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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PARAGON 28, INC.,
Petitioner,

v.

TREACE MEDICAL CONCEPTS, INC.
Patent Owner.

Case PGR2026-00022
Patent 12,274,481

**PETITION FOR POST-GRANT REVIEW OF
U.S. PATENT NO. 12,274,481**

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LIST OF EXHIBITS

Exhibit No.	Description
1001	U.S. Patent No. 12,274,481 to Santrock et al. (“the ’481 patent”)
1002	File History of the ’481 patent
1003	Declaration of Steven K. Neufeld, M.D.
1004	McGlamry’s Comprehensive Textbook of Foot and Ankle Surgery, Preface and Chapters 1, 31, 34, 36, and 55, 4 th Edition, 2013 (“McGlamry”)
1005	U.S. Patent No. 8,882,816 to Kartalian et al. (“Kartalian”)
1006	U.S. Patent App. Publ. No. 2016/0213384 to Fallin et al. (“Fallin”)
1007	U.S. Patent No. 8,328,806 to Tyber et al. (“Tyber”)
1008	RESERVED
1009	Paul Dayton, et al., <i>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> , 52(3) J. Foot & Ankle Surgery 348–354 (May-June 2013)
1010	Paul W. Lapidus, <i>Operative correction of the metatarsus varus primus in hallux valgus</i> , 58 J. Surgery Gynecology & Obstetrics 183–191 (1934)
1011	Paul W. Lapidus, <i>The author's bunion operation from 1931 to 1959</i> , 16 Clin. Orthopaedics 119-135 (1960)
1012	Mark H. Hofbauer & Jordan P. Grossman, <i>The Lapidus Procedure</i> , 13(3) Clinics Podiatric Med. & Surgery 486–496 (1996)
1013	Babak Baravarian, et al., <i>Lapidus bunionectomy: arthrodesis of the first metatarsocunieform [sic] joint</i> , 21 Clinics in Podiatric Med. & Surgery 97–111 (2004)

Exhibit No.	Description
1014	Brian C. Toolan, <i>Surgical Strategies: The Lapidus Procedure</i> , 28 Foot & Ankle Int'l 1108-1114 (2007)
1015	Timo Schmid & Fabian Krause, <i>The modified Lapidus fusion</i> , 19(2) Foot & Ankle Clinics 223–233 (June 2014)
1016	Nathan J. Young & Charles M. Zelen, <i>New techniques and alternative fixation for the lapidus arthrodesis</i> , 30(3) Clinics Podiatric Med. & Surgery 423–434 (July 2013)
1017	Lawrence A. DiDomenico, et al., <i>Correction of Frontal Plane Rotation of Sesamoid Apparatus During the Lapidus Procedure: A Novel Approach</i> , 53 J. Foot & Ankle Surgery 248–251 (Mar.-Apr. 2014)
1018	James M. Cottom & Anand M. Vora, <i>Fixation of lapidus arthrodesis with a plantar interfragmentary screw and medial locking plate: a report of 88 cases</i> . 52(4) J. Foot & Ankle Surgery 465–469 (July-Aug. 2013)
1019	Bas B.G.M. Franssen, et al., <i>One century of Kirschner wires and Kirschner wire insertion techniques: A historical review</i> , 76 Acta Orthopedic Belgium 1–6 (2010)
1020	File History for U.S. Provisional Application No. 62/108,936 (“the ‘936 application”)
1021	Curriculum Vitae of Steven K. Neufeld, M.D.
1022	U.S. Patent App. Publ. No. 2013/0150900 to Haddad et al. (“Haddad”)
1023	U.S. Patent App. Publ. No. 2007/0265634 to Weinstein (“Weinstein”)
1024	RESERVED
1025	U.S. Patent No. 5,350,382 to Armstrong et al. (“Armstrong”)
1026	U.S. Patent No. 4,349,018 to Chambers (“Chambers”)

Exhibit No.	Description
1027	U.S. Patent No. 9,220,518 to Neal et al. (“Neal”)
1028	U.S. Patent App. Publ. No. 2014/0031882 to Schmuck et al. (“Schmuck”)
1029	RESERVED
1030	U.S. Patent No. 5,112,334 to Alchermes et al. (“Alchermes”)
1031	RESERVED
1032	RESERVED
1033	RESERVED
1034	RESERVED
1035	U.S. Design Patent No. D695,402 to DaCosta et al. (“DaCosta”)
1036	Declaration of Sylvia Hall-Ellis, Ph.D.
1037	U.S. Patent App. Publ. No. 2009/0036893 to Kartalian et al.

Petitioner Paragon 28, Inc. requests post grant review (“PGR”) of claims 1-30 of U.S. Patent 12,274,481 (“the ’481 patent,” Ex.1001).

I. INTRODUCTION

The ’481 patent claims instrumented methods for bunion correction surgery. But the claimed instrumentation and techniques were well-known and routine practice before the patent’s earliest claimed priority date in 2015.

The claims of the ’481 patent recite, for example, “an instrumented surgical technique for preparing a tarsal-metatarsal joint for fusion and for repositioning a first metatarsal to correct a bunion deformity,” including: (1) engaging first and second metatarsals with “a bone positioning guide;” (2) “rotating a knob connected to a threaded shaft of the bone engagement member to push the first metatarsal laterally;” (3) “imparting a force to a pin inserted into the first metatarsal to adjust an alignment of the first metatarsal in a frontal plane;” (4) cutting an end of the first metatarsal and an end of a medial cuneiform; (5) compressing the first metatarsal and the medial cuneiform; and (6) fixating the first metatarsal in its moved position for fusion using a bone fixation device.

By the early 1900s, surgeons had described procedures for correcting misalignment of the first metatarsal and medial cuneiform. Ex.1009; Ex.1013, 97 (summarizing Lapidus’s procedure); Ex.1014, 1108 (same); Ex.1004, 322-28. These procedures involved cutting and removing bone to restore anatomical

alignment of the metatarsal and cuneiform bones and fixing them in the corrected position for fusion. Ex.1014, 1109-13 (describing operative technique); Ex.1016, 423; Ex.1015, 226-28 (same).

By August 2015, bunion correction surgeries had become highly developed and routine. In 2013, the McGlamry medical textbook disclosed a bunion correction surgery that included cutting the facing ends of the first metatarsal and cuneiform, moving the first metatarsal in multiple planes, and fixing the medial portion of the moved first metatarsal to the distal portion of the cuneiform. Similarly, in January 2015, Fallin described a surgical procedure that involved cutting both the metatarsal and cuneiform, moving the metatarsal in multiple planes, and fixating the metatarsal to the cuneiform in the moved position for fusion.

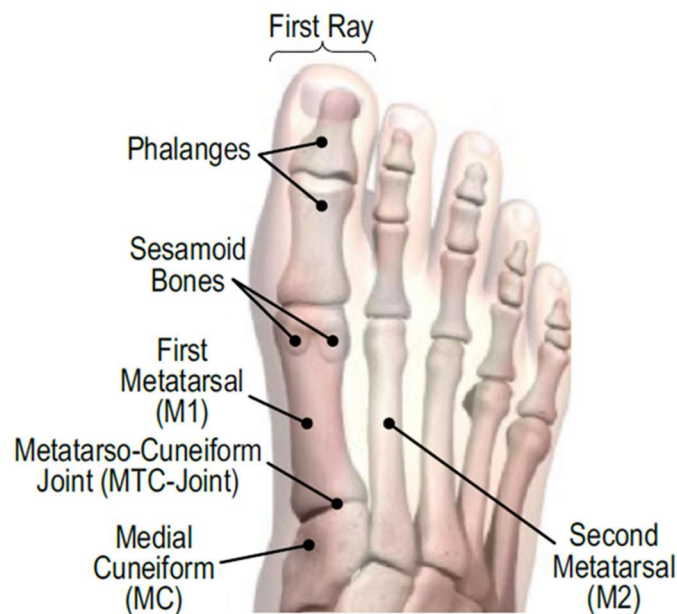
The prior art was also replete with surgical tools for performing bunion correction procedures. For example, Fallin disclosed surgical instruments used in bunion surgery, including guides for cutting the facing surfaces of the metatarsal and cuneiform bones. McGlamry disclosed using a Weber clamp and K-wires to position the metatarsal. Likewise, Kartalian described specialized “reduction forceps”-like instruments used during bunion correction surgery to reposition the first metatarsal in both the transverse and frontal planes.

As of August 2015, the methods claimed in the '481 patent were nothing more than a predictable collection of prior art elements, each performing its established function. Accordingly, all claims are obvious and should be cancelled.

II. STATE OF THE ART

A. Bunion Deformity

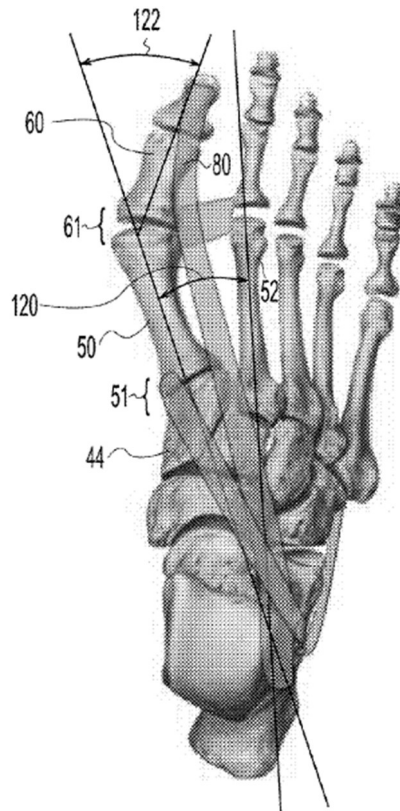
In a typical foot anatomy, the first metatarsal and medial cuneiform bones are positioned in three-dimensional alignment to permit normal foot function. Ex. 1003 ¶¶40-41. These bones meet to form the metatarsal-cuneiform joint:



*Id.*¹ A bunion can result when the first metatarsal and medial cuneiform bones become misaligned in one or more planes. *Id.*, ¶¶41-43 As part of this

¹ Annotations and highlighting added to figures unless otherwise noted. Emphasis added unless otherwise noted.

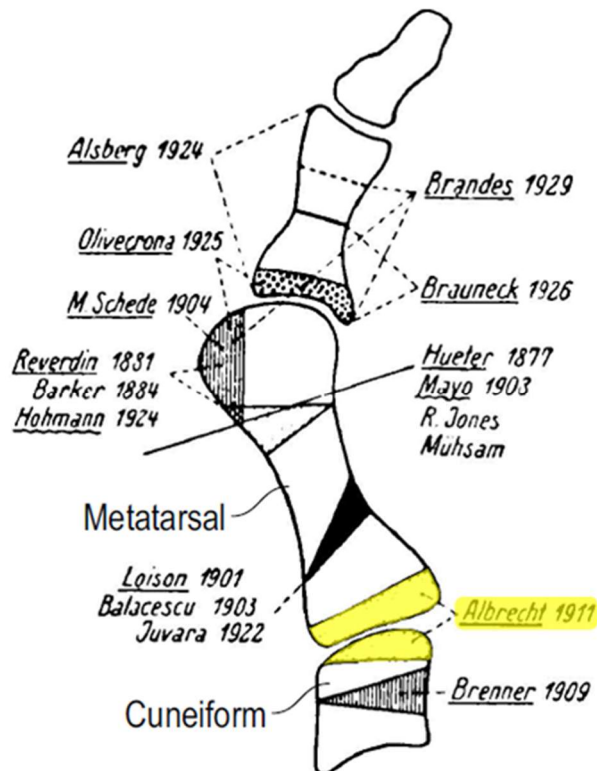
misalignment, the first metatarsal may deviate away from the second metatarsal, which increases the intermetatarsal angle (“IM angle” or “IMA”)—the angle formed between the longitudinal axes of the first and second metatarsals:



Ex.1006, Fig.11; Ex.1003, ¶44. Such misalignment can cause a visible bump on the inner portion of the foot (a “bunion”), which can impair foot function and cause pain. Ex.1003 ¶¶45-46; *see also id.*, ¶¶38-39; Ex.1017, 250 (describing anatomical changes from bunion deformities).

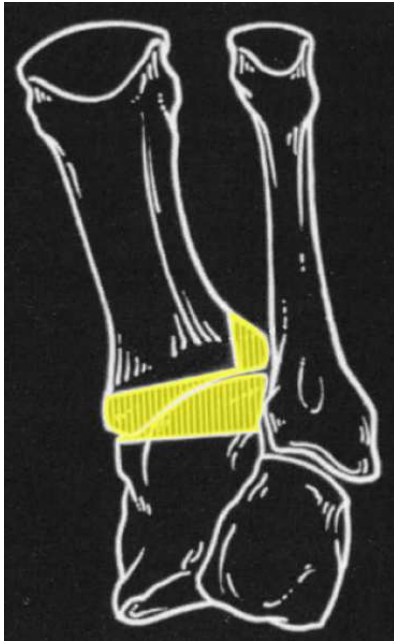
B. Instrumented Bunion Correction

Numerous operative techniques for bunion correction have been described and used for more than a century, as illustrated in the following schematic of the foot, which identifies various procedures by year and developer:



Ex.1011, 122; Ex.1003, ¶¶47-49. One such procedure involves fusing the first metatarsal and medial cuneiform—now commonly referred to as a “Lapidus” procedure (also described as metatarso-cuneiform arthrodesis)—which was developed in 1934 by Dr. Paul Lapidus. Ex.1003, ¶48; Ex.1004, 803; Ex.1010. The goal of this procedure is to fuse the metatarsal and cuneiform in the corrected position. Ex.1003, ¶50; Ex.1010, 186, 189.

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



Before Correction



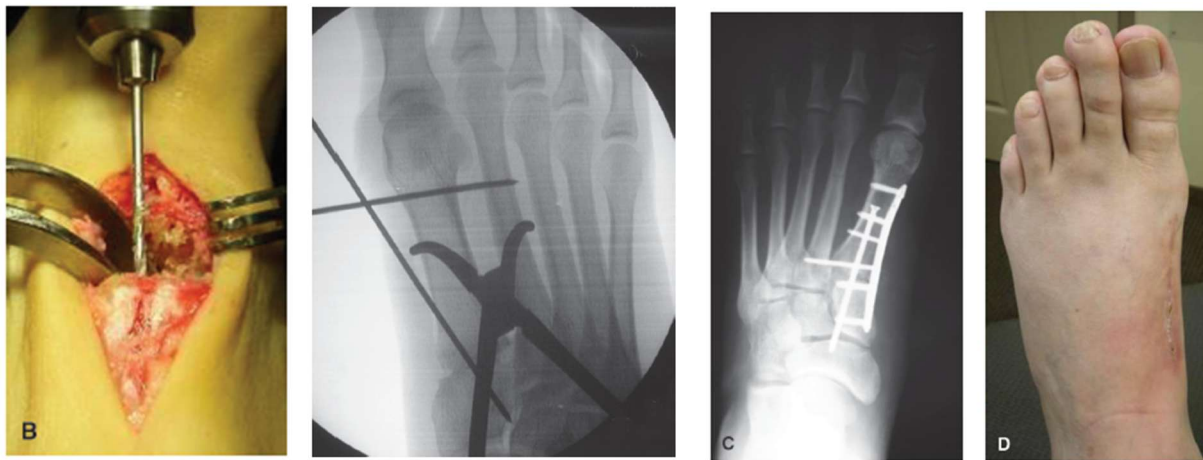
After Correction

Ex.1012, Fig.1A(excerpt); Ex.1003, ¶49. Next, the surgeon adjusts the alignment of the first metatarsal and fixes the moved first metatarsal to the first cuneiform using fixation devices (e.g., screw or plate) to achieve bone fusion in the corrected orientation. Ex.1003, ¶¶50-52; Ex.1010, 187-188; Ex.1012, 493; Ex.1004, 324-327; Ex.1018, 466.

C. Known Surgical Methods For Correcting Bunion Deformities

McGlamry describes surgical methods for correcting bunion deformities. Ex.1004, 322; Ex.1003, ¶¶53-55. Chapter 31 of McGlamry walks through the steps of a bunion correction procedure. Ex.1004, 324-327.

McGlamry teaches performing a bunion-correction surgery that includes cutting the medial end of the first metatarsal, cutting the distal end of the first cuneiform, moving the first metatarsal in the transverse plane and rotating the first metatarsal in the frontal plane, and fixing the medial portion of the moved first metatarsal to the distal portion of the cuneiform. *Id.*, 322-329.

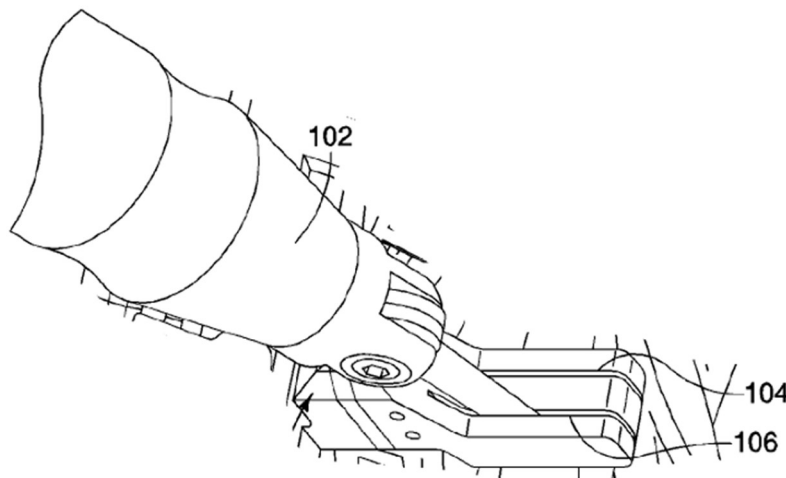


Id., Figs.31.3B (preparation of bones), 31.5 (temporary fixation of first metatarsal following bone repositioning), 31.9C (plate fixation), 31.9D (healed foot with corrected bunion) (left to right); Ex.1003, ¶55.

D. Known Bone Preparation Guides (Bone Cutting Guides)

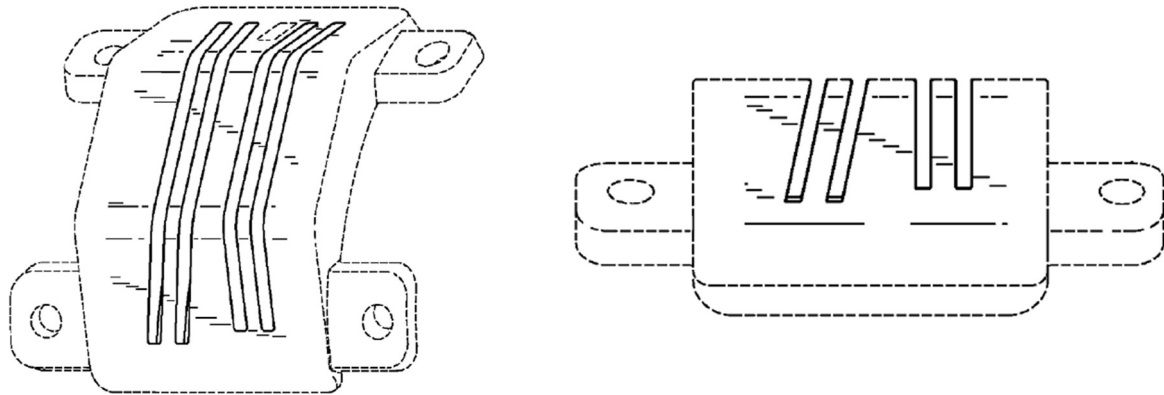
Bone cutting guides, including those for metatarso-cuneiform arthrodesis, were well known by 2015.² Ex.1003, ¶¶57-62

For example, Haddad discloses a cutting guide and a positioning jig usable “for a fusion application, [wherein] the jig likely would be secured to a metatarsal distally and a cuneiform proximally.” Ex.1022, [0058]. Haddad’s cutting guide includes slots 104/106 that allow a surgeon to use a surgical saw 102 “create two complimentary surfaces that will easily and effectively achieve a union through normal biological healing.” *Id.*, [0068].

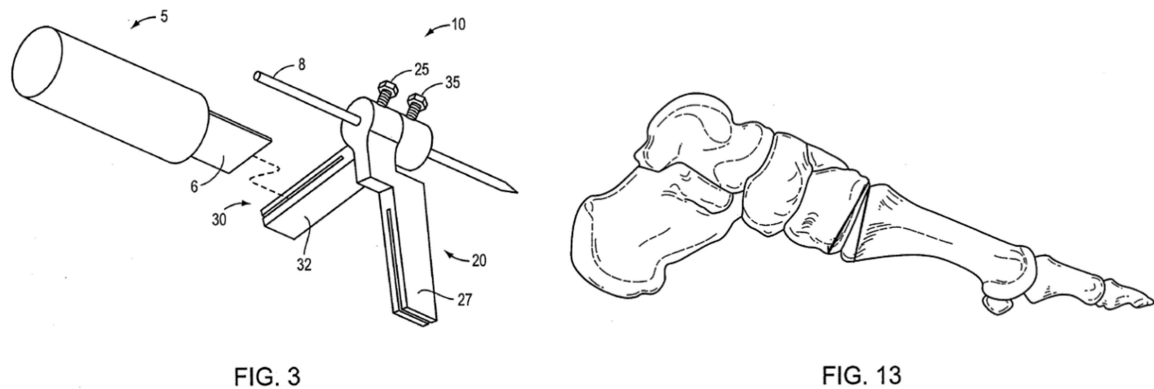


Id., Fig.9 (excerpt); Ex.1003, ¶58. DaCosta and Weinstein similarly disclose bone cutting guides for use in bunion correction surgeries:

² The term “bone preparation guide” as used in the ’481 patent is synonymous with “bone cutting guide.” Ex.1003, ¶57.

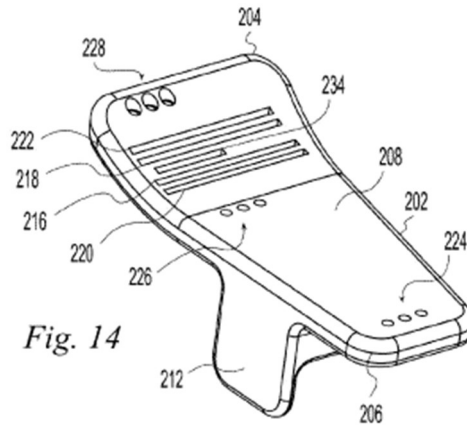


Ex.1035, Figs.1, 5; Ex.1003, ¶60.



Ex.1023, Figs.3, 13; Ex.1003, ¶59.

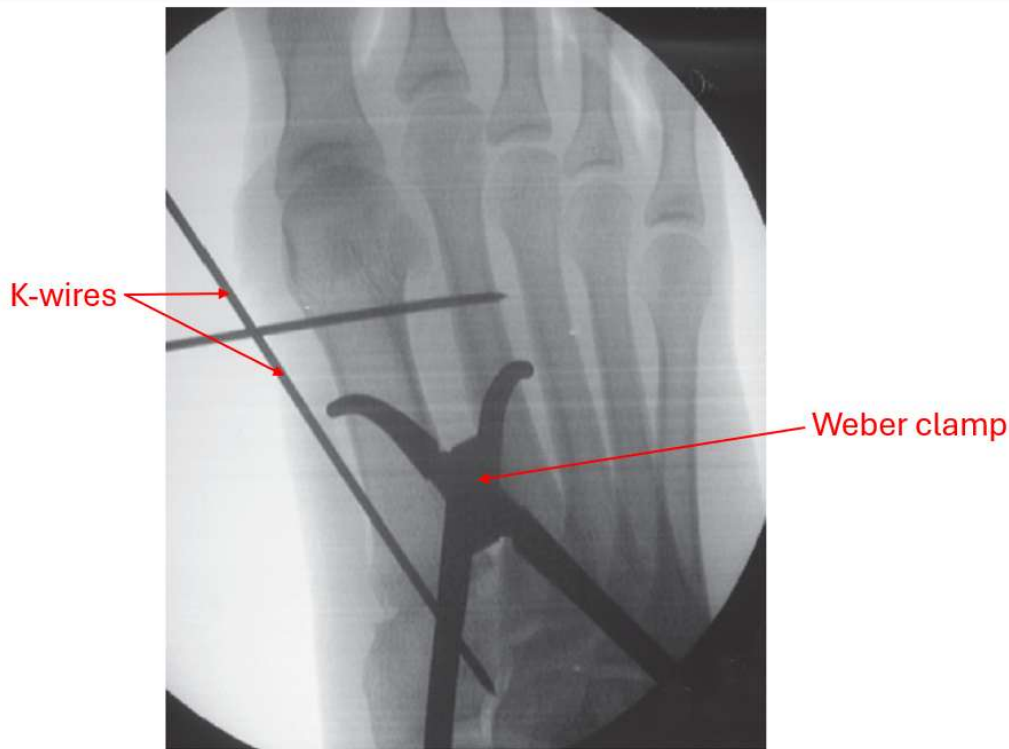
Fallin also discloses a bone cutting guide for use in a bunion correction surgery. Ex.1003, ¶¶61-62. Fallin discloses “[m]ethods and devices for performing an osteotomy,” including “forming a fusion osteotomy at a metatarsocuneiform joint on the first ray of a human foot.” Ex.1006, Abstract. Fallin further discloses an “an osteotomy guide 200” that achieves “more precision and repeatability in the relative orientation of the cuts” to the metatarsal and cuneiform. *Id.*, [0062].



