

Filed December 23, 2025

On behalf of **Paragon 28, Inc.**

By: Ali S. Razai (Reg. No. 60,771)
Benjamin J. Everton (Reg. No. 60,659)
Jacob L. Peterson (Reg. No. 65,096)
Zachary Messick (Reg. No. 77,839)
MORGAN, LEWIS & BOCKIUS LLP
600 Anton Boulevard, Suite 1800
Costa Mesa, CA 92626-7653
Tel.: (714) 830-0600
Fax: (714) 830-0700
Email: MLB-P28-PGR-428@morganlewis.com

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PARAGON 28, INC.,
Petitioner,

v.

TREACE MEDICAL CONCEPTS, INC.
Patent Owner.

Case PGR2026-00020
Patent 12,268,428

**PETITION FOR POST GRANT REVIEW OF
U.S. PATENT NO. 12,268,428**

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LIST OF EXHIBITS

Exhibit No.	Description
1001	U.S. Patent No. 12,268,428 to Bays et al. (“the ’428 patent”)
1002	File History of U.S. Patent Application No. 18/645,596
1003	Declaration of Steven K. Neufeld, M.D.
1004	Curriculum Vitae of Steven K. Neufeld, M.D.
1005	McGlamry’s Comprehensive Textbook of Foot and Ankle Surgery, Preface and Chapters 1, 31, 34, 36, and 55, 4th Edition, 2013 (“McGlamry”)
1006	U.S. Patent App. Publ. No. 2009/0216089 to Davidson (“Davidson”)
1007	U.S. Patent App. Publ. No. 2016/0213384 to Fallin et al. (“Fallin”)
1008	U.S. Patent No. 8,328,806 to Tyber et al. (“Tyber”)
1009	Mark H. Hofbauer & Jordan P. Grossman, <i>The Lapidus Procedure</i> , 13(3) CLINICS PODIATRIC MED. & SURGERY 486–496 (1996)
1010	Paul W. Lapidus, <i>The author's bunion operation from 1931 to 1959</i> , 16 CLIN. ORTHOPAEDICS 119-135 (1960)
1011	Paul W. Lapidus, <i>Operative correction of the metatarsus varus primus in hallux valgus</i> , 58 J. SURGERY GYNECOLOGY & OBSTETRICS 183–191 (1934)
1012	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)
1013	International Patent App. Publ. No. 2014/152219 to DaCosta et al. (“DaCosta-219”)

Exhibit No.	Description
1014	U.S. Design Patent No. D695402 to DaCosta et al. (“DaCosta-402”)
1015	U.S. Patent App. Publ. No. 2013/0150900 to Haddad et al. (“Haddad”)
1016	Ryuzo Okuda et al., “Proximal Abduction–Supination Osteotomy of the First Metatarsal for Adolescent Hallux Valgus: A Preliminary Report,” <i>Journal of Orthopedic Science</i> , Vol. 18, 419–425 (2013)
1017	U.S. Patent App. Publ. No. 2007/0265634 to Weinstein (“Weinstein”)
1018	File History of U.S. Patent Application No. 16/448,357
1019	U.S. Patent No. 9,107,715 to Blitz et al. (“Blitz”)
1020	File History of U.S. Patent Application No. 14/480,309
1021	File History of U.S. Provisional Application No. 62/108,936 (“the ’936 application”)
1022	McGlamry’s Comprehensive Textbook of Foot and Ankle Surgery, Chapter 6, 3rd Edition, 2001
1023	U.S. Patent No. 5,350,382 to Armstrong et al. (“Armstrong”)
1024	U.S. Patent No. 5,112,334 to Alchermes et al. (“Alchermes”)
1025	U.S. Patent App. Publ. No. 2013/0030438 to Fox (“Fox”)
1026	U.S. Patent App. Publ. No. 2011/0186456 to Bertazzoni et al. Bertazzoni (“Bertazzoni”)
1027	Bas B.G.M. Franssen et al., <i>One century of Kirschner wires and Kirschner wire insertion techniques: A historical review</i> , 76 <i>Acta Orthopedic Belgium</i> 1–6 (2010)

Exhibit No.	Description
1028	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 (2013)
1029	RESERVED
1030	Declaration of Sylvia Hall-Ellis, Ph.D.

