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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 IPR2026-00194
Patent 12,102,368

**PETITION FOR *INTER PARTES* REVIEW OF
U.S. PATENT NO. 12,102,368**

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Cases

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LIST OF EXHIBITS

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1001	U.S. Patent No. 12,102,368 to Smith et al. (“the ’368 Patent”)
1002	File History of the ’368 Patent
1003	Declaration of Steven K. Neufeld, M.D.
1004	Curriculum Vitae of Steven K. Neufeld, M.D.
1005	U.S. Patent App. Publ. No. 2016/0213384 to Fallin et al. (“Fallin”)
1006	U.S. Patent No. 8,882,816 to Kartalian et al. (“Kartalian”)
1007	McGlamry’s Comprehensive Textbook of Foot and Ankle Surgery, Preface and Chapters 1, 31, 34, 36, and 55, 4 th Edition, 2013 (“McGlamry”)
1008	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)
1009	RESERVED
1010	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)
1011	Mark H. Hofbauer & Jordan P. Grossman, <i>The Lapidus Procedure</i> , 13(3) CLINICS PODIATRIC MED. & SURGERY 486–496 (1996)
1012	Paul W. Lapidus, <i>The author's bunion operation from 1931 to 1959</i> , 16 CLIN. ORTHOPAEDICS 119-135 (1960)
1013	Paul W. Lapidus, <i>Operative correction of the metatarsus varus primus in hallux valgus</i> , 58 J. SURGERY GYNECOLOGY & OBSTETRICS 183–191 (1934)

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1014	Babak Baravarian, et al., <i>Lapidus bunionectomy: arthrodesis of the first metatarsocunieform [sic] joint</i> , 21 CLINICS IN PODIATRIC MED. & SURGERY 97–111 (2004)
1015	Brian C. Toolan, <i>Surgical Strategies: The Lapidus Procedure</i> , 28 FOOT & ANKLE INT’L 1108-1114 (2007)
1016	Timo Schmid & Fabian Krause, <i>The modified Lapidus fusion</i> , 19(2) FOOT & ANKLE CLINICS 223–233 (June 2014)
1017	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)
1018	U.S. Design Patent No. D695,402 to DaCosta et al. (“DaCosta”)
1019	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)
1020	RESERVED
1021	RESERVED
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	File History for U.S. Provisional Application No. 62/108,936 (“the ’936 application”)
1025	U.S. Patent No. 5,350,382 to Armstrong et al. (“Armstrong”)
1026	U.S. Patent No. 4,349,018 to Chambers (“Chambers”)
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”)

Exhibit No.	Description
1029	U.S. Patent No. 5,722,978 to Jenkins (“Jenkins”)
1030	U.S. Patent No. 5,112,334 to Alchermes et al. (“Alchermes”)
1031	U.S. Patent App. Publ. No. 2012/0078258 to Lo et al. (“Lo”)
1032	International App. Publ. No. 2015/123270 to Sachin et al. (“Sachin”)
1033	U.S. Patent App. Publ. No. 2013/0030438 to Fox (“Fox”)
1034	U.S. Patent App. Publ. No. 2011/0186456 to Bertazzoni et al. (“Bertazzoni”)
1035	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)
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 *inter partes* review (“IPR”) of claims 1-30 of U.S. Patent 12,102,368 (“the ’368 patent,” Ex.1001).

I. INTRODUCTION

The ’368 patent claims surgical methods and systems 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 July 2015.

The systems claimed by the ’368 patent include: a bone cutting guide for cutting the ends of the metatarsal and cuneiform bones; a bone positioning guide for moving the first metatarsal in multiple planes; and a fixation device (such as pins, screws, plates and staples) to fix the metatarsal to the cuneiform in its moved position.

By the early 1900s, surgeons had described procedures for correcting a misalignment of the first metatarsal and medial cuneiform. Ex.1010; Ex.1014, 97 (summarizing Lapidus’s procedure); Ex.1015, 1108 (same); Ex.1019, 248-50 (same); Ex.1007, 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.1015, 1109-13 (describing operative technique); Ex.1017, 423; Ex.1016, 226-28 (same).

By 2015, bunion correction surgeries were very well-developed and routine. In 2013, the McGlamry medical textbook disclosed a bunion correction surgery that

includes 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.

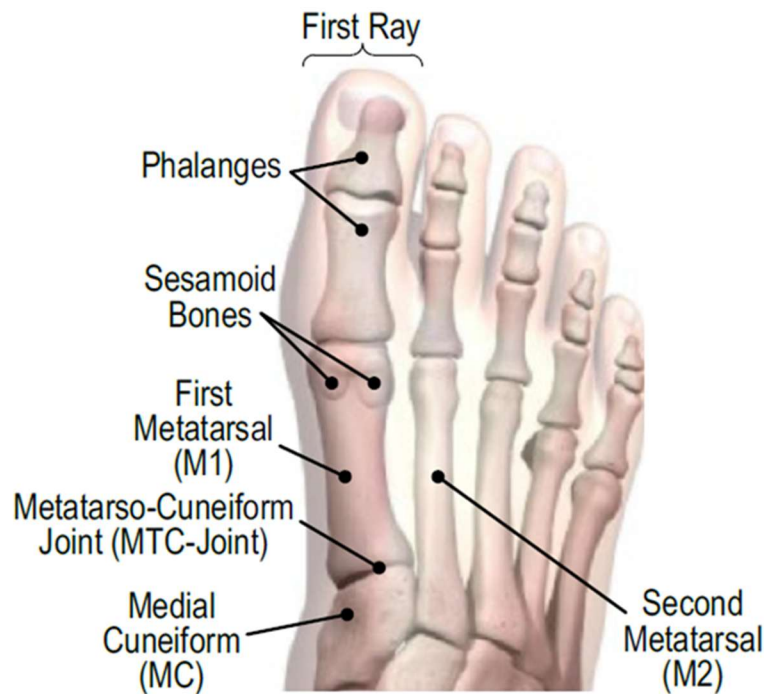
Moreover, by 2015, the art was replete with tools for use with bunion correction surgeries, like that disclosed in McGlamry. For example, Fallin discloses surgical methods and instruments used in bunion surgery, including, a guide for cutting the facing surfaces of the metatarsal and cuneiform bones. Additionally, McGlamry discloses using a Weber clamp and K-wires to position the metatarsal. Likewise, Kartalian describes specialized “reduction forceps”-like instruments for use during bunion correction surgery to reposition the first metatarsal in both the transverse and frontal planes.

By July 2015, the systems claimed in the '368 patent were nothing more than a predictable collection of prior art elements for use according to their established functions. Accordingly, all claims of the '368 patent are obvious and should be cancelled.

II. OVERVIEW OF PRIOR ART

A. Bunion Deformity

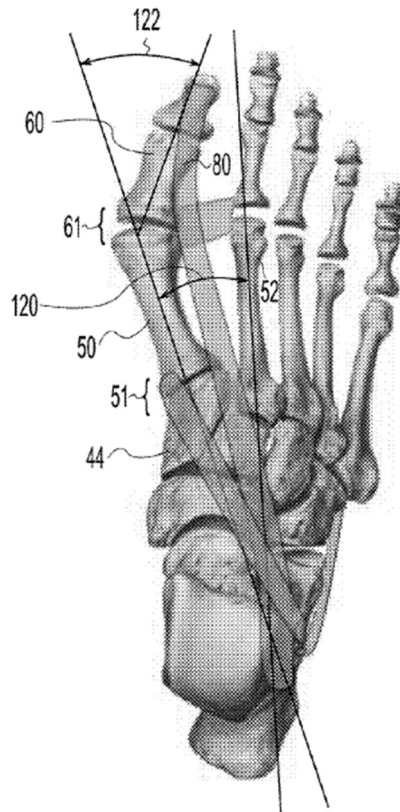
In a typical foot anatomy, the first metatarsal and medial cuneiform bones are positioned in three-dimensional alignment to permit normal foot function. Ex. 1003 ¶¶40-41. These bones meet to form the metatarsal-cuneiform joint:



Id., ¶¶41.¹ A bunion can result when the first metatarsal and medial cuneiform bones become misaligned in one or more planes. *Id.*, ¶¶42-43. As part of this misalignment, the first metatarsal may deviate away from the second metatarsal,

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

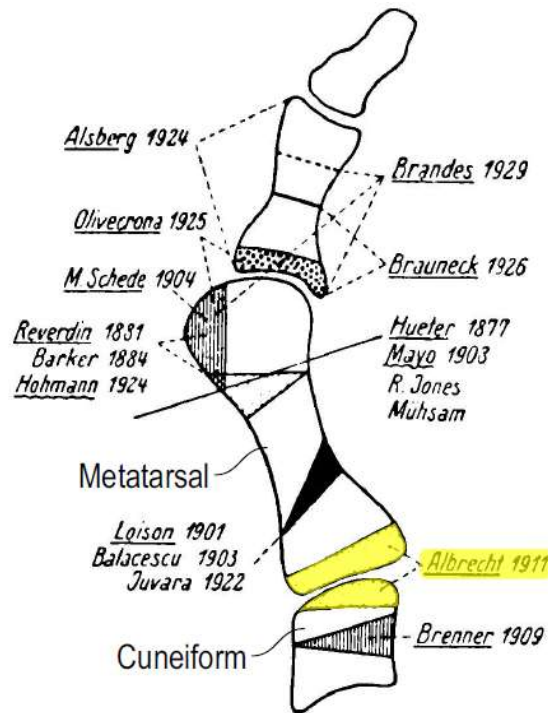
which increases the intermetatarsal angle (“IMA”)—the angle formed between the longitudinal axes of the first and second metatarsals:



Ex.1005, Fig.11. 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 ¶¶43-46; *see also* Ex.1019, 250 (describing anatomical changes from bunion deformities).

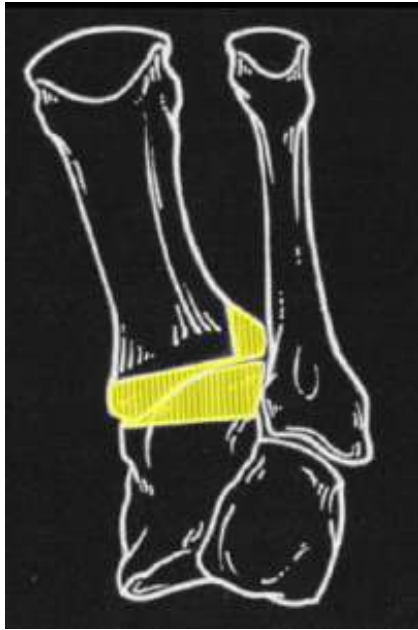
B. Instrumented Bunion Correction

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.1012, 122. 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. Lapidus. Ex.1003, ¶¶47-48; Ex.1007, 803; Ex.1013. The procedure’s goal is to fuse the metatarsal and cuneiform in the corrected position. Ex.1003, ¶¶49-52; Ex.1013, 186, 189.

To prepare the joint, 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

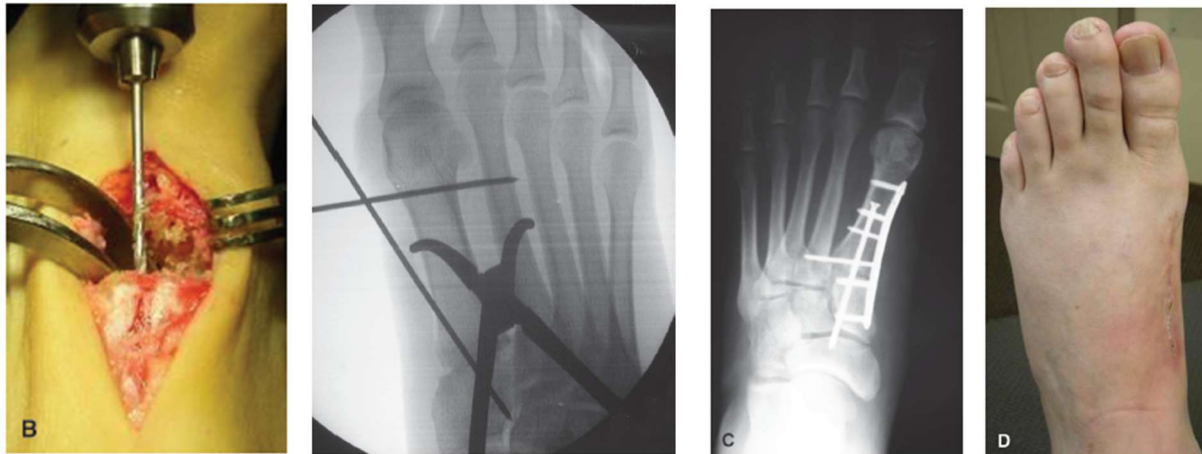
Ex.1011, Fig.1A. Next, the surgeon adjusts the alignment of the first metatarsal and fixes the moved first metatarsal to the first cuneiform using fixation devices (e.g., screw or plate) to achieve bone fusion in the corrected orientation. Ex.1003, ¶¶49-52; Ex.1013, 187-88; Ex.1011, 493; Ex.1007, 324-27; Ex.1008, 466.

C. Known Surgical Methods For Correcting Bunion Deformities

McGlamry describes surgical methods for correcting bunion deformities. Ex.1007, 322; Ex.1003, ¶¶53-56. Chapter 31 of McGlamry walks through the steps of a bunion correction procedure. Ex.1007, 324-27.

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. Ex.1007, 322-29.



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, ¶¶55-56.

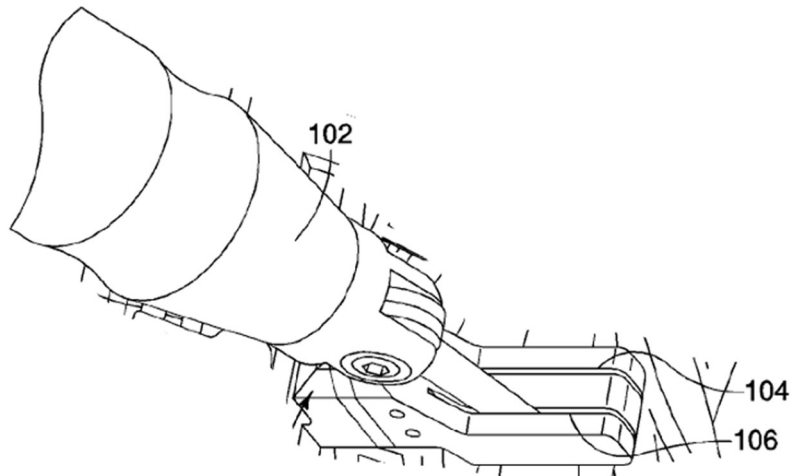
D. Known Bone Preparation Guides (Bone Cutting Guides)

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

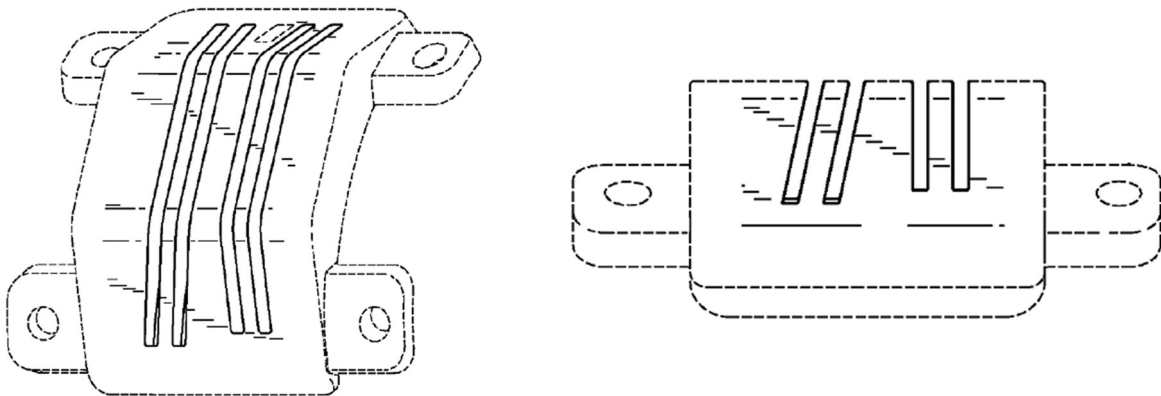
For example, Haddad discloses a cutting guide and a positioning jig usable “for a fusion application, [wherein] the jig likely would be secured to a metatarsal distally and a cuneiform proximally.” Ex.1022, [0058]. Haddad’s cutting guide

² The term “bone preparation guide” as used in the ’368 patent refers to at least a “bone cutting guide.” Ex.1003, ¶57.

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:



Ex.1018, Figs.1, 5; Ex.1003, ¶¶59-60.

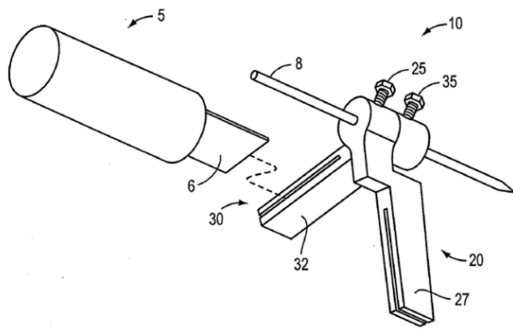


FIG. 3

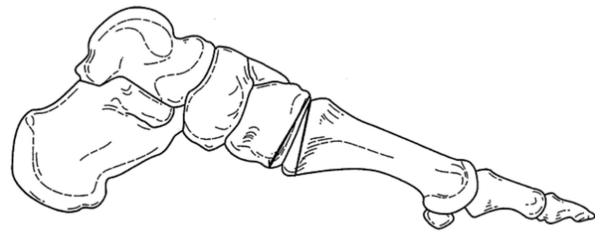


FIG. 13

Ex.1023, Figs.3, 13.

Fallin also discloses a bone cutting guide for use in a bunion correction surgery. Ex.1003, ¶61. 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.1005, Abstract. Fallin further discloses an “osteotomy guide 200” that achieves “more precision and repeatability in the relative orientation of the cuts” to the metatarsal and cuneiform. *Id.*, [0062].

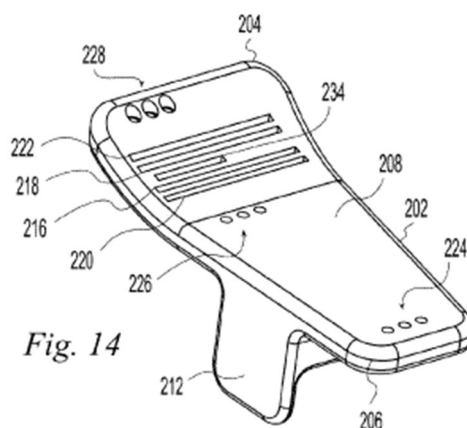


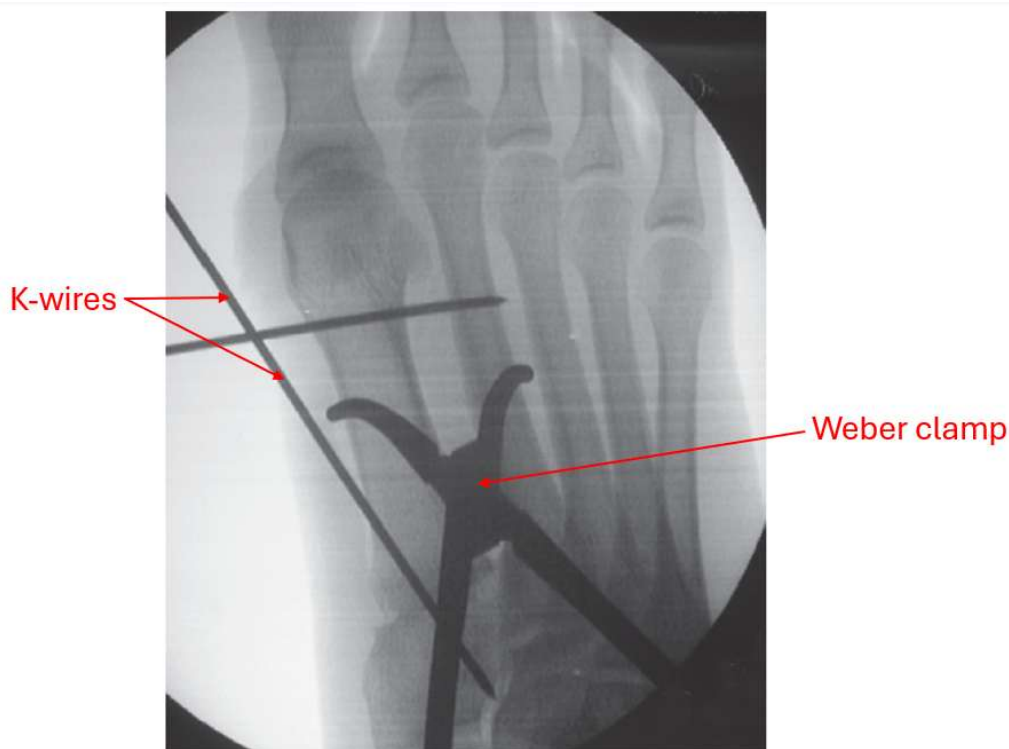
Fig. 14

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]; Ex.1003, ¶¶61-62.