Id., Fig.14. Fallin’s osteotomy guide 200 includes multiple slots 216/218/220/222 for cutting the metatarsal and cuneiform bones. *Id.*, [0052]. The guide also includes holes 224/226/228 through which pins may be inserted to attach the guide to the metatarsal and/or cuneiform. *Id.*, [0053]. In addition, Fallin’s guide includes a joint-alignment feature for positioning the guide relative to the joint such that a predetermined amount of bone is removed. *Id.*, [0055].

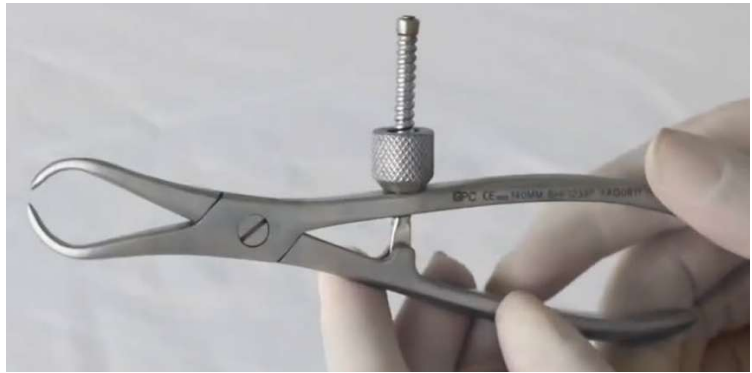
E. Known Bone Positioning Guides

As disclosed in McGlamry, one step in a bunion correction procedure involves repositioning the first metatarsal in one or more planes (e.g., transverse, frontal, sagittal). Ex.1004, 324-327. Bone positioning guides that assist with this movement have long been known in the art. Ex.1003, ¶¶63-72. For example, by 2013, McGlamry disclosed using a Weber clamp and K-wires to reposition the first metatarsal, as shown below.



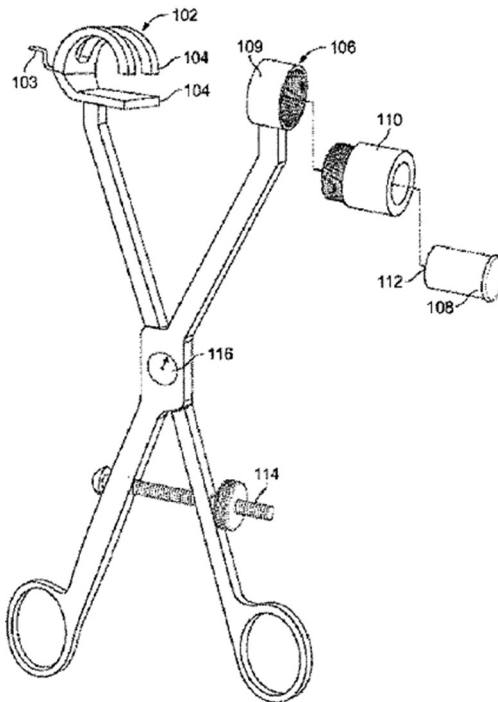
Id., Fig.31.5; Ex.1003, ¶64.

Numerous bone positioning guides for use in bunion correction procedures were commercially available before 2015. For example, a Hintermann distractor may be pinned to the first and second metatarsals to reduce an abnormal IM angle and, after preparation of the metatarsocuneiform joint, pinned to the first metatarsal and medial cuneiform to compress the cut bones. Ex.1003, ¶65. Additional bone positioning guides include Weber clamps (Ex.1004, 325-326), reduction forceps/clamps (Ex.1005; Ex.1018, 466), periarticular clamps (Ex.1003, ¶66), and joint distractors (*id.*). Surgeons have used clamps such as those shown below to position the first metatarsal for more than two decades:



Id., ¶66.

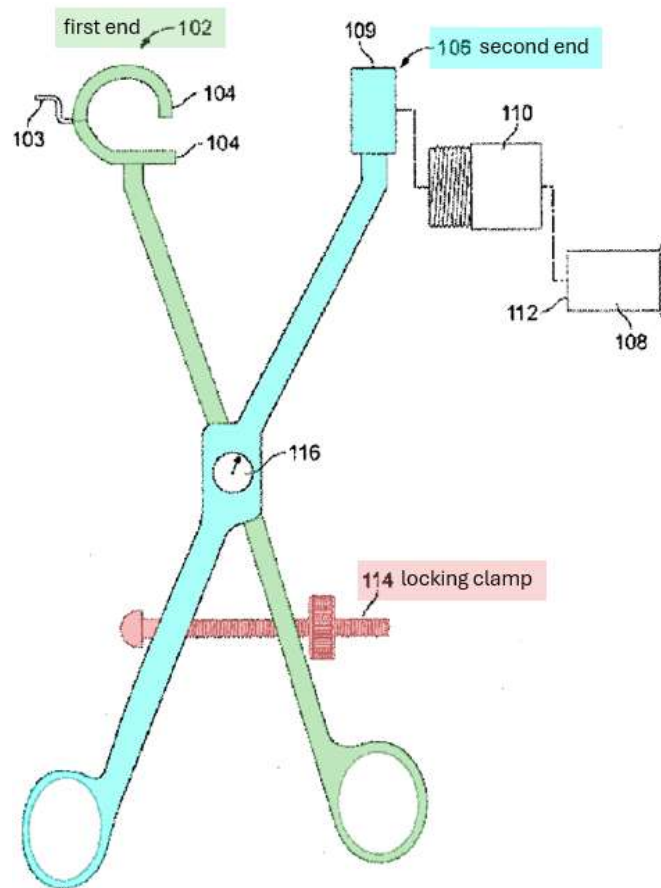
Kartalian also discloses a bone positioning guide for repositioning the first metatarsal during a bunion correction surgery—referred to as “instrument 100.” An embodiment of this instrument is shown below:



Ex.1005, Fig.1 (excerpt)³; Ex.1003, ¶67. The instrument “act[s] as reduction forceps to align two bones or reduce the distance between the bones.” Ex.1005, 9:66-10:3. More specifically, Kartalian discloses that the instrument can be used to reduce the distance between the first and second metatarsals—thereby reducing the IM angle—and to rotate the first metatarsal in the frontal plane to address rotational deformities. *Id.*; Ex.1003, ¶68.

The instrument includes a first end/arm 102 (green) configured to engage the second metatarsal, a second end 106 (blue) configured to engage the first metatarsal, and a locking clamp 114 (red) with a threaded shaft and knob. Ex.1005, 10:46-51.

³ Figure 1 from one of Kartalian’s priority applications (Ex. 1037) is used herein in place of Kartalian’s Figure 1 because it is identical and higher resolution.



Id., Fig.1 (excerpt); Ex.1003, ¶69. The first end/arm 102 may have various configurations, including, for example, “a caliper,” “towel clip,” or “vertically spaced plates.” Ex.1005, 9:33-45. In a plate configuration, first end/arm 102 may have “plates” that are “curved or other shape[d]” to engage the bone. *Id.* “[O]nce the plates have been placed around the bone, the position of the plates may be secured by a locking mechanism 103.” *Id.*, 9:42-45; Ex.1003, ¶70.

With the first end/arm 102 engaged with the second metatarsal, the second end/arm 106 can be used to engage the first metatarsal and move it toward the second metatarsal to achieve reduction or realignment of the first metatarsal to a desired

position. Ex.1005, 9:66-10:3, 10:46-51. According to Kartalian, “[t]he instrument 100 may act as reduction forceps to align two bones or reduce the distance between the bones, as desired. Ex.1003, ¶71. Moreover, instrument 100 may allow for correction of any rotational deformity (pronation) when used for surgical correction of a bunion.” Ex.1005, 9:66-10:3.

F. Known Fixation Devices

One of the final steps in a bunion correction surgery is fixation of the first metatarsal and medial cuneiform to achieve a boney fusion in the corrected position. Ex.1003, ¶¶73-75. Fixation devices for this purpose have been known since at least the 1970s, when surgeons began using devices such as screws and plates to maintain the corrected position between the bones. *Id.*, ¶73; *see also* Ex.1012, 486-487, 490.

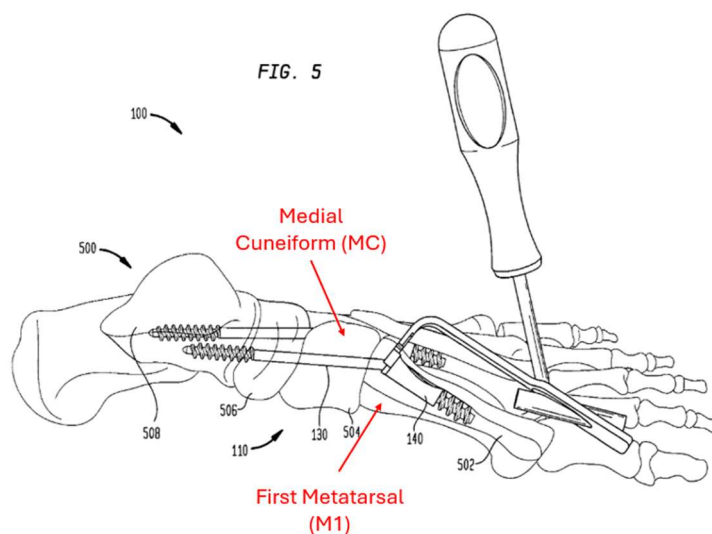
For example, in 1996, Hofbauer disclosed numerous fixation devices usable in this step, including K-wires, Steinman pins, compression screws, and plate/screw constructs. Ex.1012. 486-487; Ex.1003, ¶74. In 2013, McGlamry described the use of cortical screws and a “locking plate” as fixation devices in a bunion correction procedure, illustrated below. Ex.1004, 326; Ex.1003, ¶75.



Figure 31.7 Postoperative AP radiograph demonstrating the “three solid cortical screw technique” with restoration of anatomical alignment.

Id., Figs.31.7, 31.8.

Likewise, Fallin discloses that “fixation in the forms of pins, plates, screws, rods or other suitable fixation is applied.” Ex.1006, [0067]-[0068], [0074]-[0075]. Tyber further discloses intramedullary implants used to fix the metatarsal and cuneiform during a bunion correction procedure. Ex.1008, 1:24-30, 2:27-29.



Ex.1008, Fig.5.

III. THE '481 PATENT

A. Overview

The '481 patent relates to “devices and techniques for positioning and/or preparing bones.” Ex.1001, 1:27-28, 1:40-46, 4:40-43.

Each claim of the '481 patent is directed to “[a]n instrumented surgical technique” for correcting a bunion deformity. *Id.*, Claims 1-30. Generally, the claimed methods recite various combinations of making an incision in the foot, cutting the metatarsal and/or cuneiform, moving the metatarsal in multiple planes, compressing the metatarsal and cuneiform, and fixating the metatarsal and cuneiform for fusion. *Id.*

To perform these methods, the '481 patent claims combinations of surgical instruments as part of the surgical technique. These instruments include, for example, a “bone positioning guide” for moving the first metatarsal; a “pin” for rotating the first metatarsal in the frontal plane; a “bone preparation guide,” which is a bone cutting guide, to direct a cutting instrument for cutting the metatarsal and/or cuneiform; a “fixational device,” such as a screw or plate, for fixing the first metatarsal in its moved position for fusion. *Id.*; *see also* Ex.1003, ¶¶76-82.

B. Prosecution History

The '481 patent was filed under Track One prioritized examination. Ex.1002, 209-210. None of the claims that ultimately issued were rejected by the examiner. *Id.*, 433-436.

IV. LEVEL OF ORDINARY SKILL

The '481 patent relates to “devices and methods for positioning and/or preparing bones,” specifically the first metatarsal and medial cuneiform. Ex.1001, 1:28-29, 1:51-62. The claims recite surgical methods performed using mechanical devices and therefore include limitations directed to both surgical techniques and medical instrumentation. A hypothetical person of ordinary skill in the art would have a combination of these two skill sets. Ex.1003, ¶¶29-37. Thus, a hypothetical person of ordinary skill in the art (“POSA”) would have had medical degree and at least 3 years of surgical experience with foot surgery. *Id.* 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 in the art provided that person’s additional experience compensates for any differences in that person’s education as stated above. *Id.*

This Petition does not turn on this specific definition of the level of ordinary skill. The claims would be obvious from the perspective of any reasonable definition of a POSA. *Id.*, ¶37; *see also id.*, ¶¶16-28, 83, 432-434.

V. CLAIM CONSTRUCTION

In a post grant review, a claim “shall be construed using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. [§] 282(b).” 37 C.F.R. §42.100(b). Under this standard, claims “are generally given their ordinary and customary meaning,” as understood by a person of ordinary skill. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (citation omitted).

Petitioner submits that 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.”); *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017). The claims are unpatentable under the plain and ordinary meaning of the claim language.

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.

A. “bone positioning guide”

The plain and ordinary meaning of “bone positioning guide” is a “device that is designed to move bone(s).” Ex.1003, ¶¶84-89.

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

Function: “causing the bone engagement member to push the first metatarsal laterally toward the second metatarsal and thereby reduce the intermetatarsal angle between the first metatarsal and the second metatarsal to correct the bunion deformity,” (Ex.1001, Claims 1, 14, 27);

“reducing a distance between the bone engagement member and the contact surface, thereby reducing the intermetatarsal angle between the first metatarsal and the second metatarsal to correct the bunion deformity” (*id.*, Claim 30).

Corresponding Structure: the specification discloses multiple structures that perform the claimed function, including:

- “a tenaculum or tong structure,” which can include a “first shaft pivotably connected to a second shaft,” “[a] first end of each shaft can include an actuator, such as a handle,” “[a] second end of the first shaft can include a bone engagement member” (*id.*, 6:44-58);

- “[a] generally C-shaped configuration” that includes main body member 20, a shaft 30, bone engagement member 40, a first end 60, and second end 70 (*id.*, 4:63-5:10, Figs.1, 3B, 3C).

B. “fixation device”

The plain and ordinary meaning of “fixation device” is a “device that connects bones for fusion.” Ex.1003, ¶¶89-92.

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

Function: “fixating a moved position of the first metatarsal relative to the medial cuneiform for fusion,” (Ex.1001, Claims 1, 14, 30);

“fixating a moved position of the first metatarsal relative to the medial cuneiform,” (*id.*, Claim 27).

Corresponding Structure: The specification provides multiple examples of a fixation device, including: “compressing bone screw, bone plate, bone staple, external fixator, intramedullary implant or nail” (*id.*, 10:46-51) and “two bone plates positioned in different planes” (*id.*, 13:23-27).

C. “tissue removing instrument”

The plain and ordinary meaning of “tissue removing instrument” is a “device for cutting tissue.” Ex.1003, ¶¶93-96.

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

Function: cutting bone (Ex.1001, Claim 1).

Corresponding Structure: The specification discloses multiple structures that perform the claimed function, including: a saw blade, rotary burr, and osteotome. (*Id.*, 7:34-38).

VI. RELIEF REQUESTED

A. Grounds

Petitioner requests post-grant review on the following grounds:

Ground	Reference(s)	Basis	Challenged Claims
1	McGlamry and Kartalian	§103	1, 3-8, 10-11, 13, 27, 29
2	McGlamry, Kartalian, and Fallin	§103	2, 9, 14-24, 26, 28, 30
3	Fallin, Kartalian, and McGlamry	§103	1-11, 13-24, 26-30
4	Fallin, Kartalian, McGlamry, and Tyber	§103	12, 25
5	McGlamry, Kartalian, and Tyber	§103	12
6	McGlamry, Kartalian, Fallin, and Tyber	§103	25

In support of the Petition, Petitioner submits the expert declaration of Steven K. Neufeld, M.D. *See* Ex.1003, ¶¶1-15; *see also* Ex.1021.

B. Asserted References

The '481 patent's earliest claimed priority date is August 14, 2015. Ex. 1001.

The references⁴ relied on are prior art for the following reasons:

Ex.	Reference(s)	Date	Art Type
1004	McGlamry	Published: 2013	§102(a)(1)
1005	Kartalian	Published: Nov. 11, 2014	§§102(a)(1),(2)
1006	Fallin	Provisional Filed: Jan. 28, 2015	§102(a)(2)
1007	Tyber	Published: Dec. 11, 2012	§102(a)(1),(2)

Fallin lists an application filing date of December 4, 2015 and expressly claims the benefit of U.S. Provisional Application No. 62/108,936 (“the ’936 provisional application”), filed January 28, 2015. Ex. 1006, Front Page. The disclosures relied upon herein in Fallin—including paragraphs 1-75, claims 1-29, and Figures 1-32—are disclosed in and supported by the ’936 provisional application. *Compare* Ex.1006 with Ex.1020, 11-57. Therefore, Fallin is “effectively filed” for those disclosures as of January 28, 2015 under 35 U.S.C. §102(d), and qualifies as prior art under §102(a)(2) as of that date.

The references are analogous art because they are from the same field as the ’481 patent—namely, surgical procedures involving bone. Ex.1003, ¶¶97-98; Ex.1001, 1:32-42; *Unwired Planet, LLC v. Google Inc.*, 841 F.3d 995, 1000 (Fed.

⁴ A declaration from a professional librarian is submitted to support the publication date and public accessibility of certain cited references. Ex.1036.

Cir. 2016). The references are also pertinent to the problem addressed by the inventors, including cutting, repositioning, and fixation of bone during surgical procedures. Ex.1003, ¶¶97-98.

VII. GROUNDS OF UNPATENTABILITY

A. Ground 1: Claims 1, 3-8, 10-11, 13, 27, And 29 Are Obvious Over McGlamry And Kartalian

1. Claim 1

McGlamry and Kartalian render claim 1 obvious. Ex.1003, ¶99.

a. Preamble

The preamble recites “[a]n instrumented surgical technique for preparing a tarsal-metatarsal joint for fusion and for repositioning a first metatarsal to correct a bunion deformity.” To the extent the preamble is limiting, McGlamry discloses it. Ex.1003, ¶¶100-101

McGlamry discloses a bunion correction surgery that includes cutting the medial end of the first metatarsal, cutting the distal end of the first cuneiform, correcting the position of the metatarsal in the transverse plane and rotating it in the frontal plane, and fixing the medial portion of the moved first metatarsal to the distal portion of the cuneiform to promote fusion. Ex.1004, 324-327; Ex.1003, ¶101. McGlamry further teaches using tools during the procedure, including:

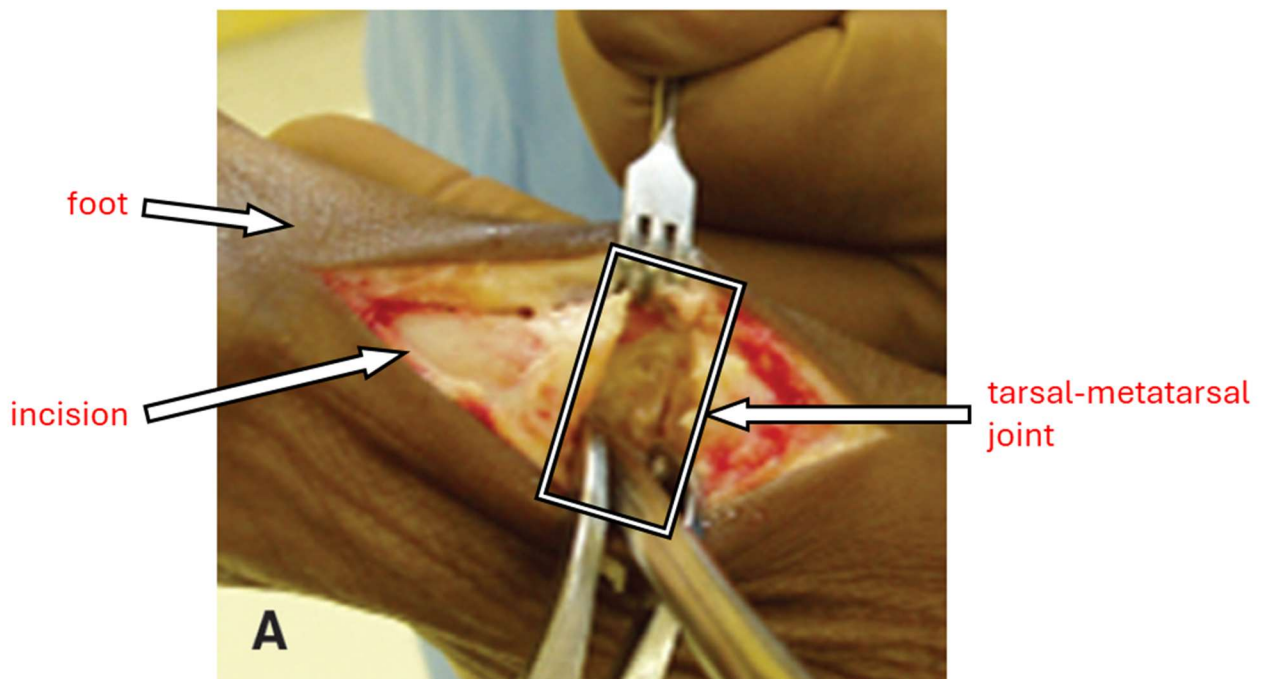
- Osteotome to cut bone (Ex.1004, 324);

- Weber clamps and/or K-wires to reposition the first metatarsal and/or hold it in place prior to fixation (*id.*, 325-326);
- Screws, locking plates, and drills to fix the metatarsal to the cuneiform (*id.*, 326-329).

b. Limitation 1[a]

This limitation recites “making an incision on a foot to provide access to a tarsal-metatarsal joint.” McGlamry discloses this limitation. Ex.1003, ¶¶102-104

According to McGlamry, “[a]n incision is made over the metatarsal-cuneiform joint approximately 4 to 6 cm in length. ... The tarsal-metatarsal incision is deepened in the same plane using sharp and blunt dissection.” Ex.1004, 324. An example of this incision is shown below:

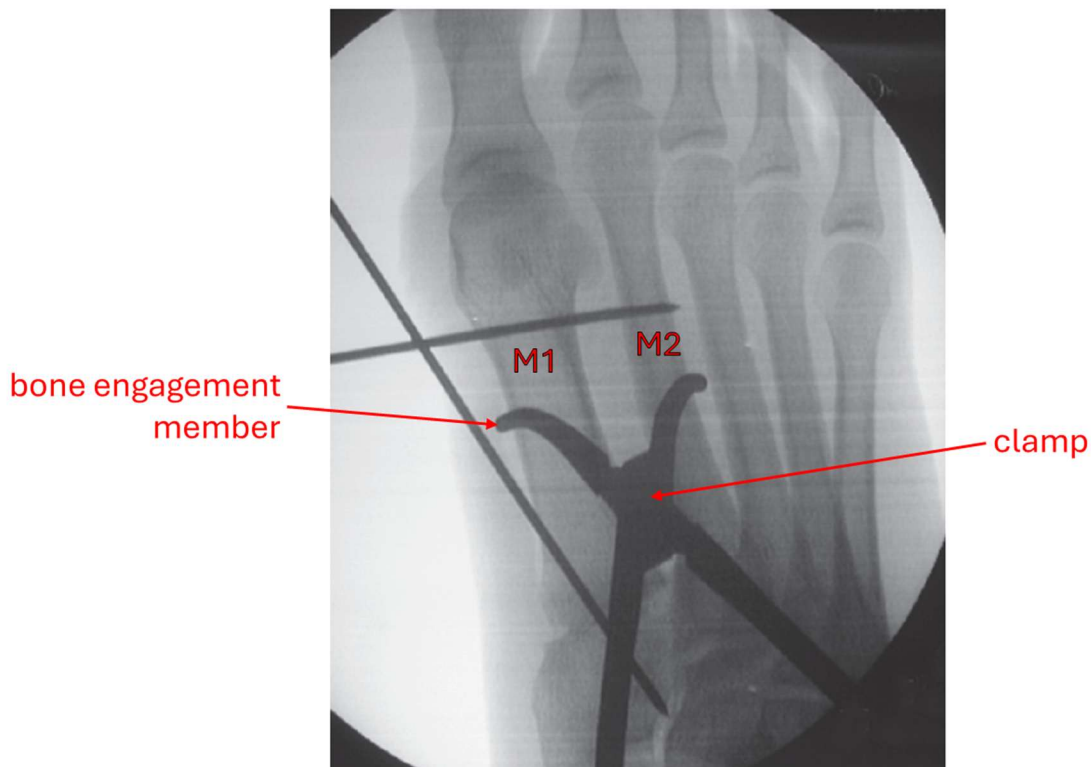


Ex.1004, Fig.31.3A (annotated); see Ex.1003, ¶¶103-104.