Petitioner Paragon 28, Inc. requests post grant review (“PGR”) of claims 1-30 of U.S. Patent 12,268,428 (“the ’428 patent,” Ex.1001).

I. INTRODUCTION

The ’428 patent claims are directed to surgical methods for correcting bunions. The independent claims include the following basic steps: (1) inserting an instrument between a first and second metatarsal; (2) cutting the end of the first metatarsal and the opposing end of the cuneiform; (3) moving the first metatarsal in at least one plane to treat the bunion deformity; (4) compressing the metatarsal and cuneiform together; and (5) fixing the metatarsal to the cuneiform in its moved position using a bone fixation device. But the claimed subject matter is directed to instrumentation and techniques that were known and routinely used in bunion surgery before the patent’s earliest claimed priority date in August 2015.

By the early 1900s, surgeons had already described procedures for correcting a misalignment of the first metatarsal and medial cuneiform. Ex.1009; Ex.1014, 1108 (same); Ex.1015, 243-244 (same); Ex.1008, 322-328. These procedures involved cutting and removing bone to restore the anatomical alignment of the metatarsal and cuneiform bones and fixing them in the corrected position for fusion. Ex.1014, 1109-1013 (describing operative technique); Ex.1017, 423; Ex.1015, 226-228 (same).

By 2015, bunion correction surgeries had become very well-developed and routine. In 2013, McGlamry, a medical textbook, described 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 those disclosed in McGlamry. For example, Fallin discloses surgical methods and instruments used in bunion surgery, including, for example 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, Davidson describes retractors for use in bunion correction surgery to move the first metatarsal and protect nearby soft tissues.

As of August 2015, the methods claimed in the '428 patent were nothing more than a predictable application of prior art elements for use according to their established functions. Accordingly, all claims of the '428 patent are obvious and should be cancelled.

II. STATE OF THE ART

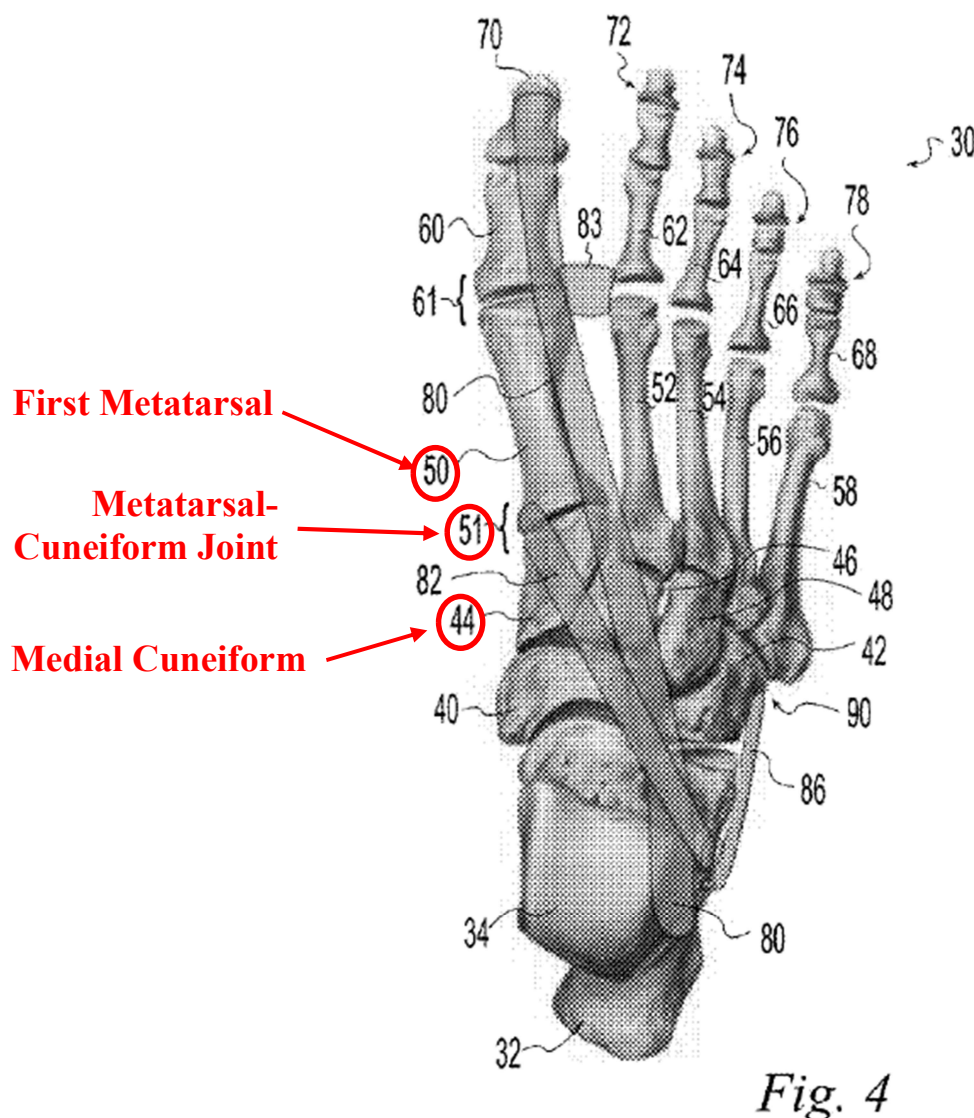
Bunion correction procedures and the use of bone cutting guides were well-known by 2015. Ex. 1003, ¶38; *see generally* Ex.1003, ¶¶38-67. The '428 patent does not acknowledge the well-developed state of the art, including bunion

