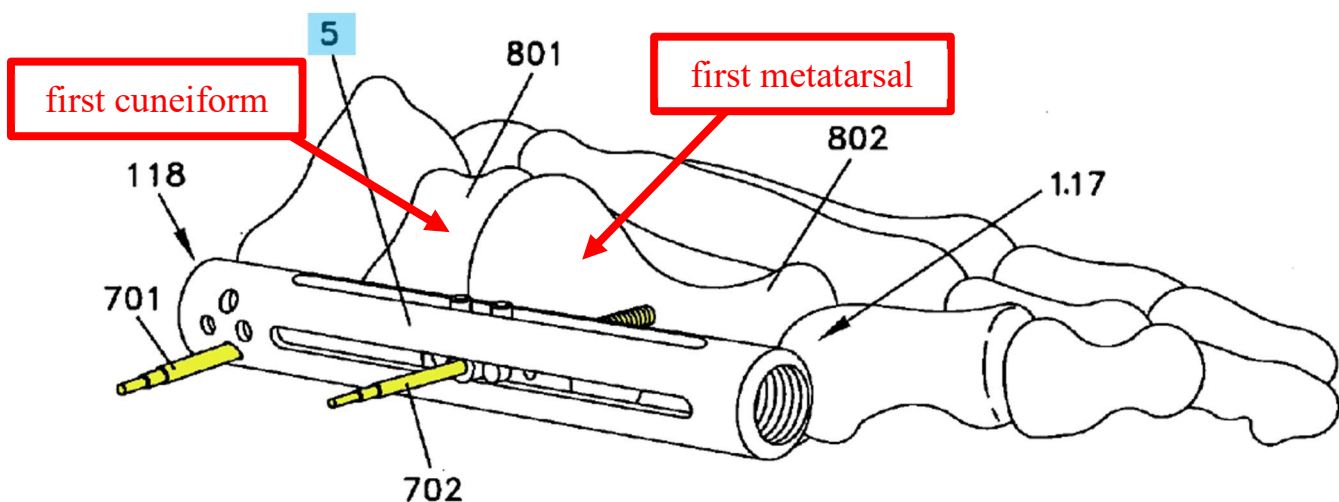
**2. Limitation 1[a]**

The combination renders this limitation obvious. Ex.1003, ¶¶263-274.

It would have been obvious to use a bone positioning device like Orsak’s in Dayton’s procedure to facilitate bone repositioning. Ex.1003, ¶264. Orsak explains “[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, [0003]. Orsak

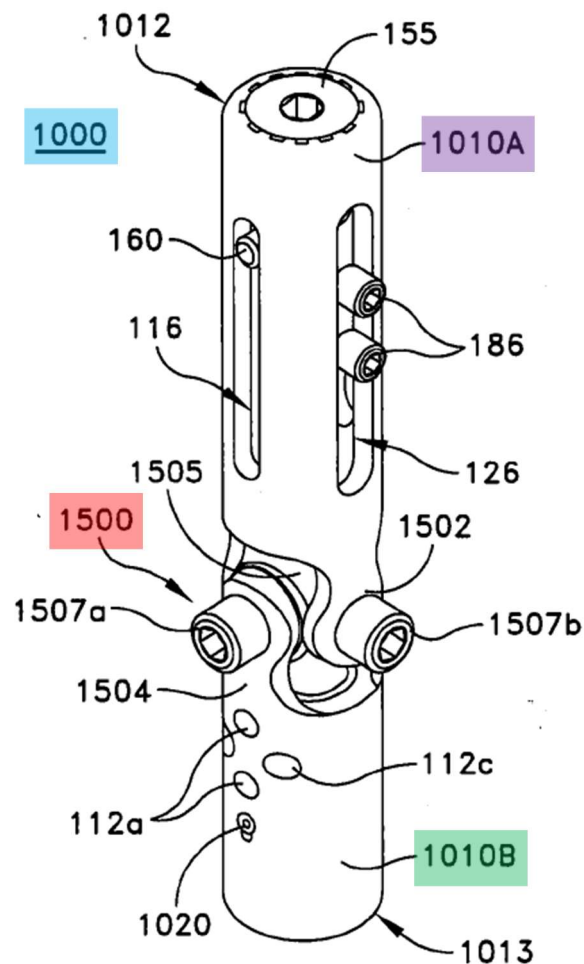
thus discloses “an external fixator device for fixating bone parts,” including “in treating...osteotomies” (*id.*, [0005]), which refer to surgical procedures where a bone is cut (Ex.1003, ¶265).

Orsak describes “placing a first fixation pin into a first bone piece [and] placing an external fixator over the first fixation pin by having the fixation pin go through a pin hole provided at one end of the external fixator’s elongated body.” Ex.1008, [0009]; *see also id.*, [0084]. Orsak explains the “elongated body’s second end is then positioned over a second bone piece,” and “a second fixation pin is inserted through a pin hole provided in the pin-holder [within the elongated body] and into the second bone piece.” *Id.*, *see also id.*, [0130]-[0131], claims 1, 7. Orsak illustrates a fixator 5 (blue) engaged with the first metatarsal and the first cuneiform using fixation pins (yellow) and extending across the joint separating those bones:



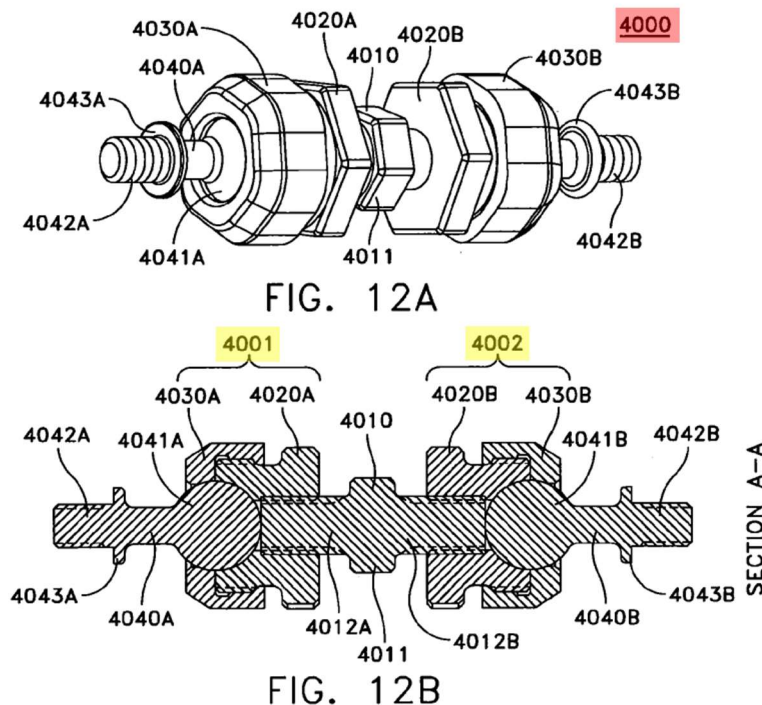
*Id.*, Fig.5C; Ex.1003, ¶267; *see also id.*, Fig.5A (showing fixation pin 801 inserted into first cuneiform), [0088]-[0089].

Orsak's fixator facilitates bone movement in multiple axes. For example, Orsak describes a fixator 1000 (blue) "includ[ing] a first portion 1010A [purple] and a second portion 1010B [green] that are linked by a universal joint 1500 [red]":



*Id.*, Fig.8A, [0094]. "[T]he universal joint 1500 allows the two portions 1010A and 1010B of the fixator body to be set at any desired angle, which in turn allows the fixation pins held in each of the two portions 1010A and 1010B of the fixator body

to be arranged into a variety of angular configurations.” *Id.*, [0094]. “Similar to the external fixator 5, a set of fixation pins can be held in the first portion 1010A of the external fixator 1000 through the pin holes 142 in the pin-holder 143 and another set of fixation pins can be held in the second portion 1010B of the external fixator 1000 through the pin holes 112a, 112b, 112c and 112d.” *Id.* In another example, Orsak describes a fixator with a double universal joint, making the “angular adjustability” of its two portions even greater. *Id.*, [0115]; *see also id.*, Figs.11A-11F, 12A-12B, [0109]-[0111], [0116]-[0117]. In yet another example, Orsak describes a joint system (red) that facilitates multiplanar movement with two ball joints (yellow):



Ex.1008, Figs.12A-12B; *see also id.*, [0118]-[0125].