c. Limitation 1[b]

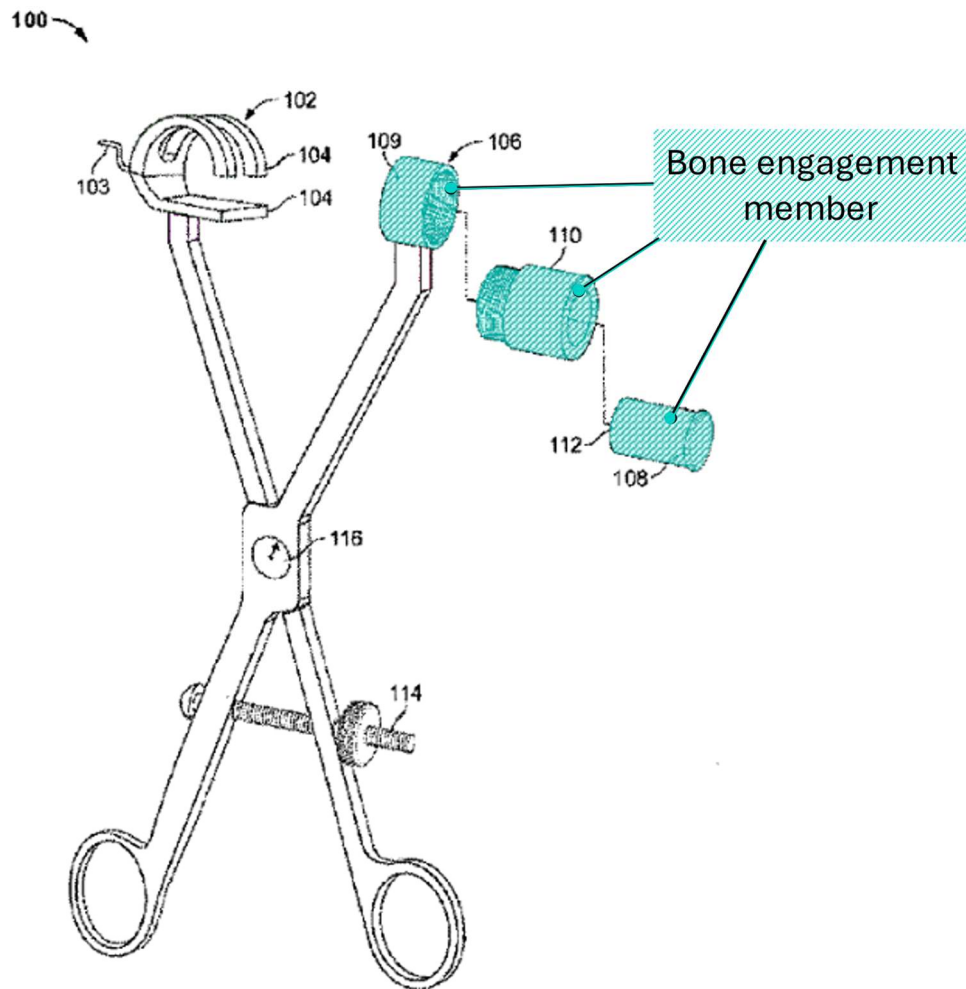
This limitation recites “engaging the first metatarsal with a bone engagement member of a bone positioning guide.” McGlamry and Kartalian render this limitation obvious. Ex.1003, ¶¶105-118.

McGlamry discloses using a Weber clamp to engage the first metatarsal for moving the first metatarsal in the transverse plane. Ex.1004, 325-326; Ex.1003, ¶106. McGlamry explains the Weber clamp “assist[s], increase[s], or maintain[s] the reduction.” Ex.1004, 325-326. McGlamry depicts its clamp in the following figure:



Ex.1004, Fig.31.5; Ex.1003, ¶107.

Similar to McGlamry, Kartalian discloses an “instrument 100” that “may act as reduction forceps to align two bones or reduce the distance between the bones, as desired.” Ex.1005, 9:66-10:3. Kartalian’s instrument is a tenaculum (forceps) and positions the bones by moving the metatarsal in the transverse plane.



Ex.1005, Fig.1 (excerpt); Ex.1003, ¶¶108-110.

It would have been obvious to use Kartalian’s instrument in McGlamry’s procedure. First, Kartalian’s instrument has features that are specifically designed for bunion correction procedures and would have been a desirable option for use in

McGlamry's procedure. Ex.1003, ¶¶111-118; *see also, e.g.*, Ex.1005, 9:58-10:18. The instrument includes features for engaging or even locking bones during movement of the first metatarsal. Ex.1005, 10:4-6; Ex.1003, ¶112. It also includes "an automatic angle indicator 116 to provide the surgeon with an estimate of the angle of the bones requiring correction." Ex.1005, 10:8-16. Kartalian explains that a POSA could use that indicator and measurements of the patient's anatomy to calibrate the instrument "to show the angle between the bones." *Id.* This feature would provide the surgeon with additional guidance on the bone's final position, improving the success rate of a surgery known for a relatively high failure rate. Ex.1003, ¶¶112-113; Ex.1005, 2:30-39. Kartalian's instrument further includes a sleeve for inserting the K-wires that McGlamry uses for temporary fixation. Ex.1003, ¶114; *infra* Section VII.A.7.

Additionally, using Kartalian's instrument instead of McGlamry's Weber clamp would have been nothing more than the substitution of one known element for another with predictable results. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007). Both Kartalian's instrument and McGlamry's Weber clamp move the metatarsal during bunion correction procedures. Ex.1005, 9:66-10:3; Ex.1004, 325-326. Both are a form of a tenaculum and used in similar bunion correction procedures. Ex.1003, ¶115. Given these similarities, the results of substituting one instrument for another would have been predictable. *Id.*

A POSA would have had a reasonable expectation of success in using Kartalian's instrument in McGlamry's procedure and in place of the Weber clamp. Ex.1003, ¶¶116-118. Kartalian's instrument was designed for a bunion correction procedure that is, in many respects, similar to McGlamry's procedure. Ex.1005, 9:58-10:18, 10:29-62; Ex.1003, ¶116. The operational principles of Kartalian's instrument would not be changed when used in McGlamry's procedure. Ex.1003, ¶116. Furthermore, the Weber clamp disclosed by McGlamry performs a similar function. *Id.* Given Kartalian's disclosure of an instrument for bunion correction procedures, modifications to Kartalian's instrument would likely have been unnecessary to perform McGlamry's procedure. *Id.*, ¶118. However, any such modification would have been within the skill of a POSA who could modify basic surgical equipment. *Id.*

Kartalian's instrument in the combination satisfies "bone positioning guide" under the plain and ordinary meaning, as it is a type of tenaculum/tong and is used to position bones, including moving the metatarsal in the transverse plane. *Id.* Under §112(f), this instrument is identical or at least equivalent to structures identified in the '481 patent for the claimed bone positioning guide discussed in Section V.A. *Id.* Kartalian's instrument is at least an equivalent of the disclosed bone-positioning structures (e.g., tenaculum/tong embodiments or C-shaped bone-positioning frame) because it performs the same function (positioning metatarsals including IMA

reduction), in substantially the same way (opposed bone-engaging members manipulated by the surgeon to apply controlled corrective forces), to achieve the same result (bones are moved to the desired alignment and stabilized while fixation is performed). Ex.1003, ¶109. Kartalian’s instrument includes end 106, which is a bone engagement member. *Id.*, ¶110. Kartalian explains the “end 106 may be placed on the proximal first bone (first metatarsal).” Ex.1006, 10:50-51.

d. Limitation 1[c]

This recites “engaging the bone positioning guide with a second metatarsal separated from the first metatarsal by an intermetatarsal angle.” McGlamry and Kartalian render this limitation obvious. Ex.1003, ¶¶119-124.

McGlamry discloses:

the surgeon can use his or her thumb against the first metatarsal to manually reduce the first *intermetatarsal angle* in the transverse plane. The primary surgeon must ensure that the first metatarsal is in the desired position, which is essentially rotated out of valgus and parallel with the second metatarsal in both the transverse and sagittal planes. In many cases, a large *Weber clamp may be used to assist, increase, maintain the reduction.*

Ex.1004, 325-326. McGlamry illustrates its Weber clamp engaging with the second metatarsal separated from the first metatarsal by an intermetatarsal angle:

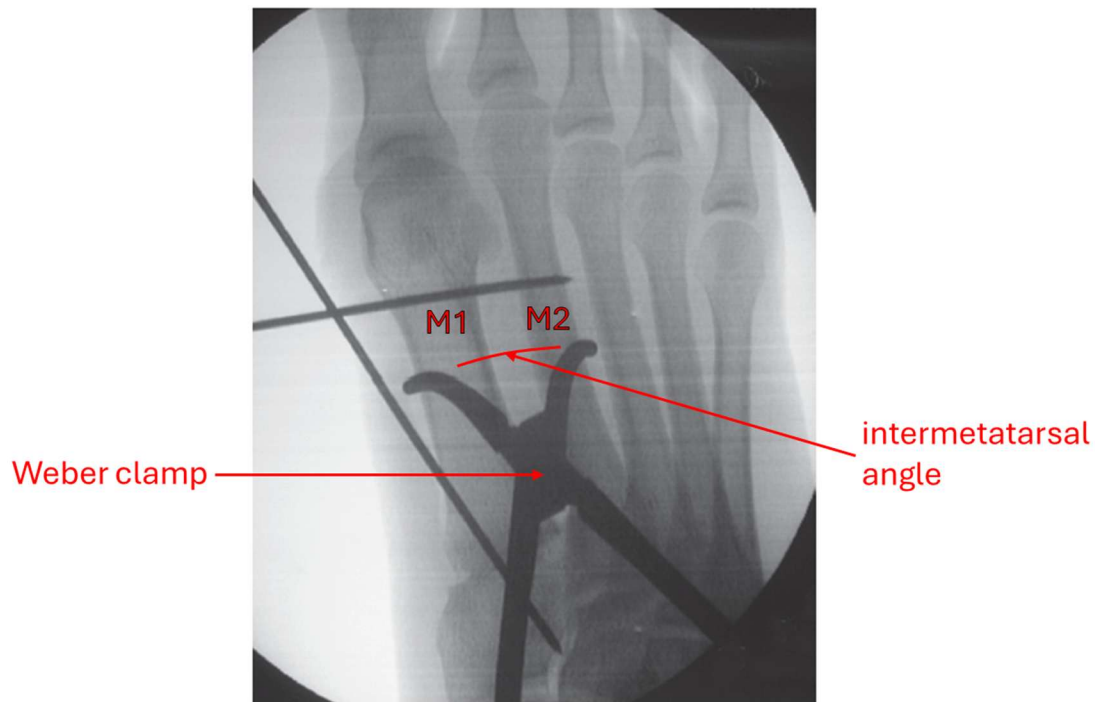


Figure 31.5 Intraoperative radiograph in a case in which a large Weber clamp was used for reduction of a large IM angle.

Ex.1004, Fig.31.5 (annotated), 325-326; Ex.1003, ¶121.

Kartalian likewise discloses that an end of its instrument engages with the second metatarsal: “first end 102 [(tip)] may be placed on the distal second bone (second metatarsal)....” Ex.1005, 10:49-51; Ex.1003, ¶122. With this end engaged to the second metatarsal, the arm 106 of the instrument engages the first metatarsal for moving it toward the second metatarsal to reduce the intermetatarsal angle. Ex.1005, 9:66-10:3, 10:46-51. Thus, when Kartalian’s instrument is used in McGlamry’s procedure to reduce an intermetatarsal angle, the instrument engages the second metatarsal while it is separated from the first metatarsal by the intermetatarsal angle. Ex.1003, ¶¶123-124.

e. Limitation 1[d]

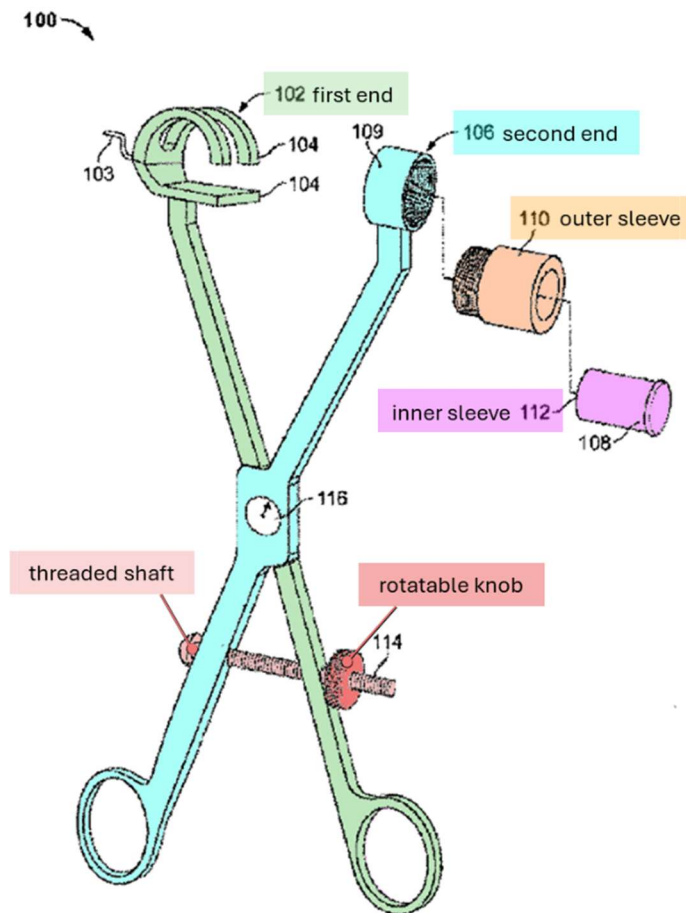
This limitation recites “cutting an end of the first metatarsal with a tissue removing instrument.” McGlamry discloses this limitation. Ex.1003, ¶¶125-128.

McGlamry teaches using, for example, an osteotome and a mallet to cut an end of the first metatarsal. Ex.1004, 324; *see also id.*, 808 (describing “use of a sagittal saw”); Ex.1003, ¶¶126-127. McGlamry explains that “[t]he initial joint resection is performed on the first metatarsal articular surface,” and that the “resection is made perpendicular to the long axis of the first metatarsal and parallel to the existing metatarsal base.” Ex.1004, 324. McGlamry’s use of an osteotome and mallet or a saw satisfies the “tissue removing instrument” limitation under its plain meaning; and if §112(f) were applied, each is corresponding structure (or an equivalent) to the saw/osteotome/bur-type tissue-removal instruments described in the ’481 patent. Ex.1003, ¶125.

f. Limitation 1[e]

This limitation recites “rotating a knob connected to a threaded shaft of the bone positioning guide to cause the bone engagement member to push the first metatarsal laterally toward the second metatarsal and thereby reduce the intermetatarsal angle between the first metatarsal and the second metatarsal to correct the bunion deformity.” McGlamry and Kartalian render this limitation obvious. Ex.1003, ¶¶129-132.

Kartalian's instrument 100 includes a rotatable knob connected to a threaded shaft:



Ex.1005, Fig.1 (excerpt); Ex.1003, ¶130. When the instrument is used in McGlamry's procedure and engaged with the first and second metatarsals, a surgeon would rotate the threaded knob to bring the handles toward each other, thereby causing the arm 106 (bone engagement member) to move toward the end 102. Ex.1003, ¶131.

Kartalian explains that movement of the arm 106 (bone engagement member) toward the end 102 pushes the first metatarsal laterally toward the second metatarsal, reducing the intermetatarsal angle between the two metatarsals: “[t]he instrument 100 may act as reduction forceps to align two bones or reduce the distance between the bones, as desired.” Ex.1005, 9:66-10:3, *see also id.*, 10:46-62 (“After the instrument 100 is placed on the bones and the bone is set in the desired orientation, the reduction or realignment may occur to the desired angle as estimated by angle indicator 116.”); Ex.1003, ¶132.

g. Limitation 1[f]

This limitation recites “imparting a force to a pin inserted into the first metatarsal to adjust an alignment of the first metatarsal in a frontal plane to correct the bunion deformity.” McGlamry discloses this limitation. Ex.1003, ¶¶133-136.

McGlamry states: “If the surgeon feels a need to obtain more correction in the frontal plane, the K-wire can be inserted into the first metatarsal ... [and] used as a rotation device and rotate the metatarsal” in the frontal plane.⁵ Ex.1004, 326;

⁵ A K-wire is a pin. Ex.1003, ¶135; *see also* Ex.1019, 1 (“A century ago, in 1909, Martin Kirschner (1879-1942) introduced a smooth pin, presently known as the Kirschner wire (K-wire).”). In bunion correction procedures, K-wires and other pins (e.g., Steinman pins) are used interchangeably for temporary fixation. *See, e.g.,*

Ex.1003, ¶134. McGlamry’s K-wire “rotation device” is used in addition to—not instead of—other means of repositioning the metatarsal, such as the Weber clamp. *Id.*, ¶136. For example, Kartalian’s instrument would be applied to draw the first metatarsal toward the second, while the K-wire would be used in conjunction to rotate the metatarsal in the frontal plane. *Id.* Kartalian’s instrument and McGlamry’s K-wire would thus be used together to provide controlled correction of the first metatarsal in multiple planes. *Id.*

h. Limitation 1[g]

This limitation recites “cutting an end of a medial cuneiform with the tissue removing instrument.” McGlamry discloses this limitation. Ex.1003, ¶¶137-138.

McGlamry describes using, for example, the osteotome and mallet to cut an end of the medial cuneiform. Ex.1004, 324; *see also id.*, 808 (disclosing “saw”). McGlamry explains that “[t]he corrective articular resection is made at the distal aspect of the convex shaped cuneiform.” *Id.*, 324; Ex.1003, ¶138.

i. Limitation 1[h]

This limitation recites “compressing the first metatarsal together with the medial cuneiform.”

Ex.1012, 487 (disclosing temporary fixation by K-wire or Steinman pin in bunion correction procedure); Ex.1009, 349 (interchangeable use of pins and wires).

The '481 patent describes bones are compressed when they are moved toward each other. Ex.1001, 14:64-15:3. For example, the '481 patent explains “a compression pin, such as a threaded olive pin 300,” creates compression. *Id.*, 13:11-14.

McGlamry discloses limitation 1[h]. Ex.1003, ¶¶139-141. For example, McGlamry describes using a screw to compress the first metatarsal and medial cuneiform, explaining that a “[homerun screw] provides interfragmentary compression and leverage,” and that “[t]he interfragmentary compression will create an excellent reduction at the base of the tarsal-metatarsal joint.” Ex.1004, 326; *see also id.*, 328; Ex.1003, ¶141.

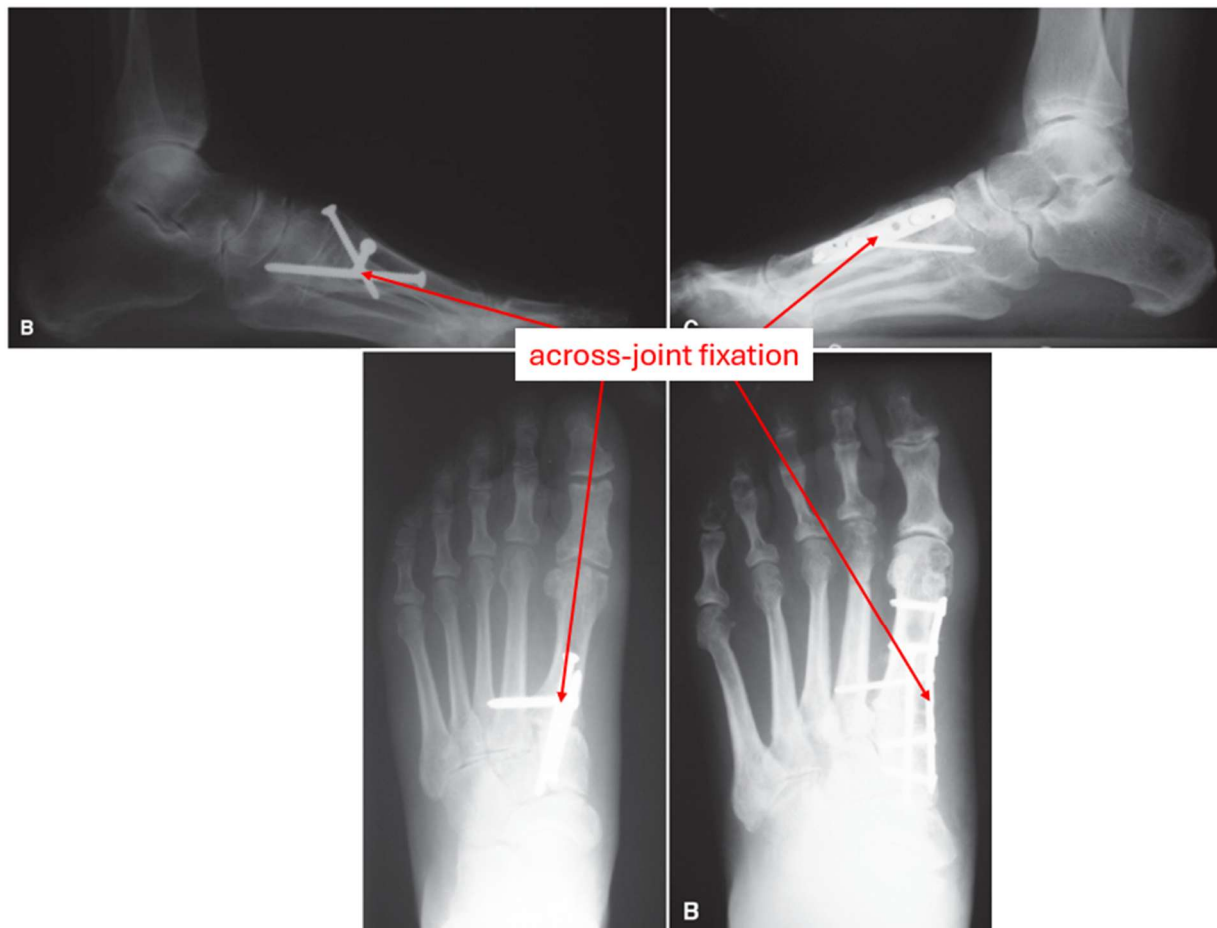
j. Limitation 1[i]

This limitation recites “fixating a moved position of the first metatarsal relative to the medial cuneiform for fusion using at least one bone fixation device.” McGlamry discloses this limitation. Ex.1003, ¶¶142-144.

McGlamry discloses that, during bunion correction surgery, fixation is applied “across the first metatarsal-cuneiform joint”⁶ using one or more screws and/or a plate, each of which is a “bone fixation device,” to fix the first metatarsal in a

⁶ The “metatarsal-cuneiform joint” refers to the joint between the first metatarsal and medial cuneiform. Ex.1003, ¶143.

corrected position relative to the medial cuneiform. Ex.1004, 329; *see also id.*, 326 (“[t]he recommended fixation techniques consist of interfragmentary compression of three solid cortical screws or an interfragmentary compression of solid cortical screw along with a medial based locking plate”); Ex.1003, ¶143. The placement of these devices is shown below:



Ex.1004, Figs. 31.6B, 31.7, 31.8B-C. Such across-joint fixation fixes the first metatarsal relative to the medial cuneiform for fusion. Ex.1003, ¶143.

This disclosure satisfies the claimed “fixation device” under its plain and ordinary meaning discussed in Section V.B. *Id.*, ¶144. Under §112(f), McGlamry’s

across-joint screws and/or plate are the same types of fixation structures identified in the '481 patent (e.g., screws/plates) and thus constitute the corresponding structure (or at least an equivalent) for fixing the moved position for fusion. *Id.*

Therefore, McGlamry and Kartalian render claim 1 obvious. *Id.*

2. Claim 3

Claim 3 depends from claim 1 and recites: “further comprising removing the bone positioning guide from the first metatarsal and the second metatarsal with the moved position of the first metatarsal remaining fixated relative to the medial cuneiform by the at least one bone fixation device.” McGlamry and Kartalian render this additional limitation obvious. Ex.1003, ¶¶145-147.