correction procedures that used instruments positioned between the metatarsals and other common instruments like bone cutting guides.

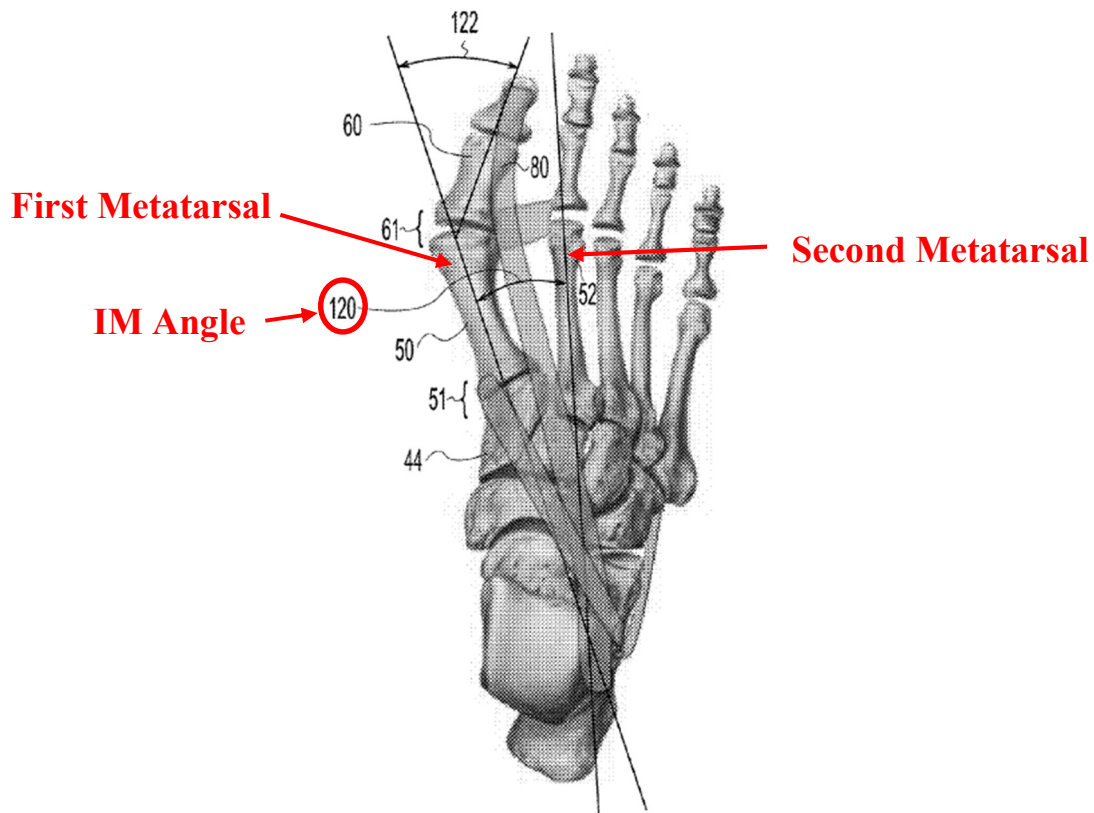
A. Bunion Deformity

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

¶¶39-41. These bones meet to form the metatarsal-cuneiform joint:



Id., ¶39 (annotating Ex.1007, Fig.4). A bunion can result when the first metatarsal and medial cuneiform bones become misaligned in one or more planes. *Id.*, ¶42. As part of this misalignment, the first metatarsal may deviate away from the second metatarsal, which increases the intermetatarsal angle (“IM angle”)—the angle formed between the longitudinal axes of the first and second metatarsals:



Id. (annotating Ex.1007, 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. *Id.*

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:

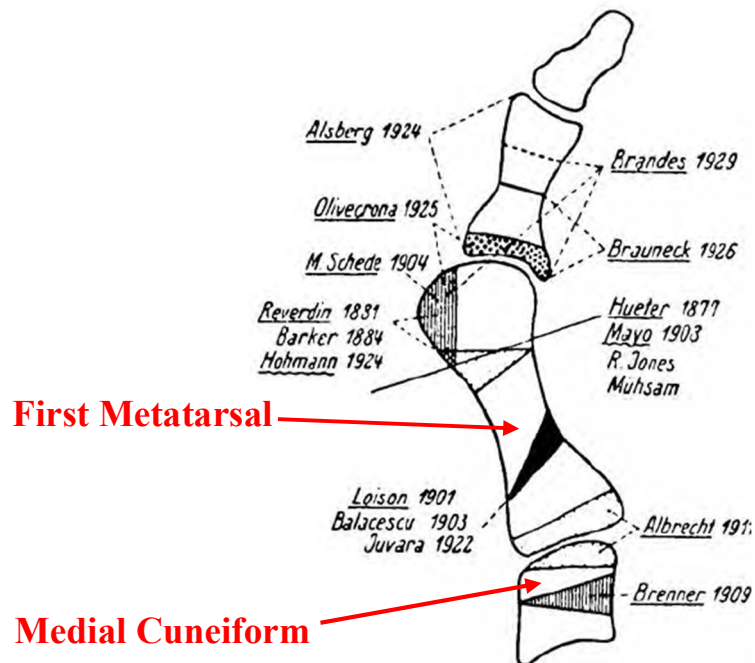
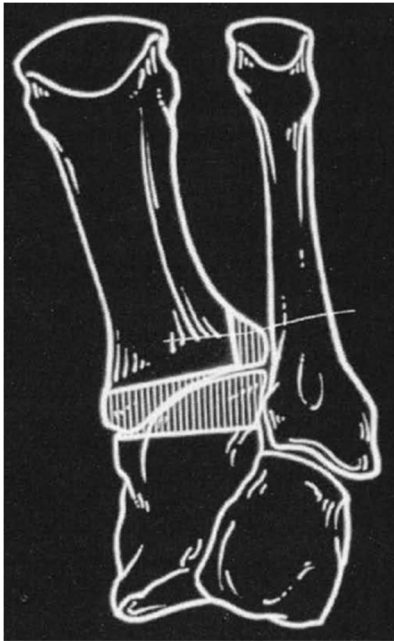


FIG. 3. Schematic drawing of various operative procedures devised for correction of bunion. The name of the author and the year of description of the operation are indicated. (Timmer, H.: Die Behandlung des Hallux valgus. Leipzig, Barth)

Ex. 1003, ¶43 (annotating Ex.1010, Fig. 3). One such procedure involves fusing the first metatarsal and medial cuneiform—now commonly referred to as a “Lapidus” procedure (also described as metatarso-cuneiform arthrodesis)—which was developed in 1934 by Dr. Paul Lapidus. Ex.1003, ¶¶44-45; Ex.1005, 803; Ex.1011. The goal of this procedure is to fuse the metatarsal and cuneiform in the corrected position. Ex.1003, ¶¶45-48; Ex.1011, 186, 189.