A POSA would have been motivated to use a bone positioning device like Orsak's in Dayton's procedure and to engage it with a first metatarsal using a first fixation pin and with a first cuneiform using a second fixation pin, such that the positioning device extends across the joint separating the first metatarsal and cuneiform. Ex.1003, ¶269. Such engagement would permit using the positioning device to achieve bone repositioning and stabilizing during Dayton's procedure. *Id.* This satisfies "bone positioning device" under the plain and ordinary meaning, as the structure positions bones in multiple planes. *Id.* Under §112(f), this positioning device is identical or at least equivalent to structures identified in the '941 patent for the claimed bone positioning device discussed in Section V.A. *Id.*, ¶270. The positioning device is at least an equivalent of the disclosed bone-positioning structures (multi-axis joint with ball-and-socket ends) because it performs the same function (adjusts first metatarsal alignment in multiple planes), in substantially the same way (two multiaxial ball joints linked by center piece), to achieve the same result (move and hold bones in intended position). *Id.*

Orsak discloses a device for repositioning the first metatarsal relative to the first cuneiform and uses pins held by adjustable device portions (Ex.1008, Fig.5A-5D, [0088]-[0089], [0094], [0115]), the same operative environment as Dayton's procedure. Ex.1003, ¶271. Combining elements from Dayton and Orsak according to their known functions would have predictably yielded the expected benefit:

instead of pins serving primarily as visual references for manual manipulation (Ex.1005, 349), a POSA would have been motivated to place the pins in the first metatarsal and cuneiform to couple them to a known external fixator to provide controlled, maintainable correction. Ex.1003, ¶271; *see also* Ex.1006, 27:7-9 (explaining a fixator is “used as temporary or final fixation”), 6:7-13 (explaining a fixator “may perform one or few, or combination of thirteen different holding fixation possibilities,” such as clockwise/anti-clockwise motion and translation), 2:30-3:1, 4:25-27; Ex.1007, 5:26-33 (describing fixation device for “mov[ing] one fragment with respect to the other in six orthogonal degrees of freedom, a combination of three orthogonal translational axes...and three orthogonal rotational axes...”), 5:52-58, 7:58-60.

The combination represents a straightforward application of a positioning device like Orsak’s to Dayton’s procedure. Ex.1003, ¶272. Orsak discloses its “device can be used for both compression as well as distraction of two bone pieces [with] one of the two bone pieces being affixed to the first set of fixation pins 5a and the second bone piece being affixed to the second set of fixation pins 5b” (Ex.1008, [0140]), exactly the type of apparatus a POSA would select to adjust and maintain relative alignment between adjacent bones during corrective surgery (Ex.1003, ¶272). Incorporating fixation engagement like Orsak’s into Dayton’s procedure would have predictability improved control and stability compared to manual

manipulation without changing Dayton’s goals or strategy. Ex.1003, ¶272. Although Orsak’s device is described as an external fixator, Orsak discloses pin-holder/sliding/screw-driven positioning mechanics and controlled compression-distraction functionality, which a POSA would have predictably used as an intraoperative positioning aid in Dayton’s osteotomy/fusion workflow before Dayton’s final fixation. *Id.*

A POSA would have recognized the combination as using a known fixation-and-adjustment technique like Orsak’s to the same type of corrective alignment task. *Id.*, ¶273. Orsak’s device supports “many orthopedic treatments to fixate, distract, or reduce bone segments” (Ex.1008, [0003]) and can be “arranged into a variety of angular configurations” (Ex.1008, [0094], [0109], [0115]), which include the same motions and configurations that a surgeon uses to correct triplanar deformity (Ex.1003, ¶273). Engaging a device like Orsak’s with pins in the first metatarsal and cunieform in Dayton’s procedure would have predictably improved intraoperative precision and retention compared to freehand manipulation by providing controlled movement and stable maintenance of corrected alignment. Ex.1003, ¶273.

A POSA would have had a reasonable expectation of success because the modification stays within the references’ disclosures and relies on predictable mechanics. *Id.*, ¶274; *see also* Ex.1006, 26:21-24. Engaging a device like Orsak’s

with metatarsal and cuneiform pins would have provided controlled repositioning and stable maintenance of the corrected alignment. Ex.1003, ¶274. Orsak explains using such devices “in many orthopedic treatments to fixate, distract, or reduce bone segments” (Ex.1008, [0003]), including foot surgeries (Ex.1008, Figs.5A-5D).

### **3. Limitation 1[b]**

The combination renders this limitation obvious for the reasons given in Ground 2: a POSA would use a cutting guide like Palmer’s in Dayton’s procedure (with Orsak substituted for Waisman) and align it with the metatarsal-cuneiform joint. *Supra* §VIII.A.3; Ex.1003, ¶¶275-276.

The guide includes a joint plate/tab offset from the resection-slot guide feature, extending downward and inserted into the joint during the alignment. Ex.1003, ¶276. Orsak’s substitution would not change motivation or expectation of success. *Id.*

### **4. Limitation 1[c]**

The combination renders this limitation obvious for the reasons explained in Ground 2. *Supra* §VIII.A.4; Ex.1003, ¶¶277-278. Orsak’s substitution would not change motivation or expectation of success. Ex.1003, ¶278.

### **5. Limitation 1[d]**

The combination renders this limitation obvious. Ex.1003, ¶¶279-283.

As explained for limitation 1[a] in this ground, it would have been obvious to use a positioning device like Orsak's to facilitate Dayton's manual repositioning and correction. *Supra* §X.A.2. Orsak explains its fixators are used to “adjust the relative orientation and spacing of the bone parts on opposing sides of a bone repair site.” Ex.1008, [0003]. Adjusting spacing produces translational movement, and adjusting orientation produces angular movement—together enabling multi-axis alignment used to achieve and hold corrected positioning during corrective surgery. Ex.1003, ¶280.

Orsak discloses mechanisms providing these adjustments. A “driving screw” moves a pin-holder “longitudinally,” pushing or pulling distal pins relative to proximal pins to adjust spacing. *Id.*, [0068], [0092]; *see also id.*, [0105]-[0107] (driving screw 1125), [0115] (explaining “external fixator 3000 includes a first portion 1010A and a second portion 1010C having the same structures as the first portion 1010A and second portion 1010C of the external fixator 2000”). This longitudinal push/pull adjustment corresponds to translational (spacing) adjustment between the bone parts. Ex.1003, ¶281. Orsak further describes a “universal joint 1500 allows the two portions 1010A and 1010B of the fixator body to be set at any desired angle, which in turn allows the fixation pins held in each of the two portions 1010A and 1010B of the fixator body to be arranged into a variety of angular configurations.” *Id.*, [0094]; *see also id.*, [0109], [0115] (“[B]ecause the external

fixator 3000 comprises two universal joints[,] the angular adjustability of the two portions 1010A and 1010C of the external fixator 3000 is greater.”). This angular adjustability corresponds to angulation/rotation adjustment of alignment. Ex.1003, ¶281. Together, these disclosures support using a positioning device like Orsak’s to perform multi-planar adjustment of the first metatarsal during bunion correction, consistent with Dayton’s triplanar correction objective. *Id.*

Even if Orsak were found to expressly describe using its positioning device to adjust bone alignment in only one plane, it still would have been obvious to use a positioning device like Orsak’s with its multi-axis capabilities (translation/spacing and angulation/orientation) to perform the multi-planar adjustments Dayton identifies for bunion correction. *Id.*, ¶282. Dayton explains that bunion correction requires addressing deformity in multiple planes. Ex.1005, 348-349. Applying known translational and angular adjustment mechanisms like Orsak’s to achieve Dayton’s triplanar correction would have been a predictable use of a device according to its intended purpose, yielding controlled multi-planar repositioning and maintenance of alignment during the procedure. Ex.1003, ¶282.

For the reasons explained for limitations 1[a]-1[b] in this ground (*supra* §§X.A.2-3), a POSA would have been motivated to use a positioning device like Orsak’s to control triplanar repositioning of the first metatarsal and would have

reasonably expected success. Ex.1003, ¶283. Thus, the positioning device adjusts the first metatarsal in multiple planes to correct a bunion. *Id.*

**6. Limitation 1[e]**

The combination renders this limitation obvious for the reasons explained in Ground 2. *Supra* §VIII.A.6; Ex.1003, ¶¶284-285. Orsak’s substitution would not change motivation or expectation of success. Ex.1003, ¶285. Moreover, such compression would, for example, be achieved using a bone positioning device like Orsak’s. *See* Ex.1008, [0140] (explaining “device can be used for both compression as well as distraction of two bone pieces”).

**7. Limitation 1[f]**

The combination renders this limitation obvious for the reasons explained in Ground 2. *Supra* §VIII.A.7; Ex.1003, ¶286. Orsak’s substitution would not change motivation or expectation of success. Ex.1003, ¶286.

Claim 1 is therefore unpatentable. *Id.*, ¶¶262-286.

**B. Claims 2-5**

These claims are obvious for the reasons explained in Ground 2. *Supra* §§VIII.B-E; Ex.1003, ¶287. Orsak’s substitution would not change motivation or expectation of success. Ex.1003, ¶287.

**C. Claim 6**

The combination renders claim 6 obvious. Ex.1003, ¶¶288-291.

As explained for limitations 1[a] and 1[d] in this ground, Orsak discloses using pins to engage its bone positioning device with the first metatarsal and cuneiform and to reposition the bones. *Supra* §§X.A.2, X.A.5. Orsak further discloses “driving bone fixation pins into a bone piece and [] removing the bone fixation pins.” Ex.1008, [0084]; *see also id.*, [0085], [0006]-[0008].

In the combination, pins are used to achieve and maintain the desired repositioning during correction, and once the corrected metatarsal-cuneiform relationship is fixed with the bone connector (e.g., Dayton’s wires/plates/screws as explained for limitation 1[f] in this ground (*supra* §X.A.7)), that fixation maintains alignment independently of the pins. Ex.1003, ¶290.