Kartalian discloses that its instrument includes “a locking clamp 114 to hold the instrument 100 in position once the final alignment of the bones has been achieved.” Ex.1005, 10:4-8. Kartalian further explains its instrument is removed after “properly aligning and *securing the reduction* of the IM angle of the first metatarsal.” *Id.*, 10:23-28; Ex.1003, ¶146.

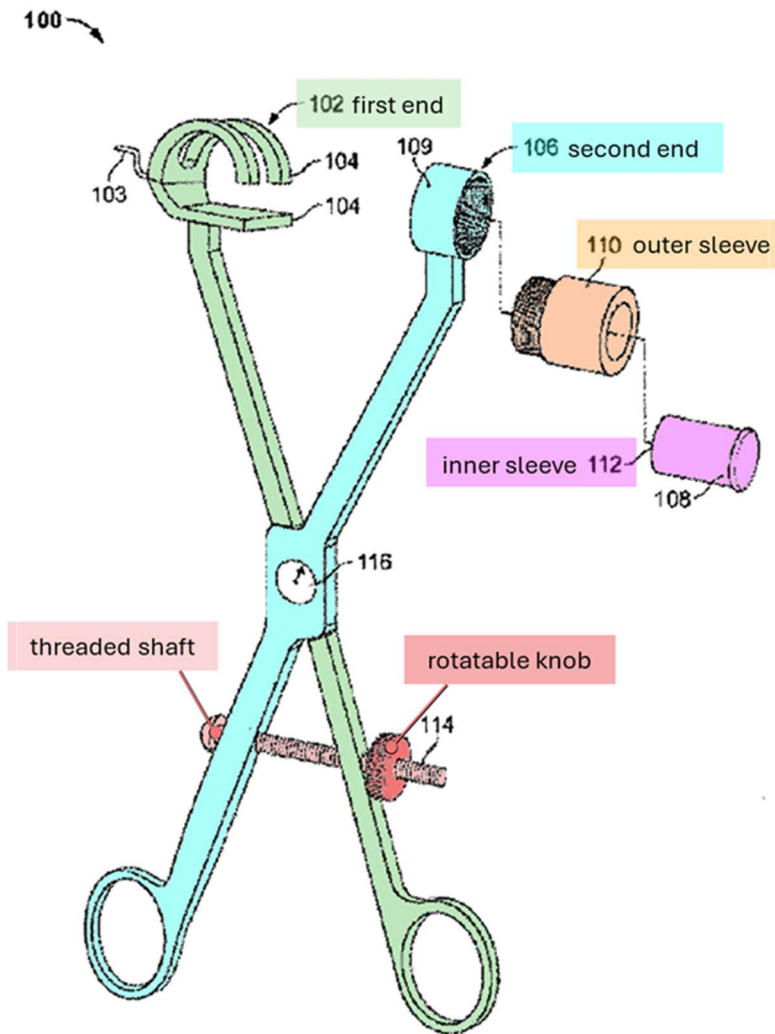
When Kartalian’s instrument is used in McGlamry’s procedure, the locking clamp would maintain the first metatarsal in the moved position while one or more bone fixation devices are installed to fix the first metatarsal in its corrected position relative to the medial cuneiform, consistent with McGlamry’s fixation techniques.

Ex.1003, ¶147. After fixation, the instrument would be removed, with the moved position of the first metatarsal remaining fixed relative to the medial cuneiform. *Id.*

3. Claim 4

Claim 4 depends from claim 1 and recites: “further comprising, prior to engaging the first metatarsal with the bone engagement member of the bone positioning guide and engaging the bone positioning guide with the second metatarsal, joining at least three components together, including the threaded shaft and the bone engagement member, to form the bone positioning guide.” McGlamry and Kartalian render this additional limitation obvious. Ex.1003, ¶¶148-150.

Kartalian discloses that its instrument is formed by joining multiple components together prior to use. As shown in Figure 1, the instrument includes, among other components, the end 102, arm 106, rotatable knob, and threaded shaft, which are assembled together to form the instrument:



Ex.1005, Fig.1 (excerpt); Ex.1003, ¶149. These components are joined prior to use so that the instrument may engage the first metatarsal with the arm 106 (bone engagement member) and engage the end 102 with the second metatarsal during bunion correction. Ex.1003, ¶¶149-150.

4. Claims 5-6

Claim 5 depends from claim 1 and recites: “further comprising making a second incision on the foot to provide access to the second metatarsal, wherein engaging the bone positioning guide with the second metatarsal comprises

positioning a bone contact surface of the bone positioning guide in contact with the second metatarsal.” Claim 6 depends from claim 5 and recites: “wherein the bone positioning guide comprises a tip defining the bone contact surface, and positioning the bone contact surface of the bone positioning guide in contact with the second metatarsal comprises inserting the tip through the second incision.”

The ’481 patent explains that a tip is the portion of the bone positioning guide configured to engage a metatarsal other than the first metatarsal, such as the second metatarsal, and that such tips can have various shapes, including straight, angled, or curved configurations. Ex.1001, 6:6-22.

McGlamry and Kartalian render the additional limitations of claims 5-6 obvious. Ex.1003, ¶¶151-157. Kartalian’s instrument includes the end 102 that is a tip having a bone contacting surface for engaging the second metatarsal. Ex.1005, 9:24-57; Ex.1003, ¶153. Kartalian further explains that its end 102 can have various shapes, including “curved or other shape[d]” configurations to engage the bone. Ex.1005, 9:33-45. Kartalian also discloses its tips are “placed around the bone,” including the second metatarsal. *Id.*, 9:42-45, 10:49-51 (“end 102 may be placed on the distal second bone (second metatarsal)”); Ex.1003, ¶153.

Kartalian further discloses making a second incision to provide access to the second metatarsal for placement of its tip. Ex.1003, ¶154. Specifically, Kartalian explains: “[t]he surgical repair of hallux valgus may commence with a medial

incision at the first metatarsal and an incision lateral to the second metatarsal at its distal portion ... followed by placement of instrument 100.” Ex.1005, 10:29-33. This second incision is thus used to insert the instrument’s tip so that its bone contacting surface is positioned in contact with the second metatarsal. *Id.*, 10:43-45 (describing placing the instrument “on two separate bones”), 10:46-51 (“first end 102 may be placed on the distal second bone (second metatarsal)”).

Thus, Kartalian discloses positioning the bone contact surface of the bone positioning guide in contact with the second metatarsal by inserting the tip through the second incision. Ex.1003, ¶155. When Kartalian’s instrument is used in McGlamry’s procedure, making a second incision to access the second metatarsal for placement of the tip would have been a straightforward and predictable application of Kartalian’s technique. *Id.*, ¶156. Making a second incision to access the second metatarsal would have been routine surgical practice when engaging a separate bone with a bone-contacting instrument. *Id.*, ¶157.

5. Claim 7

Claim 7 depends from claim 1 and recites: “wherein imparting the force to the pin inserted into the first metatarsal to adjust the alignment of the first metatarsal in the frontal plane comprises imparting the force to the pin inserted into the first metatarsal to adjust the alignment of the first metatarsal in the frontal plane after rotating the knob connected to the threaded shaft of the bone positioning guide to

cause the bone engagement member to push the first metatarsal laterally toward the second metatarsal and thereby reduce the intermetatarsal angle between the first metatarsal and the second metatarsal.”

This additional limitation requires that the step of imparting the force to the pin (limitation 1[f]) occurs after the step of rotating the knob to laterally reposition the first metatarsal (limitation 1[e]). McGlamry and Kartalian render this sequencing obvious. Ex.1003, ¶¶158-161.

McGlamry discloses first repositioning the metatarsal in the transverse plane using the Weber clamp. Ex.1004, 325-326; Ex.1003, ¶160. McGlamry then explains that, “[i]f the surgeon feels a need to obtain more correction in the frontal plane, the K-wire can be inserted into the first metatarsal [T]he K-wire can be used as a rotation device and rotate the metatarsal into more of a neutral position....” Ex.1004, 326. Substituting Kartalian’s instrument for McGlamry’s Weber clamp would not change this disclosed order of operations. Ex.1003, ¶161.

6. Claim 8

Claim 8 depends from claim 1 and recites: “further comprising moving the first metatarsal in the sagittal plane.” McGlamry and Kartalian render this additional limitation obvious. Ex.1003, ¶¶162-163.

McGlamry discloses that its “procedure allows for triplanar correction of first metatarsal pathology,” including frontal, sagittal, and transverse planes. Ex.1004,

322. With respect to the sagittal plane correction in particular, McGlamry explains that:

The sagittal plane reduction technique is performed by stabilizing the hind foot, while the surgeon dorsiflexes the first metatarsophalangeal joint initiating the windless mechanism. This hind foot stability allows the surgeon to apply retrograde forces to the plantar tarsal–metatarsal joint and allows for the first metatarsal to plantarflex to a natural occurring level, parallel with the lesser metatarsals.

Id., 325. When Kartalian’s instrument is used in McGlamry’s procedure in place of the Weber clamp, the procedure would still allow for sagittal plane movement of the first metatarsal as disclosed by McGlamry. Ex.1003, ¶163.

7. Claim 10

Claim 10 depends from claim 1 and recites: “wherein the bone positioning guide comprises a cannulation, and further comprising inserting a fixation wire through the cannulation and into the second metatarsal.” McGlamry and Kartalian render these additional limitations obvious. Ex.1003, ¶¶164-169.

Kartalian discloses the second end 106 of its instrument is “configured as a cannulated sleeve 108.” Ex.1005, 9:58-60, Fig.1. This cannulation “may be used as a drill guide” and can have a sleeve diameter between 1mm and 4mm. *Id.*, 10:46-62. Kartalian also describes that the cannulation can be used as a guide for drilling through both the first and second metatarsals. *Id.*; Ex.1003, ¶165.

McGlamry further discloses temporary fixation of the corrected position of the metatarsal using a K-wire inserted through the first and second metatarsals. Ex.1004, 325-326, Fig.31.5.

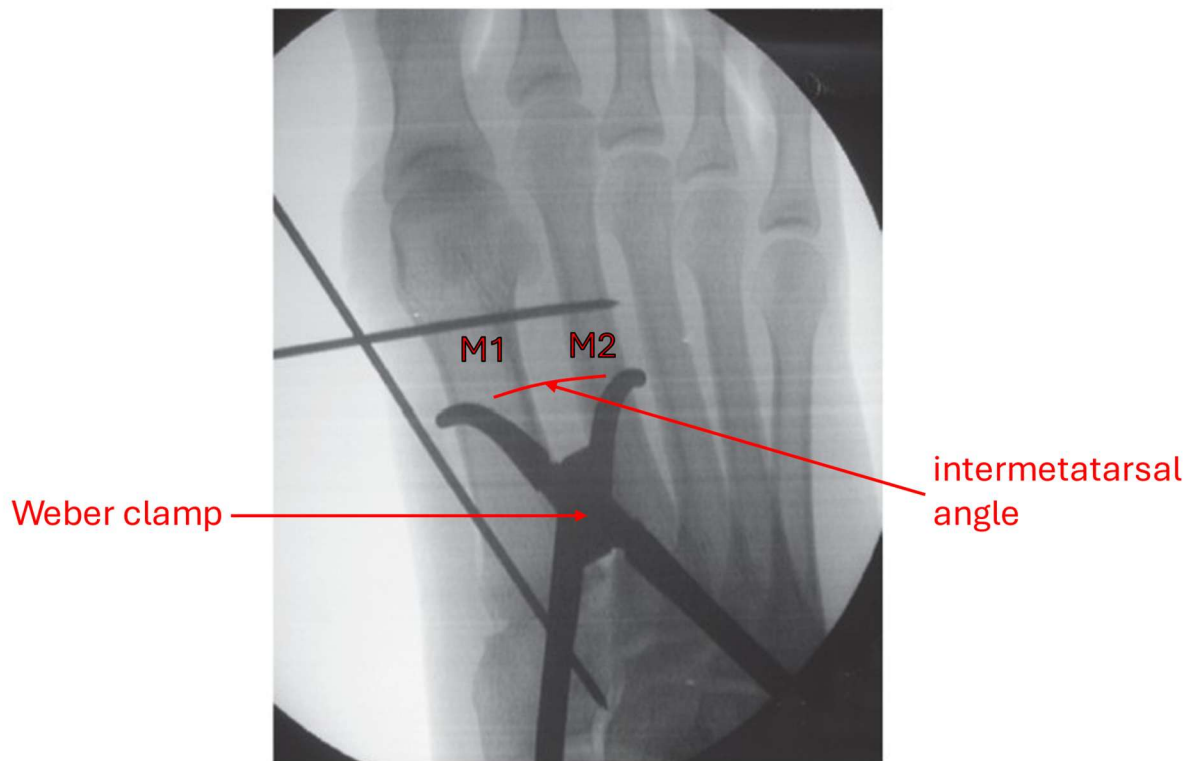


Figure 31.5 Intraoperative radiograph in a case in which a large Weber clamp was used for reduction of a large IM angle.

Id., Fig. 31.5; Ex.1003, ¶166. When Kartalian's instrument is used in McGlamry's procedure, it would have been obvious to use Kartalian's cannulated sleeve as a guide to place McGlamry's fixation wire (e.g., a K-wire) into the second metatarsal while the instrument maintains the corrected alignment between the first and second metatarsals. Ex.1003, ¶¶166-167. Doing so would allow controlled placement of the fixation wire along a desired trajectory while the reduction is held, thereby

reducing the risk of wire misplacement and interference with subsequent permanent fixation. *Id.*, ¶167.

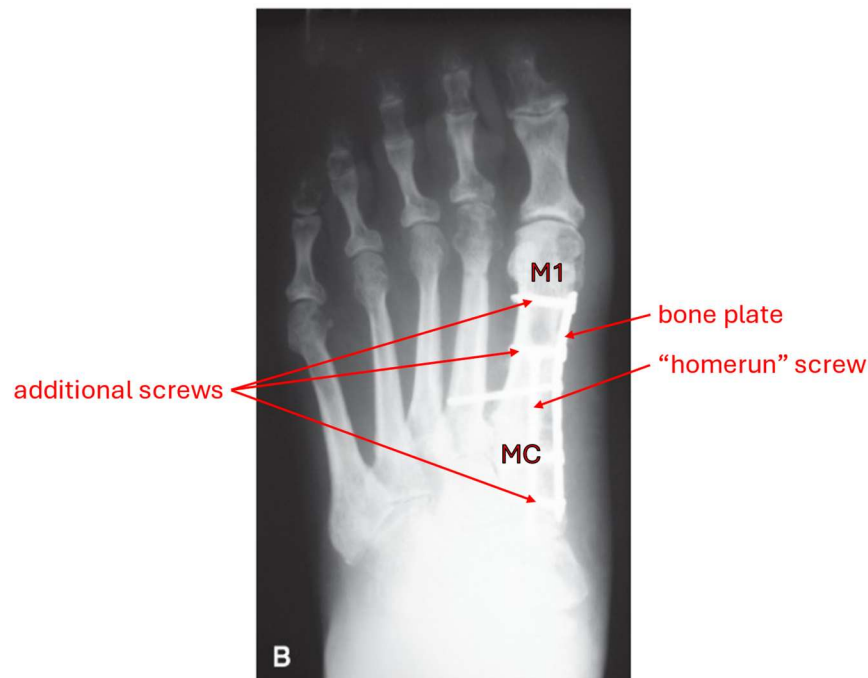
This modification would have been a routine, predictable application of Kartalian’s guidance feature to facilitate wire placement during stabilization. *Id.*, ¶168; *see also* Ex.1028, [0028]-[0030] (disclosing an opening at a clamp’s tip for accommodating a K-wire while the clamp maintains a reduction). Kartalian itself contemplates using wire-based components with guides, including passing wire limbs through cannulated guides on the instrument to achieve secure fixation while centralizing the instrument along the second metatarsal. Ex.1006, 8:26-37. In view of Kartalian’s disclosure of guides for wire passage and McGlamry’s reliance on temporary K-wire stabilization into the second metatarsal to hold the correction, a POSA would have had a reasonable expectation of success in using Kartalian’s cannulated sleeve to place a temporary fixation wire into the second metatarsal for the same stabilizing purpose, with predictable results. Ex.1003, ¶¶168-169; *see also* Ex.1028, [0028]-[0030].

8. Claims 11 and 13

Claim 11 depends from claim 1 and recites: “wherein the at least one bone fixation device comprises at least one of a screw and a plate.” Claim 13 depends from claim 1 and recites: “wherein fixating the moved position of the first metatarsal relative to the medial cuneiform for fusion using at least one bone fixation device

comprises inserting a compressing bone screw and a plate across the tarsal-metatarsal joint, wherein inserting the plate across the tarsal-metatarsal joint comprises inserting a plurality of bone screws through the bone plate to secure a first end of the bone plate to the medial cuneiform and a second end of the bone plate to the first metatarsal.” McGlamry and Kartalian render these additional limitations obvious. Ex.1003, ¶¶170-172.

As explained for limitation 1[i], McGlamry discloses fixing the corrected position using bone fixation devices, including screws, plates, or a combination thereof. *Supra* §VII.A.1.j. An example fixation configuration disclosed in McGlamry is shown below:



Ex.1004, Fig.31.8B; *see also id.*, 327 (“[f]ollowing the insertion of the homerun screw, the initial screws are placed proximal in the medial cuneiform of the plate”

and “the distal screws are placed into the metatarsal”); Ex.1003, ¶171. As illustrated and described, this fixation arrangement includes a compressing bone screw (“homerun” screw), a plate across the tarsal-metatarsal joint (bone plate), and a plurality of bone screws (additional screws) inserted through the plate to secure ends of the bone plate to the medial cuneiform and the first metatarsal. Ex.1003, ¶¶171-172. This configuration meets the fixation devices and steps recited in claims 11 and 13. *Id.*

9. Claim 27

The McGlamry-Kartalian combination renders claim 27 obvious. Ex.1003, ¶173.

a. Preamble

This preamble recites: “[a]n instrumented surgical technique for correcting a bunion deformity.” To the extent the preamble is limiting, the McGlamry-Kartalian renders it obvious for the reasons explained for the preamble of claim 1. *Supra* §VII.A.1.a; Ex.1003, ¶¶174-175.

b. Limitations 27[a]-27[c]

These limitations are the same as limitations 1[a]-1[c] and would have been obvious based on McGlamry and Kartalian for the same reasons. *Supra* §§VII.A.1.b-d; Ex.1003, ¶¶176-178.

c. Limitation 27[d]

This limitation recites “preparing an end of the first metatarsal for fusion.” McGlamry discloses this limitation for the reasons explained for limitation 1[d], because cutting the end of the first metatarsal constitutes preparing it for fusion. *Supra* §VII.A.1.e; Ex.1003, ¶¶179-181.

Furthermore, McGlamry discloses that, “[p]rior to reducing the joint... a significant amount of time should be spent with joint preparation. The metatarsal base and the distal cuneiform...are prepared. It is imperative that the surgeon is diligent to ensure the subchondral plate is penetrated demonstrating good bleeding at both the metatarsal and cuneiform.” Ex.1004, 324. This preparation of the metatarsal and cuneiform is shown in Figure 31.3B, which depicts an “[i]ntraoperative clinical view demonstrating the use of a 2-mm drill preparing the tarsal-metatarsal joint prior to fixation”:



Id., Fig.31.3B; Ex.1003, ¶180. McGlamry also discloses that “[a] substantial period of time is spent preparing this joint as this is a vital portion of the procedure to ensure

good bony healing.” Ex.1004, 324. In the context of bunion correction procedures, “bony healing” refers to achieving fusion between the prepared bone surfaces. Ex.1003, ¶181.

Thus, the McGlamry-Kartalian combination renders limitation 27[d] obvious.

Id.

d. Limitation 27[e]-27[f]

These limitations are the same as limitations 1[e]-1[f] and would have been obvious based on McGlamry and Kartalian for the same reasons. *Supra* §§VII.A.1.f-g; Ex.1003, ¶¶182-183.

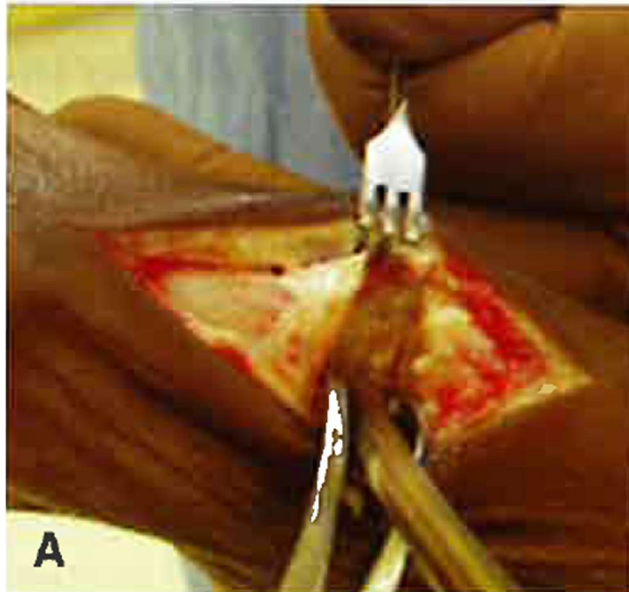
e. Limitation 27[g]

This limitation recites “preparing an end of a medial cuneiform for fusion.” For the reasons explained for limitations 27[d] and 1[g], McGlamry discloses preparing the end of the medial cuneiform for fusion, and thus the McGlamry-Kartalian combination renders the limitation obvious. *Supra* §VII.A.1.h; Ex.1003, ¶184.

f. Limitation 27[h]

This limitation recites “installing at least one fixation device through the incision to fixate a moved position of the first metatarsal relative to the medial cuneiform.” The McGlamry-Kartalian combination renders this limitation obvious. Ex.1003, ¶¶185-188.

As explained for limitation 1[i], McGlamry discloses using a bone fixation device to fixate a moved position of the first metatarsal relative to the medial cuneiform. *Supra* §VII.A.j. McGlamry further discloses that such fixation devices are installed through the incision used to access the tarsal-metatarsal joint.



Ex.1004, Fig.31.3. McGlamry explains that, when screws are used, “[t]he drill is aimed for the inferior, medial aspect of the cuneiform” (*id.*, 326), requiring exposure of the cuneiform through the incision and placement of the screw along that trajectory. Ex.1003, ¶¶187-188. The screw is therefore introduced through the incision and into the drill hole. *Id.*

McGlamry’s figures further confirm that fixation devices are installed through the incision. Figures 31.6-31.9 depict placement of screws and plates spanning the tarsal-metatarsal joint following exposure through the incision. *Id.* For example, Figure 31.9 shows a post-operative radiograph alongside a clinical photograph of the

foot, where the location of the plate corresponds with the visible incision scar, demonstrating that the fixation device was installed through that incision:

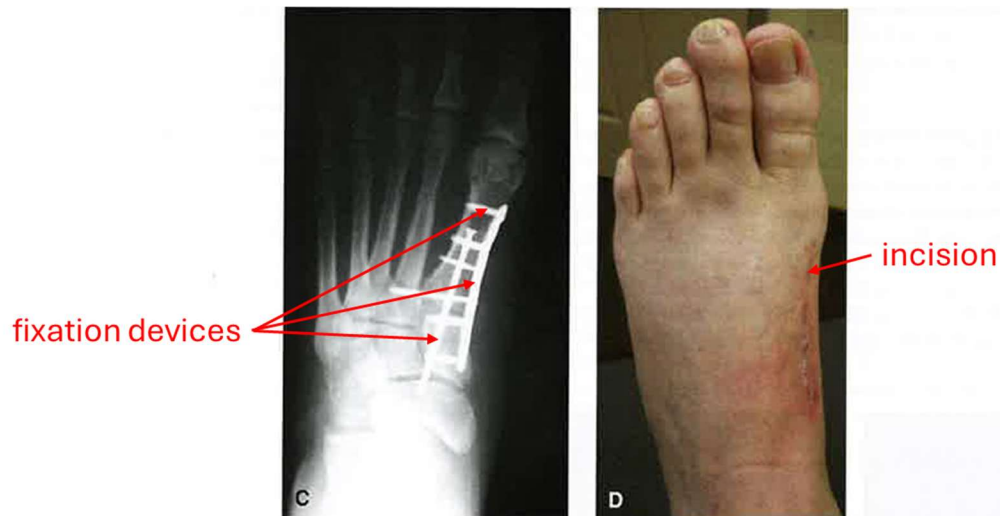


Figure 31.9 A,B: Preoperative radiograph and clinical photo of a patient with HAV deformity. C,D: Postoperative radiograph and clinical photo of the patient with the use of an interfragmental compression screw and a medial based locking plate. The correction can be seen in all three planes.