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.1007, 324-27. 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.



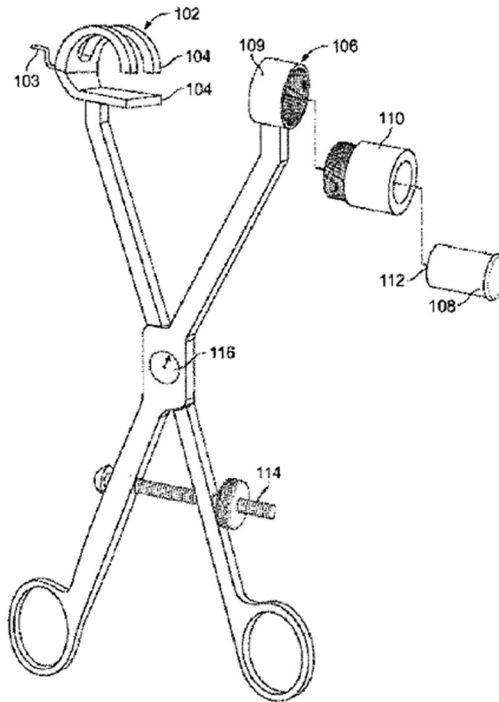
Ex.1007, Fig.31.5; Ex.1003, ¶64.

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 IMA and, after preparation of the metatarsocuneiform joint, pinned to the first metatarsal and medial cuneiform to compress the cut bones. Ex.1003, ¶65-66. Additional bone positioning guides include Weber clamps (Ex.1007, 325-326), reduction forceps/clamps (Ex.1006; Ex.1008, 466), periarticular clamps (Ex.1003, ¶66), and joint distractors (Ex.1003, ¶66). Surgeons have used clamps such as those shown below to position the first metatarsal for more than two decades:



Ex.1003, ¶66.

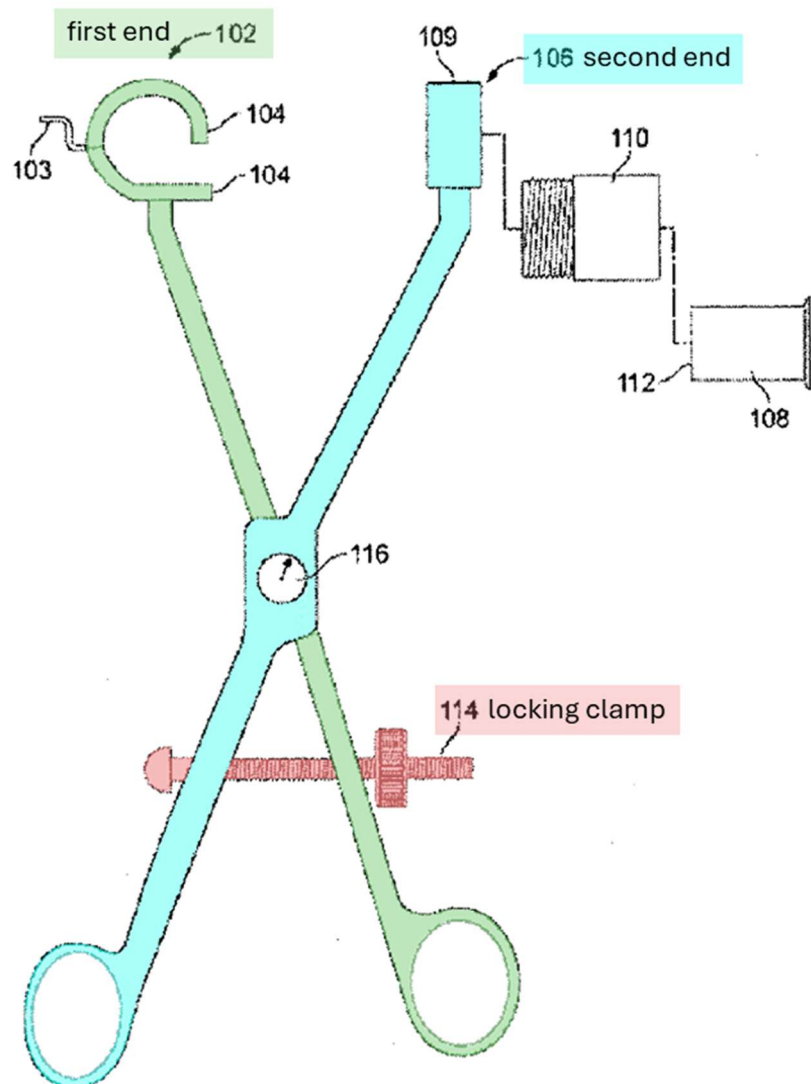
Kartalian also discloses a bone positioning guide for repositioning the first metatarsal during a bunion correction surgery—referred to as “instrument 100.” Ex.1003, ¶67. An embodiment of this instrument is shown below:



Ex.1006, Fig.1(excerpt).³ The instrument “act[s] as reduction forceps to align two bones or reduce the distance between the bones.” *Id.*, 9:66-10:3. More specifically, Kartalian discloses its instrument can be used to reduce the distance between the first and second metatarsals—thereby reducing the IMA—and to rotate the first metatarsal in the frontal plane to address rotational deformities. *Id.*; Ex.1003, ¶¶67-68.

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.

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.1006, 10:46-51.



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.1006, 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.1006, 9:66-10:3, 10:46-51; Ex.1003, ¶71. 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. Moreover, instrument 100 may allow for correction of any rotational deformity (pronation) when used for surgical correction of a bunion.” Ex.1006, 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. 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.*, ¶¶73-75; *see also* Ex.1011, 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.1011. 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.1007, 326.



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



Id., Figs.31.7, 31.8; Ex.1003, ¶75.

III. THE '368 PATENT

A. Overview

The '368 patent relates to “devices and techniques for positioning bones” and specifically in connection with bunion correction surgery. *See, e.g.*, Ex.1001, 1:27-28, 1:46-48, 5:10-16.

The claims of the '368 patent are directed to a “metatarsal bunion correction system.” *Id.*, Claims 1-30. Generally, the claimed system comprises a collection of instruments for bunion correction, including: a “bone preparation guide.” The “bone preparation guide” is a bone cutting guide for guiding a cutting instrument to cut the proximal end of the first metatarsal and/or the distal end of the medial cuneiform.

The system further includes a “bone positioning guide” to move the first metatarsal in the transverse plane and rotate it in the frontal plane and a “fixational device,” such as a screw or plate, for fixing the first metatarsal in the moved position for fusion. *Id.*

B. Prosecution History

The '368 patent was filed under Track One prioritized examination. Ex.1002, 56. None of the claims that ultimately issued were rejected by the examiner. *Id.* 385-387, 492-498.

IV. LEVEL OF ORDINARY SKILL

The '368 patent relates to devices and techniques for positioning bones and claims metatarsal bunion correction systems. Ex.1001, 1:27-28, 18:43-21:7. The claims recite that many of these claimed devices are configured to perform a particular function during surgery. *See id.*; Ex.1003, ¶¶31-33. Thus, the claims include limitations related to both mechanical devices and limitations related to how those devices would be used by a surgeon during surgery. A hypothetical person of ordinary skill in the art would have a combination of these two skill sets. Ex.1003, ¶¶31-33. 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.*, ¶34.

V. CLAIM CONSTRUCTION

In an *inter partes* 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.

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

Function: “treating a bunion deformity by ... moving the first metatarsal in a transverse plane to reduce an intermetatarsal angle between the first metatarsal and a second metatarsal, and rotating the first metatarsal in a frontal plane.” Ex.1001, Claims 1, 21.

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” (Ex.1001, 7:20-34);

- “[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.*, 5:38-46, 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.

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

Function: “to fixate a moved position of the first metatarsal relative to the medial cuneiform for fusion.” Ex.1001, Claims 1, 21.

Corresponding Structure: The specification discloses multiple structures that perform the claimed function, including: “compressing bone screw, bone plate, bone staple, external fixator, intramedullary implant or nail” (Ex.1001, 11:20-25) and “two bone plates positioned in different planes” (*id.*, 13:63-67).

C. “temporary fixation device”

The plain and ordinary meaning of “temporary fixation device” is a “removable device that maintains the relative position of bones.” Ex.1003, ¶93.

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

Function: “temporarily fixate a moved position of the first metatarsal relative to the medial cuneiform.” Ex.1001, Claims 1, 21.

Corresponding Structure: The specification discloses multiple structures that perform the claimed function, including: a wire, such as a K-wire. *Id.*, 7:1-10.

D. “tissue removing instrument”

The plain and ordinary meaning of “tissue removing instrument” is a “device for cutting tissue.” Ex.1003, ¶97.

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

Function: cutting bone. Ex.1001, Claims 1, 21.

Corresponding Structure: The specification discloses multiple structures that perform the claimed function, including: a saw blade, rotary burr, and osteotome. *Id.*, 8:9-13.

E. “a mechanism configured to move the bone engagement member and the tip relative to each other”

The plain and ordinary meaning of “mechanism” is a “device for moving the bone engagement member and tip relative to each other.”

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

Function: moving the bone engagement member and the tip relative to each other. Ex.1001, Claim 15.

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

- a shaft movably connected to a main body member (including a threaded shaft and the variants described in the specification) (Ex.1001, Abstract, 2:4-11, 5:38-65);
- a tenaculum/tong structure with first and second shafts pivotably connected (*id.*, 7:20-22); and
- rack-and-pinion structure in which the rack carries the tip and the pinion carries the bone engagement member (*id.*, 7:35-37).

VI. RELIEF REQUESTED

A. Grounds

Petitioner requests IPR for the following grounds of unpatentability:

Ground	Reference(s)	Claims	Basis
1	McGlamry and Fallin	1-2, 4-20	§103
2	McGlamry, Fallin, and Kartalian	1-30	§103
3	McGlamry, Fallin, and Schmuck	3, 21-30	§103
4	McGlamry, Fallin, Kartalian, and Schmuck	3, 21-30	§103
5	Any of Grounds 1-2 and Jenkins	7	§103
6	Any of Grounds 2-4 and Jenkins	23	§103

In support of the Petition, Petitioner submits the expert declaration of Steven K. Neufeld, M.D. *See* Ex.1003, ¶¶1-15; Ex.1004.

B. Asserted References

The '368 patent's earliest claimed priority date is July 14, 2015. Ex. 1001.

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

Ex.	Reference(s)	Date	Art Type
1005	Fallin	Provisional Filed: Jan. 28, 2015	§102(a)(2)
1006	Kartalian	Published: Nov. 11, 2014	§§102(a)(1), (2)
1007	McGlamry	Published: 2013	§102(a)(1)
1028	Schmuck	Published: Jan. 30, 2014	§§102(a)(1),(2)
1029	Jenkins	Published: Mar. 3, 1998	§§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.1005, 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.1005, *with* Ex.1024, 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.

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

The references are analogous art because they are from the same field as the '368 patent—namely, surgical procedures involving bone. Ex.1003, ¶104; Ex.1001, 1:32-42; *Unwired Planet, LLC v. Google Inc.*, 841 F.3d 995, 1000 (Fed. 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, ¶104.

VII. GROUNDS OF UNPATENTABILITY

A. Ground 1: Claims 1-2 And 4-20 Are Obvious Over McGlamry And Fallin

1. Claim 1

a. Preamble

Claim 1's preamble recites a "metatarsal bunion correction system" and includes no additional structural limitations. To the extent the preamble is limiting, both McGlamry and Fallin disclose such a system.

McGlamry discloses an instrumented technique for bunion correction surgery. Ex.1007, 324-28; Ex.1003, ¶¶106-107. McGlamry's procedure includes cutting the proximal end of the first metatarsal, cutting the distal end of the first cuneiform, correcting the metatarsal position in the transverse and frontal planes, and fixing the medial portion of the moved first metatarsal to the distal portion of the cuneiform. *Id.* McGlamry teaches the use of various instruments, including:

- An osteotome for bone cutting. Ex.1007, 324.

- Weber clamps and/or K-wires to reposition and/or stabilize the first metatarsal prior to fixation. *Id.*, 325-26.
- Screws, locking plates, and drills to fix the first metatarsal to the cuneiform. *Id.*, 328-29.

Accordingly, McGlamry discloses a “metatarsal bunion correction system.” Ex.1003, ¶107.

Fallin likewise discloses a system for correcting a metatarsal bunion. *Id.*, ¶¶108-109. Fallin describes methods, implants, and instruments used in bunion correction surgery, including those for performing “a fusion osteotomy at a metatarsocuneiform joint of the first ray of a human foot,” i.e., a first metatarsal-medial cuneiform fusion used to realign the first ray. Ex.1005, Abstract; *see also*, [0006], [0036].

Moreover, the combination of the claimed bone preparation guide, bone positioning guide, and fixation device—each known in the prior art—does not create a patentable “system.” Established tools used to perform known surgical steps do not yield an inventive arrangement. *See, e.g., 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.”).

By 2015, it would have been obvious to incorporate Fallin’s cutting guide into McGlamry’s procedure. Ex.1003, ¶¶110-125. McGlamry emphasizes the important nature of bone cutting, describing it as a “vital portion of the procedure.” Ex.1007, 324. McGlamry further notes that “joint 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.” *Id.* 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; *see also* Ex.1017, 424 (describing nonunion issues with metatarsocuneiform arthrodesis).

McGlamry also describes “freehand” bone resection (Ex.1007, 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.” *Id.*, 1:31-37; Ex.1003, ¶111. 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, ¶¶112-116; 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.1007, 381-83. 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.1005, [0056]. Further, rather than spending "a substantial amount of time" on freehand joint preparation, Ex.1007, 324, Fallin's cutting guide would make preparation predictable and repeatable, thereby simplifying and shortening the procedure. Ex.1003, ¶115. Shorter and simpler surgical procedures typically mean less time under anesthesia, which benefits the patient. *Id.*, ¶116. 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.*

Fallin’s cutting guide also mitigates complications identified by McGlamry. For example, McGlamry’s identifies “[s]ignificant shortening” of the metatarsal as a potential complication. Ex.1007, 329; Ex.1003, ¶¶117-118. Shortening refers to excessive removal of bone that alters foot biomechanics and can result in pain, deformities, and other complications. Ex.1003, ¶117; *see also* Ex.1016, 230. Fallin’s cutting guide “results in more precision and repeatability in the relative orientation of the cuts [to the metatarsal and cuneiform].” Ex.1005, [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, ¶118.

Fallin’s cutting guide also reduces the risk of delayed unions, non-unions, and malunions identified by McGlamry. Ex.1007, 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, ¶119. The use of cutting guides in metatarsal-cuneiform fusion procedures was a known technique for “easily and effectively achiev[ing] a union through normal biological healing.” Ex.1022, [0068]; *see also* Ex.1017, 429. Fallin’s cutting guide promotes effective unions because it prepares complementary joint surfaces. *See, e.g.*, Ex.1005, [0058] (“[T]he 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, ¶119.

Using Fallin’s cutting guide in McGlamry’s procedure amounts to applying a known technique to address known problems using known elements with predictable results. *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 Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007) (claims are obvious if they apply “a known technique to a piece of prior art ready for the improvement”).

It also would have been obvious to use Fallin’s cutting guide in McGlamry’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, ¶120; *KSR*, 550 U.S. at 417.

A POSA would have recognized that Fallin’s cutting guide would be adapted to McGlamry’s technique with minimal or no modifications. Cutting guides are routinely adapted across procedures and anatomical variations. Ex.1003, ¶¶121-125; *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, ¶124; 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 cutting guides in bunion correction procedures, such as Lapidus procedures. Ex.1023, [0051], Fig.13; Ex.1003, ¶124.

The relevant portions of the surgical procedures described in Fallin and McGlamry are nearly identical. Ex.1003, ¶125. 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.1005, [0056]-[0058], [0065]-[0068]; Ex.1007, 324-26. A POSA therefore would have had a reasonable expectation of success. Ex.1003, ¶125; *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).

b. Limitation 1[a]

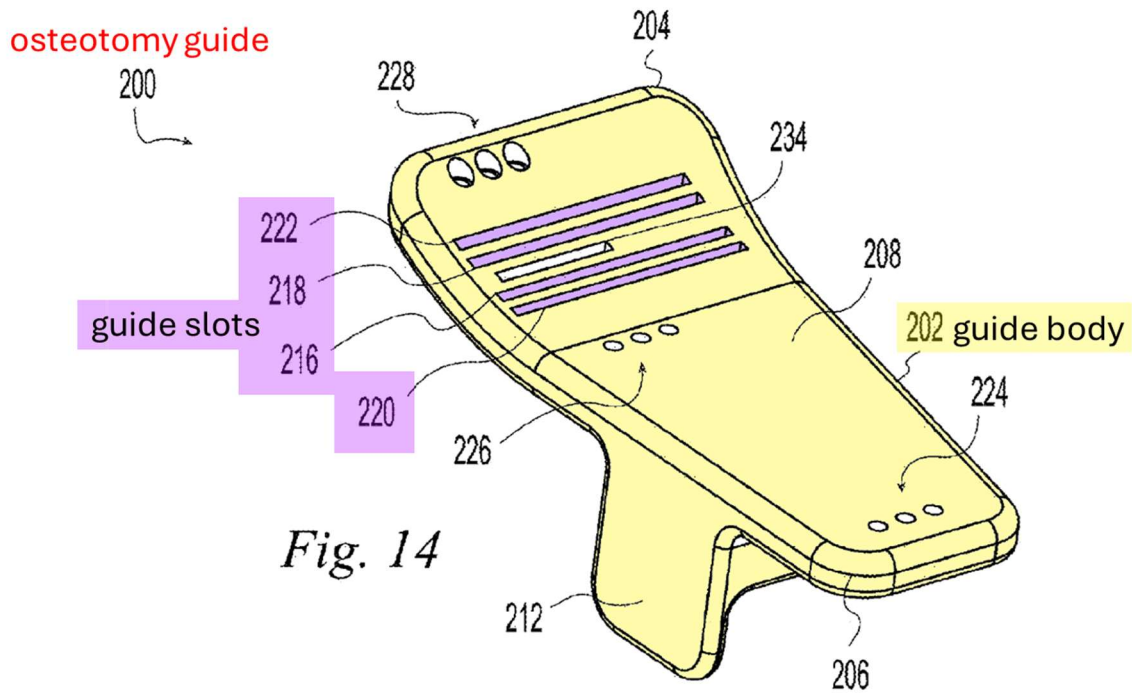
Limitation 1[a] recites: “a bone preparation guide comprising a body defining a guide surface configured to be positioned over a proximal end of a first metatarsal

and/or a distal end of a medial cuneiform, the guide surface being configured to guide a tissue removing instrument for cutting the proximal end of the first metatarsal and/or the distal end of the medial cuneiform.”