Accordingly, a POSA would have removed the first and second fixation pins after fixation with the bone connector, consistent with Orsak’s disclosure and as a predictable, routine step—leaving temporary pins in place would be unnecessary and could interfere with connector placement/function or leave unnecessary hardware at the operative site. *Id.*, ¶291.

**D. Claims 7-15**

These claims are obvious for the reasons explained in Ground 2. *Supra* §§VIII.G-O; Ex.1003, ¶¶292-293. Orsak’s substitution would not change motivation or expectation of success. Ex.1003, ¶293.

**E. Claim 16**

The combination renders claim 16 obvious. Ex.1003, ¶¶294-296.

As explained for limitation 1[e] in this ground, it would have been obvious to compress the first metatarsal and cuneiform together. *Supra* §X.A.6. Further, as explained for limitation 1[a] in this ground, Orsak discloses engaging a positioning device with bones using pins and using the device for compression. *Supra* §X.A.2. A POSA would understand Orsak's compression as applying compressive force through the device to the pinned bone interfaces, driving the pins toward one another to reduce the inter-bone gap and press the bones together. Ex.1003, ¶295.

Accordingly, it would have been obvious to use a positioning device like Orsak's with the first pin in the first metatarsal and the second pin in the first cuneiform to hold Dayton's correction and apply compressive force that presses the pins (and thus the metatarsal and cuneiform). *Id.*, ¶296. This is a predictable, routine use of disclosed compression capability like Orsak's in Dayton's procedure because compression across opposing joint surfaces is a known objective at a fusion site and uses the device according to its intended function without changing Dayton's surgical goal or Orsak's mode of operation. *Id.*

**F. Claim 17**

The combination renders claim 17 obvious. Ex.1003, ¶¶297-300.

As explained for limitation 1[e] and claim 16 in this ground, it would have been obvious to compress the first metatarsal and cuneiform using a positioning device like Orsak's. *Supra* §§X.A.6, X.E. Orsak discloses that its positioning device's pin-holder "threadably engages the internally threaded bore" and "[t]his configuration enables the pin-holder 143 to move longitudinally inside the first portion," with longitudinal slots that "guide the longitudinal movement of the pin-holder 143." Ex.1008, [0102]-[0103]. Orsak explains that a "threaded driving screw" is used such that "as the head portion is threaded in or out...it pushes or pulls the pin-holder 143 longitudinally," and that the driving screw "operates on the pin-holder 143 to move the pin-holder 143 back and forth...in longitudinal direction," including "while the pin-holder 143 is holding the fixation pins." *Id.*, [0068]-[0069]; *see also id.*, [0092], [0094] ("another embodiment of external fixator 5"), [0105], [0114], Figs.5A-5H. Orsak confirms that such repositioning "can be used for both compression as well as distraction procedures." *Id.*, [0114].

It would have been obvious to use a structure like Orsak's sliding connection and screw to implement compression across Dayton's metatarsal-cuneiform fusion site. Ex.1003, ¶299. In particular, compressing the bones comprises operating (e.g., turning) the threaded driving screw to advance/retract the screw and thereby pushing or pulling the pin-holder longitudinally and translating the fixation pins (and attached bone segments) toward one another to apply compression. *Id.* This meets

the requirement that “compressing...comprises operating the screw” because the positioning device includes a sliding connection (pin-holder’s longitudinal movement within fixator portion) and a screw (threaded driving screw) that drives that sliding movement. *Id.*, ¶300. This is a predictable, routine use with a reasonable expectation of success. *Id.*

**G. Claim 18**

**1. Preamble and Limitations 18[a]-18[d]**

For reasons explained for claim 1’s preamble and limitations 1[a]-1[d] in this ground, claim 18’s preamble and limitations 18[a]-18[d] are obvious. *Supra* §§X.A.1-5; Ex.1003, ¶301.

**2. Limitation 18[e]**

For reasons explained for claims 3-4 in this ground, this limitation is obvious. *Supra* §X.B; Ex.1003, ¶302.

**3. Limitations 18[f]-18[g]**

For reasons explained for limitations 1[e]-1[f] in this ground, limitations 18[f]-18[g] are obvious. *Supra* §§X.A.6-7; Ex.1003, ¶303.

Therefore, claim 18 is unpatentable. *Id.*, ¶¶301-303.

**H. Claims 19-27**

For reasons explained for claims 2, 6, 5, 7, 8, 12, 15, 16, and 17 in this ground, respectively, the combination renders claims 19-27 obvious. *Supra* §§X.B-F; Ex.1003, ¶304.

**XI. GROUND 5-6: CLAIMS 1-27 ARE OBVIOUS BASED ON DAYTON, ORSAK, PALMER, AND WAISMAN/TAYLOR**

Even 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, it would have been obvious—based on Waisman or Taylor—to use the bone positioning device for that adjustment. Ex.1003, ¶¶305-308; *see also* Ex.1001, claims 1 (limitation 1[d]), 4 (adding related timing limitation), 18 (reciting limitation 1[d] and claim 4 limitation).

As explained for limitation 1[d] in Ground 4, Orsak discloses a positioning device with multi-axis capabilities and using that device to perform bone alignment in at least one plane. *Supra* §X.A.5. A POSA would have been motivated to use the positioning device like Orsak's to perform the multi-planar adjustments Dayton identifies for bunion correction, in view of either Waisman or Taylor describing using similar positioning devices to reposition and maintain bone alignment and fixation as explained for limitation 1[d] in Grounds 2-3. Ex.1003, ¶307; *supra* §§VIII.A.5, IX.A.5. Using a device like Orsak's in this manner would have provided the predictable benefit of controlled repositioning and maintaining position,

consistent with the reasons explained for limitation 1[d] in Grounds 2-4 (*supra* §§VIII.A.5, IX.A.5, X.A.5), and a POSA would have thus had a reasonable expectation of success. Ex.1003, ¶308.

## **XII. GROUNDS 7-11: CLAIMS 1-27 ARE OBVIOUS OVER THE GROUNDS 2-6 COMBINATIONS WITH ORBAY SUBSTITUTED FOR PALMER**

A POSA would have substituted a cutting guide like Orbay's for one like Palmer's in each combination set forth in Grounds 2-6. Ex.1003, ¶309. Orbay, like Palmer, provides cutting-guide disclosures that satisfy the cutting-guide claim limitations, and substituting Orbay for Palmer likewise render claims 1-27 unpatentable. Ex.1003, ¶¶309-363.

The disclosures and analysis of the other references set forth in Grounds 2-6 (*supra* §§VIII-XI) are adopted and applied here for the same claims and corresponding limitations addressed in Grounds 2-6, and are not repeated in full for brevity.

### **A. Claim 1**

#### **1. Preamble**

To the extent the preamble is limiting, Dayton discloses it for the reasons explained in Ground 2. *Supra* §VIII.A.1; Ex.1003, ¶311.

#### **2. Limitation 1[a]**

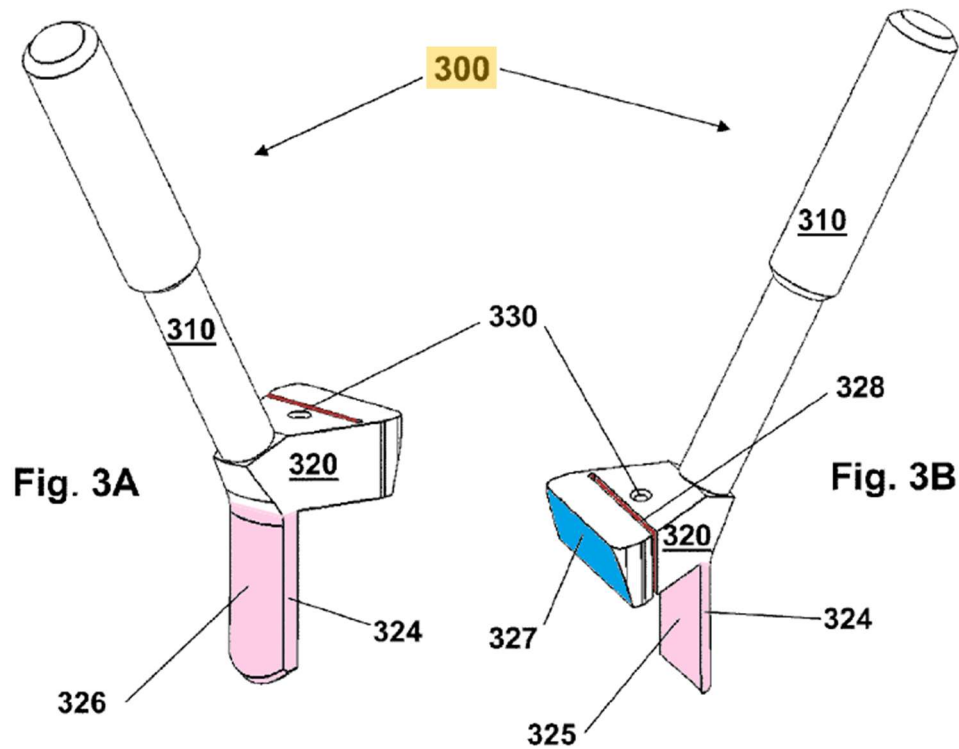
Each combination renders this limitation obvious for the reasons explained in Grounds 2-4. *Supra* §§VIII.A.2, IX.A.2, X.A.2; Ex.1003, ¶312.