Ex.1004, Fig.31.9 (annotated); *see also id.*, 327 (referring to suturing a single wound); Ex.1003, ¶188.

Thus, McGlamry and Kartalian render claim 27 obvious. Ex.1003, ¶188.

10. Claim 29

Claim 29 depends from claim 27 and recites: “further comprising: [a] after preparing the end of the first metatarsal and after preparing the end of the medial cuneiform but prior to installing the at least one fixation device, compressing a prepared end the first metatarsal together with a prepared end of the medial cuneiform; and [b] after installing the at least one fixation device through the incision to fixate the moved position of the first metatarsal relative to the medial cuneiform, removing the bone positioning guide from the first metatarsal and the second

metatarsal.” McGlamry and Kartalian render these additional limitations obvious. Ex.1003, ¶¶189-193.

a. Limitation 29[a]

As explained for limitation 1[h], McGlamry discloses compressing the first metatarsal together with the medial cuneiform. *Supra* §VII.A.1.i. In McGlamry’s procedure, this compression occurs after preparation of the first metatarsal and medial cuneiform and before installation of the fixation device. Ex.1004, 324, 326-327; Ex.1003, ¶¶191-192.

McGlamry explains that joint preparation is performed first, followed by compression using the “homerun screw,” which is placed across the prepared metatarsal and cuneiform surfaces to draw the bones together. *See* Ex.1004, 324 (describing joint preparation), 326 (describing compression occurring after preparation); Ex.1003, ¶191. McGlamry describes that, once this compression step is completed, fixation devices, such as plates or screws, are installed to maintain the compressed relationship. Ex.1004, 327. Further, McGlamry explains that: “Following the insertion of the homerun screw, the initial screws are placed proximal in the medial cuneiform of the plate in combination of lock and nonlocking screws. The distal screws are placed into the metatarsal with a combination of locking and nonlocking screws.” *Id.*; Ex.1003, ¶192.

b. Limitation 29[b]

This limitation is substantively the same as the additional limitations of claim 3 and would have been obvious based on McGlamry and Kartalian for the same reasons. *Supra* §VII.2; Ex.1003, ¶193.

B. Ground 2: Claims 2, 9, 14-24, 26, 28, And 30 Are Obvious Over McGlamry, Kartalian, And Fallin

By August 2015, it would have been obvious to use Fallin’s cutting guide in the McGlamry-Kartalian combination, including during the procedure’s cutting steps. Ex.1003, ¶¶194-195. McGlamry emphasizes the importance of bone cutting, describing it as a “vital portion of the procedure.” Ex.1004, 324; Ex. 1003, ¶195. McGlamry further notes that “[j]oint preparation is extremely important in efforts to obtain a bony union and to avoid a delayed and nonunion,” recommending that surgeons devote a “substantial period of time...preparing this [metatarsal-cuneiform] joint.” Ex.1004, 324 McGlamry also warns that imprecise cutting can lead to complications such as “[s]ignificant shortening” of the first metatarsal, delayed unions, non-unions, and malunions. *Id.*, 329.

McGlamry also describes “freehand” bone resection (Ex.1004, 324), which depends on the surgeon’s skill and may lead to complications (Ex.1025, 1:31-34). A POSA would recognize that freehand resection is “very difficult to perform and can be rather imprecise.” Ex.1025, 1:31-37; Ex.1003, ¶196. 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.1025, 1:45-50.

Fallin’s cutting guide simplifies and standardizes the cutting steps in McGlamry’s procedure. Ex.1003, ¶197; Ex.1025, 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....”); Ex.1026, 1:8-14, 3:1-5 (describing cutting guide that “remove[s] the necessity of clinical judgement and guess work” of an osteotomy). “There are numerous prior art devices for precision cutting of bones in the appendicular skeleton,” including the feet. Ex.1025, 1:55-58. For example, McGlamry discloses that commercially available cutting guides “help the surgeon resect the proper amount of bone and at the proper angles,” including when resecting the joint surface. Ex.1004, 381-383; Ex. 1003, ¶198. Fallin likewise discloses that cutting guides can be used to “remove a predetermined, and relative[ly] thin, portion of bone from the articulating ends of the metatarsus and cuneiform.” Ex.1006, [0056]. Further, rather than spending “a substantial amount of time” on freehand joint preparation (Ex.1004, 324), Fallin’s cut guide would make preparation with a saw blade predictable and repeatable, thereby simplifying and shortening the procedure. Ex.1003, ¶¶197-199. Shorter and simpler surgical procedures typically mean less time under anesthesia, which benefits the patient. *Id.*, ¶200. Moreover, simplifying

surgical procedures can broaden their accessibility to a wider range of surgeons, which in turn makes such procedures available to more patients. *Id.*, ¶201.

Fallin’s cutting guide also mitigates complications identified by McGlamry. For example, McGlamry identifies “[s]ignificant shortening” of the metatarsal as a potential complication. Ex.1004, 329. Shortening refers to excessive removal of bone that alters foot biomechanics and can result in pain, deformities, and other complications. Ex.1003, ¶202. Fallin’s cutting guide “results in more precision and repeatability in the relative orientation of the cuts [to the metatarsal and cuneiform].” Ex.1006, [0062]. By precisely defining the guide positions—and thereby the location of the cuts—Fallin’s cutting guide allows the surgeon to visualize the cuts before making them. Ex.1003, ¶203.

Fallin’s cutting guide also reduces the risk of delayed unions, non-unions, and malunions identified by McGlamry. Ex.1004, 324. These complications can occur when the cut ends of the metatarsal and cuneiform do not correctly fit together after the metatarsal is repositioned. Ex.1003, ¶204. The use of cutting guides in metatarsal-cuneiform fusion procedures was a known technique for “easily and effectively achiev[ing] unions through biological healing.” Ex.1022, [0068]; *see also* Ex.1016, 429. Fallin’s cut guide promotes effective unions because it prepares complementary joint surfaces. *See, e.g.*, Ex.1006, [0058] (“the cuneiform may be

cut to create a second cut surface in predetermined relationship (as determined by the cut guide feature) to the first cut surface.”); Ex.1003, ¶204.

Using Fallin’s cut guide in McGlamry’s procedure incorporating Kartalian’s instrument would have involved applying a known technique to address known problems using known elements, yielding predictable results. Ex.1003, ¶205; *NuVasive, Inc. v. Hirshfeld*, 2021 WL 3661208, at *4-5 (Fed. Cir. Aug. 18, 2021) (use of a known nerve-monitoring technology to avoid a 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*, 550 U.S. at 417 (claims are obvious if they apply “a known technique to a piece of prior art ready for the improvement”).

It also would have been obvious to use Fallin’s cutting guide in McGlamry-Kartalian’s procedure because doing so would have been nothing more than applying a known technique to improve a similar method in the same way. Ex.1003, ¶¶206-207; *KSR*, 550 U.S. at 417.

A POSA would have recognized that Fallin’s cutting guide and its corresponding saw blade would be adapted to McGlamry-Kartalian’s technique with minimal or no modifications. Ex.1003, ¶¶208-211. Cutting guides are routinely adapted across procedures and anatomical variations. *Id.*, ¶209; *see also* Ex.1025, Abstract (describing a knee cutting guide that “is applicable to any bone-cutting

procedure which might benefit from improved accuracy”). Small-bone cutting guides, including Fallin’s, were known to be adaptable across multiple metatarsal and small-bone procedures. Ex.1003, ¶209; Ex.1022, [0057]-[0058] (describing how the jig and guide can be used in multiple metatarsal procedures and other anatomies, such as the hand); Ex.1027, 21:14-27 (describing various shapes and configurations of a cut guide); Ex.1030, 7:41-48. (describing a wedge osteotomy cutting guide that is “not only...applicable [to the toe], but rather, is [also] applicable to such cutting as related to any skeletal elements of the body.”). Indeed, prior art such as Weinstein confirms the established use of cut guides in bunion correction procedures, such as Lapidus procedures. Ex.1023, [0051], Fig.13; Ex.1003, ¶209.

The relevant portions of the surgical procedures described in Fallin and McGlamry are nearly identical. Ex.1003, ¶210. Both involve bunion correction procedures in which the proximal end of the first metatarsal and the distal end of the cuneiform are cut, and the first metatarsal is repositioned relative to the cuneiform. Ex.1006, [0056]-[0058], [0065]-[0068]; Ex.1004, 324-326. A POSA therefore would have had a reasonable expectation of success. Ex.1003, ¶210; *see, e.g., Intuitive Surgical, Inc. v. Ethicon LLC*, IPR2019-01110, Paper 30, 2020 WL 684908, at *13-14 (P.T.A.B. Nov. 20, 2020) (finding reasonable expectation of success to modify surgical instrumentation).

In the McGlamry-Kartalian-Fallin combination, Fallin’s “cutter, such as a saw blade” (Ex.1006, [0052]), would be selected as the tool to cut bones in the procedure. Ex.1003, ¶211. This cutter satisfies the “tissue removing instrument” limitation under its plain meaning; and if §112(f) were applied, it is corresponding structure (or an equivalent) to the saw/osteotome/bur-type tissue-removal instruments described in the ’481 patent. *Id.*

1. Claim 2

Claim 2 depends from claim 1 and recites: “wherein: rotating the knob connected to the threaded shaft comprises rotating the knob connected to the threaded shaft after cutting the end of the first metatarsal; imparting the force to the pin inserted into the first metatarsal comprises imparting the force to the pin inserted into the first metatarsal after cutting the end of the first metatarsal; and cutting the end of the medial cuneiform comprises cutting the end of the medial cuneiform after rotating the knob and after imparting the force to the pin to correct the bunion deformity.”

These additional limitations require that the steps of rotating the knob (limitation 1[e]) and imparting the force to the pin (limitation 1[f]) occur after cutting the end of the first metatarsal (limitation 1[d]) and before cutting the end of the medial cuneiform (limitation 1[g]). McGlamry, Kartalian, and Fallin render this sequencing obvious. Ex.1003, ¶¶212-221.

McGlamry discloses that, in its procedure, preparation (e.g., cutting) of the first metatarsal occurs before the first metatarsal is repositioned using the Weber clamp and pin. Ex.1004, 324-325 (explaining that “prior to reducing the joint into the appropriate desired position, a significant amount of time should be spent with joint preparation”); Ex.1003, ¶214. When Kartalian’s instrument is used in McGlamry’s procedure, a POSA would have understood that this sequencing is preserved because Kartalian simply provides instrumentation for performing the cutting and repositioning steps already disclosed by McGlamry. Ex.1003, ¶219.

Moreover, when using Kartalian’s instrument in the McGlamry-Kartalian-Fallin combination, it would have been obvious to cut the medial cuneiform after adjusting the position of the first metatarsal by the rotating the knob and imparting the force to the pin. *Id.*, ¶¶219-221.

The ’481 patent itself acknowledges that the order of its cutting and moving steps is not critical, identifying no particular order as imparting an advantage over another and expressly stating that “unless otherwise indicated, the steps described need not be carried out in the order described.” Ex.1003, ¶217; *see* Ex.1001, 10:55-56, 12:23-34 & 12:42-54 (indicating cutting can be performed before or after moving).

Consistent with this understanding, McGlamry explains that steps in its bunion correction procedure may be performed in different orders. Ex.1004, 324,

808-809. McGlamry also does not identify any technical advantage to the order of its cutting and adjusting steps relative to each other. Ex.1003, ¶218.

Fallin discloses cutting the end of the medial cuneiform after adjusting the position of the first metatarsal to correct a bunion deformity. Ex.1006, [0006], [0065]-[0068]. A POSA using Kartalian’s instrument in the McGlamry-Kartalian-Fallin combination would therefore have found it obvious to cut the metatarsal, adjust the metatarsal position, and then cut the cuneiform, as this sequence naturally accommodates Fallin’s correction technique while achieving the same surgical endpoint. Ex.1003, ¶¶219-221.

Furthermore, there are only two options for the timing of cutting the cuneiform relative to metatarsal repositioning—before or after adjustment. *Id.* Both options were known. *Id.* Selecting Fallin’s disclosed order represents nothing more than choosing between known alternatives. *Id.*

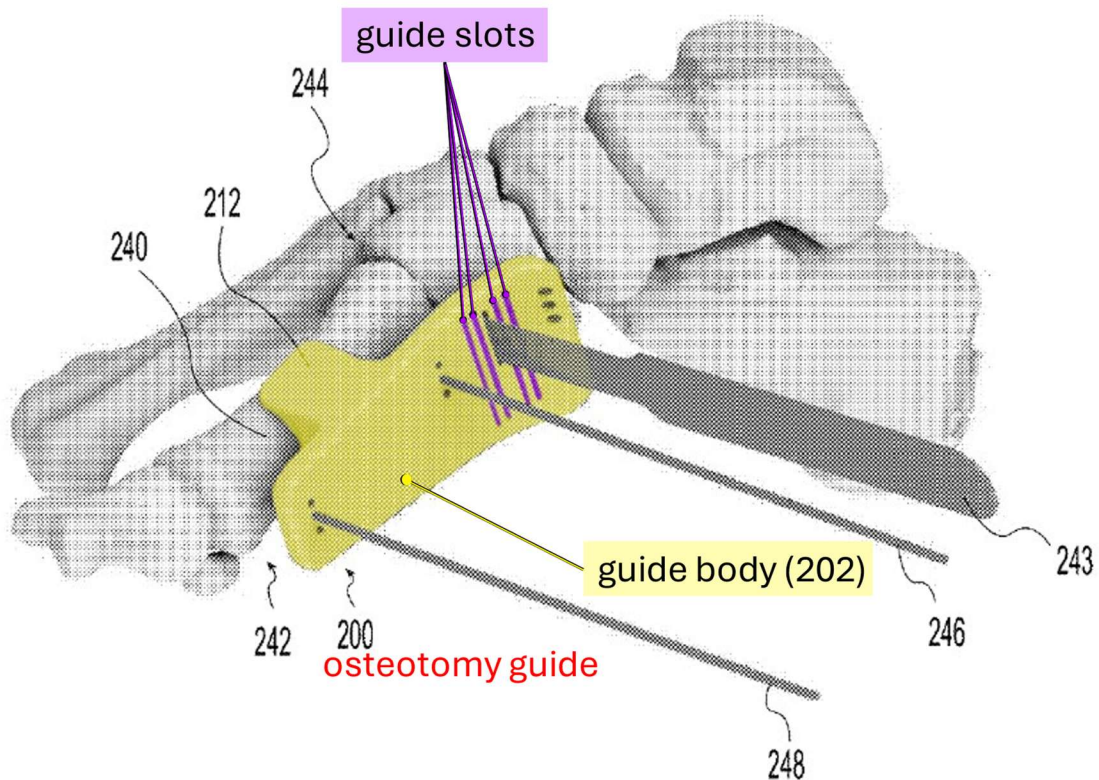
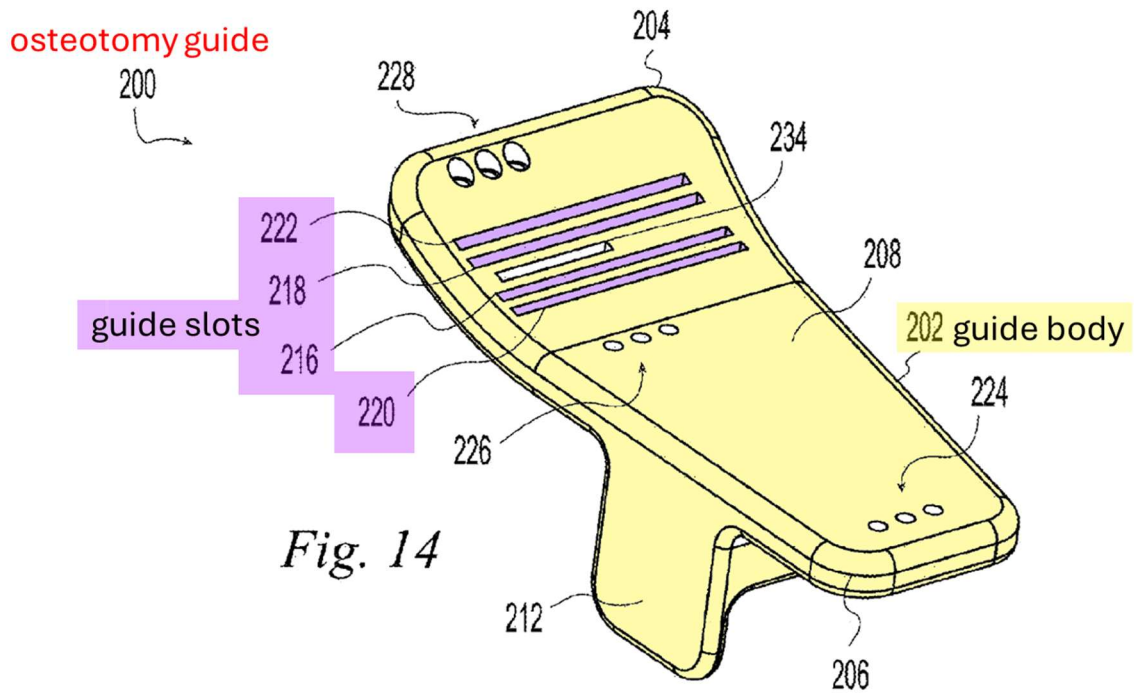
Reordering of steps constitutes a predictable variation and is insufficient to confer patentability. *KSR*, 550 U.S. at 417 (2007) (claims are obvious when they “involve [nothing] more than the simple substitution of one known element for another.”). Substituting one of two known alternatives for the other is obvious where the result is predictable. *KSR*, 550 U.S. at 416-18; *Uber Techs., Inc. v. X One, Inc.*, 957 F.3d 1334, 1340 (Fed. Cir. 2020) (holding substitution of one of two alternatives for the other “is obvious because it would have been a ‘predictable variation’”).

Because Fallin’s order of steps produces the same clinical and structural outcome as McGlamry’s disclosed technique, a POSA would have had a reasonable expectation of success in performing bunion correction by first adjusting the position of the first metatarsal and then cutting the medial cuneiform. Ex.1003, ¶¶219-221.

2. Claim 9

Claim 9 depends from claim 1 and recites: “wherein: the tissue removing instrument is a saw blade; cutting the end of the first metatarsal comprises guiding the saw blade through a first bone preparation guide cutting slot; and cutting the end of the medial cuneiform comprises guiding the saw blade through a second bone preparation guide cutting slot.” McGlamry, Kartalian, and Fallin render these additional limitations obvious. Ex.1003, ¶¶222-226.

Fallin describes an “osteotomy guide [that] includes a first guide feature operable to guide a cutter to cut the metatarsus and a second guide feature operable to guide a cutter to cut the cuneiform.” Ex.1006, claim 24; *see also id.*, [0052] (disclosing a “cutter, such as a saw blade”), [0065], [0067]. An osteotomy guide and a bone preparation guide are each bone cutting guides. Ex.1003, ¶224. Fallin discloses that its osteotomy guide includes a guide body 202 having guide slots 216, 218, 220, 222, which are positioned for receiving and guiding a tissue removing instrument (e.g., saw blade). Ex.1006, [0055]; Ex.1003, ¶¶225-226.



Ex.1006, Figs.14, 21.

3. Claim 14

McGlamry, Kartalian, and Fallin render claim 14 obvious. Ex.1003, ¶¶227-246.

a. Preamble And Limitations 14[a]-14[c]

The preamble and these limitations are the same as the preamble of claim 1 and limitations 1[a]-1[c] and would have been obvious based on the McGlamry-Kartalian-Fallin combination for the reasons explained for claim 1’s preamble and limitations 1[a]-1[c] in Ground 1. *Supra* §§VII.A.1.a-d; Ex.1003, ¶¶228-231.

b. Limitation 14[d]

This limitation substantively recites the saw-blade-and-first-slot limitations of claim 9 and would have been obvious based on the McGlamry-Kartalian-Fallin combination for the reasons explained for limitation 1[d] and claim 9 in this ground. *Supra* §§VII.A.1.e, VII.B.2; Ex.1003, ¶232.

c. Limitation 14[e]

This limitation recites “removing a cut portion of the first metatarsal from the tarsal-metatarsal joint.” McGlamry discloses this limitation. Ex.1003, ¶¶233-234.

McGlamry discloses that “[t]he initial joint resection is performed on the first metatarsal articular surface.” Ex.1004, 324. Performing such a resection necessarily entails cutting and removing a portion of the first metatarsal at the tarsal-metatarsal joint. Ex.1003, ¶234; *see also* Ex.1006, [0058] (“[A] first cut may be made on one

of the metatarsus and cuneiform to remove a portion of bone creating a first cut surface and a space resulting in increased mobility between the metatarsus and cuneiform to allow them to be freely repositioned.”), [0056]. Consistent with this disclosure, McGlamry further explains that, during the procedure, “it is vital that the entire plantar ledge of the metatarsal base and medial cuneiform are removed in entirety.” Ex.1004, 328. The plantar ledge is a portion of the first metatarsal at the tarsal-metatarsal joint, and its removal exemplifies removing a cut portion of the first metatarsal from that joint. Ex.1003, ¶234.

d. Limitation 14[f]

This limitation recites the rotating-after-cutting limitation of claim 2 and would have been obvious based on the McGlamry-Kartalian-Fallin combination for the reasons explained for limitation 1[e] and claim 2 in this ground. *Supra* §§VII.A.1.f, VII.B.1; Ex.1003, ¶235.

e. Limitation 14[g]

This limitation recites the imparting-force-after-cutting-metatarsal limitation of claim 2 and would have been obvious based on the McGlamry-Kartalian-Fallin combination for the reasons explained for claim 2 in this ground. *Supra* §VII.B.1; Ex.1003, ¶236.

f. Limitation 14[h]

This limitation 14[h] substantively combines the cutting-cuneiform-after-rotating-and-imparting-force limitation of claim 2 and the saw-blade-and-second-slot limitations of claim 9 and would have been obvious based on the McGlamry-Kartalian-Fallin combination for the reasons explained for claims 2 and 9 in this ground. *Supra* §§VII.B.1-2; Ex.1003, ¶237.

g. Limitation 14[i]

This limitation recites “removing a cut portion of the medial cuneiform from the tarsal-metatarsal joint.” McGlamry discloses this limitation. Ex.1003, ¶¶238-239.

McGlamry discloses that “[t]he corrective articular resection is made at the distal aspect of the convex-shaped cuneiform.” Ex.1004, 324. Performing such a resection necessarily entails cutting and removing a portion of the medial cuneiform from the tarsal-metatarsal joint. Ex.1003, ¶239; *see also id.*, 328 (“[E]ntire plantar ledge of...medial cuneiform [is] removed in entirety.”); Ex.1006, [0067] (“A saw blade 250 is guided in one of the proximal guide slots 218 to remove bone from the distal end of the cuneiform.”).

h. Limitations 14[j]-14[k]

These limitations recite “fenestrating a cut end of the first metatarsal” and “fenestrating a cut end of the medial cuneiform.” McGlamry discloses these limitations. Ex.1003, ¶¶240-243.

McGlamry describes preparing the cut ends of the first metatarsal and medial cuneiform by penetrating the subchondral plate to promote bleeding and fusion. *Id.*, ¶241. Specifically, McGlamry discloses that the “metatarsal base and distal cuneiform...are prepared” such that “the subchondral plate is penetrated demonstrating good bleeding at both the metatarsal and cuneiform.” Ex.1004, 324.

Figure 31.3 illustrates an “[i]nteroperative clinical view demonstrating the use of a 2-mm drill preparing the tarsal-metatarsal joint prior to fixation.” *Id.*



Id., Fig. 31.3B. As shown, the exposed bone surface exhibits multiple drill penetrations, which constitute fenestrations of the cut bone surfaces. Ex.1003,

¶¶241-242. A POSA would have understood that using a drill to penetrate the subchondral plate of prepared bone surfaces, as disclosed by McGlamry, is a conventional technique for fenestrating bone to promote bleeding and fusion. *Id.*, ¶243; *see also* Ex.1004, 449 (“When using a 1.5-mm wire pass drill bit to generously fenestrate these surfaces, the bone will be excavated while creating recesses for neovascularization and capillary ingrowths.”), 433 (Fig.36.15C showing metatarsal head “fenestrated using a 2.0-mm wire pass drill bit”), 439 (Fig.36.18 showing fenestration).

i. Limitation 14[l]-14[m]

These limitations are the same as limitations 1[h]-1[i] and would have been obvious based on the McGlamry-Kartalian-Fallin combination for the reasons explained for limitations 1[h]-1[i] in Ground 1. *Supra* §§VII.A.1.i-j; Ex.1003, ¶¶244-245.

j. Limitation 14[n]

This limitation recites the removing-bone-positioning-guide limitation of claim 3 and would have been obvious based on the McGlamry-Kartalian-Fallin combination for the reasons explained for claim 3 in Ground 1. *Supra* §VII.A.2; Ex.1003, ¶246.