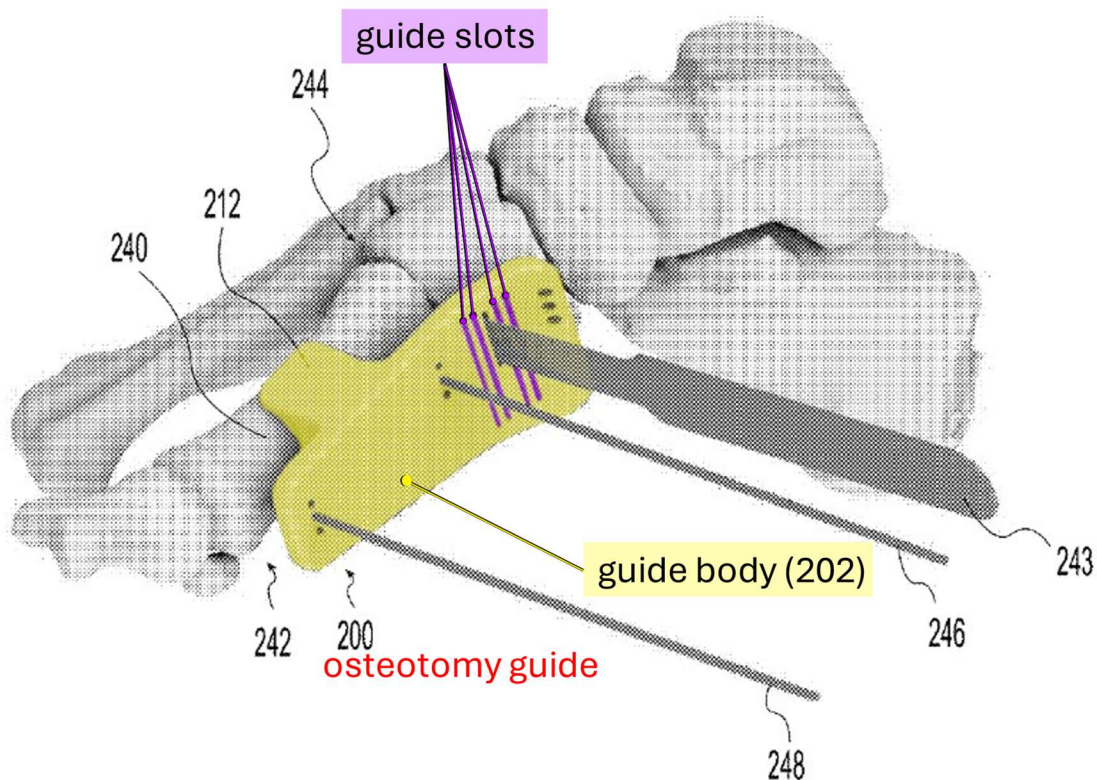
As discussed above, it would have been obvious to perform McGlamry’s bunion correction surgery with a bone cutting guide when cutting the medial end of the first metatarsal and the distal end of the first cuneiform, as McGlamry discloses. Ex.1003, ¶¶126-136.

Fallin discloses this limitation. *Id.*, ¶¶128-136. 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.1005, claim 24; *see also*, [0052] (“cutter, such as a saw blade”), [0065], [0067]. An osteotomy guide and a bone preparation guide are each bone cutting guides. Ex.1003, ¶129. 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., a “cutter”).⁵ Ex.1005, [0055]; Ex.1003, ¶¶129-132.

⁵ Fallin’s guided “cutter” satisfies the “tissue removing instrument” limitation under plain meaning; and if §112(f) were applied, the cutter is corresponding structure (or



an equivalent) to the saw/osteotome/bur-type tissue-removal instruments described in the '368 patent. Ex.1003, ¶136.

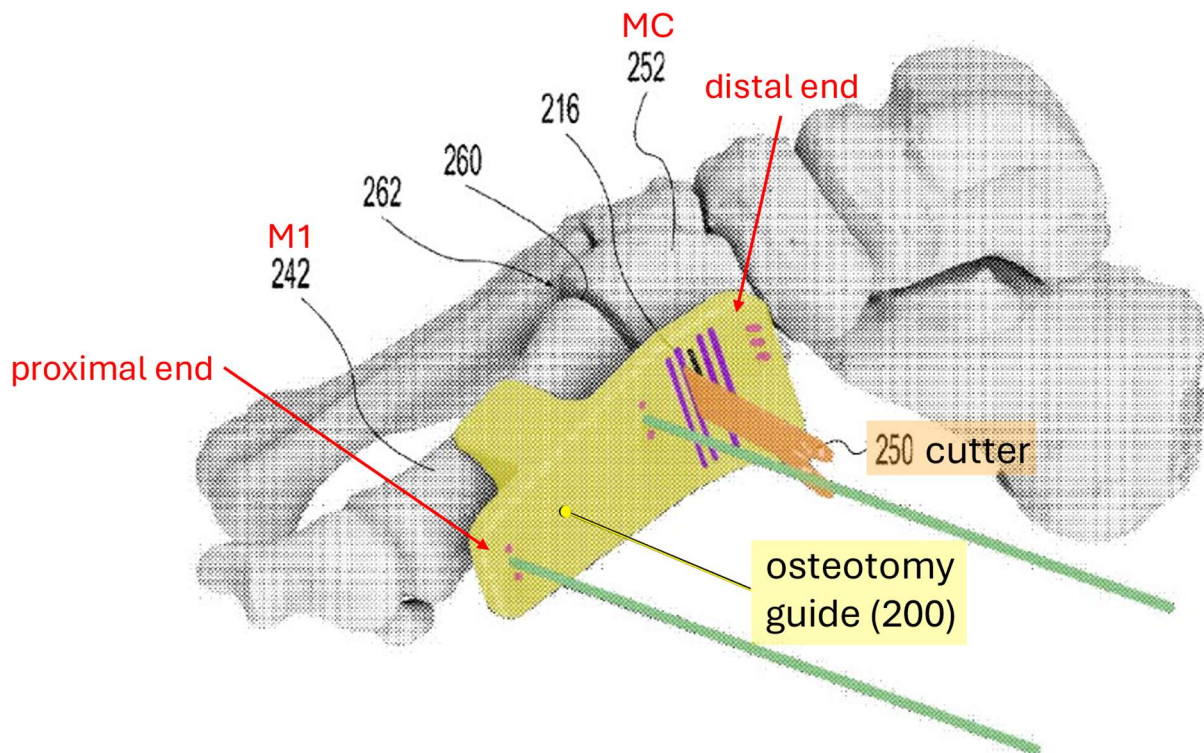


Ex.1005, Figs.14, 21. As illustrated, for example, in Figures 14 and 21, each of Fallin’s guide slots includes at least one plane that is the claimed guide surface. *Id.*; Ex.1003, ¶¶130-131; *see also* Ex.1001, 8:1-33 (“[B]one preparation guide 150 includes a body 154 defining a first guide surface to define a first preparing plane.”).

Fallin discloses the osteotomy guide as positioned directly on the bones at the metatarsocuneiform joint (i.e., the metatarsal and cuneiform). Ex.1003, ¶¶133-135. For example, Fallin teaches “fixing an osteotomy guide to the metatarsus” by “abutting” indexing features against the metatarsus, and separately teaches “guiding a cutter with the osteotomy guide to cut the metatarsus at a predetermined angle relative to the osteotomy guide to produce a first cut surface and remove a first

portion of bone adjacent the joint.” Ex.1005, claims 14, 19; *see also*, [0056], [0064]-[0065], [0067]. Fallin further describes “guiding a cutter with the osteotomy guide to cut the cuneiform at a predetermined angle relative to the osteotomy guide to produce a second cut surface and remove a second portion of bone adjacent the joint to create a gap between the metatarsus and cuneiform.” *Id.*, claim 14.

Fallin illustrates positioning its osteotomy guide over the proximal end of the first metatarsal (M1) and the distal end of the medial cuneiform (MC):

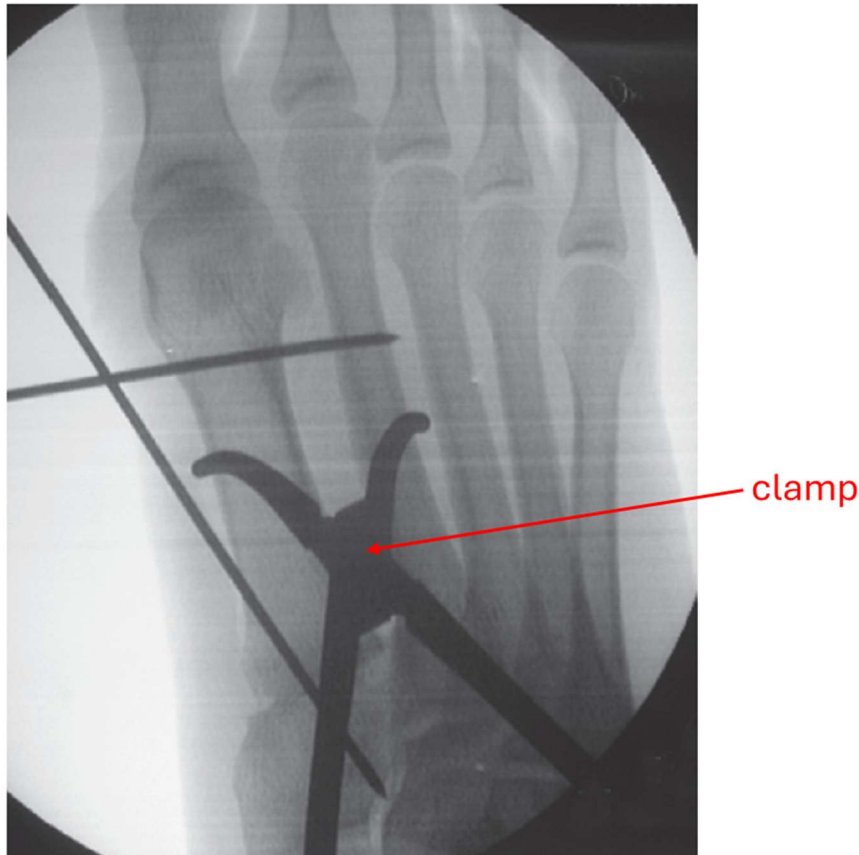


Id., Fig.22; Ex.1003, ¶134. Fallin further describes cutting the proximal end of the metatarsal and distal end of the cuneiform using the guide slots. Ex.1005, [0065], [0067]; Ex.1003, ¶135.

c. Limitation 1[b]

Limitation 1[b] recites: “a bone positioning guide configured to move the first metatarsal to treat a bunion deformity by at least: moving the first metatarsal in a transverse plane to reduce an intermetatarsal angle between the first metatarsal and a second metatarsal, and rotating the first metatarsal in a frontal plane.”

McGlamry renders this limitation obvious. Ex.1003, ¶¶137-146. McGlamry discloses repositioning the first metatarsal in multiple planes as part of its procedure. Ex.1007, 325-326. McGlamry discloses that a Weber clamp can be used to move the metatarsal in the transverse plane and rotate it in the frontal plane. *Id.*; Ex.1003, ¶¶138-139. McGlamry’s Weber clamp is shown below:



Ex.1007, Fig.31.5. McGlamry's Weber clamp is a bone positioning guide under any construction discussed in Section V.A., as it is a tenaculum and is used to position bones, including moving the metatarsal in the transverse plane. Ex.1003, ¶¶140-141. Under §112(f), McGlamry's Weber clamp is identical or at least equivalent to structures identified in the '368 patent for the claimed bone positioning guide. *Id.* McGlamry's Weber clamp is at least an equivalent of the disclosed bone-positioning structures (e.g., tenaculum/tong/reduction-forceps type instruments) because it uses opposed bone-engaging jaws/arms actuated through a pivot/handle/screw mechanism to apply controlled corrective forces and hold the bones in the corrected relationship. *Id.* It therefore performs the same function, in substantially the same way (opposed jaws applying/maintaining a corrective clamp force), to achieve the same result (controlled repositioning and maintenance of correction during fixation). *Id.* The Weber clamp was a well-known and widely adopted surgical instrument for use in bunion correction procedures. Ex.1007, 325-326; *see also* Ex.1003, ¶142; Ex.1008, 466 ("The first IMA was then reduced with a large, pointed, bone reduction clamp" and Fig.2 showing use of clamp).

McGlamry explains that the Weber clamp (bone positioning guide) is used to "assist, increase, or maintain the reduction." Ex.1007, 325-326. Thus, McGlamry discloses that the Weber clamp is configured to move the first metatarsal in a transverse plane to reduce an intermetatarsal angle between the first metatarsal and

a second metatarsal and rotate the first metatarsal in a frontal plane. Ex.1003, ¶¶138-142; *see also* Ex.1015, 1112 (disclosing that a lateral force applied to the first metatarsal both reduces the IMA and corrects a hallux valgus deformity). McGlamry discloses that this reduction treats the bunion deformity. Ex.1007, 324-26; Ex.1003, ¶¶138-142.

Even if McGlamry did not disclose that the Weber clamp rotates the metatarsal in the frontal plane, it would have been obvious to employ the Weber clamp to rotate the metatarsal in the frontal plane. Ex.1003, ¶¶143-146. A POSA would have understood that a Weber clamp engaged across adjacent metatarsals can transmit not only compressive force (transverse correction) but also torsional movement (frontal-plane derotation) as part of controlled reduction. *Id.*; *see also* Ex.1006, 9:66-10:3. A POSA would have been motivated to use the Weber clamp to correct the frontal plane rotation of the first metatarsal. Ex.1003, ¶146. McGlamry describes that maintaining the corrected position “in all three planes” is important during temporary fixation and further explains that where additional frontal-plane correction is needed: “[a] K-wire can be used as a rotation device and rotate the metatarsal into more of a neutral position.” Ex.1007, 326, 328-329. Fallin likewise discloses that, after creating increased mobility, the metatarsus and cuneiform may be freely repositioned in a “new relative orientation” and “in one or more planes” before fusion. Ex.1005, [0057]-[0058]. In that context, selecting a

familiar reduction clamp already used in McGlamry's procedure to transmit controlled corrective forces (including a rotational component) during repositioning would have been a predictable modification that improves control and stability (e.g., freeing the surgeon's hands during temporary fixation), with a reasonable expectation of success, while leaving the overall surgical approach unchanged. Ex.1003, ¶146.

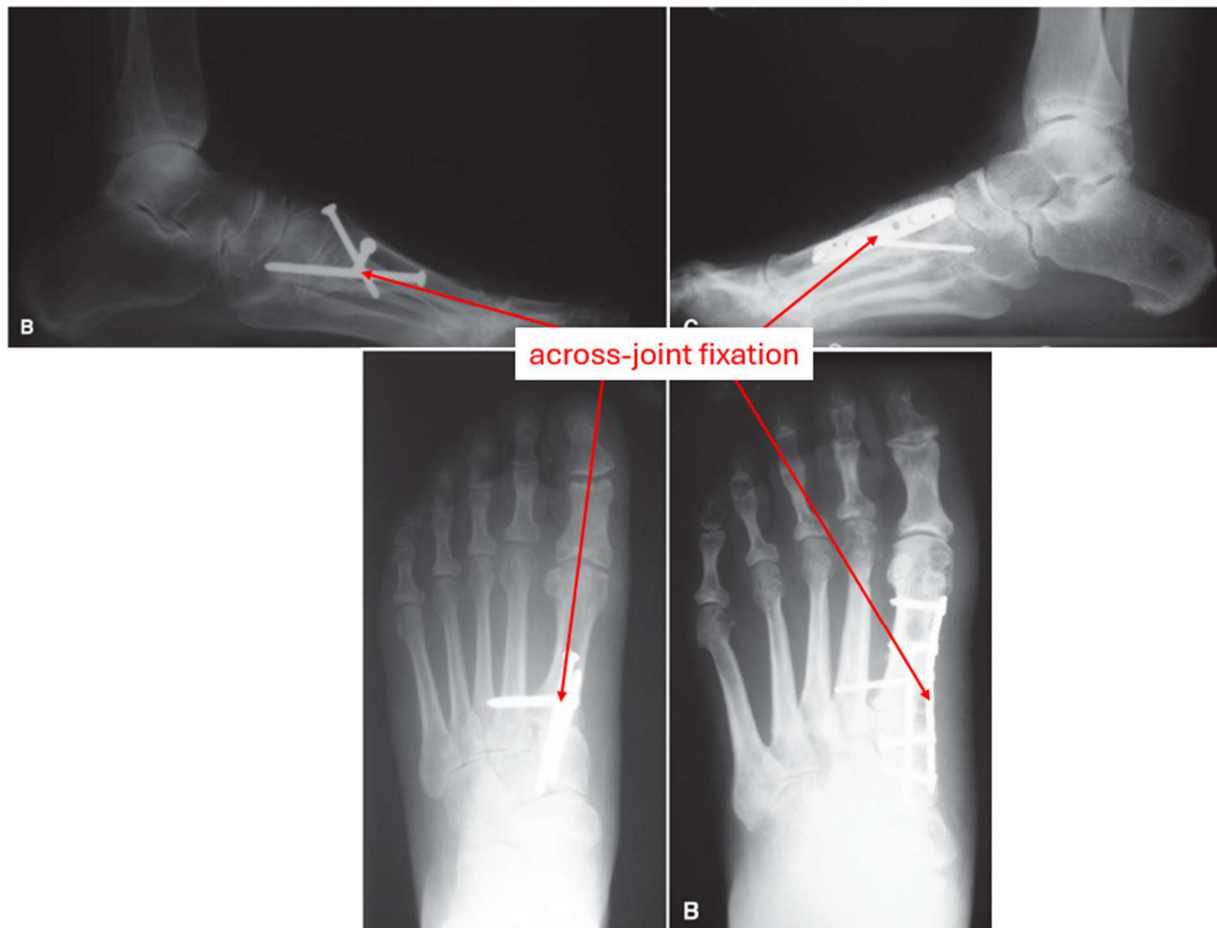
d. Limitation 1[c]

Limitation 1[c] recites: “at least one fixation device positionable across a tarsal-metatarsal joint separating the first metatarsal from the medial cuneiform, the at least one fixation device being configured to fixate a moved position of the first metatarsal relative to the medial cuneiform for fusion.”

McGlamry discloses this limitation. Ex.1003, ¶¶147-149. McGlamry discloses that, during bunion correction surgery, the surgeon applies fixation “across the first metatarsal-cuneiform joint”⁶ using one or more screws and/or a plate (each a “fixation device”) that traverse the metatarsal-cuneiform joint and fix the first metatarsal in corrected alignment to the medial cuneiform for fusion. Ex.1007, 329, 326 (“[t]he recommended fixation techniques consist of interfragmentary

⁶ The “metatarsal-cuneiform joint” refers to the “tarsal-metatarsal joint” recited in the claims. Ex.1003, ¶148.

compression of three solid cortical screws or an interfragmentary compression of solid cortical screw along with a medial based locking plate”); Ex.1003, ¶148. The placement of these fixation devices across the joint is shown below.