### **3. Limitation 1[b]**

Each combination renders this limitation obvious. Ex.1003, ¶¶313-322.

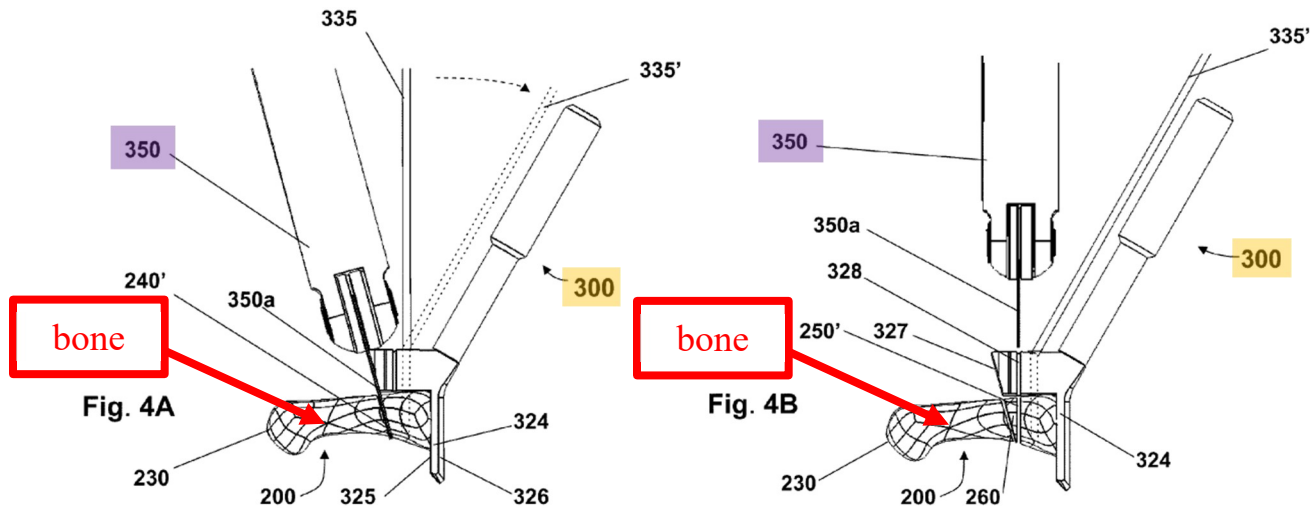
It would have been obvious to use a bone cutting guide like Orbay's in each combination's procedure to facilitate bone cutting. Ex.1003, ¶¶314, 318-322. Orbay discloses using a vertical slot or planar surface to cut a distal portion of a bone (Ex.1010, [0037])—which is the same cutting in Dayton's metatarsal-cuneiform joint-surface preparation. Ex.1003, ¶314.

Orbay discloses “[a] cutting guide 300 for performing small bone osteotomy.” Ex.1010, [0037]; *see also id.*, [0002] (“The invention is particularly useful in connection with surgical treatment of the carpo-metacarpal joint and other similarly configured joints.”). The guide's “body portion 320 includes an angled plane surface 327, adapted to align a cutting blade along the angled line 240, and a vertical slot 328, adapted to align a cutting blade along cutting line 250.” *Id.*, [0037]; *see also id.*, [0033], [0040], claims 1, 5, 13-14, 18. The guide includes a divider piece 324 that is placed into the joint with “aligning surface 325 abutting the proximal articular surface 220 of [one bone] and its opposite surface 326 abutting the distal articular surface 120 of [another bone]” so that “[t]hese surfaces 325, 326 align the saw guide at a desired, relative cutting angle and position.” *Id.*, [0037]; *see also id.*, [0038]. This guide 300 (orange), including the plane surface 327 (blue), vertical slot 328 (red), and divider piece 324 (pink), is shown in the following figures:



*Id.*, Figs.3A-3B.

Orbay explains “an oscillating saw 350 [purple] may be used to make a first distal cut 240’ in the [one bone], by aligning the oscillating saw blade with angled plane surface 327” and further “the blade 350a of the oscillating saw 350 [is] inserted into the vertical slot 328 to make the proximal cut 250’, substantially perpendicular to the longitudinal axis of [the one bone].” *Id.*, [0039].



*Id.*, Figs.4A-4B.

A guide like Orbay's is a bone cutting guide. Ex.1003, ¶317. The portions of such a guide that structurally define the plane surface 327 and vertical slot 328 each constitutes a guide feature, and a divider piece like Orbay's divider piece 324 constitutes a joint plate. *Id.* The divider piece 324 extends downwardly relative to the plane surface 327 and vertical slot 328, as shown in Figures 3A-3B/4A-4B. *Id.* As shown in these figures, the divider piece 324 is offset from the portions of Orbay's guide that structurally define the plane surface 327 and vertical slot 328. *Id.*

A POSA would have been motivated to use a cutting guide like Orbay's in Dayton's procedure and to align it with the joint between the first metatarsal and cuneiform. Ex.1003, ¶318. In such an arrangement, the cutting guide would include a joint plate (e.g., divider piece) offset from a guide feature (e.g., portion of cutting guide structurally defining plane surface or vertical slot), with the joint plate

extending downwardly relative to the guide feature and being inserted into the joint during the alignment with the joint. *Id.*

As explained for limitation 1[b] in Ground 2, a POSA would understand the benefits of using a cutting guide over freehand resection. *Supra* §VIII.A.3; Ex.1003, ¶319. Further, using a cutting guide like Orbay's would have been understood to reduce the risk of complications and delayed unions, non-unions, and malunions. Ex.1003, ¶320; *see also supra* §VIII.A.3. A cutting guide like Orbay's with its divider piece would make cutting predictable and repeatable. Ex.1003, ¶319. Using such a cutting guide would have been nothing more than the use of a known technique to solve a known problem using prior art elements according to their established functions. Ex.1003, ¶321; *KSR*, 550 U.S. at 417.

It would likewise have been obvious to use a cutting guide like Orbay's because doing so applies a known technique to improve a similar method in the same way. Ex.1003, ¶321; *KSR*, 550 U.S. at 417. As explained, Orbay improves resection using a cutting guide that precisely defines cuts, and a POSA would have looked to such guides to improve Dayton's procedure. Ex.1003, ¶321. Dayton and Orbay both involve cutting at the joint between bones (Ex.1005, 349; Ex.1010, [0037]), and Orbay discloses that the aligning surface 325 of the divider piece 324 can abut the proximal surface a bone (Ex.1010, [0037]). This confirms a cutting guide like Orbay's is applicable to Dayton's metatarsal-cuneiform joint. Ex.1003, ¶321. Each

combination thus represents a predictable application of known cutting-guide to a closely analogous procedure. *Id.*

A POSA would have had a reasonable expectation of success in using a cutting guide like Orbay's. *Id.*, ¶322; *see also* Ex.1011, 382 (describing use of similar cutting guide on foot bone). Orbay discloses its guide can be adapted for different joints and manufactured in different sizes to accommodate anatomy. Ex.1010, [0066], [0040]. Incorporating Orbay's divider-piece alignment approach (joint insertion to register against opposing articular surfaces) into Dayton's metatarsal-cuneiform joint preparation would not change Dayton's surgical objective or principle of operation; it would provide a predictable alignment/registration mechanism for guiding resection at the same joint interface. Ex.1003, ¶322. Moreover, a POSA would position and use the cutting guide and positioning device to avoid undue interference. *Id.*

#### **4. Limitation 1[c]**

Each combination renders this limitation obvious. Ex.1003, ¶¶323-327.

As explained for limitation 1[c] in Ground 2, Dayton's disclosed resection/cutting of the metatarsal articular surface involves cutting that "leading edge" portion. *Supra* §VIII.A.4. Using the cutting guide like Orbay's to perform Dayton's joint-surface preparation would include using the cutting guide's guide feature (e.g., portion of cutting guide structurally defining plane surface or vertical

slot) to guide a cutting tool, like Orbay’s disclosed saw (Ex.1010, [0039]), while making the metatarsal cut at the joint interface. Ex.1003, ¶324. The saw satisfies the “cutting tool” limitation under its plain meaning discussed in Section V.C; and if §112(f) were applied, the saw is corresponding structure (or an equivalent) to the saw instrument described in the ’941 patent. *Id.*, ¶325.

**5. Limitations 1[d]-1[f]**

Each combination renders these limitations obvious for the reasons explained in Grounds 2-6. Ex.1003, ¶¶326-327; *supra* §§VIII.A.5-7, IX.A.5-7, X.A.5-7, XI. Orbay’s substitution would not change motivation or expectation of success. Ex.1003, ¶327.

Claim 1 is therefore unpatentable. *Id.*, ¶¶311-327.