4. Claim 15

Claim 15 incorporates the additional limitations of claim 8 into claim 14, and these limitations would have been obvious based on the McGlamry-Kartalian-Fallin combination for the reasons explained for claim 8 in Ground 1. *Supra* §VII.A.6; Ex.1003, ¶247.

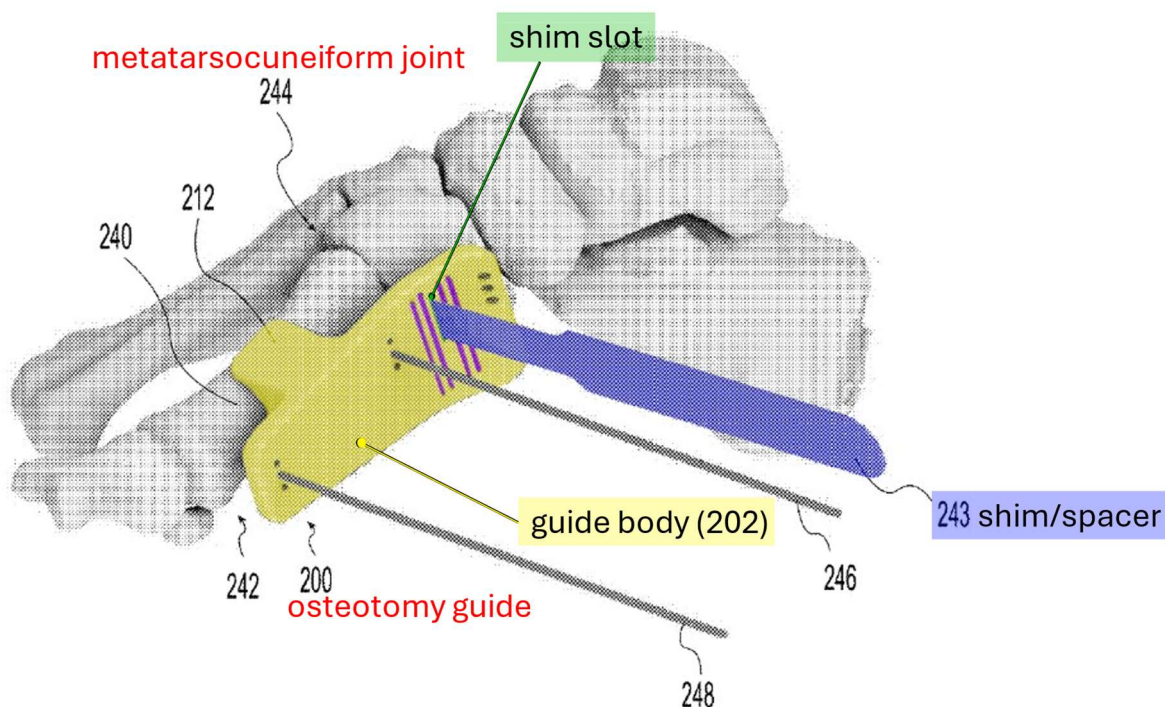
5. Claims 16-17

Claim 16 depends from claim 14 and recites: “further comprising positioning a joint spacer offset from the first bone preparation guide cutting slot into the tarsal-metatarsal joint simultaneous with positioning the first bone preparation guide cutting slot over an end of the first metatarsal to be cut.” Claim 17 depends from claim 14 and recites: “further comprising positioning a joint spacer offset from the second bone preparation guide cutting slot into the tarsal-metatarsal joint simultaneous with positioning the second bone preparation guide cutting slot over an end of the medial cuneiform to be cut.” McGlamry, Kartalian, and Fallin render these additional limitations obvious. Ex.1003, ¶¶248-254.

Fallin discloses that the guide body 202 of its osteotomy guide 200 “may include a joint alignment feature to aid in positioning the guide body 202 relative to a joint,” and that joint alignment feature can be “a projection from the guide body 202 engageable with the joint.” Ex. 1005, [0055]. “The joint alignment feature allows a user to position the guide relative to the joint.” *Id.* Fallin applies this

disclosure to the tarsal-metatarsal (first metatarsal-medial cuneiform) joint. Ex.1003, ¶249. In this context, Fallin’s “projection from the guide body 202 engageable with the joint” is a joint spacer placed into the tarsal-metatarsal joint. *Id.*, ¶¶250-251.

In another embodiment, Fallin discloses that its “joint alignment feature” is a shim 243 inserted through a slot 234 of the osteotomy guide into the tarsal-metatarsal (first metatarsal-medial cuneiform) joint, as shown below. Ex.1005, [0055], [0056] (“A feeler gauge 243, or shim, is inserted through the joint alignment slot 234 and used to align the guide 200 with the metatarsocuneiform joint 244.”), Fig.21.



Id., Fig.21; Ex.1003, ¶253.

Because Fallin’s joint spacer is a projection from the osteotomy guide 200 (bone preparation guide), it is positioned into the joint simultaneously with positioning the bone preparation guide over the ends of the first metatarsal and medial cuneiform to be cut. Ex.1003, ¶254; *supra* §VII.B.2. Joint alignment and guide positioning thus occur together as part of a single placement step. Ex.1003, ¶254.

Further, Fallin’s joint spacer is offset from the guide cutting slots. Ex.1003, ¶250. The joint spacer cannot occupy the same location as the cutting slots because the cutting slots must remain unobstructed to permit insertion of a cutting instrument. *Id.*

6. Claim 18

Claim 18 incorporates the additional limitations of claim 7 into claim 14 and would have been obvious based on the McGlamry-Kartalian-Fallin combination for the reasons explained for claim 7 in Ground 1. *Supra* §VII.A.5; Ex.1003, ¶255.

7. Claim 19

Claim 19 incorporates the additional limitations of claim 5 into claim 14, and these limitations would have been obvious based on the McGlamry-Kartalian-Fallin combination for the reasons explained for claims 5-6 in Ground 1. *Supra* §VII.A.4; Ex.1003, ¶¶256-258. Further, claim 19 recites “rotating the knob connected to a threaded shaft of the bone positioning guide to cause the bone engagement member

to push the first metatarsal laterally toward the second metatarsal comprises rotating the knob connected to a threaded shaft of the bone positioning guide to reduce a distance between the bone engagement member and the contact surface.” This further limitation is also obvious based on the McGlamry-Kartalian-Fallin combination. Ex.1003, ¶258.

As explained for limitation 1[e] in Ground 1, a surgeon would rotate Kartalian’s threaded knob in the combination to bring the instrument’s handles toward each other, thereby causing the arm 106 (bone engagement member) to move toward the end 102. *Supra* §VII.A.1.c. This movement reduces a distance between the arm 106 (bone engagement member) and the end 102’s bone contacting surface. Ex.1003, ¶259.

8. Claim 20

Claim 20 incorporates the additional limitations of claim 6 into claim 19 and would have been obvious based on the McGlamry-Kartalian-Fallin combination for the reasons explained for claim 6 in Ground 1. *Supra* §VII.A.4; Ex.1003, ¶260.

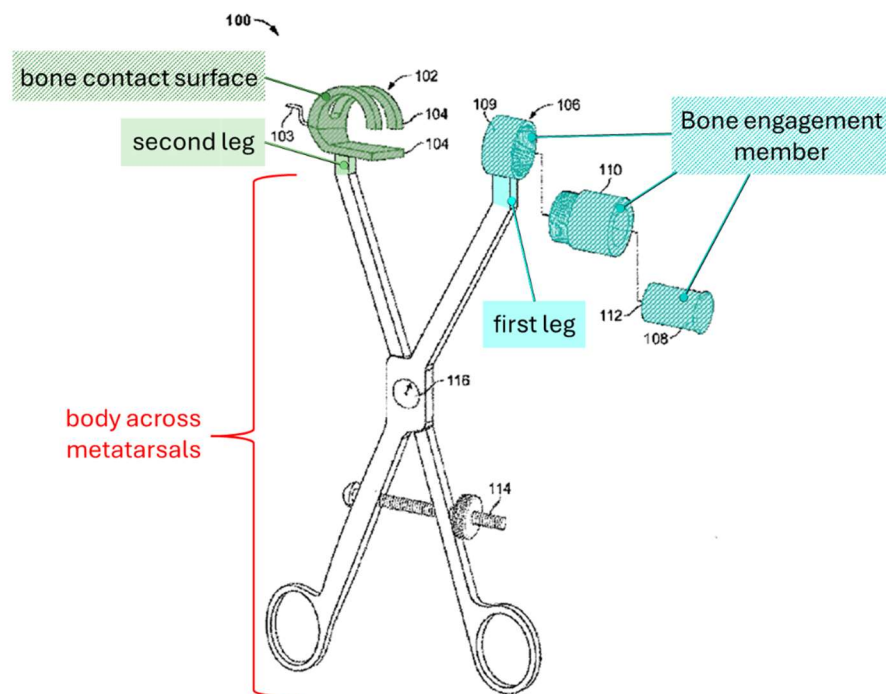
9. Claim 21

Claim 21 depends from claim 19 and recites: “wherein: [a] the bone positioning guide comprises a body, a first leg carrying the bone engagement member, and a second leg defining the bone contact surface; and [b] engaging the first metatarsal with the bone engagement member and positioning the bone contact

surface in contact with the second metatarsal comprises positioning the body extending in a medial-to-lateral direction across the first metatarsal and across the second metatarsal with the first leg positioned on a medial side of the first metatarsal.” McGlamry, Kartalian, and Fallin render these additional limitations obvious. Ex.1003, ¶¶261-265.

a. Limitation 21[a]

Kartalian’s instrument 100 (bone positioning guide) includes a body and first and second legs extending from the body. Ex.1005, Fig.1; Ex.1003, ¶262. The body connects the legs and defines the instrument’s overall structure:

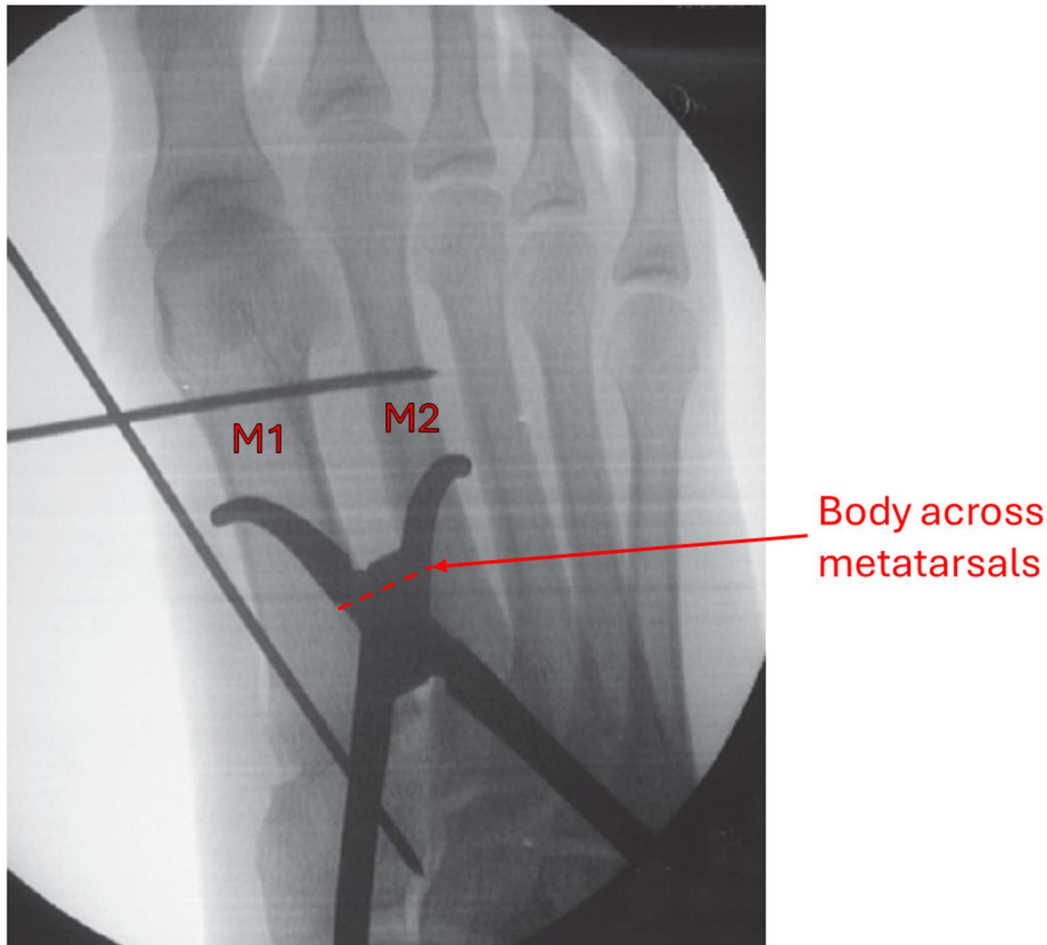


Ex.1005, Fig.1 (excerpt); Ex.1003, ¶262. Kartalian discloses that the first leg carries the end 106 (bone engagement member) and the second leg defines the end 102’s bone contacting surface. Ex.1003, ¶262.

b. Limitation 21[b]

Kartalian discloses that its instrument's end 106 (bone engagement member) is inserted through the “medial incision at the first metatarsal” such that it is placed on the first metatarsal. Ex.1005, 10:29-62. Similarly, Kartalian discloses that the end 102, which includes the bone contacting surface, is inserted through “an incision lateral to the second metatarsal at its distal portion” and placed on the second metatarsal. *Id.* As a result, Kartalian's instrument is positioned with its body extending in a medial-to-lateral direction across the first and second metatarsals, with the instrument's first leg positioned on a medial side of the first metatarsal. Ex.1003, ¶¶263-264. This configuration corresponds to the claimed positioning of the bone positioning guide. *Id.*

This positioning of Kartalian's instrument would remain unchanged when used in the combination's procedure. *Id.*, ¶265. McGlamry's Weber clamp is similarly positioned, with its body extending in a medial-to-lateral direction across the first and second metatarsals and opposing ends placed on the first and second metatarsals:



Ex.1004, Fig.31.5. A POSA would understand Kartalian's instrument to be used in place of McGlamry's Weber clamp to engage the metatarsals in the same medial-to-lateral orientation. Ex.1003, ¶264.

10. Claim 22

Claim 22 incorporates the additional limitations of claim 10 into claim 14 and would have been obvious based on the McGlamry-Kartalian-Fallin combination for the reasons explained for claim 10 in Ground 1. *Supra* §VII.A.7; Ex.1003, ¶266.

11. Claim 23

Claim 23 incorporates the additional limitations of claim 4 into claim 14 and would have been obvious based on the McGlamry-Kartalian-Fallin combination for the reasons explained for claim 4 in Ground 1. *Supra* §VII.A.3; Ex.1003, ¶267.

12. Claim 24

Claim 24 incorporates the additional limitations of claim 11 into claim 14 and would have been obvious based on the McGlamry-Kartalian-Fallin combination for the reasons explained for claim 11 in Ground 1. *Supra* §VII.A.8; Ex.1003, ¶268.

13. Claim 26

Claim 26 incorporates the additional limitations of claim 13 into claim 14 and would have been obvious based on the McGlamry-Kartalian-Fallin combination for the reasons explained for claim 13 in Ground 1. *Supra* §VII.A.8; Ex.1003, ¶269.

14. Claim 28

The additional limitations of claim 28 are substantially the same as the additional limitations of claim 2, differing in that claim 28 recites “preparing” rather than “cutting.” Claim 28 would have been obvious based on the McGlamry-Kartalian-Fallin combination for the reasons explained for claim 2 in this ground. *Supra* §VII.B.1; Ex.1003, ¶¶270-272. As explained for limitations 27[d] and 27[g] in Ground 1, cutting the end of the first metatarsal or the medial cuneiform constitutes preparing those bone ends for fusion. *Supra* §§VII.A.9.c, VII.A.9.e.

Further, to the extent “preparing” were interpreted to refer to penetrating the bone ends, it would have been obvious to penetrate each bone end as a next step after cutting. Ex.1003, ¶¶271-272. Doing so would prepare the resected bone surfaces for fusion by promoting bleeding and healing, a well-known and conventional surgical technique. *Id.*; *see also* Ex.1004, 449, 433, 439.

15. Claim 30

McGlamry, Kartalian, and Fallin render claim 30 obvious. Ex.1003, ¶¶273-286.

a. Preamble And Limitation 30[a]

The preamble and this limitation are the same as claim 1’s preamble and limitation 1[a] and would have been obvious based on the McGlamry-Kartalian-Fallin combination for the reasons explained for claim 1’s preamble and limitation 1[a] in Ground 1. *Supra* §§VII.A.1.a-b; Ex.1003, ¶¶274-275.

b. Limitation 30[b]

This limitation recites the second-incision limitation of claim 5 and the metatarsals-separated-by-IMA limitation of limitation 1[c] and would have been obvious based on the McGlamry-Kartalian-Fallin combination for the reasons explained for limitation 1[c] and claims 5-6 in Ground 1. *Supra* §§VII.A.1.d, VII.A.4; Ex.1003, ¶276.

c. Limitation 30[c]

This limitation is the same as limitation 1[b] and would have been obvious based on the McGlamry-Kartalian-Fallin combination for the reasons explained for limitation 1[b] in Ground 1. *Supra* §VII.A.1.c; Ex.1003, ¶277.

d. Limitation 30[d]

This limitation recites the positioning-bone-contact-surface limitation of claim 5 and would have been obvious based on the McGlamry-Kartalian-Fallin combination for the reasons explained for claims 5-6 in Ground 1. *Supra* §VII.A.4; Ex.1003, ¶278.

e. Limitation 30[e]

This limitation is the same as limitation 14[d] and would have been obvious based on the McGlamry-Kartalian-Fallin combination for the reasons explained for limitation 14[d] in this ground. *Supra* §VII.B.3.b; Ex.1003, ¶279.

f. Limitation 30[f]

This limitation recites the rotating-knob-to-reduce-distance limitation of claim 19 and the reduce-IMA limitation of limitation 14[f] and would have been obvious based on the McGlamry-Kartalian-Fallin combination for the reasons explained for limitation 14[f] and claim 19 in this ground. *Supra* §§VII.B.3.d, VII.B.7; Ex.1003, ¶280.

g. Limitation 30[g]

This limitation is the same as limitation 1[f] and would have been obvious based on the McGlamry-Kartalian-Fallin combination for the reasons explained for limitation 1[f] in Ground 1. *Supra* §VII.A.1.g; Ex.1003, ¶281.

h. Limitation 30[h]

This limitation recites the cutting-cuneiform limitation of limitation 14[h] and would have been obvious based on the McGlamry-Kartalian-Fallin combination for the reasons explained for limitation 14[h] in this ground. *Supra* §VII.B.3.f; Ex.1003, ¶282.

i. Limitations 30[i]-30[j]

These limitations are the same as limitations 1[h]-1[i] and would have been obvious based on the McGlamry-Kartalian-Fallin combination for the reasons explained for limitations 1[h]-1[i] in Ground 1. *Supra* §§VII.A.1.i-j; Ex.1003, ¶¶283-284.

j. Limitation 30[k]

This limitation recites the removing-bone-positioning-guide limitation of claim 3 and would have been obvious based on the McGlamry-Kartalian-Fallin combination for the reasons explained for claim 3 in Ground 1. *Supra* §VII.A.2; Ex.1003, ¶285.

k. Limitation 30[l]

This limitation recites “wherein one or both of the first metatarsal and the medial cuneiform is cut after reducing the intermetatarsal angle between the first metatarsal and the second metatarsal to correct the bunion deformity and after adjusting the alignment of the first metatarsal in the frontal plane to correct the bunion deformity.” For the reasons explained for limitations 1[e]-1[f] and the cutting-cuneiform-after-rotating-and-imparting-force limitation of claim 2, the McGlamry-Kartalian-Fallin combination renders limitation 30[l] obvious. *Supra* §§VII.A.1.f-g, VII.B.1; Ex.1003, ¶286. Specifically, the combination renders obvious cutting the medial cuneiform after reducing the intermetatarsal angle and after adjusting the alignment of the first metatarsal in the frontal plane. Ex.1003, ¶286.

C. Ground 3: Claims 1-11, 13-24, And 26-30 Are Obvious Over Fallin, Kartalian, And McGlamry

1. Claim 1

Fallin, McGlamry, and Kartalian render claim 1 obvious. Ex.1003, ¶¶287-321.

a. Preamble

To the extent the preamble is limiting, Fallin discloses the preamble. Ex.1006, [0047]-[0049], [0057]; Ex.1003, ¶¶288-291. Fallin describes a bunion correction surgery that includes: cutting a proximal portion of the first metatarsal, moving the

first metatarsal in multiple planes, cutting a distal portion of the first cuneiform, and fixing the first metatarsal to the first cuneiform to promote fusion of the joint.

Ex.1006, [0058]. For example, Fallin discloses that:

a first cut may be made on one of the metatarsus and cuneiform to remove a portion of bone creating a first cut surface The bones may then be repositioned in one or more planes. For example, the metatarsus may be rotated laterally in the transverse plane ... rotated in the coronal plane ... and rotated in the sagittal plane Once the new position is established, the cuneiform may be cut to create a second cut surface The first and second cut surfaces may be brought together and fixed so that they heal together fusing the joint in the new position.

Id. Fallin further discloses that “bone portions can be fixed together relative to one another to promote healing with fixation elements such as pins, plates, screws, rods, or other suitable fixation elements.” *Id.*, [0060]; Ex.1003, ¶291.

b. Limitation 1[a]

As discussed for the preamble in this ground, Fallin discloses a surgical method for correcting a bunion deformity that involves operating on the first metatarsal and the medial cuneiform. The joint connecting the first metatarsal and the medial cuneiform is the tarsal-metatarsal joint. Ex.1003, ¶293. Accessing that joint in Fallin’s procedure necessarily requires making an incision on a foot to expose the joint and permit the disclosed surgical steps to be performed. *Id.* Accordingly, Fallin discloses limitation 1[a]. *Id.*

Even if Fallin had not disclosed this limitation, it would have been obvious based on McGlamry and Kartalian. *Id.*, ¶¶294-296. Like Fallin, McGlamry

describes a bunion correction procedure that includes cutting a first metatarsal and medial cuneiform, moving the first metatarsal in multiple planes, and fixing the first metatarsal to the medial cuneiform. Ex.1004, 324-327. McGlamry expressly discloses that, as part of this procedure, “[a]n incision is made over the metatarsal-cuneiform joint.” *Id.*, 324. Kartalian similarly discloses that “[t]he surgical repair of hallux valgus may commence with a medial incision at the first metatarsal....” Ex.1005, 10:29-33. A POSA would have been motivated to include an incision as disclosed in McGlamry and Kartalian when performing Fallin’s procedure because exposing the tarsal-metatarsal joint is a prerequisite to performing the disclosed cutting, moving, and fixation steps. Ex.1003, ¶¶294-296.

c. Limitation 1[b]

Fallin discloses performing bunion correction using surgical tools, including a cut guide, saw, and forceps/clamp, to manipulate and reposition bone. *See, e.g.*, Ex.1006, [0052], [0057]-[0058], [0075].

It would have been obvious to further use Kartalian’s instrument in Fallin’s procedure. Ex.1003, ¶¶297-306. As explained for limitation 1[b] in Ground 1, Kartalian discloses an instrument that functions as reduction forceps to engage bone and apply controlled force to align bones or reduce the distance between them, including by moving the first metatarsal in the transverse plane. *Supra* §VII.A.1.c. Kartalian’s instrument includes features specifically designed for bunion correction

procedures—such as a bone engagement member, locking mechanism, alignment indicator, and sleeve (*id.*)—which make it well suited for reliably engaging and manipulating the first metatarsal during correction. Ex.1003, ¶¶300-302. These features would have rendered Kartalian’s instrument a predictable and advantageous choice for use in Fallin’s procedure. *Id.*

A POSA would have been motivated to use Kartalian’s instrument in Fallin’s procedure to reliably engage and manipulate the first metatarsal while adjusting its position in multiple planes and maintaining that position during fixation, rather than relying on less controlled techniques such as manual manipulation. Ex.1003, ¶301-303; *see also* Ex.1009, 353 (“If we can accept that HAV deformity is triplane, it follows that each of these planes should be addressed in the correction operation.”). Achieving proper anatomical alignment in multiple planes is associated with more consistent and favorable patient outcomes. Ex.1003, ¶304.