Ex.1007, Figs.31.6B, 31.7, 31.8B-C. This disclosure satisfies “fixation device” under its plain and ordinary meaning discussed in Section V.B. Ex.1003, ¶149. Under §112(f), McGlamry’s across-joint screws and/or plate are the same types of fixation structures identified in the ’368 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 Fallin render claim 1 obvious. *Id.*, ¶¶105-149.

2. Claim 2

Claim 2 depends from claim 1 and recites: “further comprising a pin configured to be inserted into the first metatarsal, the pin being configured to receive a force to rotate the first metatarsal in the frontal plane.” The McGlamry-Fallin combination renders this claim obvious. *Supra* §VII.A.1; Ex.1003, ¶¶150-153.

McGlamry discloses: “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] can be used as a rotation device and rotate the metatarsal” in the frontal plane.⁷ Ex.1007, 326; Ex.1003, ¶153. McGlamry’s K-wire “rotation device” is used in addition to—not instead of—other means of rotating the metatarsal in the frontal plane. For example, a Weber clamp would be applied to draw the first metatarsal toward the second and rotate the metatarsal in the frontal plane. Ex.1003, ¶153. The K-wire

⁷ A K-wire is a pin. Ex.1003, ¶152; *see also* Ex.1035, 1 (“[I]n 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 are used interchangeably for temporary fixation. *See, e.g.*, Ex.1011, 487 (disclosing temporary fixation by K-wire or Steinman pin in bunion correction procedure); Ex.1010, 349 (interchangeable use of pins and wires).

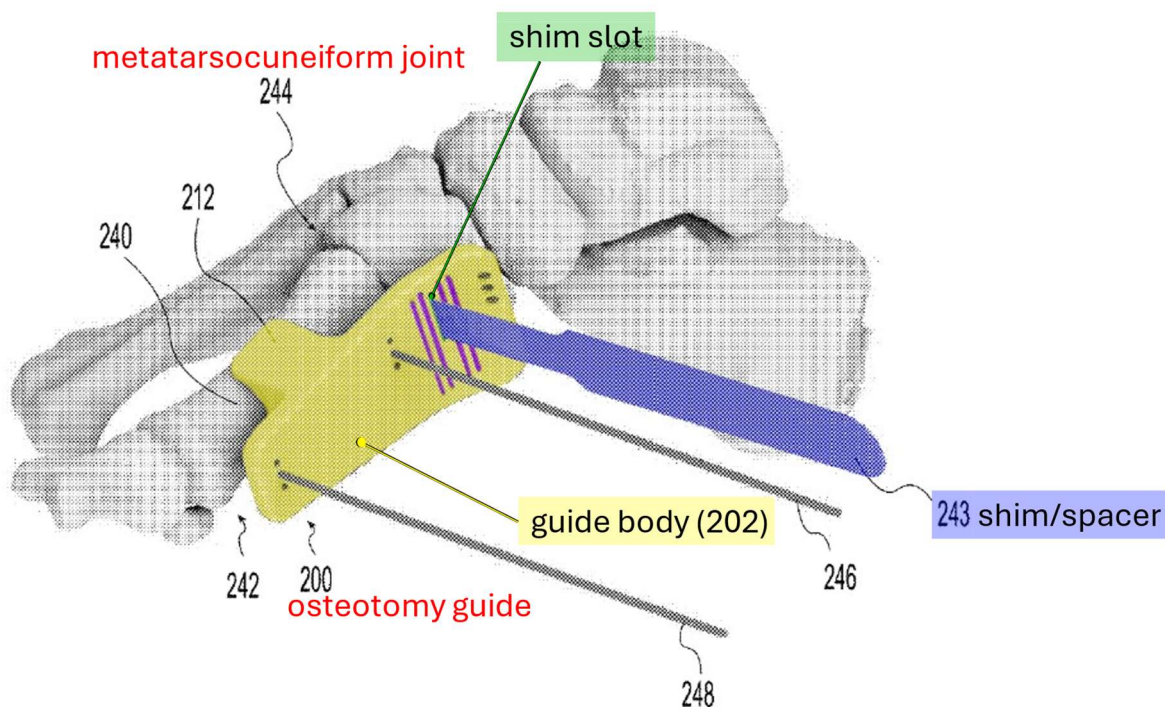
would be used in conjunction to further rotate the metatarsal. *See* Ex.1007, 326 (suggesting “K-wire can be used as a rotation device” when “the surgeon feels a need to obtain more correction in the frontal plane.”). The Weber clamp and K-wire are thus used in conjunction to provide controlled correction of the first metatarsal in multiple planes. Ex.1003, ¶153.

3. Claim 4

Claim 4 depends from claim 1 and recites: “wherein the bone preparation guide further comprises a spacer extending downwardly from the body and configured to be placed into the tarsal-metatarsal joint.” The McGlamry-Fallin combination renders this claim obvious. *Supra* §VII.A.1; Ex.1003, ¶¶154-158.

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 refers to the tarsal-metatarsal (first metatarsal-medial cuneiform) joint. Ex.1003, ¶156. Fallin’s “projection from the guide body 202 engageable with the joint” is a spacer that extends downwardly from the body and is configured to be placed into the tarsal-metatarsal joint. *Id.*, ¶¶155-157.

In yet 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.



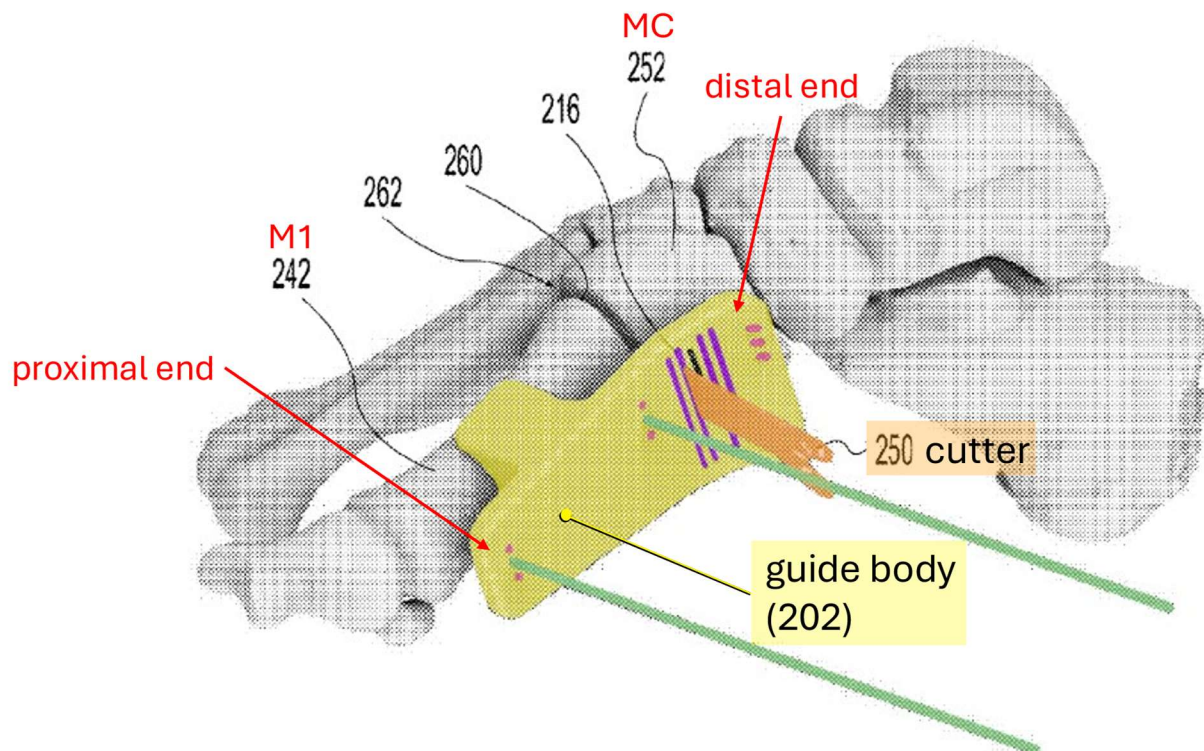
Id., Fig.21; Ex.1003, ¶158.

4. Claim 5

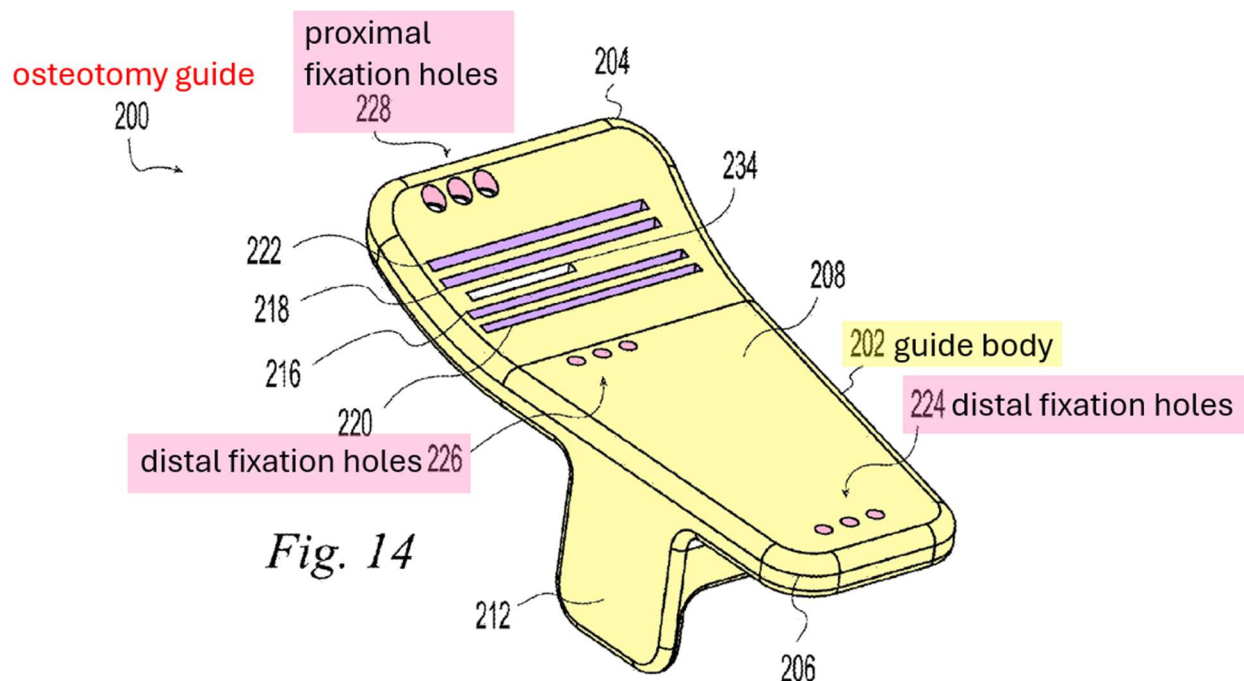
Claim 5 depends from claim 1 and recites: “wherein the body extends from a first end configured to be positioned over the first metatarsal to a second end configured to be positioned over the medial cuneiform, the body including a first fixation aperture configured to receive a first fixation pin and a second fixation

aperture configured to receive a second fixation pin.” The McGlamry-Fallin combination renders this claim obvious. *Supra* §VII.A.1; Ex.1003, ¶¶159-163.

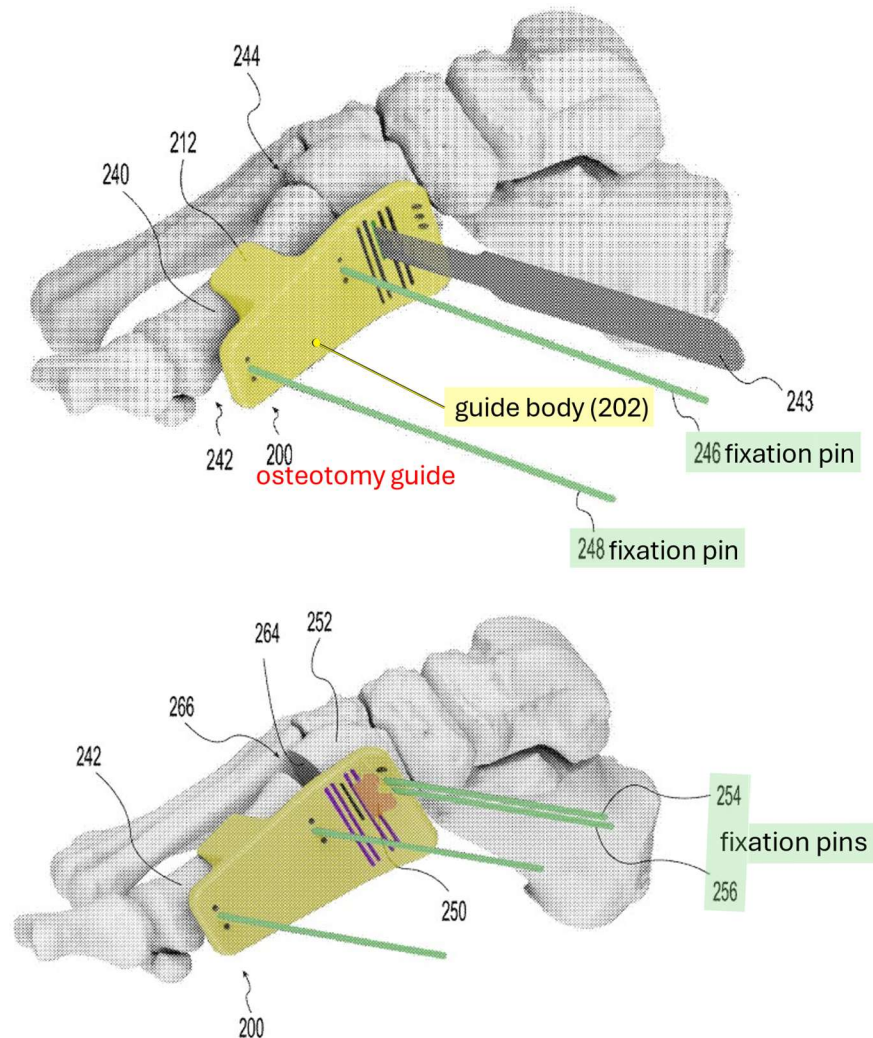
As explained regarding limitation 1[a], Fallin discloses a bone preparation guide with a body positioned over the proximal end of the first metatarsal and the distal end of the medial cuneiform. *Supra* §VII.A.1.b; Ex.1003, ¶160. Fallin further states that the osteotomy guide “includes a guide body 202 having a proximal end 204...[and] a distal end 206.” Ex.1005, [0051]. The ends are located over the metatarsus and cuneiform as the surgeon prepares the joint surfaces as shown in Figure 22, below. *Id.*, [0053], [0056], Figs.21-24.



Id., Fig.22; Ex.1003, ¶160. As shown in Figure 22 (above) and Figure 14 (below), the guide body “includes fixation elements in the form of holes operable to receive pins or screws to attach the guide 200 to bone.” Ex.1005, [0053], [0067].



Id., Fig.14; Ex.1003, ¶161. Fallin further discloses that each pin is placed in a different aperture, and that at least two pins are used in the surgical procedure. Ex.1005, [0064], [0067].



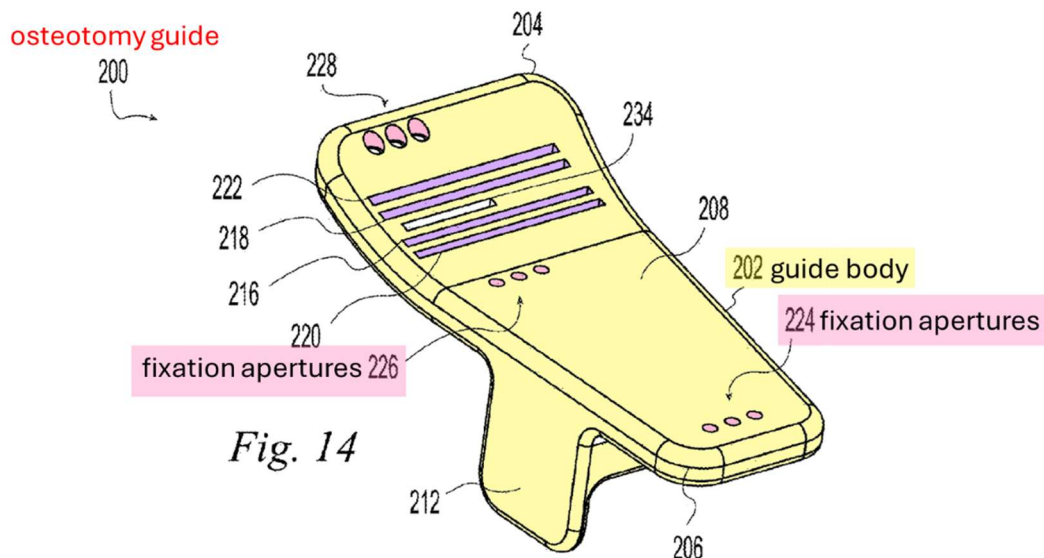
Id., Figs.21, 24; Ex.1003, ¶162. Any of holes 224 and pin 248 correspond to the first fixation aperture and first fixation pin, respectively, and any of holes 226 and pin 246 correspond to the second fixation aperture and second fixation pin, respectively. Ex.1003, ¶163.

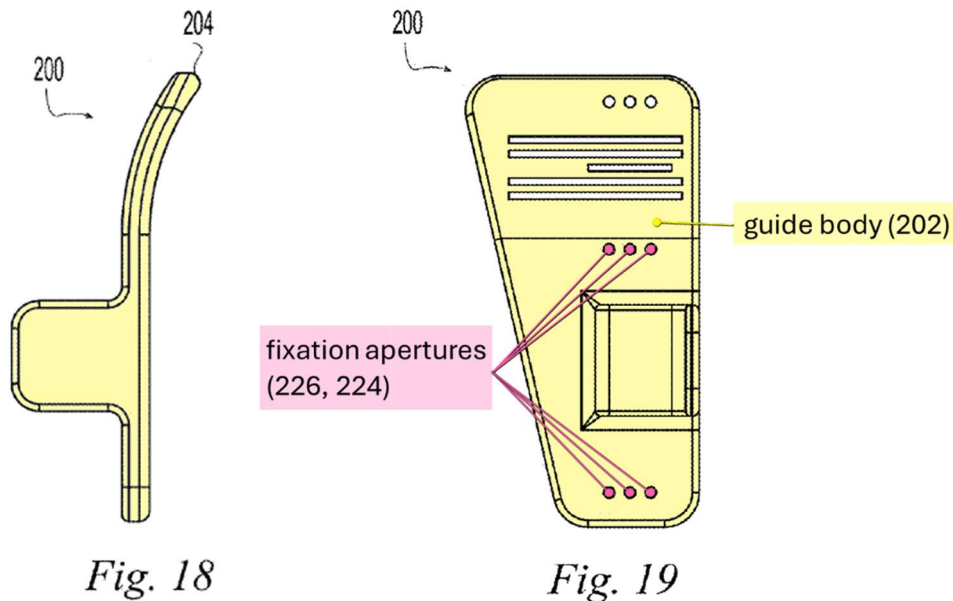
5. Claim 6

Claim 6 depends from claim 5 and recites: “wherein the first fixation aperture and the second fixation aperture are generally parallel to each other.” The

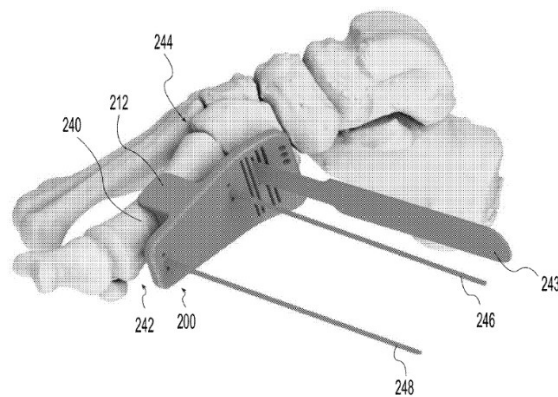
McGlamry-Fallin combination renders this claim obvious. *Supra* §VII.A.4; Ex.1003, ¶¶164-167.