**B. Claims 2-4**

These claims are obvious for the reasons explained in Grounds 2-6. *Supra* §§VIII.B-D, IX.B, X.B, XI; Ex.1003, ¶¶328-329. Orbay’s substitution would not change motivation or expectation of success. Ex.1003, ¶329.

**C. Claim 5**

Each combination renders claim 5 obvious. Ex.1003, ¶¶330-334.

As explained for limitations 1[b]-1[c], Orbay discloses a cutting guide having a guide feature (e.g., portion of cutting guide structurally defining plane surface or

vertical slot) that is used to guide a cutting tool during bone resection. *Supra* §§XII.A.3-4.

It would have been obvious to use a cutting guide like Orbay's and its guide feature to guide the cutting tool while performing Dayton's disclosed "cuneiform cut" at the metatarsal-cuneiform interface. Ex.1003, ¶332. For the reasons explained for claim 5 in Ground 2, it would have been a predictable, routine design choice to use the same cutting guide (and its guide feature) to guide the cutting tool during resections of each of the two bones forming the fusion interface—i.e., the first metatarsal and cuneiform—rather than requiring separate guides for different bones. *Supra* §VIII.E; Ex.1003, ¶333. A POSA would have had a reasonable expectation of success in doing so because a guide feature like Orbay's is expressly intended to guide resection of a target bone, which is the same objective of the metatarsal-cuneiform joint preparation in each combination. Ex.1003, ¶334.

**D. Claim 6**

This claim is obvious for the reasons explained in Grounds 2-6. *Supra* §VIII.F, IX.C, X.C, XI; Ex.1003, ¶335. Orbay's substitution would not change motivation or expectation of success. Ex.1003, ¶335.

**E. Claim 7**

Each combination renders claim 7 obvious. Ex.1003, ¶¶336-338.

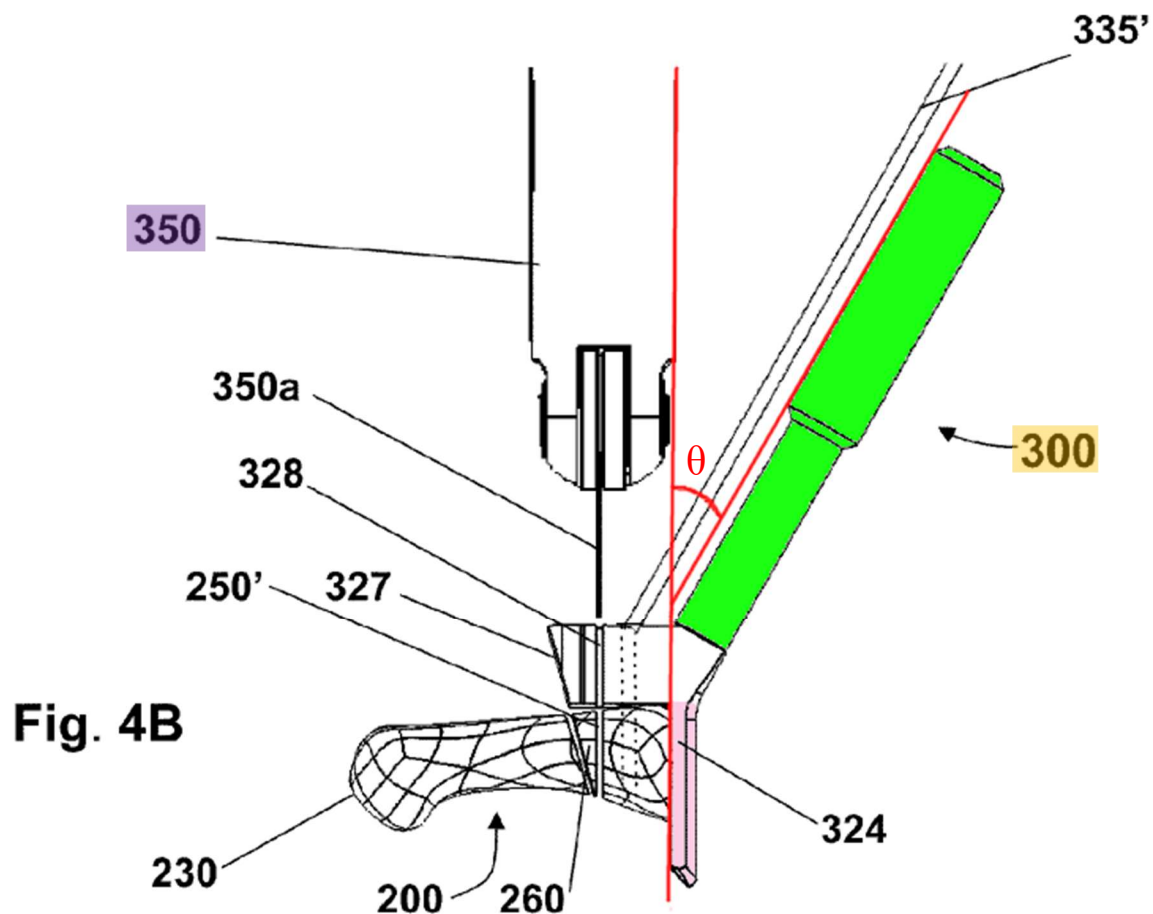


(divider-defined) plane, so that the guided cut is made in a plane aligned to the reference plane established by the divider piece when inserted into the joint, yielding predictable, repeatable planar bone preparation at the metatarsal-cuneiform interface. Ex.1003, ¶338.

**F. Claim 8**

Each combination renders claim 8 obvious. Ex.1003, ¶¶339-342.

Orbay discloses that its “cutting guide 300 includes a body portion 320 and a removable handle 310.” Ex.1010, [0037]. As shown in the illustrated embodiments, the handle (green) extends away from the joint-plate plane at an angle  $\theta$ :



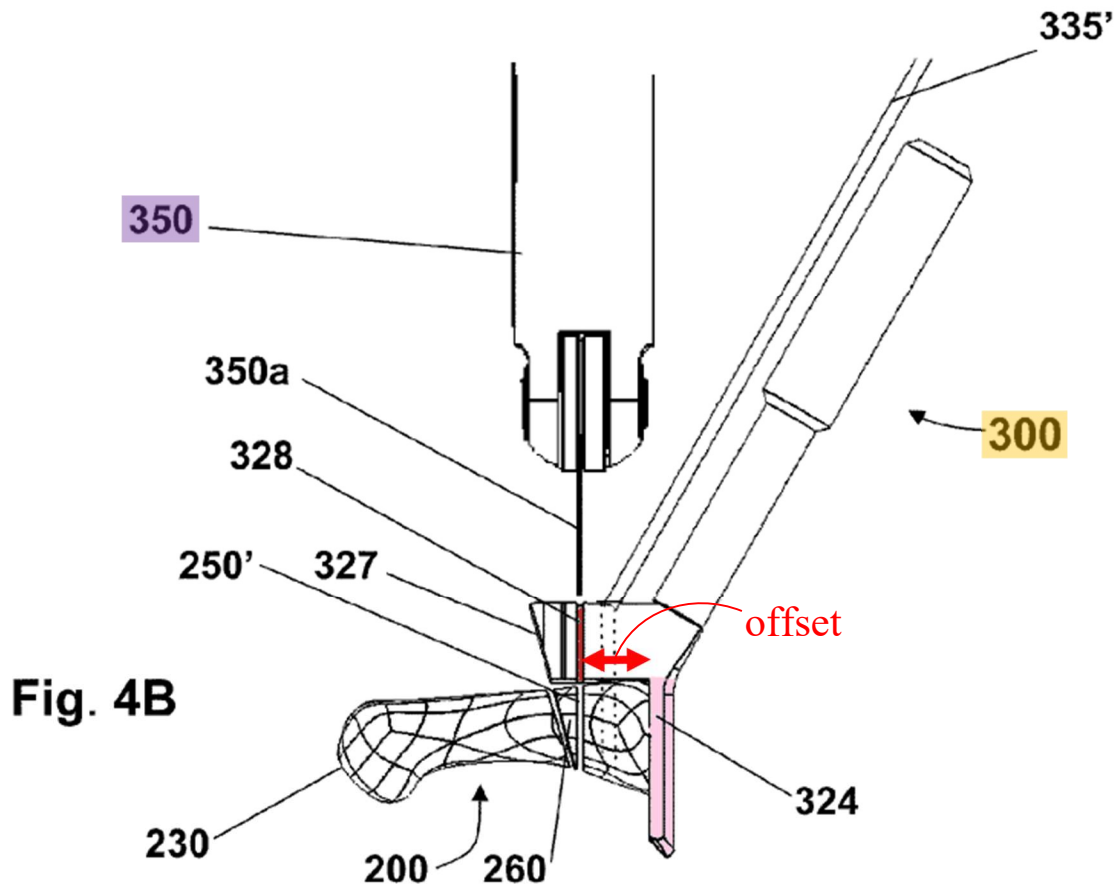
Ex.1003, ¶340 (annotating Ex.1010, Fig.4B); *see also* Ex.1010, Figs.3A-3B.