Using Kartalian’s instrument in Fallin’s procedure would amount to the predictable use of a known surgical tool for its intended purpose—engaging and repositioning the first metatarsal during bunion correction—and would not alter the underlying principles of Fallin’s technique. *See KSR*, 550 U.S. at 416-18; *see also Sundance, Inc. v. DeMonte Fabricating Ltd.*, 550 F.3d 1356, 1366–67 (Fed. Cir. 2008) (“In many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle. Such a combination is more likely

to be obvious where it simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement.”); *NuVasive*, 2021 WL 3661208, at *4-5. A POSA would have had a reasonable expectation of success in doing so because Kartalian’s instrument was expressly designed for bunion correction procedures similar to Fallin’s. Ex.1003, ¶306.

As explained for limitation 1[b] in Ground 1, Kartalian’s instrument satisfies “bone positioning guide” under both the plain and ordinary meaning and §112(f). *Supra* §VII.A.1.c. Further, Kartalian’s instrument includes an end 106, which is a bone engagement member and may be placed on the first metatarsal, as previously explained. *Id.*; Ex1003, ¶305.

d. Limitation 1[c]

Kartalian discloses this limitation for the reasons explained for limitation 1[c] in Ground 1. *Supra* §VII.A.1.d; Ex.1003, ¶307. The Fallin-Kartalian-McGlamry combination thus renders the limitation obvious. Ex.1003, ¶307.

e. Limitation 1[d]

Fallin discloses this limitation. Ex.1003, ¶308. Fallin explains that “a saw blade...is guided...to remove bone from the proximal end of the metatarsus.” Ex.1006, [0065]; *see also id.*, [0006] (“cutting one of the metatarsus and cuneiform to remove a first portion of bone adjacent the joint”), claim 14 (“guiding a cutter

with the osteotomy guide to cut the metatarsus...and remove a first portion of bone adjacent the joint”). Fallin’s use of a saw satisfies the “tissue removing instrument” limitation under its plain meaning; and if §112(f) were applied, each is corresponding structure (or an equivalent) to the saw/osteotome/bur-type tissue-removal instruments described in the ’481 patent. Ex.1003, ¶308.

f. Limitation 1[e]

Kartalian discloses this limitation for the reasons explained for limitation 1[e] in Ground 1. *Supra* §VII.A.1.f; Ex.1003, ¶309. The Fallin-Kartalian-McGlamry combination thus renders the limitation obvious. Ex.1003, ¶309.

g. Limitation 1[f]

It would have been obvious to use McGlamry’s pin in the procedure in the Fallin-Kartalian-McGlamry combination, for the reasons explained for limitation 1[f] in Ground 1. *Supra* §VII.A.1.g; Ex.1003, ¶¶310-313. McGlamry states: “If the surgeon feels a need to obtain more correction in the frontal plane, the K-wire can be inserted into the metatarsal ... [and] can be used as a rotation device and rotate the metatarsal” in the frontal plane. Ex.1004, 326; Ex.1003, ¶311. This directly corresponds to the recited step of imparting force to a pin inserted into the first metatarsal to adjust alignment in the frontal plane to correct the bunion deformity. Ex.1003, ¶311.

As previously explained, McGlamry’s K-wire would be used in addition to—rather than instead of—Kartalian’s instrument. *Id.* For example, Kartalian’s instrument would be applied to engage and reposition the first metatarsal relative to the second metatarsal, while McGlamry’s K-wire would be used in conjunction to impart rotational force to the first metatarsal in the frontal plane. *Id.* In this manner, McGlamry’s pin provides a straightforward mechanism for fine-tuning rotational alignment of the metatarsal. *Id.*, ¶312.

A POSA would have been motivated to include McGlamry’s K-wire in the combination because it provides an established, predictable technique for achieving or refining frontal-plane rotational alignment during bunion correction, which is usable with other repositioning tools. *Id.*, ¶¶310-313. Using the K-wire in this manner would merely add a known surgical tool performing its known function to address an additional aspect of metatarsal alignment. *Id.*; see *KSR*, 550 U.S. at 416-418.

A POSA would have had a reasonable expectation of success in doing so because McGlamry expressly discloses using the K-wire to rotate the first metatarsal in the frontal plane, and such rotational manipulation is performed during bunion correction procedures like Fallin’s. Ex.1003, ¶313. Combining Kartalian’s instrument with McGlamry’s K-wire would therefore predictably allow controlled

correction of the first metatarsal in multiple planes in Fallin’s disclosed bunion correction procedure, without altering the underlying surgical technique. *Id.*

h. Limitation 1[g]

Fallin discloses this limitation. Ex.1003, ¶314. Fallin explains that “[a] saw blade...is guided...to remove bone from the distal end of the cuneiform.” Ex.1006, [0067]; *see also id.*, [0006] (“cutting one of the metatarsus and cuneiform to remove a first portion of bone adjacent the joint”), claim 14 (“guiding a cutter with the osteotomy guide to cut the cuneiform...and remove a second portion of bone adjacent the joint”).

i. Limitation 1[h]

Fallin discloses this limitation. Ex.1003, ¶¶315-318. Fallin’s procedure involves “compression of the bone surfaces together,” specifically compressing the first metatarsal against the medial cuneiform at the tarsal-metatarsal joint. Ex.1006, [0075] (“[C]ompression may be facilitated...to press the bone portions together.”); Ex.1003, ¶316.

Even if Fallin had not disclosed this limitation, it would have been obvious based on McGlamry. Ex.1003, ¶¶317-318. McGlamry describes using a screw to compress the first metatarsal and medial cuneiform together, explaining that a “[homerun screw] provides interfragmentary compression and leverage,” and that “[t]he interfragmentary compression will create an excellent reduction at the base of

the tarsal-metatarsal joint.” Ex.1004, 326, 328; Ex.1003, ¶317. Applying such compression to press the first metatarsal and medial cuneiform together in Fallin’s procedure would have been nothing more than the predictable use of a known technique from McGlamry for its established purpose—achieving compression at the tarsal-metatarsal joint to promote reduction and fusion—with a reasonable expectation of success. Ex.1003, ¶318.

j. Limitation 1[i]

Fallin discloses this limitation. Ex.1003, ¶¶319-321. Fallin explains that after the bones are brought into the desired relative position, “the guide 200 may be used to hold the bones in the desired orientation while...additional fixation in the forms of pins, plates, screws, rods or other suitable fixation is applied.” Ex.1006, [0067]-[0068], [0074]-[0075]. Applying such fixation devices fixates the moved position of the first metatarsal relative to the medial cuneiform so that the bones remain immobilized and fuse. Ex.1003, ¶¶320-321.

2. Claim 2

Fallin, Kartalian, and McGlamry render the claimed sequencing obvious. Ex.1003, ¶¶322-325. Fallin discloses that the first metatarsal is repositioned after preparing (e.g., cutting) the first metatarsal and before preparing (e.g., cutting) the medial cuneiform. Ex.1006, [0057]-[0062], [0065]-[0068]; Ex.1003, ¶323. Accordingly, when Kartalian’s instrument and McGlamry’s pin are used in the

procedure in the Fallin-Kartalian-McGlamry combination, it would have been obvious to first cut the metatarsal, next adjust the metatarsal position (e.g., by rotating the knob and imparting force to the pin), and then cut the cuneiform. Ex.1003, ¶¶323. Kartalian’s instrument and McGlamry’s pin merely provide known tools for performing the repositioning step disclosed in Fallin and would not alter Fallin’s disclosed sequence. *Id.*, ¶¶324-325.

3. Claim 3

The Fallin-Kartalian-McGlamry combination renders the additional limitations of claim 3 obvious. Ex.1003, ¶¶326-329.

Kartalian discloses that its instrument includes “a locking clamp 114 to hold the instrument 100 in position once the final alignment of the bones has been achieved.” Ex.1005, 10:4-8. Kartalian further explains its instrument is removed after “properly aligning and securing the reduction of the IM angle of the first metatarsal.” *Id.*, 10:23-28; Ex.1003, ¶327.

When Kartalian’s instrument is used in the procedure in the Fallin-Kartalian-McGlamry combination, the locking clamp would maintain the first metatarsal in the moved position while one or more bone fixation devices are installed to fix the first metatarsal in its corrected position relative to the medial cuneiform, consistent with Fallin’s fixation techniques. Ex.1003, ¶¶328-329. After fixation, the

instrument would be removed, with the moved position of the first metatarsal remaining fixed relative to the medial cuneiform. *Id.*

4. Claim 4

The Fallin-Kartalian-McGlamry combination renders the additional limitations of claim 4 obvious for the reasons explained for claim 4 in Ground 1. *Supra* §VII.A.3; Ex.1003, ¶330.

5. Claims 5-6

The Fallin-Kartalian-McGlamry combination renders the additional limitations of claims 5-6 obvious for the reasons explained for claims 5-6 in Ground 1. *Supra* §VII.A.4; Ex.1003, ¶¶331-334. When Kartalian's instrument is used in the procedure in the Fallin-Kartalian-McGlamry combination, making a second incision to access the second metatarsal for placement of the tip would have been a straightforward and predictable application of Kartalian's technique. Ex.1003, ¶¶331-334. Making a second incision to access the second metatarsal would have been routine surgical practice when engaging a separate bone with such a bone-contacting instrument. *Id.*

6. Claim 7

Fallin, Kartalian, and McGlamry render this sequencing obvious. Ex.1003, ¶¶335-338. McGlamry discloses first repositioning the metatarsal in the transverse plane using the Weber clamp. Ex.1004, 325-326. McGlamry then explains that,

“[i]f the surgeon feels a need to obtain more correction in the frontal plane, the K-wire can be inserted into the first metatarsal [T]he K-wire can be used as a rotation device and rotate the metatarsal into more of a neutral position....” *Id.*, 326. Adopting this same order of laterally repositioning the first metatarsal toward the second metatarsal before adjusting its alignment in the frontal plane would have been obvious when using Kartalian’s instrument and McGlamry’s K-wire, as those tools would be applied to perform the same respective operations without altering McGlamry’s disclosed order of operations. Ex.1003, ¶¶337-338.

7. Claim 8

Fallin discloses that “the metatarsus may be...rotated in the sagittal plane” (Ex.1006, [0058]); the Fallin-Kartalian-McGlamry combination thus renders the additional limitations of this claim obvious. Ex.1003, ¶¶339-340.

8. Claim 9

Fallin discloses the additional limitations of claim 9 for the reasons explained for claim 9 in Ground 2; the Fallin-Kartalian-McGlamry combination thus renders the additional limitations of this claim obvious. *Supra* §VII.B.2; Ex.1003, ¶341.

9. Claim 10

The Fallin-Kartalian-McGlamry combination render the additional limitations of claim 10 obvious for the reasons explained for claim 10 in Ground 1. *Supra* §VII.A.7; Ex.1003, ¶¶342-343.

10. Claim 11

The Fallin-Kartalian-McGlamry combination renders the additional limitations of this claim obvious for the reasons explained for limitation 1[i] in Ground 1. *Supra* §VII.A.j; Ex.1003, ¶¶344-345.

11. Claim 13

Fallin discloses that the first metatarsal and medial cuneiform may be fixated in the moved position using “fixation elements such as pins, plates, screws, rods, or other suitable fixation elements.” Ex.1006, [0060], [0068]. Thus, Fallin expressly contemplates using both plates and screws to secure the first metatarsal relative to the medial cuneiform for fusion. Ex.1003, ¶347.

Like Fallin, McGlamry discloses specific fixation configurations using screws, plates, or a combination thereof across the tarsal-metatarsal joint. Ex.1004, 329; *see also id.*, 326 (“[t]he recommended fixation techniques consist of interfragmentary compression of three solid cortical screws or an interfragmentary compression of solid cortical screw along with a medial based locking plate”); Ex.1003, ¶348. As explained for claims 11 and 13 in Ground 1, McGlamry describes one configuration that satisfies the additional limitations of claim 13. *Supra* §VII.A.8; Ex.1003, ¶¶347-349.

It would have been obvious to use McGlamry’s disclosed fixation devices and configuration in the procedure in the Fallin-Kartalian-McGlamry combination

because McGlamry's plate-and-screw construct is designed for the same type of tarsal-metatarsal fusion procedure performed in Fallin. Ex.1003, ¶¶346-350. Applying that known fixation configuration to stabilize the repositioned bones in Fallin's procedure would have been nothing more than the predictable use of known orthopedic fixation elements according to their established functions to achieve rigid fixation and compression for fusion. *Id.* A POSA would have had a reasonable expectation of success in doing so because McGlamry demonstrates that this plate-and-screw construct reliably achieves interfragmentary compression and stabilization across the tarsal-metatarsal joint in a closely analogous bunion procedure. *Id.* Using that same configuration in the combination's procedure would therefore have predictable produced the same fixation and fusion results. *Id.*

12. Claim 14

Fallin, McGlamry, and Kartalian render claim 14 obvious. Ex.1003, ¶¶351-368.

a. Preamble And Limitations 14[a]-14[c]

The Fallin-Kartalian-McGlamry combination renders this preamble and limitations 14[a]-14[c] obvious for the reasons explained for claim 1's preamble and limitations 1[a]-1[c] in this ground. *Supra* §§VII.C.a-d; Ex.1003, ¶¶351-354.

b. Limitation 14[d]

The Fallin-Kartalian-McGlamry combination renders this limitation obvious for the reasons explained for limitation 1[d] and claim 9 in this ground. *See* §§VII.C.1.e, VII.C.8; Ex.1003, ¶355.

c. Limitation 14[e]

Fallin discloses this limitation. Ex.1003, ¶356. Fallin explains that “a first cut may be made on one of the metatarsus and cuneiform to remove a portion of bone creating a first cut surface and a space resulting in increased mobility between the metatarsus and cuneiform.” Ex.1006, [0058].

d. Limitation 14[f]

The Fallin-Kartalian-McGlamry combination renders this limitation obvious for the reasons explained for limitation 1[e] and claim 2 in this ground. *See* §§VII.C.1.f, VII.C.2; Ex.1003, ¶357.

e. Limitation 14[g]

The Fallin-Kartalian-McGlamry combination renders this limitation obvious for the reasons explained for claim 2 in this ground. *Supra* §VII.C.2; Ex.1003, ¶358.

f. Limitation 14[h]

The Fallin-Kartalian-McGlamry combination renders this limitation obvious for the reasons explained for claims 2 and 9 in this ground. *Supra* §§VII.C.2, VII.C.8; Ex.1003, ¶359.

g. Limitations 14[i]

Fallin discloses this limitation for the reasons explained for limitation 14[e] in this ground. *Supra* §VII.C.12.c; Ex.1003, ¶360; *see also* Ex.1006, [0067] (“remove bone from the distal end of the cuneiform”), Fig.25.

h. Limitations 14[j]-14[k]

Fallin explains that one objective of its procedure is that “[t]he first and second surfaces may be brought together and fixed so that they heal together fusing the joint in the new position.” Ex.1006, [0058]; *see also id.*, [0060] (“fixed relative to one another to promote healing”), [0078], [0084].

It would have been obvious to fenestrate the cut ends of the first metatarsal and the medial cuneiform using McGlamry’s disclosed fenestration technique in the Fallin-Kartalian-McGlamry combination. Ex.1003, ¶¶361-365. As explained for limitations 14[j]-14[k] in Ground 2, McGlamry discloses that fenestrating the cut bone surfaces promotes bleeding at the fusion site, which a POSA would understand enhances bone healing and facilitates fusion. *Supra* §VII.B.3.h.

Applying McGlamry’s fenestration to the cut bone ends in Fallin’s procedure would further Fallin’s stated goal of promoting healing and fusion between the first metatarsal and medial cuneiform. Ex.1003, ¶365. Because Fallin already discloses preparing opposing cut bone surfaces for fusion, adding fenestration to those cut ends would have been a predictable refinement to improve biological fusion at the

joint. *Id.* Using McGlamry’s fenestration technique in Fallin-Kartalian-McGlamry’s procedure would therefore have been nothing more than the predictable application of a known bone-healing technique to a known fusion procedure. Ex.1003, ¶365; *KSR*, 550 U.S. at 416-18. A POSA would have had a reasonable expectation of success because McGlamry demonstrates that fenestration of cut bone surfaces in the same anatomical context, and Fallin seeks the same biological outcome—fusion of the metatarsal and cuneiform. Ex.1003, ¶365.

i. Limitation 14[l]-14[m]

The Fallin-Kartalian-McGlamry combination renders these limitations obvious for the reasons explained for limitations 1[h]-1[i] in this ground. *Supra* §§VII.C.1.i-j; Ex.1003, ¶¶366-367.

j. Limitation 14[n]

The Fallin-Kartalian-McGlamry combination renders this limitation obvious for the reasons explained for claim 3 in this ground. *Supra* §VII.C.3; Ex.1003, ¶368.

13. Claim 15

The Fallin-Kartalian-McGlamry combination renders the additional limitations of this claim obvious for the reasons explained for claim 8 in this ground. *Supra* §VII.C.7; Ex.1003, ¶369.

14. Claims 16-17

The Fallin-Kartalian-McGlamry combination renders the additional limitations of these claims obvious for the reasons explained for claims 16-17 in Ground 2. *Supra* §VII.B.5; Ex.1003, ¶370.

15. Claim 18

The Fallin-Kartalian-McGlamry combination renders the additional limitations of this claim obvious for the reasons explained for claim 7 in this ground. *Supra* §VII.C.6; Ex.1003, ¶371.

16. Claim 19

The Fallin-Kartalian-McGlamry combination renders the additional limitations of this claim obvious for the reasons explained for claims 5-6 in this ground and claim 19 in Ground 2. *Supra* §VII.B.7; Ex.1003, ¶372.

17. Claim 20

The Fallin-Kartalian-McGlamry combination renders the additional limitations of this claim obvious for the reasons explained for claims 5-6 in this ground. *Supra* §VII.C.5; Ex.1003, ¶373.

18. Claim 21

The Fallin-Kartalian-McGlamry combination renders the additional limitations of this claim obvious for the reasons explained for claim 21 in Ground 2. *Supra* §VII.B.9; Ex.1003, ¶¶374-378. Kartalian discloses positioning its instrument

in the claimed anatomical location relative to the first metatarsal and medial cuneiform. *Supra* §VII.B.9. Using Kartalian’s instrument in Fallin’s procedure would not alter that disclosed positioning because Fallin operates on the same bones and joint and uses the same access and working geometry. Ex.1003, ¶¶376-377; *Supra* §VII.B.9.

19. Claim 22

The Fallin-Kartalian-McGlamry combination renders the additional limitations of this claim obvious for the reasons explained for claim 10 in Ground 1. *Supra* §VII.A.7; Ex.1003, ¶379.

20. Claim 23

The Fallin-Kartalian-McGlamry combination renders the additional limitations of this claim obvious for the reasons explained for claim 4 in Ground 1. *Supra* §VII.A.3; Ex.1003, ¶380.

21. Claim 24

The Fallin-Kartalian-McGlamry combination renders the additional limitations of this claim obvious for the reasons explained for limitation 1[i] in Ground 2. *Supra* §VII.B.1.j; Ex.1003, ¶381.

22. Claim 26

The Fallin-Kartalian-McGlamry combination renders the additional limitations of this claim obvious for the reasons explained for claim 13 in this ground. *Supra* §VII.C.11; Ex.1003, ¶382.

23. Claim 27

Fallin, McGlamry, and Kartalian render claim 27 obvious. Ex.1003, ¶¶383-400.

a. Preamble

Fallin discloses this preamble for the reasons explained for claim 1's preamble in this ground. *Supra* §VII.C.1.a; Ex.1003, ¶383.

b. Limitations 27[a]-27[c]

The Fallin-Kartalian-McGlamry combination renders these limitations obvious for the reasons explained for limitations 1[a]-1[c] in this ground. *Supra* §§VII.C.1.b-d; Ex.1003, ¶¶384-386.

c. Limitation 27[d]

Fallin discloses this limitation for the reasons explained for limitation 1[d] in this ground, because Fallin's cutting of the end of the first metatarsal prepares the bone surface for fusion. *Supra* §VII.C.1.e; Ex.1003, ¶¶387-389. In addition, it would have been obvious apply McGlamry's fenestration technique to Fallin's procedure for the reasons explained for limitations 14[j]-14[k] in this ground. *Supra*

§VII.C.12.h. As explained, McGlamry describes that fenestration of a cut bone promotes bleeding, preparing the bone surface for fusion. *Id.*; Ex.1003, ¶389.

d. Limitation 27[e]-27[f]

The Fallin-Kartalian-McGlamry combination renders these limitations obvious for the reasons explained for limitations 1[e]-1[f] in this ground. *Supra* §§VII.C.1.f-g; Ex.1003, ¶¶390-391.

e. Limitation 27[g]

The Fallin-Kartalian-McGlamry combination renders this limitation obvious for the reasons explained for limitations 27[d] and 1[g] in this ground. *Supra* §§VII.C.1.h, VII.C.23.c; Ex.1003, ¶¶392-394.

f. Limitation 27[h]

As explained for limitations 1[a] and 1[i], Fallin discloses both making an incision to access the tarsal-metatarsal joint and installing a fixation device to fixate the moved position of the first metatarsal relative to the medial cuneiform. *Supra* §§VII.C.1.b, VII.C.1.j. Accessing the tarsal-metatarsal joint in Fallin's procedure necessarily requires making the incision to expose the joint and permit the disclosed fixation step to be performed. Ex.1003, ¶¶395-400. Accordingly, Fallin discloses limitation 27[h]. *Id.*

Even if Fallin had not disclosed using an incision to install a fixation device, McGlamry and Kartalian render the limitation obvious. *Id.* As explained for

limitation 1[i], McGlamry and Kartalian expressly disclose making an incision to access the metatarsal-cuneiform joint for bunion correction surgery. *Supra* §VII.C.1.j. McGlamry’s Figures 31.6, 31.7, 31.8, and 31.9 further show screws and plates securing the first metatarsal to the medial cuneiform, demonstrating that those fixation devices are installed through an incision. Ex.1004, Figs.31.6-31.9; Ex.1003, ¶398. For example, Figure 31.9 pairs a postoperative radiograph showing a plate and screws with a clinical photograph of the patient’s foot showing the surgical scar at the same location, confirming that the fixation devices were installed through the incision:



Figure 31.9 A,B: Preoperative radiograph and clinical photo of a patient with HAV deformity. C,D: Postoperative radiograph and clinical photo of the patient with the use of an interfragmental compression screw and a medial based locking plate. The correction can be seen in all three planes.

Ex.1004, Fig.31.9; *see also id.*, 327 (referring to suturing a single wound). A POSA would have understood that the same types of fixation devices disclosed by McGlamry and Fallin are installed in the same manner—through the surgical incision—when used in Fallin’s procedure. Ex.1003, ¶399. A POSA would thus

have been motivated to use that incision in Fallin-Kartalian-McGlamry's procedure to expose the tarsal-metatarsal joint, as access to that joint is a prerequisite to installing the disclosed fixation devices. *Id.*

24. Claim 28

The Fallin-Kartalian-McGlamry combination renders the additional limitations of this claim obvious for the reasons explained for claim 2 in this ground. *Supra* §VII.C.2; Ex.1003, ¶¶401-402.

25. Claim 29

The Fallin-Kartalian-McGlamry combination renders the additional limitations of this claim obvious. Ex.1003, ¶¶403-409.

a. Limitation 29[a]

As explained for limitation 1[h] in this ground, Fallin discloses compressing the first metatarsal together with the medial cuneiform. *Supra* §VII.C.1.i. In Fallin's procedure, compression occurs after the preparation of the first metatarsal and medial cuneiform, and prior to the installation of the fixation device. Ex.1006, [0075]; Ex.1003, ¶405. Fallin thus discloses the claimed sequence. Ex.1003, ¶405.

Even if Fallin had not disclosed this sequence, it would have been obvious based on McGlamry. *Id.*, ¶¶406-408. As explained for limitation 29[a] in Ground 1, McGlamry discloses the claimed sequence. *Id.* Applying McGlamry's order in Fallin's procedure would have been nothing more than the predictable use of a

known technique from McGlamry for its established purpose—achieving compression at the tarsal-metatarsal joint to promote reduction and fusion—with a reasonable expectation of success. *Id.*, ¶¶407-408.

b. Limitation 29[b]

Fallin-Kartalian-McGlamry combination renders this additional limitation obvious for the reasons explained for claim 3 in this ground. *Supra* §VII.C.3; Ex.1003, ¶409.