As explained regarding claim 5, Fallin discloses its guide includes first and second fixation apertures for receiving first and second fixation pins, respectively. *Supra* §VII.A.4; Ex.1003, ¶165. These fixation apertures are circular openings, which correspond to cylindrical bores extending through the thickness of the guide body:





Ex.1005, Figs.14, 18-19; Ex.1003, ¶166. As illustrated by the placement of the pins in Figure 21 below, these bores are generally parallel.



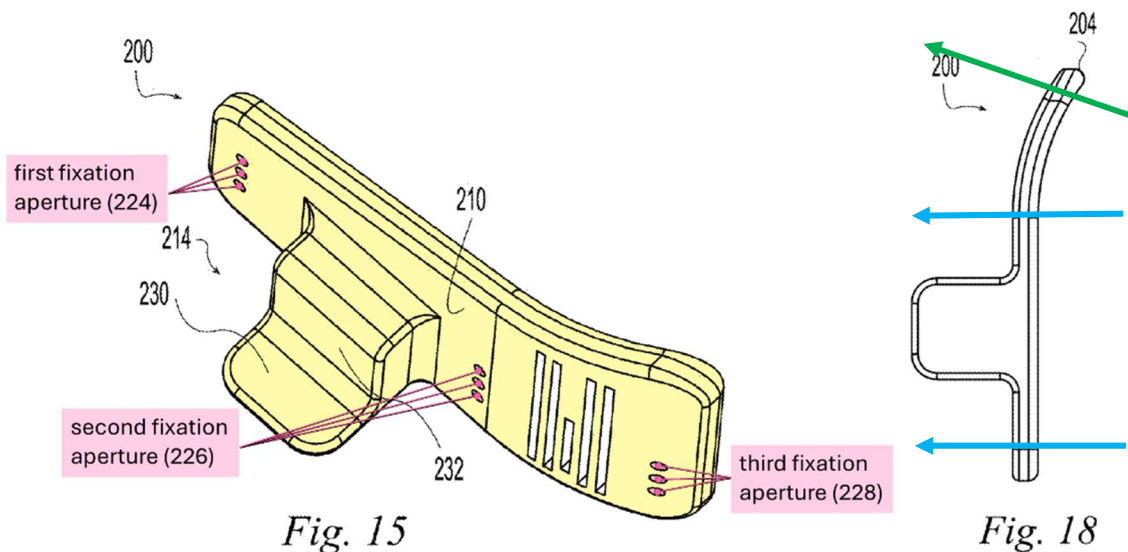
Ex.1005, Fig.21. Thus, a POSA would have understood that the fixation apertures through which the pins are inserted are also generally parallel. Ex.1003, ¶167.

6. Claim 7

Claim 7 depends from claim 6 and recites: “wherein the body further comprises a third fixation aperture that is skewed relative to the first fixation aperture

and the second fixation aperture, the third fixation aperture being configured to receive a third fixation pin.” The McGlamry-Fallin combination renders this claim obvious. *Supra* §VII.A.5; Ex.1003, ¶¶168-173.

As explained for claims 5-6, Fallin discloses a guide body with fixation apertures in different regions, including distal apertures 224, 226 for fixing the guide over the metatarsal and proximal apertures 228 for fixing the guide over the cuneiform, all of which receive pins. *Supra* §§VII.A.4-5; Ex.1003, ¶169. Figures 15 and 18 illustrate Fallin’s guide body defining first, second, and third fixation apertures, with the third fixation aperture skewed⁸ relative to the first and second fixation apertures:



⁸ In the '368 patent, “skewed” refers to non-parallel configurations. Ex.1001, 8:28-29 (“The first and second slots may be parallel or skewed”); Ex.1003, ¶171.

Ex.1005, Figs.15, 18, [0056]; Ex.1003, ¶170. Arrows in Figure 18 above depict this skew, with the first and second fixation apertures oriented in one direction (blue) and the third fixation aperture oriented in a different direction (green). *Id.*

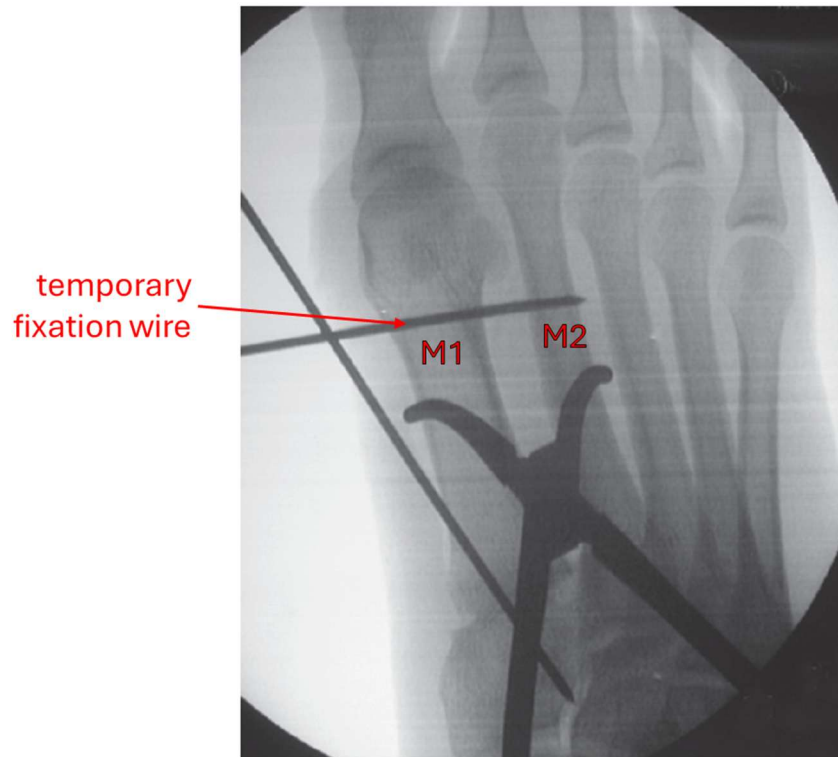
It further would have been obvious to modify at least one of Fallin’s fixation apertures to be skewed relative to other fixation apertures. There are a finite number of options for the orientation of a third fixation aperture relative to the first and second apertures—skewed or parallel. *Id.*, ¶¶172-173. Both options were available and would have been a matter of designer preference. *Id.*, ¶172. Indeed, there were known reasons to have fixation apertures (and therefore fixation pins) in a non-parallel orientation. For example, a non-parallel orientation provides additional stabilization for the guide and prevents it from being removed or lifted off the bone unintentionally. *Id.*; Ex.1029, Abstract (“At least two fixation holes are formed through the osteotomy guide in directions which are non-parallel to the guide holes so that additional fixation pins may be placed into the tibia for more stable positioning of the osteotomy guide.”); Ex.1031, [0071] (“two non-parallel pin holes for additional stability of the block”); Ex.1032, [0030] (“The non-parallel axes of the holes may provide an advantage ... of more positively coupling the cutting block 1 to a femur or a tibia in view of the fact that nonparallel axes prevent sliding...”), [0048]. The substitution of one known element for another where both variations are predictable is obvious. *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.’”).

7. Claims 8-9

Claim 8 depends from claim 1 and recites: “further comprising a temporary fixation device configured to be applied to the first metatarsal to temporarily fixate the moved position of the first metatarsal prior to permanent fixation using the at least one fixation device.” Claim 9 depends from claim 8 and recites: “wherein the temporary fixation device comprises a fixation wire.” The McGlamry-Fallin combination renders these claims obvious. *Supra* §VII.A.1; Ex.1003, ¶¶174-177.

McGlamry discloses the use of a temporary fixation device applied to the first metatarsal. McGlamry explains that once metatarsal is aligned a “K-wire is used to stabilize the reduction and position” of the metatarsal. Ex.1007, 326. This temporary fixation device “prevent[s] derotation in the frontal plane and maintains reduction in the transverse plane” until the final fixation device is applied. Ex.1007, 326; Ex.1003, ¶175. McGlamry shows this temporary fixation:



Ex.1007, Fig.31.5; Ex.1003, ¶175. Under either plain meaning or (if applied) §112(f), McGlamry’s K-wire/fixation wire constitutes the claimed temporary fixation device because it temporarily stabilizes the moved position prior to final fixation. See §V.C; Ex.1003, ¶176. McGlamry further discloses applying permanent fixation across the joint after this temporary fixation, as discussed in limitation 1[c]. *Supra* §VII.A.1.d; Ex.1003, ¶177.

8. Claim 10

Claim 10 depends from claim 1 and recites: “wherein the bone positioning guide comprises a rotatable knob connected to a threaded shaft.” The McGlamry-Fallin combination renders this claim obvious. *Supra* §VII.A.1; Ex.1003, ¶¶178-182.

A POSA would have recognized a “Weber clamp” as disclosed in McGlamry encompasses clamps with threaded shafts. Ex.1003, ¶¶179-180. For example, one type of prior art Weber clamp is the GPC Medical bone reduction forceps, which has a threaded shaft that moves the ends of the clamp:



Id.; see also Ex.1006, Fig.1 (illustrating bunion reduction instrument with rotatable knob and threaded shaft), 8:51-53. Weber clamps were commonly used by surgeons before July 2015. Ex.1003, ¶180. This includes configurations of the Weber clamp with a rotatable knob connected to a threaded shaft for incrementally moving the jaws and holding the reduction hands-free during subsequent fixation. *Id.* Such a screw-driven adjustment provides controlled, fine movement and stable retention of the reduced position—advantages that are directly aligned with McGlamry’s step of holding the metatarsal in its corrected alignment while temporary fixation (e.g., K-wire) is placed. *Id.*, ¶181. Selecting a screw-adjustable Weber clamp for

McGlamry’s reduction step would have been an obvious implementation choice yielding no more than predictable results. *Id.*, ¶182.

9. Claim 11

Claim 11 depends from claim 1 and recites: “wherein the at least one fixation device comprises one or more of a bone plate, a screw, a staple, and an intramedullary implant.” As explained in limitation 1[c], McGlamry discloses that its fixation device includes one or more screws or a plate; the McGlamry-Fallin combination thus renders this claim obvious. *Supra* §VII.A.1; Ex.1003, ¶183.

10. Claim 12

Claim 12 depends from claim 1 and recites: “wherein the bone positioning guide is formed of at least three components joinable together to form the bone positioning guide.” The McGlamry-Fallin combination renders this claim obvious. Ex.1003, ¶¶184-186.

A POSA would have understood that a Weber clamp of the type used in McGlamry is a multi-part instrument assembled from at least (i) a first arm, (ii) a second arm, and (3) a pivot/hinge member (e.g., a screw/bolt/pin) that join the arms together and permit the arms to pivot to apply and maintain clamping force. *Id.*, ¶¶185-186. Thus, McGlamry’s Weber clamp meets, or at least renders obvious, the “at least three components joinable together” limitation.

Even if McGlamry did not spell out the internal construction of the Weber clamp, it would have been obvious to use a Weber clamp having the conventional multi-component construction (two arms joined by a pivot/fastener) because such construction was commonplace, enabled the expected pivoting/clamping function, and provided predictable benefits in manufacture, maintenance/cleaning/sterilization, and repair/replacement of worn parts—yielding no more than predictable results. *Id.*, ¶186.

11. Claims 13-14

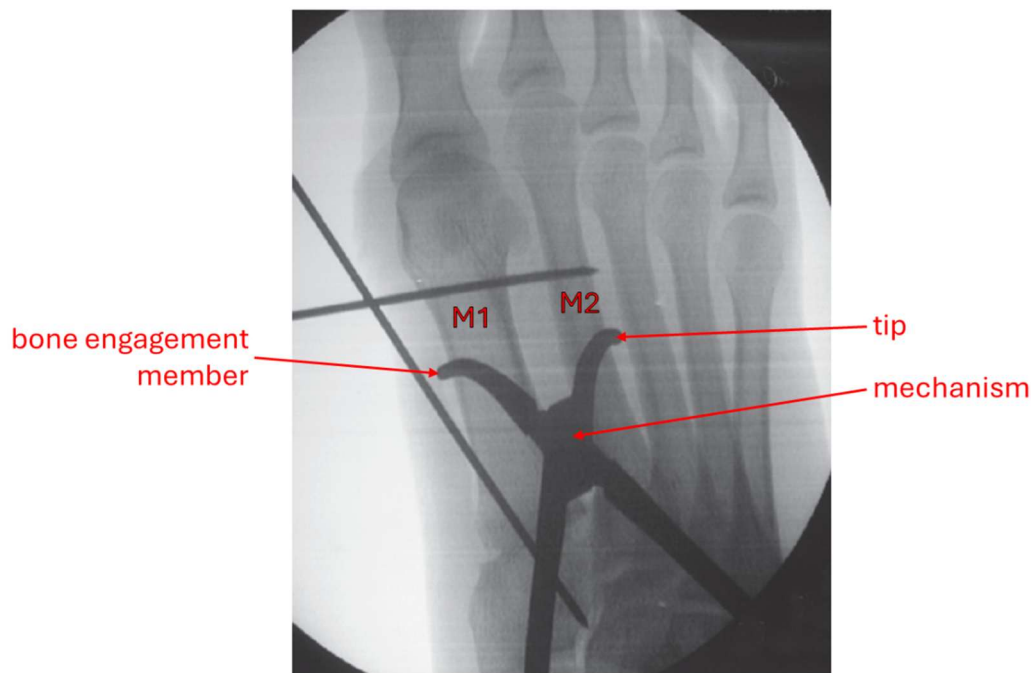
Claim 13 depends from claim 1 and recites: “further comprising the tissue removing instrument.” Claim 14 depends from claim 13 and recites: “wherein the tissue removing instrument comprises a saw blade.” As explained regarding limitation 1[a], Fallin discloses that the guide receives “a cutter, such as a saw blade.” Ex.1005, [0052]; *supra* §§V.D, VII.A.1.b. The cutter cuts and removes the bone. Ex.1005, [0052], [0065], [0067]; Ex.1003, ¶¶187-190. The McGlamry-Fallin combination thus renders these claims obvious. *Supra* §VII.A.1; Ex.1003, ¶¶187-190.

12. Claims 15-16

Claim 15 depends from claim 1 and recites: “wherein the bone positioning guide comprises: a bone engagement member; a tip; and a mechanism configured to move the bone engagement member and the tip relative to each other.” Claim 16

depends from claim 15 and recites: “wherein the mechanism comprises a threaded shaft.” The McGlamry-Fallin combination renders these claims obvious. *Supra* §VII.A.1; Ex.1003, ¶¶191-199.

As explained for limitation 1[b], McGlamry discloses a bone positioning guide—a Weber clamp. *Supra* §VII.A.1.c. McGlamry’s Weber clamp meets each of the structural limitations recited in claim 15. These features are noted in annotated Figure 31.5 of McGlamry below. Ex.1003, ¶¶192-197.



Ex.1007, Fig.31.5. Specifically, the structure of the Weber clamp that is engaged with the first metatarsal is the claimed “bone engagement member.” Ex.1003, ¶194. The structure engaged with the second metatarsal is the claimed tip. *Id.*, ¶¶195-196. The ’368 patent describes that its tip is merely the portion of the bone positioning guide that is meant to engage a metatarsal other than the first metatarsal (e.g., the

second metatarsal). Ex.1001, 6:46-67. The tip can have various shapes and can be, for example, straight or have a non-linear orientation, for example a tip that is angled or curved. *Id.*, 6:48-64.

A Weber clamp is a type of tenaculum/tong structure where the ends of the shafts are urged together when the handles are squeezed. Ex.1003, ¶197. Thus, it is the claimed mechanism under either construction discussed in Section V.E. *Id.* Under §112(f), McGlamry’s Weber clamp is identical or at least equivalent to structures identified in the ’368 patent for the claimed mechanism. *Id.* McGlamry’s Weber clamp is at least an equivalent of the disclosed mechanism because its clamp-actuation/adjustment structure move the opposing bone-engaging members relative to one another, thereby performing the same function in substantially the same way to achieve the same result as the ’368 patent’s disclosed threaded-shaft/ratchet-type mechanisms. *Id.*

For claim 16, as explained for claim 10, a POSA would have recognized that a “Weber clamp” as disclosed in McGlamry encompasses clamps with threaded shafts and were commonly available (and used by surgeons) in screw-adjustable configurations in which screw-adjustable configurations. *Supra* §VII.A.8; Ex.1003, ¶198. For the reasons discussed for claim 10, it would have been obvious to select a screw-adjustable Weber clamp for McGlamry’s reduction step, as it would have

been an obvious implementation choice yielding no more than predictable results.
Supra §VII.A.8; Ex.1003, ¶199.

13. Claim 17

Claim 17 depends from claim 15 and recites: “wherein the bone engagement member is configured to engage the first metatarsal and the tip is configured to engage the second metatarsal.” As explained for claim 15, McGlamry discloses these limitations. *Supra* §VII.A.12; Ex.1003, ¶200. The McGlamry-Fallin combination thus renders this claim obvious. *Supra* §VII.A.12; Ex.1003, ¶200.

14. Claim 18

Claim 18 depends from claim 1 and recites: “further comprising a sterile kit containing at least the bone preparation guide and the bone positioning guide.” The McGlamry-Fallin combination renders this claim obvious. *Supra* §VII.A.1; Ex.1003, ¶¶201-205.

As explained regarding claim 1, McGlamry discloses an instrumented surgical procedure for correcting a bunion. *Supra* §VII.A.1. McGlamry also discloses that such surgical instruments are commonly provided as organized, sterile instrument sets or “packs” that are opened in the operating room for a particular procedure. Ex.1007, 12; Ex.1003, ¶202. McGlamry describes the use of pre-arranged trays of reduction clamps, forceps, K-wires, screws, and related instruments for foot and ankle surgery, and further explains that these sets are sterilized and maintained as a

unit, so the surgeon has all instruments and implants for the procedure. Ex.1007, 12-14; Ex.1003, ¶203. Thus, McGlamry discloses using sterile kits for surgical procedures. Ex.1003, ¶¶202-203.

It would have been obvious to include the bone positioning guide and the bone preparation guide in a sterile kit for McGlamry's procedure. *Id.*, ¶204. With a sterile kit, both tools would have been readily available, sterile, and ready for use at the start of the procedure. *Id.* This would reduce operating room set up time, simplify hospital inventory procedures, and reduce the risk of contamination by minimizing the number of separate packages opened onto the sterile field. *Id.*; see Ex.1033, [0266] ("This pre-sterilized combination instrument, cartridge and implant can be packaged with a drill and drill guide so that the medical procedure kit fully supports the surgical technique. Hospital costs savings are achieved because there is no hospital cleaning or sterilization required and the patients and hospital benefit from fewer infections and patient complications."), [0260], [0264]; Ex.1034, [0002] ("Any surgical procedure typically requires a number of instruments. In order to simplify inventory and procedure in the operating room it is known to group the instruments required in a surgical procedure together in one or more trays."), [0010] ("Sterilising and packaging each instrument separately is impractical because of the need to maintain organisation, minimise packaging cost and waste and avoid use of excessive space in the operating room."). Having these instruments in a sterile kit

would therefore have been nothing more than the use prior art elements according to known methods, and the result of a sterile kit would have been predictable. *KSR*, 550 U.S. at 417. A POSA would have had a reasonable expectation of success in creating a sterile kit with these instruments. Ex.1003, ¶205. It would have merely been the use of a known technique (McGlamry’s packaging of instruments in a sterile kit) to a known method (McGlamry’s procedure) that was ready for improvement by packaging the instruments in a sterile kit. *Id.*, ¶205.