Selecting a particular handle angle within the claimed range of 30°-60° would have been an obvious design choice. Ex.1003, ¶341. A POSA would have understood the handle's angular orientation relative to the joint-plate plane to be a routine ergonomic/clearance design parameter chosen for the reasons explained for claim 8 in Ground 2. *Supra* §VIII.H; Ex.1003, ¶341. The claimed range reflects a finite set of predictable angle configurations that balance access, clearance, and control, and choosing a moderate angle within 30°-60° would predictably preserve or improve access to the resection slot rather than obstruct it. Ex.1003, ¶341. A POSA would have had a reasonable expectation of success because selecting such an angle does not alter the guiding relationship between the guide feature, cutting tool, and cut plane, but instead relocates the grasp point. *Id.*, ¶342.

**G. Claim 9**

Each combination renders claim 9 obvious. Ex.1003, ¶¶343-346.

As shown in Orbay's illustrated embodiments, Orbay discloses its cutting guide's joint plate (pink) is spaced laterally from the guide feature (portion of cutting guide structurally defining vertical slot (red)), such that the guide feature's guiding surface is laterally offset from the joint plate:



Ex.1003, ¶344 (annotating Ex.1010, Fig.4B). In Orbay’s configuration, the divider piece 324 is positioned to be received at the joint while the slot-defined guiding surface is laterally displaced from that divider piece by a distance. Ex.1003, ¶344. Orbay does not merely show an offset; it affirmatively teaches designing that offset as a “predetermined distance.” See Ex.1010, claims 1-3. This disclosure confirms that the lateral spacing between the joint-inserted divider piece and the slot-defined guiding surface is an intentional, selectable geometric parameter. Ex.1003, ¶344.

It would have been obvious to provide (and/or select) the magnitude of that lateral offset such that the guiding surface is offset from the joint plate by a distance

within the claimed range of 1-20 mm. Ex.1003, ¶345. That lateral spacing is a predictable, result-effective design parameter: a POSA would choose it based on ordinary surgical and anatomical considerations, such as anatomical clearance, maintaining stable seating of the joint plate in the joint while permitting the cutting tool to pass through and be constrained by the guide feature, and achieving the intended resection location at the fusion interface. *Id.* Orbay even contemplates adapting cutting guides for “accommodate[ing] different patient anatomies” (Ex.1010, [0040]), reinforcing that dimensional variations were expected and routine. Ex.1003, ¶345.

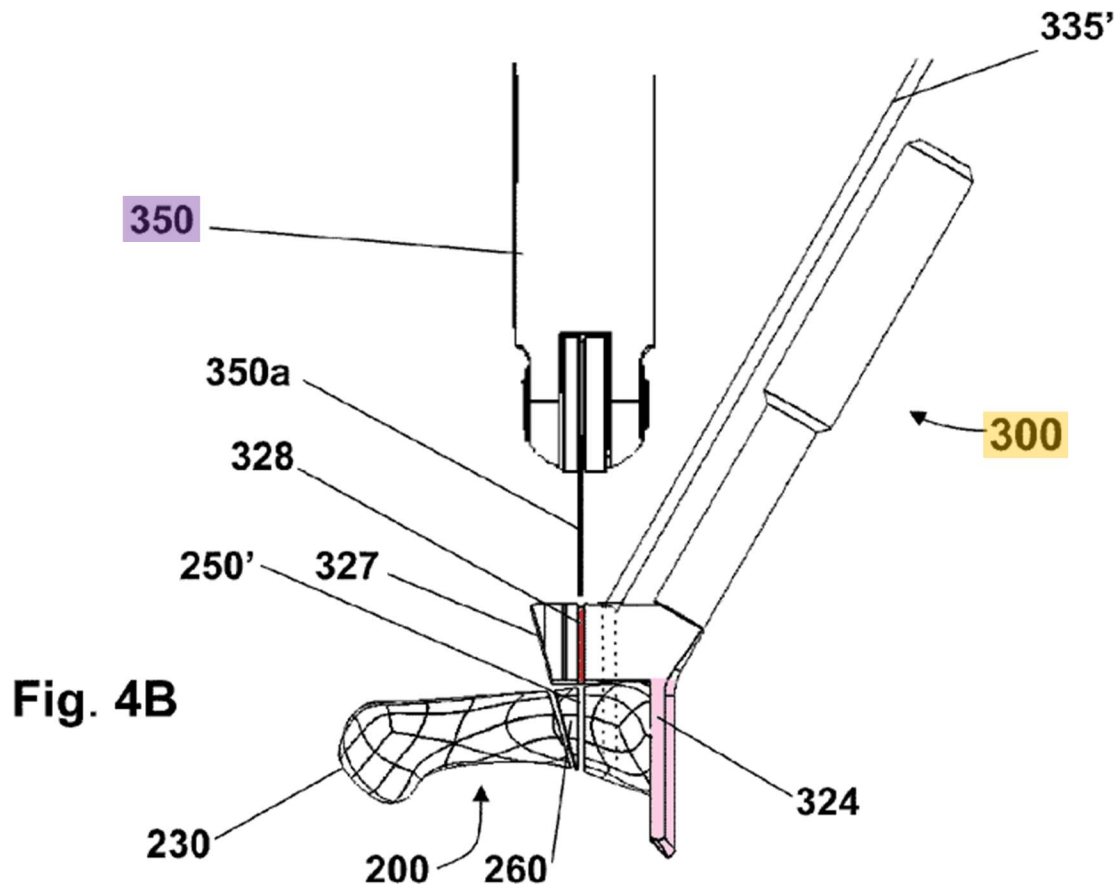
“[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d at 456. A POSA would have had a reasonable expectation of success because selecting the offset to be within a millimeter-scale range does not change the fundamental guiding function of the guide feature; it positions the guided cut relative to the locating/abutment structure used to position the guide on the bone. Ex.1003, ¶346.

#### **H. Claim 10**

Each combination renders claim 10 obvious. Ex.1003, ¶¶347-348.

In Orbay, the guide’s joint plate (pink) is shown as a unitary extension from the same cutting-guide body that defines the guide feature (portion of cutting guide

structurally defining vertical slot (red)), such that the joint plate and guide feature form a single, undivided component rather than separate parts:



Ex.1003, ¶348 (annotating Ex.1010, Fig.4B). Orbay’s claims likewise describe “[a] surgical guide comprising...a body portion...; and a divider piece extending from the body portion” (Ex.1010, claim 1), confirming the joint plate (divider piece) is part of (i.e., integral with) the cutting guide body that provides the guiding surface. Ex.1003, ¶348. Thus, it would have been obvious to use such an integral cutting device like Orbay’s with a reasonable expectation of success. *Id.*

**I. Claim 11**

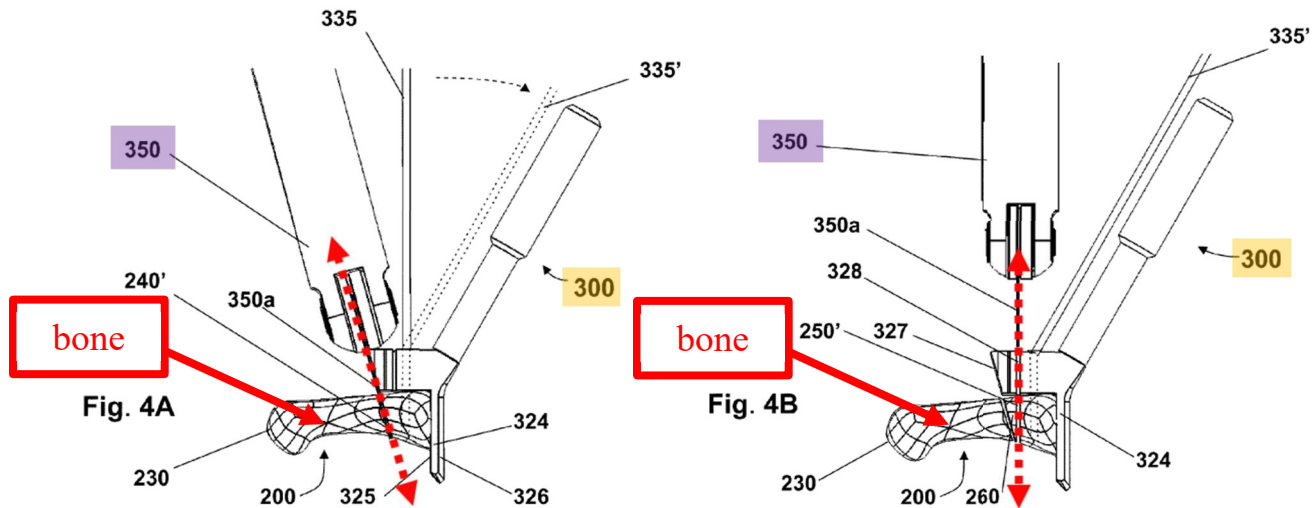
Each combination renders claim 11 obvious. Ex.1003, ¶¶349-350.