26. Claim 30

Fallin, McGlamry, and Kartalian render claim 30 obvious. Ex.1003, ¶¶410-423.

a. Preamble And Limitation 30[a]

The Fallin-Kartalian-McGlamry combination renders this preamble and limitation 30[a] obvious for the reasons explained for claim 1’s preamble and limitation 1[a] in this ground. *Supra* §§VII.C.1.a-b; Ex.1003, ¶¶411-412.

b. Limitation 30[b]

The Fallin-Kartalian-McGlamry combination renders this limitation obvious for the reasons explained for limitation 1[c] and claims 5-6 in this ground. *Supra* §§VII.C.1.d, VII.C.5; Ex.1003, ¶413.

c. Limitation 30[c]

The Fallin-Kartalian-McGlamry combination renders this limitation obvious for the reasons explained for limitation 1[b] in this ground. *Supra* §VII.C.1.c; Ex.1003, ¶414.

d. Limitation 30[d]

The Fallin-Kartalian-McGlamry combination renders this limitation obvious for the reasons explained for claims 5-6 in this ground. *Supra* §VII.C.5; Ex.1003, ¶415.

e. Limitation 30[e]

The Fallin-Kartalian-McGlamry combination renders this limitation obvious for the reasons explained for limitation 14[d] in this ground. *Supra* §VII.C.12.b; Ex.1003, ¶416.

f. Limitation 30[f]

The Fallin-Kartalian-McGlamry combination renders this limitation obvious for the reasons explained for limitation 14[f] and claim 19 in this ground. *Supra* §VII.C.12.d; Ex.1003, ¶417.

g. Limitation 30[g]

The Fallin-Kartalian-McGlamry combination renders this limitation obvious for the reasons explained for limitation 1[f] in this ground. *Supra* §VII.C.1.g; Ex.1003, ¶418.

h. Limitation 30[h]

The Fallin-Kartalian-McGlamry combination renders this limitation obvious for the reasons explained for limitation 14[f] in this ground. *Supra* §VII.C.12.d; Ex.1003, ¶419.

i. Limitations 30[i]-30[j]

The Fallin-Kartalian-McGlamry combination renders these limitations obvious for the reasons explained for limitations 1[h]-1[i] in this ground. *Supra* §§VII.C.1.i-j; Ex.1003, ¶¶420-421.

j. Limitation 30[k]

The Fallin-Kartalian-McGlamry combination renders this limitation obvious for the reasons explained for claim 3 in this ground. *Supra* §VII.C.3; Ex.1003, ¶422.

k. Limitation 30[l]

The Fallin-Kartalian-McGlamry combination renders this limitation obvious for the reasons explained for limitations 1[e]-1[f] and claim 2 in this ground. *Supra* §§VII.C.1.f-g, VII.C.2; Ex.1003, ¶423. Specifically, the combination renders obvious cutting the medial cuneiform after reducing the intermetatarsal angle and after adjusting the alignment of the first metatarsal in the frontal plane. Ex.1003, ¶423.

D. Grounds 4-6: Claims 12 And 25 Are Obvious Over The Ground 1-3 Combinations Further In View Of Tyber

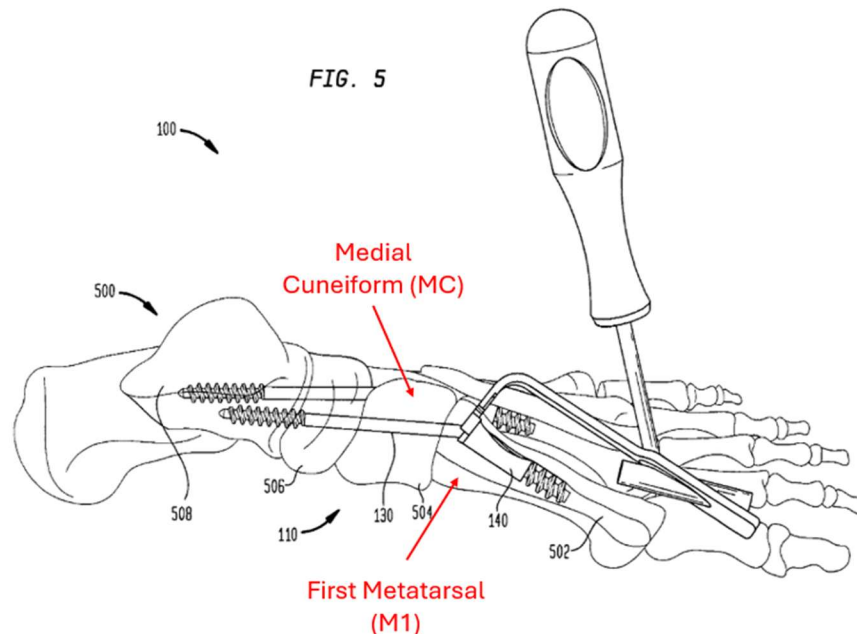
Claim 12 depends from claim 1 and recites: “wherein the at least one bone fixation device comprises an intramedullary implant.” Claim 25 depends from claim 14 and recites: “wherein the at least one bone fixation device comprises an intramedullary implant.”

As explained in Grounds 1-3, McGlamry in view of Kartalian (Ground 1), McGlamry in view of Kartalian and Fallin (Ground 2), and Fallin in view of Kartalian and McGlamry (Ground 3), render one or both of claims 1 and 14 obvious. *Supra* §§VII.A.1, VII.B.3., VII.C.1, VII.C.12. McGlamry discloses use of bone fixation devices including screws and plates, as explained in Ground 1. *Supra* §VII.A.1.j. Fallin likewise discloses fixation using pins, plates, screws, rods or other suitable fixation, as explained in Ground 3. *Supra* §VII.C.1.j.

Tyber discloses an “intramedullary fixation assembly that may be utilized to treat bones in a mid-foot and forefoot regions.” Ex.1007, 2:27-29. Tyber explains that its intramedullary implant may be used to treat podiatric deformities, including “hallux valgus deformities,” i.e. bunions. *Id.*, 1:24-30. Tyber discloses an intramedullary implant including a proximal screw 130 and a distal screw 140 configured for placement within bone. *Id.*, 5:15-18; Ex. 1003, ¶428.

As shown in Tyber’s Figure 5, “the intramedullary assembly is coupled to the medullary canals of the first metatarsal 502, medial cuneiform 504, navicular, and

talus bones 508,” thereby fixing the first metatarsal relative to the cuneiform.
Ex.1007, 7:36-39.



Id., Fig.5; Ex.1003, ¶428. Tyber further teaches inserting the intramedullary fixation assembly through the joint selected for fusion, such that rigid coupling of the components maintains alignment of the bones during healing. Ex.1007, 7:30-8:50; *see also id.*, Claims 23 & 64-65 (describing a “method of compressing bone” and “thereby compressing the first bone to the second bone”).

It would have been obvious to use an intramedullary implant like Tyber’s as the fixation device in the McGlamry-Kartalian combination (claim 1 in Ground 1), McGlamry-Kartalian-Fallin combination (claim 14 in Ground 2), and Fallin-Kartalian-McGlamry combination (claims 1 and 14 in Ground 3) to fix the first metatarsal relative to the medial cuneiform. Ex.1003, ¶¶429-430. McGlamry and

Fallin recognize that multiple fixation options are suitable for achieving stable fixation across the joint, and that the fixation selected must hold the bones in close, stable apposition until fusion occurs. *Id.*

Tyber provides a known alternative fixation approach that achieves the same objective—maintaining close, stable apposition across the fusion site—using an intramedullary fixation configuration. *See, e.g.,* Ex.1007, 1:44-46, Figs. 5-6. A POSA would have understood that such intramedullary fixation to be a suitable substitute for the fixation devices disclosed in McGlamry and Fallin for stabilizing the first metatarsal relative to the medial cuneiform during healing. Ex.1003, ¶431. Substituting an intramedullary implant like Tyber’s for one of McGlamry’s or Fallin’s fixation devices therefore constitutes nothing more than the substitution of one known fixation element for another, with each performing its established function of stabilizing bones across a fusion site. *Id.*; *KSR*, 550 U.S. at 416-18.

Because Tyber’s intramedullary implant was designed for use in forefoot and mid-foot fusion procedures including bunion correction, a POSA would have had a reasonable expectation of success in using an intramedullary implant such as Tyber’s in the procedures in the McGlamry-Kartalian combination (claim 1 in Ground 1), McGlamry-Kartalian-Fallin combination (claim 14 in Ground 2), and the Fallin-Kartalian-McGlamry combination (claims 1 and 14 in Ground 3). Ex.1003, ¶431. The McGlamry-Kartalian-Tyber combination and the Fallin-Kartalian-McGlamry-

Tyber combination each thus renders the additional limitations of claim 12 obvious, and the McGlamry-Kartalian-Fallin-Tyber combination and the Fallin-Kartalian-McGlamry-Tyber combination each thus renders the additional limitations of claim 25 obvious. *Id.*, ¶¶424-431. Moreover, because a POSA would have implemented these combinations using an intramedullary implant like Tyber's, the McGlamry-Kartalian-Tyber and Fallin-Kartalian-McGlamry-Tyber combinations further satisfy limitation 1[h] and the McGlamry-Kartalian-Fallin-Tyber and Fallin-Kartalian-McGlamry-Tyber combinations further satisfy limitation 14[l] because Tyber's implant compresses the first metatarsal together with the medial cuneiform. *Id.*, ¶432.

VIII. 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.

IX. 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 '481 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). *Sotera Wireless, Inc. v. Masimo Corp.*, IPR2020-01019, Paper 12 at 18-19 (P.T.A.B. Dec. 1, 2020) (precedential as to §II.A).

**X. MANDATORY NOTICES, GROUNDS FOR STANDING,
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 ’481 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”), and 12,102,368 (“the ’368 patent”) in the district court litigation, and the ’397, ’428, and ’368 patents are currently the subject of AIA Review Nos. PGR2026-00017, PGR2026-00020, 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.

Lead Counsel	Back-up Counsel
Ali S. Razai (Reg. No. 60,771) <i>ali.razai@morganlewis.com</i> <u>Postal and Hand-Delivery Address:</u> MORGAN, LEWIS & BOCKIUS LLP 600 Anton Boulevard, Suite 1800 Costa Mesa, CA 92626-7653 Tel.: (714) 830-0600 Fax: (714) 830-0700	Jacob L. Peterson (Reg. No. 65,096) <i>jacob.peterson@morganlewis.com</i> Brandon G. Smith (provisionally recognized PTAB attorney) <i>brandon.g.smith@morganlewis.com</i> <u>Postal and Hand-Delivery Address:</u> Morgan, Lewis & Bockius LLP 600 Anton Boulevard, Suite 1800 Costa Mesa, CA 92626-7653 Tel.: (714) 830-0600 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-481@morganlewis.com.

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

The '481 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 thirty claims is requested.

XI. CONCLUSION

Petitioner requests that the Board institute an PGR and cancel claims 1–30 of the '481 patent.

Dated: January 13, 2026 By: /Ali S. Razai/

Ali S. Razai (Reg. No. 60,771)
Morgan, Lewis & Bockius LLP

Attorney for Petitioner Paragon 28, Inc.

APPENDIX

Listing of Claims from U.S. 12,274,481	
Claim 1 ⁷	
1[pre]	An instrumented surgical technique for preparing a tarsal-metatarsal joint for fusion and for repositioning a first metatarsal to correct a bunion deformity, the instrumented surgical technique comprising:
1[a]	making an incision on a foot to provide access to a tarsal-metatarsal joint;
1[b]	engaging the first metatarsal with a bone engagement member of a bone positioning guide;
1[c]	engaging the bone positioning guide with a second metatarsal separated from the first metatarsal by an intermetatarsal angle;
1[d]	cutting an end of the first metatarsal with a tissue removing instrument;
1[e]	rotating a knob connected to a threaded shaft of the bone positioning guide to cause the bone engagement member to push the first metatarsal laterally toward the second metatarsal and thereby reduce the intermetatarsal angle between the first metatarsal and the second metatarsal to correct the bunion deformity;
1[f]	imparting a force to a pin inserted into the first metatarsal to adjust an alignment of the first metatarsal in a frontal plane to correct the bunion deformity;
1[g]	cutting an end of a medial cuneiform with the tissue removing instrument;

⁷ Bracketed labels have been added for convenient referencing to the claim limitations.

Listing of Claims from U.S. 12,274,481	
1[h]	compressing the first metatarsal together with the medial cuneiform; and
1[i]	fixating a moved position of the first metatarsal relative to the medial cuneiform for fusion using at least one bone fixation device.
Claim 2	
--	The instrumented surgical technique of claim 1, wherein: rotating the knob connected to the threaded shaft comprises rotating the knob connected to the threaded shaft after cutting the end of the first metatarsal; imparting the force to the pin inserted into the first metatarsal comprises imparting the force to the pin inserted into the first metatarsal after cutting the end of the first metatarsal; and cutting the end of the medial cuneiform comprises cutting the end of the medial cuneiform after rotating the knob and after imparting the force to the pin to correct the bunion deformity.
Claim 3	
--	The instrumented surgical technique of claim 1, further comprising removing the bone positioning guide from the first metatarsal and the second metatarsal with the moved position of the first metatarsal remaining fixated relative to the medial cuneiform by the at least one bone fixation device.

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Claim 4	
--	The instrumented surgical technique of claim 1, further comprising, prior to engaging the first metatarsal with the bone engagement member of the bone positioning guide and engaging the bone positioning guide with the second metatarsal, joining at least three components together, including the threaded shaft and the bone engagement member, to form the bone positioning guide.
Claim 5	
--	The instrumented surgical technique of claim 1, further comprising making a second incision on the foot to provide access to the second metatarsal, wherein engaging the bone positioning guide with the second metatarsal comprises positioning a bone contact surface of the bone positioning guide in contact with the second metatarsal.
Claim 6	
--	The instrumented surgical technique of claim 5, wherein the bone positioning guide comprises a tip defining the bone contact surface, and positioning the bone contact surface of the bone positioning guide in contact with the second metatarsal comprises inserting the tip through the second incision.

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Claim 7	
--	The instrumented surgical technique of claim 1, wherein imparting the force to the pin inserted into the first metatarsal to adjust the alignment of the first metatarsal in the frontal plane comprises imparting the force to the pin inserted into the first metatarsal to adjust the alignment of the first metatarsal in the frontal plane after rotating the knob connected to the threaded shaft of the bone positioning guide to cause the bone engagement member to push the first metatarsal laterally toward the second metatarsal and thereby reduce the intermetatarsal angle between the first metatarsal and the second metatarsal.
Claim 8	
--	The instrumented surgical technique of claim 1, further comprising moving the first metatarsal in a sagittal plane.
Claim 9	
--	The instrumented surgical technique of claim 1, wherein: the tissue removing instrument is a saw blade; cutting the end of the first metatarsal comprises guiding the saw blade through a first bone preparation guide cutting slot; and cutting the end of the medial cuneiform comprises guiding the saw blade through a second bone preparation guide cutting slot.
Claim 10	
--	The instrumented surgical technique of claim 1, wherein the bone positioning guide comprises a cannulation, and further comprising inserting a fixation wire through the cannulation and into the second metatarsal.

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Claim 11	
--	The instrumented surgical technique of claim 1, wherein the at least one bone fixation device comprises at least one of a screw and a plate.
Claim 12	
--	The instrumented surgical technique of claim 1, wherein the at least one bone fixation device comprises an intramedullary implant.
Claim 13	
--	The instrumented surgical technique of claim 1, wherein fixating the moved position of the first metatarsal relative to the medial cuneiform for fusion using at least one bone fixation device comprises inserting a compressing bone screw and a plate across the tarsal-metatarsal joint, wherein inserting the plate across the tarsal-metatarsal joint comprises inserting a plurality of bone screws through the bone plate to secure a first end of the bone plate to the medial cuneiform and a second end of the bone plate to the first metatarsal.
Claim 14	
14[pre]	An instrumented surgical technique for preparing a tarsal-metatarsal joint for fusion and for repositioning a first metatarsal to correct a bunion deformity, the instrumented surgical technique comprising:
14[a]	making an incision on a foot to provide access to a tarsal-metatarsal joint;
14[b]	engaging the first metatarsal with the bone engagement member of a bone positioning guide;

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14[c]	engaging the bone positioning guide with a second metatarsal separated from the first metatarsal by an intermetatarsal angle;
14[d]	cutting an end of the first metatarsal by guiding a saw blade through a first bone preparation guide cutting slot;
14[e]	removing a cut portion of the first metatarsal from the tarsal-metatarsal joint;
14[f]	after cutting the end of the first metatarsal, rotating a knob connected to a threaded shaft of the bone positioning guide to cause the bone engagement member to push the first metatarsal laterally toward the second metatarsal and thereby reduce the intermetatarsal angle between the first metatarsal and the second metatarsal to correct the bunion deformity;
14[g]	after cutting the end of the first metatarsal, imparting a force to a pin inserted into the first metatarsal to adjust an alignment of the first metatarsal in a frontal plane to correct the bunion deformity;
14[h]	after rotating the knob and after imparting the force to the pin to correct the bunion deformity of the first metatarsal, cutting an end of a medial cuneiform by guiding the saw blade through a second bone preparation guide cutting slot;
14[i]	removing a cut portion of the medial cuneiform from the tarsal-metatarsal joint;
14[j]	fenestrating a cut end of the first metatarsal;
14[k]	fenestrating a cut end of the medial cuneiform;
14[l]	compressing the first metatarsal together with the medial cuneiform;

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14[m]	fixating a moved position of the first metatarsal relative to the medial cuneiform for fusion using at least one bone fixation device; and
14[n]	removing the bone positioning guide from the first metatarsal and the second metatarsal.
Claim 15	
--	The instrumented surgical technique of claim 14, further comprising after cutting the end of the first metatarsal, moving the first metatarsal in a sagittal plane.
Claim 16	
--	The instrumented surgical technique of claim 14, further comprising positioning a joint spacer offset from the first bone preparation guide cutting slot into the tarsal-metatarsal joint simultaneous with positioning the first bone preparation guide cutting slot over an end of the first metatarsal to be cut.
Claim 17	
--	The instrumented surgical technique of claim 14, further comprising positioning a joint spacer offset from the second bone preparation guide cutting slot into the tarsal-metatarsal joint simultaneous with positioning the second bone preparation guide cutting slot over an end of the medial cuneiform to be cut.

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Claim 18	
--	The instrumented surgical technique of claim 14, wherein imparting the force to the pin inserted into the first metatarsal to adjust the alignment of the first metatarsal in the frontal plane comprises imparting the force to the pin inserted into the first metatarsal adjust the alignment of the first metatarsal in the frontal plane after rotating the knob connected to the threaded shaft of the bone positioning guide to cause the bone engagement member to push the first metatarsal laterally toward the second metatarsal and thereby reduce the intermetatarsal angle between the first metatarsal and the second metatarsal.
Claim 19	
--	The instrumented surgical technique of claim 14, further comprising making a second incision on the foot to provide access to the second metatarsal, wherein: engaging the bone positioning guide with the second metatarsal comprises positioning a bone contact surface of the bone positioning guide in contact with the second metatarsal; and rotating the knob connected to a threaded shaft of the bone positioning guide to cause the bone engagement member to push the first metatarsal laterally toward the second metatarsal comprises rotating the knob connected to a threaded shaft of the bone positioning guide to reduce a distance between the bone engagement member and the contact surface.

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Claim 20	
--	The instrumented surgical technique of claim 19, wherein the bone positioning guide comprises a tip defining the bone contact surface, and positioning the bone contact surface of the bone positioning guide in contact with the second metatarsal comprises inserting the tip through the second incision.
Claim 21	
--	The instrumented surgical technique of claim 19, wherein: the bone positioning guide comprises a body, a first leg carrying the bone engagement member, and a second leg defining the bone contact surface; and engaging the first metatarsal with the bone engagement member and positioning the bone contact surface in contact with the second metatarsal comprises positioning the body extending in a medial-to-lateral direction across the first metatarsal and across the second metatarsal with the first leg positioned on a medial side of the first metatarsal.
Claim 22	
--	The instrumented surgical technique of claim 14, wherein the bone positioning guide comprises a cannulation, and further comprising inserting a fixation wire through the cannulation and into the second metatarsal.
Claim 23	
--	The instrumented surgical technique of claim 14, wherein the bone positioning guide is formed by joining at least three components together, including the threaded shaft and the bone engagement member, to provide the bone positioning guide.

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Claim 24	
--	The instrumented surgical technique of claim 14, wherein the at least one bone fixation device comprises at least one of a screw and a plate.
Claim 25	
--	The instrumented surgical technique of claim 14, wherein the at least one bone fixation device comprises an intramedullary implant.
Claim 26	
--	The instrumented surgical technique of claim 14, wherein fixating the moved position of the first metatarsal relative to the medial cuneiform for fusion using at least one bone fixation device comprises inserting a compressing bone screw and a plate across the tarsal-metatarsal joint, wherein inserting the plate across the tarsal-metatarsal joint comprises inserting a plurality of bone screws through the bone plate to secure a first end of the bone plate to the medial cuneiform and a second end of the bone plate to the first metatarsal.
Claim 27	
27[pre]	An instrumented surgical technique for correcting a bunion deformity, the instrumented surgical technique comprising:
27[a]	making an incision on a foot to provide access to a tarsal-metatarsal joint;
27[b]	engaging the first metatarsal with the bone engagement member of the bone positioning guide;

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27[c]	engaging the bone positioning guide with the second metatarsal separated from the first metatarsal by an intermetatarsal angle;
27[d]	preparing an end of the first metatarsal for fusion;
27[e]	rotating a knob connected to a threaded shaft of the bone positioning guide to cause the bone engagement member to push the first metatarsal laterally toward the second metatarsal and thereby reduce the intermetatarsal angle between the first metatarsal and the second metatarsal to correct a bunion deformity;
27[f]	imparting a force to a pin inserted into the first metatarsal to adjust an alignment of the first metatarsal in a frontal plane to correct the bunion deformity;
27[g]	preparing an end of a medial cuneiform for fusion; and
27[h]	installing at least one fixation device through the incision to fixate a moved position of the first metatarsal relative to the medial cuneiform.
Claim 28	
--	The instrumented surgical technique of claim 27, wherein: rotating the knob connected to the threaded shaft comprises rotating the knob connected to the threaded shaft after preparing the end of the first metatarsal; imparting the force to the pin inserted into the first metatarsal comprises imparting the force to the pin inserted into the first metatarsal after preparing the end of the first metatarsal; and preparing the end of the medial cuneiform comprises preparing the end of the medial cuneiform after rotating the knob and after imparting the force to the pin to correct the bunion deformity.

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Claim 29	
29[pre]	The instrumented surgical technique of claim 28, further comprising:
29[a]	after preparing the end of the first metatarsal and after preparing the end of the medial cuneiform but prior to installing the at least one fixation device, compressing a prepared end the first metatarsal together with a prepared end of the medial cuneiform; and
29[b]	after installing the at least one fixation device through the incision to fixate the moved position of the first metatarsal relative to the medial cuneiform, removing the bone positioning guide from the first metatarsal and the second metatarsal.
Claim 30	
30[pre]	An instrumented surgical technique for preparing a tarsal-metatarsal joint for fusion and for repositioning a first metatarsal to correct a bunion deformity, the instrumented surgical technique comprising:
30[a]	making an incision on a foot to provide access to a tarsal-metatarsal joint;
30[b]	making a second incision on the foot to provide access to a second metatarsal separated from the first metatarsal by an intermetatarsal angle;
30[c]	engaging the first metatarsal with the bone engagement member of a bone positioning guide;
30[d]	positioning a bone contact surface of the bone positioning guide in contact with the second metatarsal;

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30[e]	cutting an end of the first metatarsal by guiding a saw blade through a first bone preparation guide cutting slot;
30[f]	rotating a knob connected to a threaded shaft of the bone positioning guide to reduce a distance between the bone engagement member and the contact surface, thereby reducing the intermetatarsal angle between the first metatarsal and the second metatarsal to correct the bunion deformity;
30[g]	imparting a force to a pin inserted into the first metatarsal to adjust an alignment of the first metatarsal in a frontal plane to correct the bunion deformity;
30[h]	cutting an end of a medial cuneiform by guiding the saw blade through a second bone preparation guide cutting slot;
30[i]	compressing the first metatarsal together with the medial cuneiform;
30[j]	fixating a moved position of the first metatarsal relative to the medial cuneiform for fusion using at least one bone fixation device; and
30[h]	removing the bone positioning guide from the first metatarsal and the second metatarsal,
30[i]	wherein one or both of the first metatarsal and the medial cuneiform is cut after reducing the intermetatarsal angle between the first metatarsal and the second metatarsal to correct the bunion deformity and after adjusting the alignment of the first metatarsal in the frontal plane to correct the bunion deformity.

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. 12,274,481 contains 17,897 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: January 13, 2026 By: / Ali S. Razai/
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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on the date below a copy of this
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12,274,481, AND EXHIBITS 1001-1007, 1009-1023, 1025-1028, 1030, AND
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