15. Claim 19

Claim 19 depends from claim 1 and recites: “wherein the bone positioning guide is configured to move the first metatarsal in the transverse plane to reduce the intermetatarsal angle to 10 degrees or less and to rotate the first metatarsal in the frontal plane to position sesamoid bones generally parallel to ground and positioned under the first metatarsal.” The McGlamry-Fallin combination renders this claim obvious. *Supra* §VII.A.1; Ex.1003, ¶¶206-211.

McGlamry uses a Weber clamp to “restore first metatarsophalangeal joint congruency and realign[] the sesamoid apparatus in addition to correction of the IM[A].” Ex.1007, 323; *see also supra* §§II.E, VII.A.1.c. With respect to the IMA, McGlamry explains that the first metatarsal is repositioned such that it is “parallel with the second metatarsal” in the transverse plane. Ex.1007, 325. When the first metatarsal is parallel with the second metatarsal in the transverse plane, the IMA is

less than 10 degrees. Ex.1003, ¶¶207-208. McGlamry discusses the importance of moving the first metatarsal in the transverse plane to reduce the IMA. Ex.1007, 325. Fallin, for example, expressly states that an IMA of “9 degrees or greater” is considered “abnormal.” Ex.1005, [0047]; Ex.1003, ¶209. Accordingly, it would have been obvious to move the first metatarsal in the transverse plane to reduce the intermetatarsal angle to 10 degrees or less. Ex.1003, ¶¶206-211; *see also, e.g.*, Ex.1007, 325.

For positioning the first metatarsal in the frontal plane, McGlamry discloses that “[t]he surgeon derotates the hallux out of valgus in order to get the nail plate to be parallel with the ground. Ex.1003, ¶210. This derotation allows for the entire hallux, sesamoid, and first metatarsal complex to be rotated from a position of valgus and into a neutral position as one unit.” Ex.1007, 324. When the nail plate is parallel with the ground and the first metatarsal complex is in a neutral position, the sesamoid bones are generally parallel to the ground and positioned under the first metatarsal as shown in McGlamry’s post-operative radiographs:



Ex.1007, Figs.31.7, 31.8B; Ex.1003, ¶¶210-211; *see also* Ex.1014, 101.

16. Claim 20

Claim 20 depends from claim 1 and recites: “wherein the guide surface defined by the body of the bone preparation guide comprises a first guide surface configured to be positioned over the proximal end of the first metatarsal and a second guide surface configured to be positioned over the distal end of a medial cuneiform, the first guide surface being configured to guide the tissue removing instrument for cutting the proximal end of the first metatarsal and the second guide surface being configured to guide the tissue removing instrument for cutting the distal end of the medial cuneiform.” For the reasons discussed for limitation 1[b], the Fallin discloses the additional limitations of claim 20. *Supra* §VII.A.1.c; Ex.1003, ¶212. The

McGlamry-Fallin combination thus renders this claim obvious. *Supra* §VII.A.1; Ex.1003, ¶212.

B. Ground 2: Claims 1-30 Are Obvious Over McGlamry, Fallin, And Kartalian

1. Claim 1

a. Preamble

As explained in Ground 1, this preamble is disclosed by both McGlamry and Fallin. *Supra* §VII.A.1.a; Ex.1003, ¶214.

b. Limitation 1[a]

As explained in Ground 1, Fallin discloses this limitation. *Supra* §VII.A.1.b; Ex.1003, ¶215.

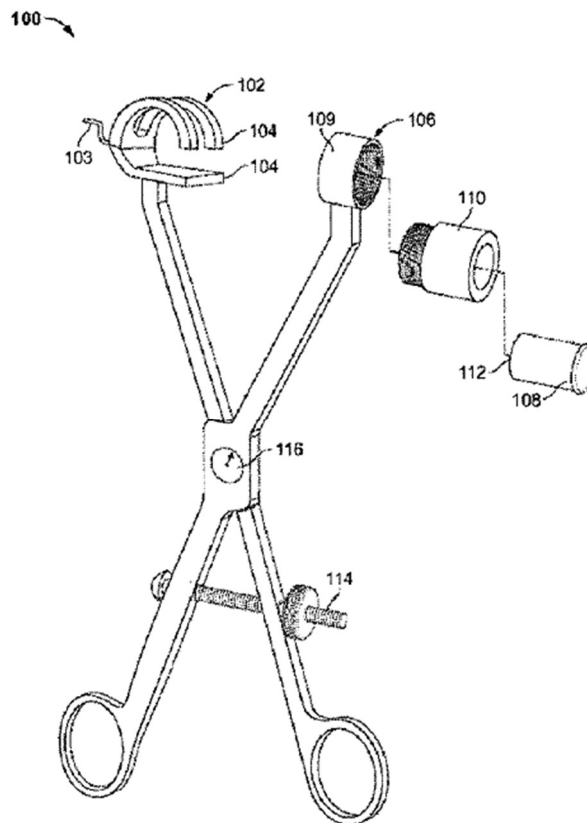
c. Limitation 1[b]

As explained in Ground 1, McGlamry discloses this limitation. *Supra* §VII.A.1.c. However, even if McGlamry did not disclose the limitation, Kartalian does. Ex.1003, ¶¶216-228.

McGlamry discloses moving the metatarsal in the transverse plane to reduce the intermetatarsal angle and rotating it in the frontal plane to correct the bunion deformity. Ex.1007, 324-326; Ex.1003, ¶217. Kartalian likewise discloses correcting a bunion by moving the metatarsal in the transverse plane to reduce the

IMA and “correcti[ng]...any rotational deformity (pronation)”⁹ of the metatarsal.
Ex.1006, 1:64-2:9, 9:66-10:3, 10:43-49; Ex.1003, ¶218.

Kartalian further discloses an “instrument 100” that “may act as reduction forceps to align two bones or reduce the distance between the bones, as desired” and that “allow[s] for correction of any rotational deformity (pronation) when used for surgical correction of a bunion.” Ex.1006, 9:66-10:3. As shown below, Kartalian’s instrument is a tenaculum (forceps).



⁹ In the bunion context, “pronation” refers to rotation of the metatarsal in the frontal plane. Ex.1003, ¶218.

Id., Fig.1(excerpt); Ex.1003, ¶219. Kartalian’s instrument functions to position the bones by moving the metatarsal in the transverse plane and rotate it in the frontal plane. Ex.1003, ¶220. Accordingly, this instrument 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 ’368 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) because it performs the same function (positioning metatarsals including IMA reduction and rotational correction), in substantially the same way (opposed bone-engaging ends/arms of a forceps manipulated by the surgeon to apply controlled corrective forces and hold alignment), to achieve the same result (bones are moved to the desired alignment and stabilized while fixation is performed). *Id.*

It would have been obvious to use Kartalian’s bone positioning guide in McGlamry’s procedure. *Id.*, ¶221-228. First, Kartalian has features that are specifically designed for bunion correction procedures and would have been a desirable option for use in McGlamry’s procedure. *See, e.g.*, Ex.1006, 9:58-10:18; Ex.1003, ¶¶222-224. This includes features for engaging or even locking bones during movement of the first metatarsal. Ex.1006, 10:4-6. Kartalian’s instrument

also includes “an automatic angle indicator 116 to provide the surgeon with an estimate of the angle of the bones requiring correction.” *Id.*, 10:8-16. Kartalian explains that a POSA could use that feature and measurements of the patient’s anatomy to calibrate the instrument to “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 surgery known for a relatively high failure rate. Ex.1003, ¶¶222-224; Ex.1006, 2:30-39. Kartalian’s instrument also includes a sleeve useful for inserting the K-wires that McGlamry uses for temporary fixation. Ex.1003, ¶224; *infra* §VII.B.3.

Additionally, using Kartalian’s bone positioning guide instead of McGlamry’s Weber clamp would have been nothing more than the substitution of one known element for another with predictable results. *KSR*, 550 U.S. at 417. Both Kartalian’s bone positioning guide and McGlamry’s Weber clamp are disclosed as capable of moving the metatarsal during a bunion correction procedure. Ex.1006, 9:66-10:3; Ex.1007, 325-26. Both are a form a tenaculum/tongs. Ex.1003, ¶225. Both are used in bunion correction procedures. *Id.*, ¶226. Given these similarities, the results of substituting one instrument for another would have been predictable. *Id.*, ¶227.

A POSA would have had a reasonable expectation of success in using Kartalian’s instrument in McGlamry’s procedure. *Id.*, ¶¶227-228. Kartalian’s instrument was designed for a bunion correction procedure that is, in many respects,

similar to McGlamry's procedure. Ex.1006, 9:58-10:18, 10:29-62; Ex.1003, ¶¶227-228. The operational principles of Kartalian's instrument would not be changed when used in McGlamry's procedure. Ex.1003, ¶¶227-228. 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.* However, any such modification would have been within the skill of a POSA who could modify basic surgical equipment. *Id.*

d. Limitation 1[c]

As explained in Ground 1, McGlamry discloses this limitation. *Supra* §VII.A.1.d. Therefore, claim 1 would have been obvious in view of McGlamry, Fallin, and Kartalian. Ex.1003, ¶229.

2. Claim 2

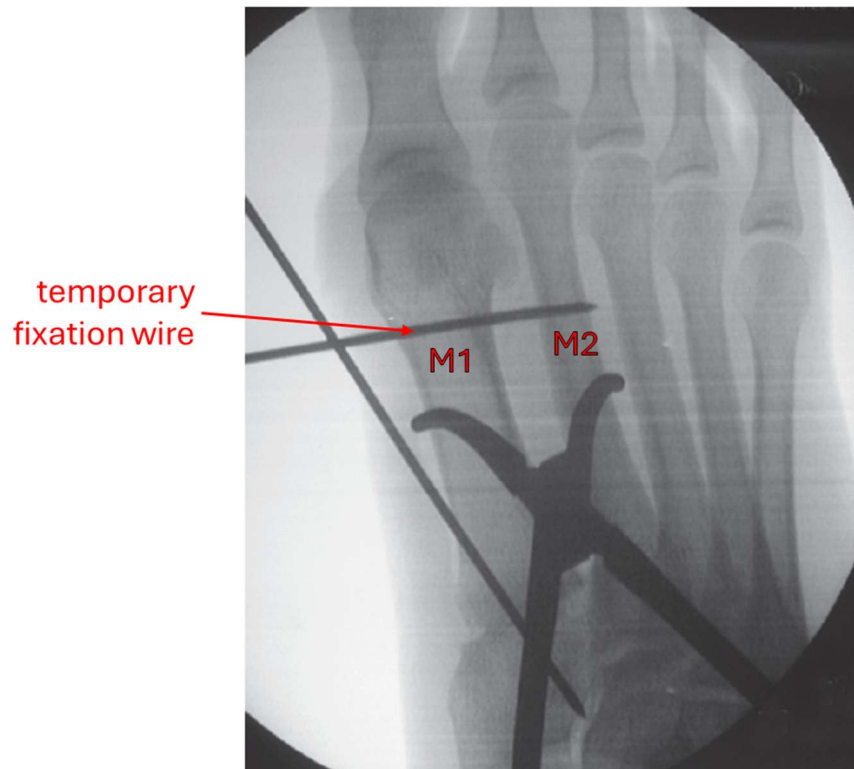
As explained in Ground 1, McGlamry discloses the additional limitations of claim 2; the McGlamry-Fallin-Kartalian combination thus renders this claim obvious. *Supra* §VII.A.2; Ex.1003, ¶230.

3. Claim 3

Claim 3 depends from claim 1 and recites: “wherein the bone positioning guide comprises an opening, and further comprising a fixation wire configured to be inserted into the second metatarsal and extending through the opening.”

The McGlamry-Fallin-Kartalian combination renders this claim obvious. Ex.1003, ¶¶231-237. Kartalian discloses the second end 106 of its bone positioning guide is “configured as a cannulated sleeve 108.” Ex.1006, 9:58-60, Fig.1. The sleeve “may be used as a drill guide” and can have a sleeve with a diameter of between 1mm and 4mm. *Id.*, 10:46-62. Kartalian also describes that this sleeve can be used as a guide for drilling through both the first and second metatarsals. *Id.* Kartalian’s sleeve is an opening in the bone positioning guide. Ex.1003, ¶¶232-233.

McGlamry further discloses temporary fixation of the corrected position of the metatarsal using a K-wire inserted through the first and second metatarsals. Ex.1007, 325-26, Fig.31.5.



Id., Fig.31.5; Ex.1003, ¶234. When Kartalian’s bone positioning guide is used in McGlamry’s procedure, it would have been obvious to use Kartalian’s sleeve as a guide to place fixation wire (e.g., a K-wire) into the second metatarsal and through the sleeve to temporarily fix the corrected relationship between the first and second metatarsals. Ex.1003, ¶¶235-237. It therefore would have been obvious to use Kartalian’s sleeve to guide and place McGlamry’s temporary fixation wire at a precise trajectory while the reduction instrument is holding alignment, reducing the risk of wire misplacement and avoiding interference with subsequent permanent fixation. *Id.*

This modification would have been a routine, predictable use of Kartalian’s guidance feature to pass an elongate wire through the instrument and into bone. *Id.* 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 sleeve to place a temporary fixation wire into the second metatarsal for the same stabilizing purpose, with predictable results. Ex.1003, ¶237;

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).

4. Claims 4-6

As explained in Ground 1, Fallin discloses the additional limitations of claims 4-6; the McGlamry-Fallin-Kartalian combination thus renders these claims obvious. *Supra* §§VII.A.3-5; Ex.1003, ¶¶238-240.

5. Claim 7

As explained in Ground 1, Fallin renders the additional limitations of claim 7 obvious; the McGlamry-Fallin-Kartalian combination thus renders this claim obvious. *Supra* §VII.A.6; Ex.1003, ¶241.

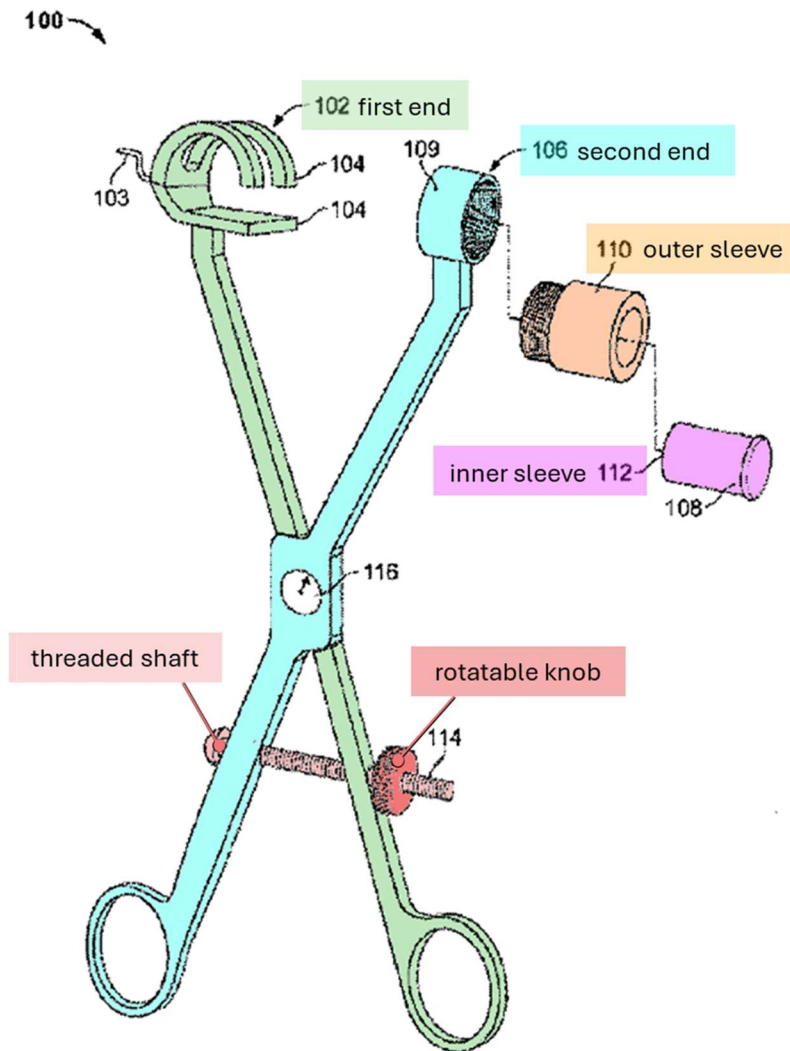
6. Claims 8-9

As explained in Ground 1, McGlamry discloses the additional limitations of claims 8-9; the McGlamry-Fallin-Kartalian combination thus renders these claims obvious. *Supra* §VII.A.7; Ex.1003, ¶242.

7. Claim 10

Claim 10 depends from claim 1 and recites: “wherein the bone positioning guide comprises a rotatable knob connected to a threaded shaft.” The McGlamry-Fallin-Kartalian combination renders this claim obvious. Ex.1003, ¶¶243-244.

As shown in Kartalian, the instrument 100 (bone positioning guide) has a rotatable knob (dark red) connected to a threaded shaft (light red):



Ex.1006, Fig.1(excerpt); *see also*, 8:51-53; Ex.1003, ¶244.

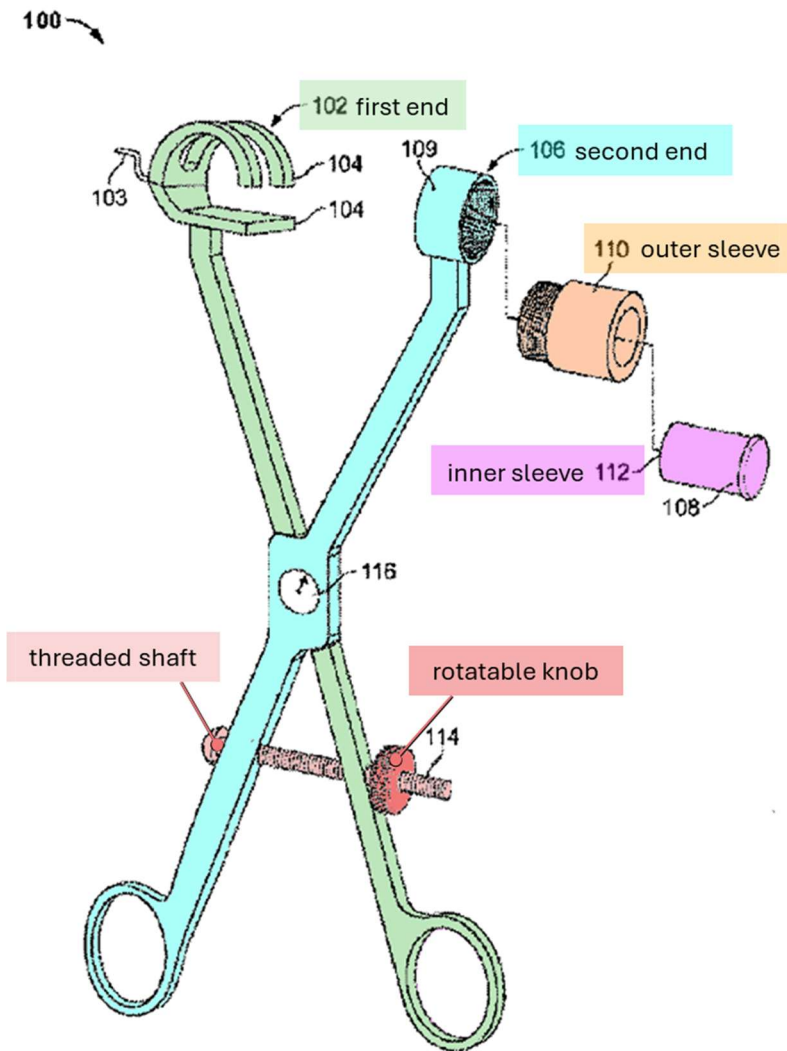
8. Claim 11

As explained in Ground 1, McGlamry discloses the additional limitations of claim 11; the McGlamry-Fallin-Kartalian combination thus renders this claim obvious. *Supra* §VII.A.9; Ex.1003, ¶245.