Orbay discloses its guide’s “body portion 320 includes an angled plane surface 327, adapted to align a cutting blade along the angled line 240, and a vertical slot 328, adapted to align a cutting blade along cutting line 250.” Ex.1010, [0037]; *see also id.*, [0039] (“aligning the oscillating saw blade with angled plane surface 327”). In use, the cutting blade is guided because it is placed against the guide surface provided by the guide feature so that the guide constrains blade motion along the intended cutting path. Ex.1003, ¶350. This is a routine, predictable manner in which slot-based cutting guides operate and would have been implemented in ordinary course. *Id.*

**J. Claim 12**

Each combination renders claim 12 obvious. Ex.1003, ¶¶351-353.

Orbay discloses its cutting guide’s “body portion 320 includes an angled plane surface 327, adapted to align a cutting blade along the angled line 240, and a vertical slot 328, adapted to align a cutting blade along cutting line 250.” Ex.1010, [0037]; *see also id.*, [0039]. The angled line 240 and cutting line 250 are identified with dotted lines in the following figures, alongside the saw 250 (purple):



*Id.*, Figs.4A-4B. As shown, the blade's permitted motion during resection is guided along the corresponding guide surface, such that the blade path lies in a plane parallel to the guide surface. Ex.1003, ¶352.

Accordingly, in each combination, when the cutting tool is placed in apposition to the guide surface, that guide surface is operable to guide the cutting tool in a plane parallel to the guide surface. *Id.*, ¶353.

#### K. Claim 13

Each combination renders claim 13 obvious. Ex.1003, ¶¶354-355.

As explained for claim 11 in these grounds, it would have been obvious to place the cutting tool in apposition to and against a guide surface defined by the guide feature. *Supra* §XII.I. Using the guide feature to guide the cutting tool necessarily involves placing the cutting tool in contact with that guide surface—at least during guided movement through the slot—because the guide's function of

constraining the tool's path is achieved by contact between the tool and guide surface. Ex.1003, ¶355.

**L. Claim 14**

Each combination renders claim 14 obvious. Ex.1003, ¶¶356-357.

Orbay discloses using a “saw blade” with its cutting guide. Ex.1010, [0039]; *see also id.*, [0037]. Thus, a POSA would have been motivated to use a saw blade as the cutting tool when performing guided resection using the cutting guide. Ex.1003, ¶357.

**M. Claims 15-17**

These claims are obvious for the reasons explained in Grounds 2-6. *Supra* §§VIII.O-Q, IX.D-F, X.D-F, XI; Ex.1003, ¶358. Orbay's substitution would not change motivation or expectation of success. Ex.1003, ¶358.

**N. Claim 18**

**1. Preamble and Limitations 18[a]-18[d]**

For reasons explained for the preamble of claim 1 and limitations 1[a]-1[d] in these grounds, claim 18's preamble and limitations 18[a]-18[d] are obvious. *Supra* §§XII.A.1-5; Ex.1003, ¶¶359-360.

**2. Limitation 18[e]**

For reasons explained for claims 3-4 in these grounds, this limitation is obvious. *Supra* §§XII.B; Ex.1003, ¶361.

**3. Limitations 18[f]-18[g]**

For reasons explained for limitations 1[e]-1[f] in these grounds, limitations 18[f]-18[g] are obvious. *Supra* §§XII.A.5; Ex.1003, ¶362.

Therefore, claim 18 is unpatentable. *Id.*, ¶¶359-362.

**O. Claims 19-27**

For reasons explained for claims 2, 6, 5, 7, 8, 12, 15, 16, and 17 in these grounds, respectively, each combination renders claims 19-27 obvious. *Supra* §§XII.B-F, XII.J, XII.M; Ex.1003, ¶363.

**XIII. GROUNDS 12-16: CLAIMS 1-27 ARE OBVIOUS BASED ON ANY OF GROUNDS 2-6 AND ORBAY**

Even if the Ground 2-6 combinations do not disclose or render obvious using a cutting tool like a saw blade, it would have been obvious based on Orbay to use a cutting tool, such as a saw blade, with the cutting guide to cut using the guide feature. Ex.1003, ¶¶364-367; *see also* Ex.1001, claims 1, 5, 11-14, 18, 21, 24. As explained for limitations 1[b]-1[c] in Grounds 7-11, Orbay discloses inserting a cutting tool like a saw blade into its guide's vertical slot for cutting bone. *Supra* §§XII.A.3-4; Ex.1003, ¶365. A POSA would have been motivated to use such a saw blade with a cutting guide like Palmer's to achieve the cuts and done so with a reasonable expectation of success. Ex.1003, ¶¶366-367.

#### **XIV. SECONDARY CONSIDERATIONS**

Petitioner is not aware of any evidence of secondary considerations. If Patent Owner identifies evidence of secondary considerations, Petitioner respectfully requests an opportunity to respond.

#### **XV. STIPULATION**

Petitioner hereby stipulates that, in the event the Board institutes review, Petitioner will not pursue in *Treace Medical Concepts, Inc. v. Zimmer Biomet Holdings, Inc. and Paragon 28, Inc.*, C.A. No. 1:25-cv-00592-GBW (D. Del.), any invalidity ground against the challenged claims of the '941 patent that was raised or reasonably could have been raised in this Petition. This stipulation weighs strongly against discretionary denial under §314(a) (*Fintiv* factor 4). *Sotra Wireless, Inc. v. Masimo Corp.*, IPR2020-01019, Paper 12 at 18-19 (Dec. 1, 2020) (precedential as to §II.A).

#### **XVI. MANDATORY NOTICES AND FEE PAYMENT**

Pursuant to 37 C.F.R. §42.8(a)(1), the mandatory notices identified in 37 C.F.R. §42.8(b) are provided below as part of this Petition.

##### **A. Real Party-In-Interest (37 C.F.R. §42.8(b)(1))**

Paragon 28, Inc. is the real party in interest for Petitioner. The parent company for Paragon 28, Inc. is Zimmer, Inc. whose parent company is Zimmer Biomet Holdings, Inc. Furthermore, in an abundance of caution and erring on the side of

inclusivity, Petitioner identifies the following additional subsidiaries of Zimmer, Inc. as having a financial interest in, or potentially being affected by the outcome of, this proceeding: Zimmer US, Inc.; Paragon Advanced Technologies, Inc.; Disior Oy; Paragon 28 Italia SRL; Paragon 28 UK, LTD; Paragon 28 Medical Devices Trading Limited; Paragon 28 Medical Devices Trading Limited – South African Branch; Paragon 28 Australia PTY LTD; Paragon 28 Japan K.K.; Paragon 28 DE GmbH.

**B. Related Matters (37 C.F.R. §42.8(b)(2))**

The parties are currently engaged in district court litigation in the case captioned *Treace Medical Concepts, Inc. v. Zimmer Biomet Holdings, Inc. and Paragon 28, Inc.*, C.A. No. 1:25-cv-00592-GBW (D. Del.). Treace Medical Concepts, Inc. (“Treace” or “Patent Owner”) has asserted the ’941 patent against Petitioner in the district court litigation. Treace has also asserted U.S. Patent Nos. 12,268,397 (“the ’397 patent”), 12,268,428 (“the ’428 patent”), 12,274,481 (“the ’481 patent”), and 12,102,368 (“the ’368 patent”) in the district court litigation, and the ’397, ’428, ’481, and ’368 patents are currently the subject of AIA Review Nos. PGR2026-00017, PGR2026-00020, PGR2026-00022, and IPR2026-00194, respectively.

**C. Lead and Backup Counsel (37 C.F.R. §42.8(b)(3))**

Petitioner provides the following designation of counsel, all of whom are included in Customer No. 24,341 or identified in Petitioner’s Power of Attorney.

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

**D. Service Information (37 C.F.R. §42.8(b)(4))**

Please direct all correspondence to lead counsel and back-up counsel at the addresses shown above. Petitioner also consents to electronic service by email to MLB-P28-PGR-941@morganlewis.com.

**E. Grounds for Standing (37 C.F.R. §42.104)**

The '941 patent is available for PGR and no bar or estoppel applies.

**F. Payment of Fees (37 C.F.R. §42.15(a))**

The Office may charge the §42.15(a) fee to Deposit Account No. 50-0310.  
Review of twenty-seven claims is requested.

**XVII. CONCLUSION**

The Board should institute PGR and cancel claims 1-27.

Dated: March 3, 2026

By: /Ali S. Razai/

Ali S. Razai (Reg. No. 60,771)

Morgan, Lewis & Bockius LLP

Attorney for Petitioner Paragon 28, Inc.