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



Before Correction



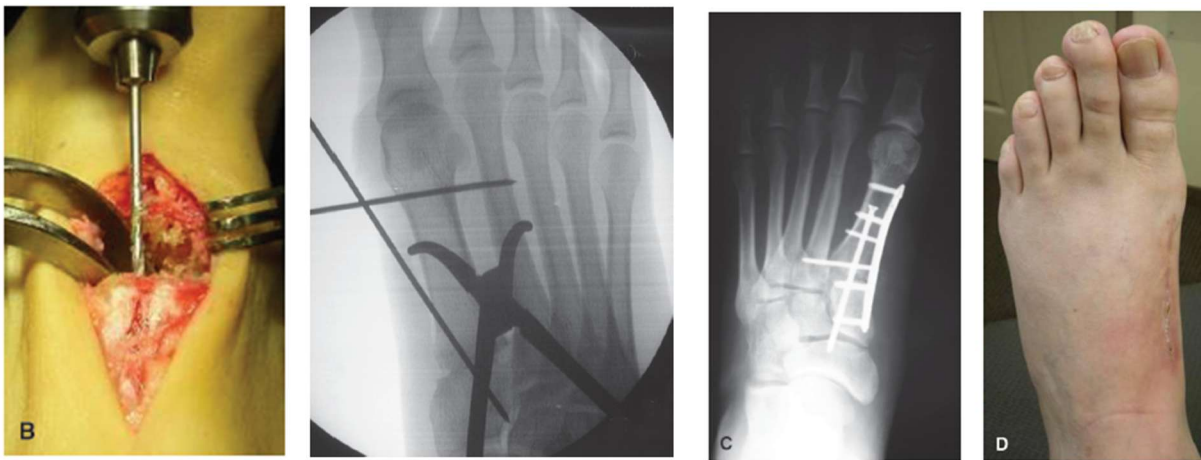
After Correction

Ex.1003, ¶45 (describing Ex.1009, Fig.1A (excerpts)). 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. *Id.*, ¶¶46-48; Ex.1011, 187-188; Ex.1009, 493; Ex.1005, 324-27.

C. Known Surgical Methods For Correcting Bunion Deformities

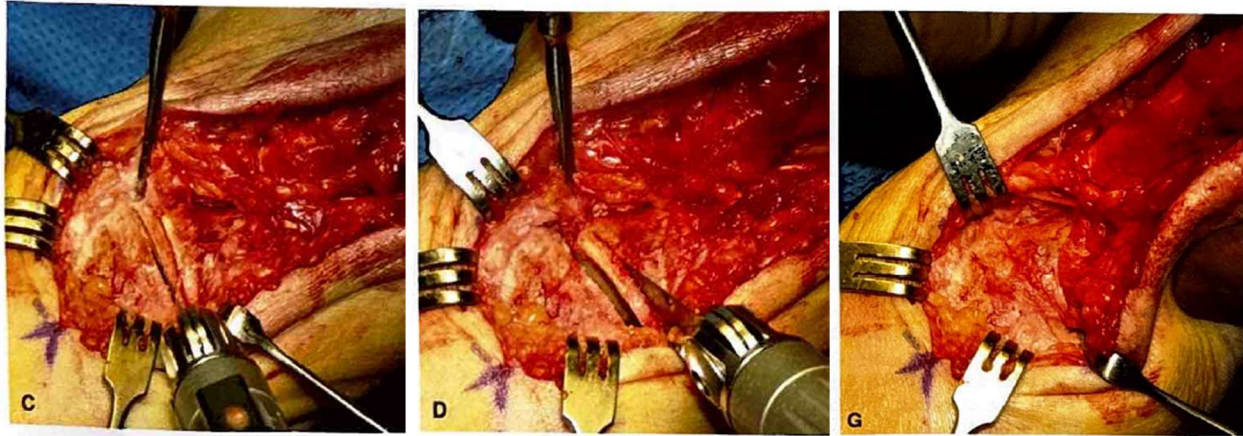
McGlamry describes surgical methods for correcting bunion deformities. Ex.1005, 322; Ex.1003, ¶¶49-54. In particular, Chapter 31 of McGlamry walks through the steps of a bunion correction procedure. Ex.1005, 324-327.

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



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

Chapter 55 of McGlamry discloses techniques for resection of the first metatarsal and cuneiform during a bunion correction surgery procedure that provides a “close apposition of fusion surfaces.” *Id.*, 807-809.



Id., 808-809 (left to right) Fig.55.7C (showing resection of the medial cuneiform with a saw), Fig.55.7D (showing resection of the first metatarsal with the saw), Fig.55.7G (showing bones after resection).