9. Claim 12

The McGlamry-Fallin-Kartalian combination renders this claim obvious.
Ex.1003, ¶¶246-248.

Kartalian discloses that its instrument 100 (bone positioning guide) comprises at least three components: (i) a first end 102 (green), (ii) a second end 106 (blue), (iii) an outer sleeve 110 (orange) of the cannulated sleeve 108 removably attached to ring 109 of the second end 106, (iv) an inner sleeve 112 (purple) of the cannulated sleeve 108, (v) a rotatable knob (dark red), and (vi) a threaded shaft (light red).
Ex.1006, 8:12-14, 8:38-55. Figure 1 depicts these components:



Id., Fig.1(excerpt), 8:12-14, 8:38-55; Ex.1003, ¶¶247-248. The components are joinable to form the instrument. Ex.1003, ¶248. As an illustrative example, the threaded shaft, rotatable knob, cannulated sleeves, and the forceps are joinable. *Id.*

10. Claims 13-14

As explained in Ground 1, Fallin discloses the additional limitations of claims 13-14; the McGlamry-Fallin-Kartalian combination thus renders these claims obvious. *Supra* §VII.A.11; Ex.1003, ¶249.

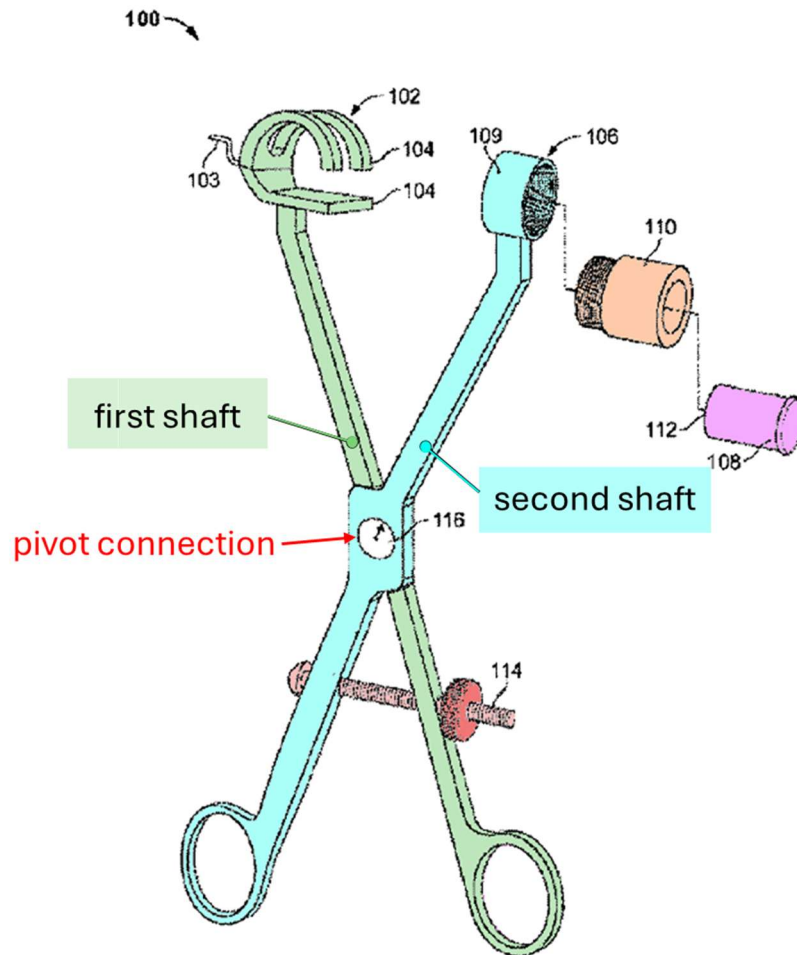
11. Claims 15-16

The McGlamry-Fallin-Kartalian combination renders these claims obvious. Ex.1003, ¶¶250-256. Kartalian’s instrument includes a bone engagement member, a tip, and a mechanism for moving the bone engagement member and tip relative to one another. *Id.*, ¶¶251-256. Kartalian’s end 106 is a bone engagement member. *Id.*, ¶251. Kartalian describes that the “end 106 may be placed on the proximal first bone (first metatarsal).” Ex.1006, 10:49-51.

As described above, the ’368 patent describes the tip can have various shapes and can be, for example, straight or have a non-linear orientation, for example an angled or curved tip. Ex.1001, 6:48-64. Similarly, Kartalian describes end 102 can have various shapes, including “curved or other shape[d]” to engage the bone. Ex.1006, 9:33-45. Kartalian’s end 102 is a tip that is disclosed to engage the second metatarsal. *Id.*, 9:24-57; Ex.1003, ¶252.

Kartalian also discloses a mechanism configured to move the bone engagement member and the tip relative to each other under either construction. Ex.1003, ¶¶252-253. When the surgeon moves the handles towards each other, the bone engagement member and tip move relative to one another to reduce the distance between the first metatarsal and second metatarsal: “[t]he instrument 100 may act as reduction forceps to align two bones or reduce the distance between the bones, as desired.” Ex.1006, 9:66-10:3.

Kartalian's instrument 100 is a tenaculum/tong structure that includes first and second shafts that are pivotably connected:



Ex.1006, Fig.1(excerpt); Ex.1003, ¶254; *see also* Ex.1006, 8:51-53. As shown in Figure 1, the surgeon can rotate the threaded knob to bring the ends of Kartalian's instrument together thereby moving the handles towards each other and, thus, the bone engagement member and the tip relative to each other. Ex.1003, ¶¶255-256. Accordingly, Kartalian's mechanism comprises a threaded shaft. *Id.*

Thus, Kartalian discloses the claimed mechanism under either construction discussed in Section V.E. *Id.* Under §112(f), Kartalian’s instrument 100 includes a mechanism that is identical or at least equivalent to structures identified in the ’368 patent for the claimed mechanism. *Id.* Kartalian’s instrument 100 is at least an equivalent of the disclosed mechanism because its forceps/tenaculum actuation and locking structure (e.g., handle/ratchet and associated linkage) moves the opposing bone-engaging members relative to one another, thereby performing the same relative-movement function in substantially the same way to achieve the same result as the ’368 patent’s disclosed threaded-shaft/ratchet-type mechanisms. *Id.*

12. Claim 17

The McGlamry-Fallin-Kartalian combination renders this claim obvious. Ex.1003, ¶¶257-259. Kartalian’s instrument 100 has a first end 102 configured to engage the second metatarsal and a second end 106 configured to engage the first metatarsal: “first end 102 [tip] may be placed on the distal second bone (second metatarsal) and second end 106 [bone engagement member] may be placed on the proximal bone (first metatarsal).” Ex.1006, 10:49-51. With the distal arm 102 engaged to the second metatarsal, the 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. *Id.*, 9:66-10:3, 10:46-51; Ex.1003, ¶¶258-259.

13. Claim 18

The McGlamry-Fallin-Kartalian combination renders this claim obvious. Ex.1003, ¶¶260-261. The placement of the bone preparation guide and bone positioning guide into a sterile kit would have been obvious as explained in Ground 1. *Supra* §VII.A.14. Placing Kartalian’s bone positioning guide into that kit rather than McGlamry’s does not change the Ground 1 analysis. Ex.1003, ¶¶260-261.

14. Claim 19

As explained in Ground 1, McGlamry discloses the additional limitations of claim 19. *Supra* §VII.A.15. The final position of the metatarsal in McGlamry’s procedure would not be impacted by using Kartalian’s bone positioning guide in place of McGlamry’s Weber clamp. Ex.1003, ¶¶262-264. The McGlamry-Fallin-Kartalian combination thus renders this claim obvious. *Id.*

15. Claim 20

As explained in Ground 1, Fallin discloses the additional limitations of claim 20; the McGlamry-Fallin-Kartalian combination thus renders this claim obvious. *Supra* §VII.A.20; Ex.1003, ¶265.

16. Claim 21

Independent claim 21 recites all limitations of claim 1, and further recites the limitations of claims 2-4. Ex.1003, ¶¶266-275. For limitation 21[a] (adding spacer to limitation 1[a]), Fallin discloses these limitations as explained for limitation 1[a]

and claim 4. *Supra* §§VII.A.1.b, VII.A.3; Ex.1003, ¶¶268-270. For limitation 21[b] (adding opening and fixation wire to limitation 1[b]), Kartalian renders these limitations obvious as explained for limitation 1[b] and claim 3. *Supra* §§VII.B.1.c, VII.B.3; Ex.1003, ¶¶271-273. For limitation 21[c] (pin for frontal-plane rotation), McGlamry's discloses this limitation as explained for claim 2. *Supra* §VII.A.2; Ex.1003, ¶274. For limitation 21[d], McGlamry's discloses this limitation as explained for limitation 1[c]. *Supra* §§VII.A.1.d; Ex.1003, ¶¶275. Accordingly, the McGlamry-Fallin-Kartalian combination renders this claim obvious. Ex.1003, ¶¶266-275.

17. Claim 22

Claim 22 depends from claim 21 and recites the same additional limitations as claims 5-6. As explained in Ground 1, Fallin discloses these limitations. *Supra* §§VII.A.4-5; Ex.1003, ¶¶276-278. The McGlamry-Fallin-Kartalian combination thus renders this claim obvious. Ex.1003, ¶¶276-278.

18. Claim 23

Claim 23 depends from claim 22 and recites the same additional limitations as claim 7. As explained in Ground 1, Fallin renders these limitations obvious. *Supra* §VII.A.6; Ex.1003, ¶279. The McGlamry-Fallin-Kartalian combination thus renders this claim obvious. Ex.1003, ¶279.

19. Claim 24

Claim 24 depends from claim 21 and recites the same additional limitations as claim 10. As explained, Kartalian discloses these limitations. *Supra* §VII.B.7; Ex.1003, ¶280. The McGlamry-Fallin-Kartalian combination thus renders this claim obvious. Ex.1003, ¶280.

20. Claim 25

Claim 25 depends from claim 21 and recites the same additional limitations as claim 11. As explained in Ground 1, McGlamry discloses these limitations. *Supra* §VII.A.9; Ex.1003, ¶281. The McGlamry-Fallin-Kartalian combination thus renders this claim obvious. Ex.1003, ¶281.

21. Claim 26

Claim 26 depends from claim 21 and recites the same additional limitations as claims 13-14. As explained in Ground 1, Fallin discloses these limitations. *Supra* §VII.A.11; Ex.1003, ¶282. The McGlamry-Fallin-Kartalian combination thus renders this claim obvious. Ex.1003, ¶282.

22. Claims 27-28

Claim 27 depends from claim 21 and recites the same additional limitations as claim 15, and claim 28 depends from claim 27 and recites the same additional limitations as claim 16. Kartalian discloses these limitations. *Supra* §VII.B.11;

Ex.1003, ¶283-284. The McGlamry-Fallin-Kartalian combination thus renders these claims obvious. Ex.1003, ¶¶283-284.

23. Claim 29

Claim 29 depends from claim 21 and recites the same additional limitations as claim 18. These limitations would have been obvious. *Supra* §VII.B.13; Ex.1003, ¶285. The McGlamry-Fallin-Kartalian combination thus renders this claim obvious. Ex.1003, ¶285.

24. Claim 30

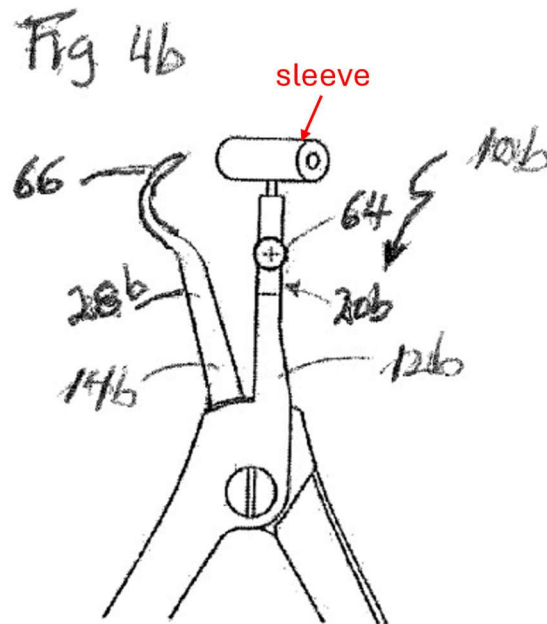
Claim 30 depends from claim 21 and recites the same additional limitations as claim 20. As explained in Ground 1, Fallin discloses these limitations. *Supra* §VII.A.16; Ex.1003, ¶286. The McGlamry-Fallin-Kartalian combination thus renders this claim obvious. Ex.1003, ¶286.

C. Ground 3: Claims 3 And 21-30 Are Unpatentable As Obvious Over McGlamry, Fallin, And Schmuck

1. Overview of Schmuck

Schmuck discloses “[a] surgical reduction clamp ha[ving] a first clamping arm and a second clamping arm movable relative to the first clamping arm.” Ex.1028, Abstract. The surgical reduction clamp includes a tip portion that “form[s] the proximal end of the first clamping arm and represent that portion of the first clamping arm that engages the human anatomy when applied in a surgical

procedure.” *Id.*, [0011]. “The tip portion may comprise...a sleeve to accommodate a surgical wire or another elongate member.” *Id.*



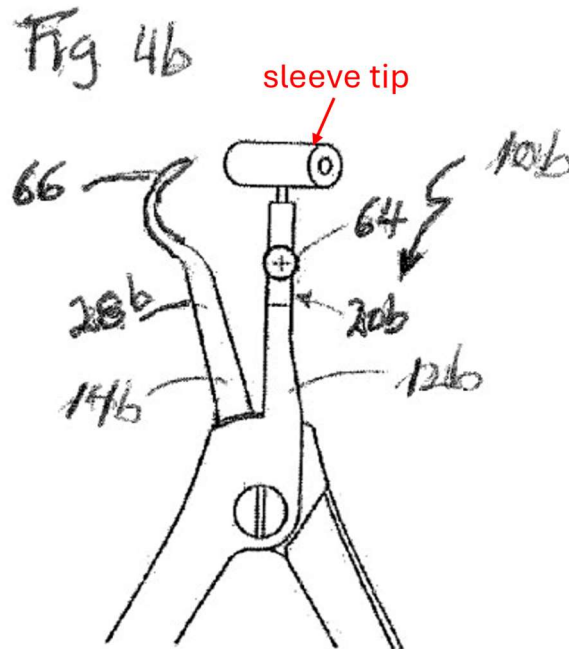
Id., Fig.4b. According to Schmuck, “a clamping capability between the tip portions 18 and 26 is provided which allows the operating surgeon to align bone fragments in a surgical procedure with the help of, for example, k-wires.” *Id.*, [0030].

2. Claim 3

The McGlamry-Fallin-Schmuck combination renders claim 3 obvious.
Ex.1003, ¶¶287-295.

As explained regarding limitation 1[b] in Ground 1, McGlamry discloses the use of a bone positioning guide—a Weber clamp—for the claimed reductions. *Supra* §VII.A.1.c; Ex.1003, ¶289. Schmuck likewise discloses a “surgical reduction clamp.” Ex.1028, [0002]; Ex.1003, ¶¶290-291. Schmuck describes embodiments

in which one arm of the clamp includes a tip “formed as a sleeve for accommodating a surgical wire, such as a k-wire.” Ex.1028, [0028]-[0029], [0011].



Id., Fig.4b, [0056]; Ex.1003, ¶291. Schmuck explains that the wire extends through the sleeve while the clamp is used to reduce and hold bone fragments. Ex.1028, [0028], [0030]; Ex.1003, ¶292. Schmuck’s sleeve is therefore an “opening” in the bone positioning guide that is configured to receive a fixation wire for passage into the underlying bone. *Id.*

It would have been obvious to configure McGlamry’s Weber clamp to include a wire-accommodating sleeve at the clamp tip contacting the second metatarsal, as taught by Schmuck, and to insert a K-wire through that sleeve such that the wire enters the second metatarsal while the clamp maintains the reduction. *Id.*, ¶¶293-295. McGlamry discloses inserting a second K-wire “into the lesser metatarsals”

while maintaining the corrected position “in all three planes,” including to “prevent derotation in the frontal plane and maintain[] reduction in the transverse plane.” Ex.1007, 326. Because the second metatarsal is the adjacent “lesser metatarsal” used for stabilizing the first metatarsal’s corrected relationship, a POSA would have understood McGlamry’s disclosure to encompass placement into the second metatarsal. Ex.1003, ¶294; *see also* Ex.1007, Fig.31.5 (showing ends of the Weber clamp positioned around the first and second metatarsals). Adding Schmuck’s sleeve provides an “opening” that guides the K-wire along a controlled trajectory into the second metatarsal while the clamp shifts relative to the second metatarsal during temporary fixation—i.e., applying a known wire-guidance technique in a reduction clamp to McGlamry’s reduction clamp use for a predictable improvement in intraoperative stability. Ex.1003, ¶294. Without such stabilization, movement of the Weber clamp relative to the second metatarsal could affect the position of the first metatarsal. *Id.*, ¶295. Adding the sleeve and K-wire as taught by Schmuck would reduce this risk by limiting clamp movement relative to the second metatarsal. *Id.* A POSA, faced with this routine design choice, would have had a reasonable expectation of achieving the improved stability taught by Schmuck. *Id.*

3. Claim 21

Independent claim 21 recites all limitations of claim 1 and further recites the limitations of claims 2-4. One of McGlamry or Fallin renders each of the limitations

of claims 1-2 and 4 obvious as explained in Ground 1, and Schmuck discloses the additional limitations of claim 3. Ex.1003, ¶296; *supra* §§VII.A.1-3, VII.C.2. Accordingly, the McGlamry-Fallin-Schmuck combination renders this claim obvious. Ex.1003, ¶296.

4. Claim 22

Claim 22 depends from claim 21 and recites the same additional limitations as claims 5-6. As explained in Ground 1, Fallin discloses these limitations. *Supra* §VII.A.4-5; Ex.1003, ¶297. The McGlamry-Fallin-Schmuck combination thus renders this claim obvious. Ex.1003, ¶297.

5. Claim 23

Claim 23 depends from claim 22 and recites the same additional limitations as claim 7. As explained in Ground 1, Fallin renders these limitations obvious. *Supra* §VII.A.6; Ex.1003, ¶298. The McGlamry-Fallin-Schmuck combination thus renders this claim obvious. Ex.1003, ¶298.

6. Claim 24

Claim 24 depends from claim 21 and recites the same additional limitations as claim 10. As explained in Ground 1, McGlamry renders these limitations obvious. *Supra* §VII.A.8; Ex.1003, ¶299. The McGlamry-Fallin-Schmuck combination thus renders this claim obvious. Ex.1003, ¶299.

7. Claim 25

Claim 25 depends from claim 21 and recites the same additional limitations as claim 11. As explained in Ground 1, McGlamry discloses these limitations. *Supra* §VII.A.9; Ex.1003, ¶300. The McGlamry-Fallin-Schmuck combination thus renders this claim obvious. Ex.1003, ¶300.