# APPENDIX

| Claim 1 <sup>4</sup> |                                                                                                                                                                                                                                                                                                                                                                                          |
|----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1[pre]               | A method of performing a bunion surgery to correct an alignment between a first metatarsal and a first cuneiform, the method comprising:                                                                                                                                                                                                                                                 |
| 1[a]                 | 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;                                                                                                                             |
| 1[b]                 | 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; |
| 1[c]                 | using the guide feature of the bone cutting guide to guide a cutting tool to cut a leading edge of the first metatarsal;                                                                                                                                                                                                                                                                 |
| 1[d]                 | using the bone positioning device to adjust an alignment of the first metatarsal in multiple planes to correct a bunion;                                                                                                                                                                                                                                                                 |
| 1[e]                 | compressing the first metatarsal and the first cuneiform together; and                                                                                                                                                                                                                                                                                                                   |
| 1[f]                 | fixing a position of the first metatarsal relative to the first cuneiform with a bone connector.                                                                                                                                                                                                                                                                                         |

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<sup>4</sup> Bracketed labels have been assigned to elements of the independent claims for convenience.

| <b>Claim 2</b> |                                                                                                                                                                                                                                                                                         |
|----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| --             | The method of claim 1, further comprising,<br>prior to fixing the position of the first metatarsal relative to the first<br>cuneiform with the bone connector,<br>temporarily fixing the position of the first metatarsal relative to the first<br>cuneiform.                           |
| <b>Claim 3</b> |                                                                                                                                                                                                                                                                                         |
| --             | The method of claim 1, further comprising cutting a leading edge of the<br>first cuneiform.                                                                                                                                                                                             |
| <b>Claim 4</b> |                                                                                                                                                                                                                                                                                         |
| --             | The method of claim 3, wherein cutting the leading edge of the first<br>cuneiform comprises cutting the leading edge of the first cuneiform<br>after using the bone positioning device to adjust the alignment of the<br>first metatarsal.                                              |
| <b>Claim 5</b> |                                                                                                                                                                                                                                                                                         |
| --             | The method of claim 3, wherein cutting the leading edge of the first<br>cuneiform comprises using the guide feature of the bone cutting guide<br>to guide the cutting tool to cut the leading edge of the first cuneiform.                                                              |
| <b>Claim 6</b> |                                                                                                                                                                                                                                                                                         |
| --             | The method of claim 1, further comprising, after fixing the position of<br>the first metatarsal relative to the first cuneiform with the bone<br>connector, removing the first fixation pin from the first metatarsal and<br>removing the second fixation pin from the first cuneiform. |

| <b>Claim 7</b>  |                                                                                                                                                                                                                                                                               |
|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| --              | The method of claim 1, wherein the joint plate defines a plane, the guide feature defines a plane, and the plane defined by the joint plate is parallel to the plane defined by the guide feature.                                                                            |
| <b>Claim 8</b>  |                                                                                                                                                                                                                                                                               |
| --              | The method of claim 7, wherein the bone cutting guide comprises a handle extending away from the joint plate at an angle between 30 degrees and 60 degrees with respect to the plane.                                                                                         |
| <b>Claim 9</b>  |                                                                                                                                                                                                                                                                               |
| --              | The method of claim 1, wherein the joint plate is offset from the guide feature by being spaced laterally from the guide feature, and the guide feature defines a guiding surface that is offset from the joint plate a distance ranging from 1 millimeter to 20 millimeters. |
| <b>Claim 10</b> |                                                                                                                                                                                                                                                                               |
| --              | The method of claim 1, wherein the joint plate is integral with the guide feature.                                                                                                                                                                                            |
| <b>Claim 11</b> |                                                                                                                                                                                                                                                                               |
| --              | The method of claim 1, wherein using the guide feature of the bone cutting guide to guide the cutting tool comprises placing the cutting tool in apposition to a guide surface defined by the guide feature of the bone cutting guide.                                        |
| <b>Claim 12</b> |                                                                                                                                                                                                                                                                               |
| --              | The method of claim 11, wherein the guide surface is operable to guide the cutting tool in a plane parallel to the guide surface.                                                                                                                                             |

| <b>Claim 13</b>     |                                                                                                                                                                                                                                                                              |
|---------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| --                  | The method of claim 1, wherein using the guide feature of the bone cutting guide to guide the cutting tool comprises placing the cutting tool in contact with a guide surface defined by the guide feature of the bone cutting guide.                                        |
| <b>Claim 14</b>     |                                                                                                                                                                                                                                                                              |
| --                  | The method of claim 1, wherein the cutting tool is a saw blade.                                                                                                                                                                                                              |
| <b>Claim 15</b>     |                                                                                                                                                                                                                                                                              |
| --                  | The method of claim 1, wherein the bone connector comprises one or more of a plate, a screw, and a pin.                                                                                                                                                                      |
| <b>Claim 16</b>     |                                                                                                                                                                                                                                                                              |
| --                  | The method of claim 1, wherein compressing the first metatarsal and the first cuneiform together comprises applying a force to press a first fixation pin inserted into the first metatarsal and a second fixation pin inserted into the first cuneiform toward one another. |
| <b>Claim 17</b>     |                                                                                                                                                                                                                                                                              |
| --                  | The method of claim 1, wherein the bone positioning device comprises a sliding connection and a screw, and compressing the first metatarsal and the first cuneiform together comprises operating the screw.                                                                  |
| <b>Claim 18</b>     |                                                                                                                                                                                                                                                                              |
| 18 <pre>[pre]</pre> | A method of performing a bunion surgery to correct an alignment between a first metatarsal and a first cuneiform, the method comprising:                                                                                                                                     |

|                 |                                                                                                                                                                                                                                                                                                                                                                                          |
|-----------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 18[a]           | 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;                                                                                                                             |
| 18[b]           | 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; |
| 18[c]           | using the guide feature of the bone cutting guide to guide a cutting tool to cut a leading edge of the first metatarsal;                                                                                                                                                                                                                                                                 |
| 18[d]           | using the bone positioning device to adjust an alignment of the first metatarsal in multiple planes to correct a bunion;                                                                                                                                                                                                                                                                 |
| 18[e]           | after using the bone positioning device to adjust the alignment of the first metatarsal in multiple planes to correct the bunion, cutting a leading edge of the first cuneiform;                                                                                                                                                                                                         |
| 18[f]           | compressing the first metatarsal and the first cuneiform together; and                                                                                                                                                                                                                                                                                                                   |
| 18[g]           | fixing a position of the first metatarsal relative to the first cuneiform with a bone connector.                                                                                                                                                                                                                                                                                         |
| <b>Claim 19</b> |                                                                                                                                                                                                                                                                                                                                                                                          |
| --              | The method of claim 18, further comprising, prior to fixing the position of the first metatarsal relative to the first cuneiform with the bone connector, temporarily fixing the position of the first metatarsal relative to the first cuneiform.                                                                                                                                       |

| <b>Claim 20</b> |                                                                                                                                                                                                                                                                                 |
|-----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| --              | The method of claim 18, further comprising, after fixing the position of the first metatarsal relative to the first cuneiform with the bone connector, removing the first fixation pin from the first metatarsal and removing the second fixation pin from the first cuneiform. |
| <b>Claim 21</b> |                                                                                                                                                                                                                                                                                 |
| --              | The method of claim 18, wherein cutting the leading edge of the first cuneiform comprises using the guide feature of the bone cutting guide to guide the cutting tool to cut the leading edge of the first cuneiform.                                                           |
| <b>Claim 22</b> |                                                                                                                                                                                                                                                                                 |
| --              | The method of claim 18, wherein the joint plate defines a plane, the guide feature defines a plane, and the plane defined by the joint plate is parallel to the plane defined by the guide feature.                                                                             |
| <b>Claim 23</b> |                                                                                                                                                                                                                                                                                 |
| --              | The method of claim 22, wherein the bone cutting guide comprises a handle extending away from the joint plate at an angle.                                                                                                                                                      |
| <b>Claim 24</b> |                                                                                                                                                                                                                                                                                 |
| --              | The method of claim 18, wherein the guide surface is operable to guide the cutting tool in a plane parallel to the guide surface.                                                                                                                                               |
| <b>Claim 25</b> |                                                                                                                                                                                                                                                                                 |
| --              | The method of claim 18, wherein the bone connector comprises one or more of a plate, a screw, and a pin.                                                                                                                                                                        |

| <b>Claim 26</b> |                                                                                                                                                                                                                                                                                   |
|-----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| --              | The method of claim 18, wherein compressing the first metatarsal and the first cuneiform together comprises applying a force to press the first fixation pin inserted into the first metatarsal and the second fixation pin inserted into the first cuneiform toward one another. |
| <b>Claim 27</b> |                                                                                                                                                                                                                                                                                   |
| --              | The method of claim 18, wherein the bone positioning device comprises a sliding connection and a screw, and compressing the first metatarsal and the first cuneiform together comprises operating the screw.                                                                      |

**CERTIFICATE OF COMPLIANCE**

Pursuant to 37 C.F.R. §42.24(d), the undersigned certifies that this PETITION FOR POST-GRANT REVIEW OF U.S. PATENT NO. 12,349,941 contains 18,669 words according to the word-processing program used to prepare this paper. The foregoing word count complies with the 18,700-word type-volume limit specified by 37 C.F.R. §42.24(a)(1).

Dated: March 3, 2026

By: /Ali S. Razai/

Ali S. Razai (Reg. No. 60,771)

Morgan, Lewis & Bockius LLP

**CERTIFICATE OF SERVICE**

The undersigned hereby certifies that on the date below a copy of this  
**PETITION FOR POST-GRANT REVIEW OF U.S. PATENT NO.  
12,349,941, AND EXHIBITS 1001-1026** were served by FedEx on the Patent  
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