8. Claim 26

Claim 26 depends from claim 21 and recites the same additional limitations as claims 13-14. As explained in Ground 1, Fallin discloses these limitations. *Supra* §VII.A.11; Ex.1003, ¶301. The McGlamry-Fallin-Schmuck combination thus renders this claim obvious. Ex.1003, ¶301.

9. Claims 27-28

Claim 27 depends from claim 21 and recites the same additional limitations as claim 15, and claim 28 depends from claim 27 recites the same additional limitations as claim 16. As explained for Ground 1, McGlamry discloses these limitations. *Supra* §VII.A.12; Ex.1003, ¶¶302-303. The McGlamry-Fallin-Schmuck combination thus renders these claims obvious. Ex.1003, ¶¶302-303.

10. Claim 29

Claim 29 depends from claim 21 and recites the same additional limitations as claim 18. These limitations would have been obvious. *Supra* §VII.A.14;

Ex.1003, ¶304. The McGlamry-Fallin-Schmuck combination thus renders this claim obvious. Ex.1003, ¶304.

11. Claim 30

Claim 30 depends from claim 21 and recites the same additional limitations as claim 20. As explained in Ground 1, Fallin discloses these limitations. *Supra* §VII.A.16; Ex.1003, ¶305. The McGlamry-Fallin-Schmuck combination thus renders this claim obvious. Ex.1003, ¶305.

D. Ground 4: Claims 3 And 21-30 Are Unpatentable As Obvious Over McGlamry, Fallin, Kartalian, And Schmuck

1. Claim 3

Even if Kartalian and McGlamry together did not render obvious a fixation wire configured to be inserted into the second metatarsal and extending through the opening in the bone positioning guide, this would have been obvious in view of Schmuck. Ex.1003, ¶¶306-311. As explained for claim 3 in Ground 3, Schmuck discloses the use of a sleeve on a clamp to accommodate a surgical wire and discusses K-wires as alignment aids, making clear that incorporating a wire-accommodating sleeve into a reduction clamp was a known, predictable design choice. *Supra* §VII.C.2; Ex.1003, ¶308. A POSA would have been motivated to modify Kartalian's opening to function as a wire guide for McGlamry's temporary fixation wire because doing so would improve accuracy and stability—allowing the reduction instrument to hold alignment while the wire is placed along a controlled

trajectory—without changing the underlying reducing and fixation technique, and with a reasonable expectation of success given Schmuck’s sleeve-for-wire disclosure and the routine nature of guided K-wire placement in this surgical context. Ex.1003, ¶¶309-310. The McGlamry-Fallin-Kartalian-Schmuck combination thus renders this claim obvious. *Id.*, ¶311.

2. Claim 21

One of McGlamry, Fallin, or Kartalian renders each of the limitations of claims 1-2 and 4 obvious as explained in Ground 2, and one of Kartalian and Schmuck discloses the additional limitations of claim 3 as explained in Ground 2 and this ground. Ex.1003, ¶312; *supra* §§VII.B.1-4, VII.C.2. Accordingly, the McGlamry-Fallin-Kartalian-Schmuck combination renders this claim obvious. Ex.1003, ¶312.

3. Claims 22-30

The McGlamry-Fallin-Kartalian-Schmuck combination renders these claims obvious as explained for claims 22-30 in Ground 2. *Supra* §§VII.B.16-24; Ex.1003, ¶¶313-321. The inclusion of Schmuck in the combination does not alter the analysis for these claims, which depend from claim 21. Ex.1003, ¶¶313-321.

E. Ground 5: Claim 7 Is Unpatentable As Obvious Over The Ground 1-2 Combinations Further In View Of Jenkins

1. Overview of Jenkins

Jenkins discloses “devices and methods for removing bone,” including using “[a]n osteotomy guide.” Ex.1029, 1:6-9, Abstract. Jenkins’ osteotomy guide 1 includes guide holes 15 (blue) and fixation holes 51/52 (green):

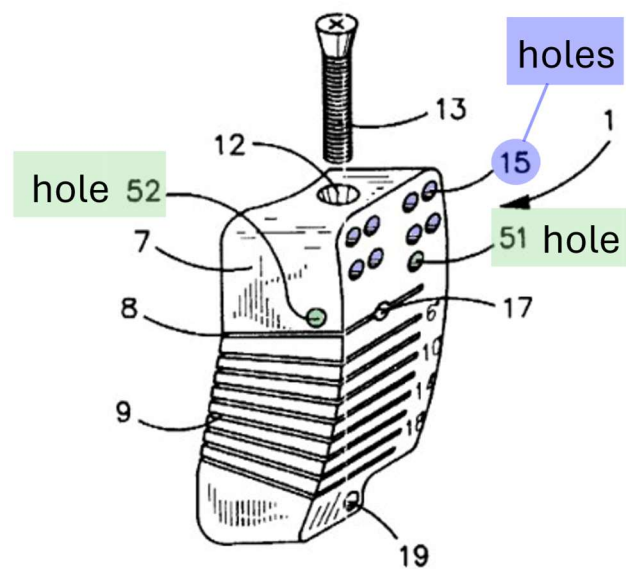
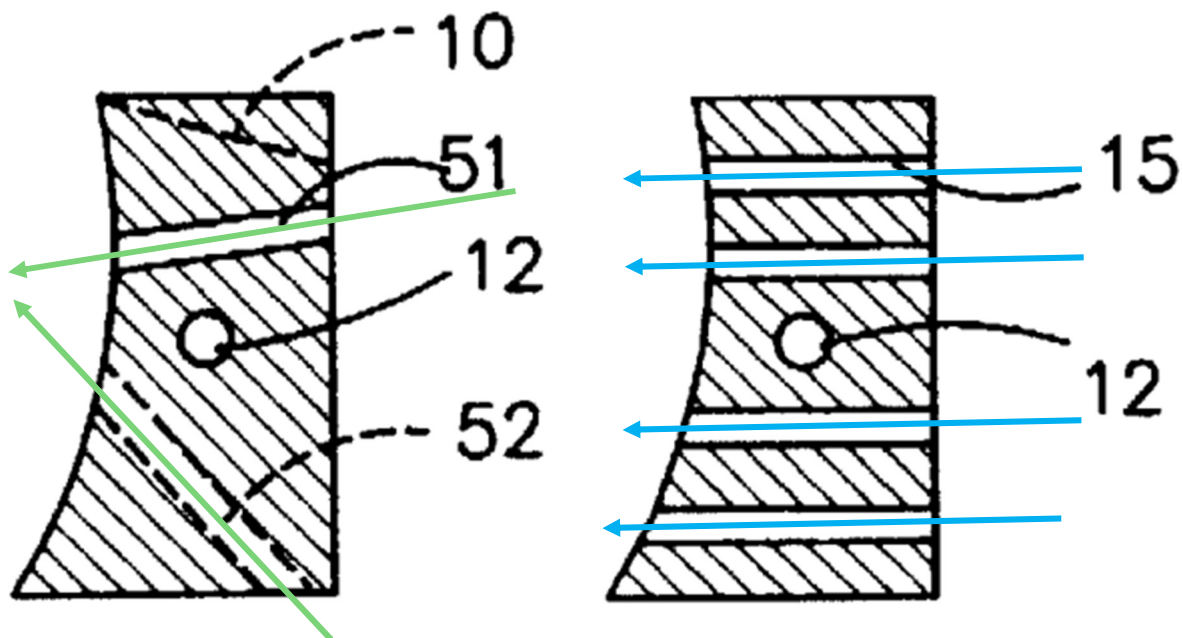


FIGURE 1A

Id., Fig.1A; *see also*, 5:61-6:13, 7:20-40; Ex.1003, ¶323. Jenkins describes that “pins [are] placed into guide holes 15” and “serve as the means for holding and stabilizing the osteotomy guide 1.” Ex.1029, 6:3-13. Similarly, “an additional method of fixation for the osteotomy guide 1 is available through the use of one or more pins 22 placed through angular fixation holes 51,52.” *Id.*, 7:20-22. According to Jenkins, “[f]ixation holes 51,52 are formed through the body 7 of the osteotomy

guide 1 in directions that are non-parallel to guide holes 15 and non-parallel to one another.” *Id.*, 7:22-25.



Id., Figs.1C-1D (arrows added to illustrate angular orientation of holes); Ex.1003, ¶324. “When a single pin 22 is used in either of fixation holes 51,52, the guide is prevented from sliding along the pins 22 in guide holes 15,” resulting in “more stable positioning of the osteotomy guide.” Ex.1029, 7:30-32, Abstract.

2. Claim 7

Any of the McGlamry-Fallin (Ground 1) or McGlamry-Fallin-Kartalian (Ground 2) combinations in view Jenkins renders claim 7 obvious. *Supra* §§VII.A.6, VII.B.5; Ex.1003, ¶¶325-329.

As explained for claim 5 in Ground 1, Fallin discloses a guide body with distal apertures for fixing the guide over the metatarsal and proximal apertures for fixing

the guide over the cuneiform, all of which receive pins. *Supra* §VII.A.4. Even if Fallin did not render obvious a third aperture that is skewed relative to the first and second apertures, such a configuration would have been obvious in view of Jenkins. Ex.1003, ¶¶327-329.

Jenkins discloses “[f]ixation holes 51,52 are formed through the body 7 of the osteotomy guide 1 in directions that are non-parallel to guide holes 15 and non-parallel to one another.” Ex.1029, 7:22-25; *see also*, Figs.1B-1D. Jenkins further explains that this non-parallel arrangement provides “more stable positioning of the osteotomy guide” when pins are placed through the holes. *Id.*, Abstract; *see also*, 7:30-32; Ex.1003, ¶327.

In view of Jenkins’ teaching that non-parallel fixation holes improve stability, a POSA would have been motivated to modify Fallin’s guide body to include a third fixation aperture skewed relative to Fallin’s first and second fixation apertures to achieve the same well-understood benefit. Ex.1003, ¶¶328-329; *see also* Ex.1031, [0071]; Ex.1032, [0030], [0048]. Adding a skewed third fixation aperture to Fallin’s guide body is merely the predictable use of a known technique to improve stability in exactly the manner taught by Jenkins. Ex.1003, ¶¶328-329. Implementing this modification would have required nothing more than routine skill in the art and would have been straightforward in view of Jenkins’ disclosure. *Id.*

F. Ground 6: Claim 23 Is Unpatentable As Obvious Over The Ground 2-4 Combinations Further In View Of Jenkins

Any of the McGlamry-Fallin-Kartalian (Ground 2), McGlamry-Fallin-Schmuck (Ground 3), or McGlamry-Fallin-Kartalian-Schmuck (Ground 4) combinations in view of Jenkins renders claim 23 obvious. *Supra* §§VII.B.18, VII.C.5, VII.D.3; Ex.1003, ¶¶330-331. For the reasons explained for claim 7 in Ground 5, Jenkins discloses the limitation added in claim 23, and it would have been obvious to modify Fallin’s guide body in the combinations in the manner taught by Jenkins. *Supra* §VII.E.2; Ex.1003, ¶¶330-331. Implementing this modification would have required nothing more than routine skill in the art and would have been straightforward in view of Jenkins’ disclosure. Ex.1003, ¶¶330-331.

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 ’368 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 (Dist. Del.). Treace Medical

Concepts, Inc. (“Treace” or “Patent Owner”) has asserted the ’368 patent against Petitioner in the district court litigation. Treace has also asserted U.S. Patent Nos. 12,268,397 (“the ’397 patent”) and 12,268,428 (“the ’428 patent”) in the district court litigation, and the ’397 and ’428 patents are currently the subject of PGR Review Nos. PGR2026-00017 and PGR2026-00020, 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
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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-IPR-368@morganlewis.com.

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

The '368 patent is available for IPR 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 IPR and cancel claims 1-30 of the '368 patent.

Dated: January 5, 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. 12,102,368	
Claim 1¹⁰	
1[pre]	A metatarsal bunion correction system comprising:
1[a]	a bone preparation guide comprising a body defining a guide surface configured to be positioned over a proximal end of a first metatarsal and/or a distal end of a medial cuneiform, the guide surface being configured to guide a tissue removing instrument for cutting the proximal end of the first metatarsal and/or the distal end of the medial cuneiform;
1[b]	a bone positioning guide configured to move the first metatarsal to treat a bunion deformity by at least: moving the first metatarsal in a transverse plane to reduce an intermetatarsal angle between the first metatarsal and a second metatarsal, and rotating the first metatarsal in a frontal plane; and
1[c]	at least one fixation device positionable across a tarsal-metatarsal joint separating the first metatarsal from the medial cuneiform, the at least one fixation device being configured to fixate a moved position of the first metatarsal relative to the medial cuneiform for fusion.
Claim 2	
--	The system of claim 1, further comprising a pin configured to be inserted into the first metatarsal, the pin being configured to receive a force to rotate the first metatarsal in the frontal plane.

¹⁰ Bracketed labels have been added for convenient referencing to the claim limitations.

Listing of Claims from U.S. 12,102,368	
Claim 3	
--	The system of claim 1, wherein the bone positioning guide comprises an opening, and further comprising a fixation wire configured to be inserted into the second metatarsal and extending through the opening.
Claim 4	
--	The system of claim 1, wherein the bone preparation guide further comprises a spacer extending downwardly from the body and configured to be placed into the tarsal-metatarsal joint.
Claim 5	
--	The system of claim 1, wherein the body extends from a first end configured to be positioned over the first metatarsal to a second end configured to be positioned over the medial cuneiform, the body including a first fixation aperture configured to receive a first fixation pin and a second fixation aperture configured to receive a second fixation pin.
Claim 6	
--	The system of claim 5, wherein the first fixation aperture and the second fixation aperture are generally parallel to each other.
Claim 7	
--	The system of claim 6, wherein the body further comprises a third fixation aperture that is skewed relative to the first fixation aperture and the second fixation aperture, the third fixation aperture being configured to receive a third fixation pin.

Listing of Claims from U.S. 12,102,368	
Claim 8	
--	The system of claim 1, further comprising a temporary fixation device configured to be applied to the first metatarsal to temporarily fixate the moved position of the first metatarsal prior to permanent fixation using the at least one fixation device.
Claim 9	
--	The system of claim 8, wherein the temporary fixation device comprises a fixation wire.
Claim 10	
10	The system of claim 1, wherein the bone positioning guide comprises a rotatable knob connected to a threaded shaft.
Claim 11	
--	The system of claim 1, wherein the at least one fixation device comprises one or more of a bone plate, a screw, a staple, and an intramedullary implant.
Claim 12	
--	The system of claim 1, wherein the bone positioning guide is formed of at least three components joinable together to form the bone positioning guide.
Claim 13	
--	The system of claim 1, further comprising the tissue removing instrument.

Listing of Claims from U.S. 12,102,368	
Claim 14	
--	The system of claim 13, wherein the tissue removing instrument comprises a saw blade.
Claim 15	
--	The system of claim 1, wherein the bone positioning guide comprises: a bone engagement member; a tip; and a mechanism configured to move the bone engagement member and the tip relative to each other.
Claim 16	
--	The system of claim 15, wherein the mechanism comprises a threaded shaft.
Claim 17	
--	The system of claim 15, wherein the bone engagement member is configured to engage the first metatarsal and the tip is configured to engage the second metatarsal.
Claim 18	
--	The system of claim 1, further comprising a sterile kit containing at least the bone preparation guide and the bone positioning guide.

Listing of Claims from U.S. 12,102,368	
Claim 19	
--	The system of claim 1, wherein the bone positioning guide is configured to move the first metatarsal in the transverse plane to reduce the intermetatarsal angle to 10 degrees or less and to rotate the first metatarsal in the frontal plane to position sesamoid bones generally parallel to ground and positioned under the first metatarsal.
Claim 20	
--	The system of claim 1, wherein the guide surface defined by the body of the bone preparation guide comprises a first guide surface configured to be positioned over the proximal end of the first metatarsal and a second guide surface configured to be positioned over the distal end of a medial cuneiform, the first guide surface being configured to guide the tissue removing instrument for cutting the proximal end of the first metatarsal and the second guide surface being configured to guide the tissue removing instrument for cutting the distal end of the medial cuneiform.
Claim 21	
21[pre]	A metatarsal bunion correction system comprising:
21[a]	a bone preparation guide comprising a body defining a guide surface configured to be positioned over a proximal end of a first metatarsal and/or a distal end of a medial cuneiform, the guide surface being configured to guide a tissue removing instrument for cutting the proximal end of the first metatarsal and/or the distal end of the medial cuneiform, wherein the bone preparation guide comprises a spacer extending downwardly from the body and configured to be placed into a tarsal-metatarsal joint separating the first metatarsal from the medial cuneiform;

Listing of Claims from U.S. 12,102,368	
21[b]	a bone positioning guide configured to move the first metatarsal to treat a bunion deformity by at least moving the first metatarsal in a transverse plane to reduce an intermetatarsal angle between the first metatarsal and a second metatarsal and rotating the first metatarsal in a frontal plane, wherein the bone positioning guide comprises an opening, and further comprising a fixation wire configured to be inserted into the second metatarsal and extending through the opening;
21[c]	a pin configured to be inserted into the first metatarsal, the pin being configured to receive a force to rotate the first metatarsal in the frontal plane; and
21[d]	at least one fixation device positionable across the tarsal-metatarsal joint, the at least one fixation device being configured to fixate a moved position of the first metatarsal relative to the medial cuneiform for fusion.
Claim 22	
--	The system of claim 21, wherein the body extends from a first end configured to be positioned over the first metatarsal to a second end configured to be positioned over the medial cuneiform, the body including a first fixation aperture configured to receive a first fixation pin and a second fixation aperture configured to receive a second fixation pin, wherein the first fixation aperture and the second fixation aperture are generally parallel to each other.

Listing of Claims from U.S. 12,102,368	
Claim 23	
--	The system of claim 22, wherein the body further comprises a third fixation aperture that is skewed relative to the first fixation aperture and the second fixation aperture, the third fixation aperture being configured to receive a third fixation pin.
Claim 24	
--	The system of claim 21, wherein the bone positioning guide comprises a rotatable knob connected to a threaded shaft.
Claim 25	
--	The system of claim 21, wherein the at least one fixation device comprises one or more of a bone plate, a screw, a staple, and an intramedullary implant.
Claim 26	
--	The system of claim 21, further comprising the tissue removing instrument, wherein the tissue removing instrument comprises a saw blade.
Claim 27	
--	<p>The system of claim 21, wherein the bone positioning guide comprises:</p> <p>a bone engagement member;</p> <p>a tip; and</p> <p>a mechanism configured to move the bone engagement member and the tip relative to each other.</p>

Listing of Claims from U.S. 12,102,368	
Claim 28	
--	The system of claim 27, wherein the mechanism comprises a threaded shaft.
Claim 29	
--	The system of claim 21, further comprising a sterile kit containing at least the bone preparation guide and the bone positioning guide.
Claim 30	
--	The system of claim 21, wherein the guide surface defined by the body of the bone preparation guide comprises a first guide surface configured to be positioned over the proximal end of the first metatarsal and a second guide surface configured to be positioned over the distal end of a medial cuneiform, the first guide surface being configured to guide the tissue removing instrument for cutting the proximal end of the first metatarsal and the second guide surface being configured to guide the tissue removing instrument for cutting the distal end of the medial cuneiform.

CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. § 42.24(d), the undersigned certifies that this PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 12,102,368 contains 13,946 words according to the word-processing program used to prepare this paper. The foregoing word count complies with the 14,000-word type-volume limit specified by 37 C.F.R. § 42.24(a)(1).

Dated: January 5, 2026 By: / Ali S. Razai/
Ali S. Razai (Reg. No. 60,771)
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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on the date below a copy of this
**PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 12,102,368
AND EXHIBITS 1001-1008, 1010-1019, AND 1022-1037** were served by FedEx
on the Patent Owner at the correspondence address of record for the subject patent
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