Fallin also discloses an instrumented bunion correction surgery. *See, e.g.*, Ex.1007, [0057]-[0068]. Like McGlamry, Fallin’s bunion correction surgery includes (1) cutting the end of the first metatarsal, (2) moving the first metatarsal in one or more planes to realign the bone and correct the bunion deformity, (3) cutting the cuneiform, and (4) fixing the metatarsal and cuneiform to fuse the bones in the moved position. *Id.*

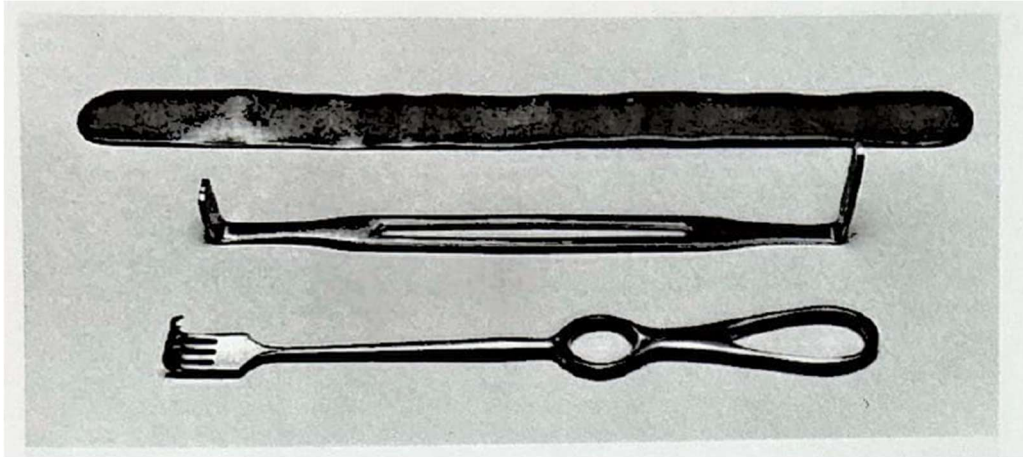
D. Known Use of Retractors and Elevators

Retractors and elevators were commonly used surgical instruments and part of “the basic set of podiatric surgical instruments.” Ex.1005, 3; Ex. 1003 ¶55.

“Retractors are used to hold tissues aside, thereby increasing exposure and protecting vital structures.” Ex.1005, 7. McGlamry discloses many different retractor designs. For example, McGlamry discloses a Seeburger malleable retractor that is used to move and visualize a distal end of the first metatarsal as shown below. *See id.*; Ex.1003, ¶56.

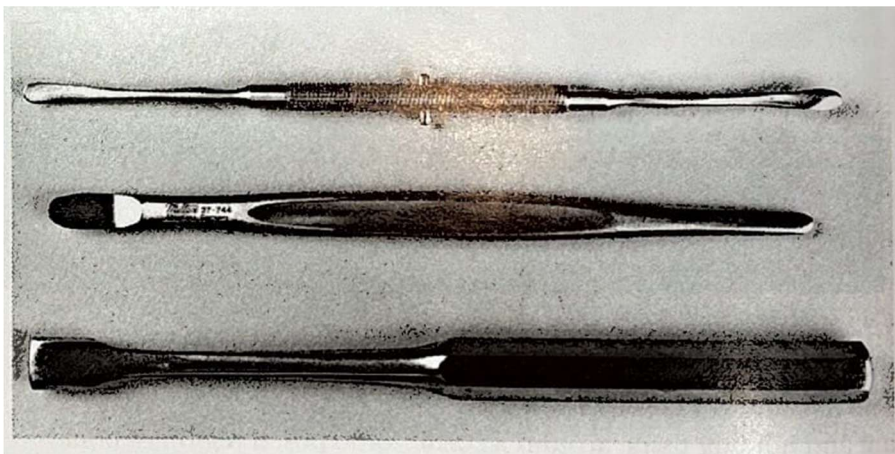


Ex.1005, 7 (Fig.1.14 showing the Seeburger retractor on the bottom (plantar) side of the first metatarsal). Large handheld retractors like those shown below “are helpful in providing full exposure.” *Id.*



Id., 8 (Fig.1.18).

Similarly, surgeons use periosteal elevators “to separate periosteum from underlying bone and, occasionally to provide leverage for retracting deep fascia, ligaments, and periosteum.” *Id.*, 8; Ex.1003, ¶57. For example, the Freer elevator (shown below) is “ideal” for use with the metatarsals. *See* Ex.1005, 8.

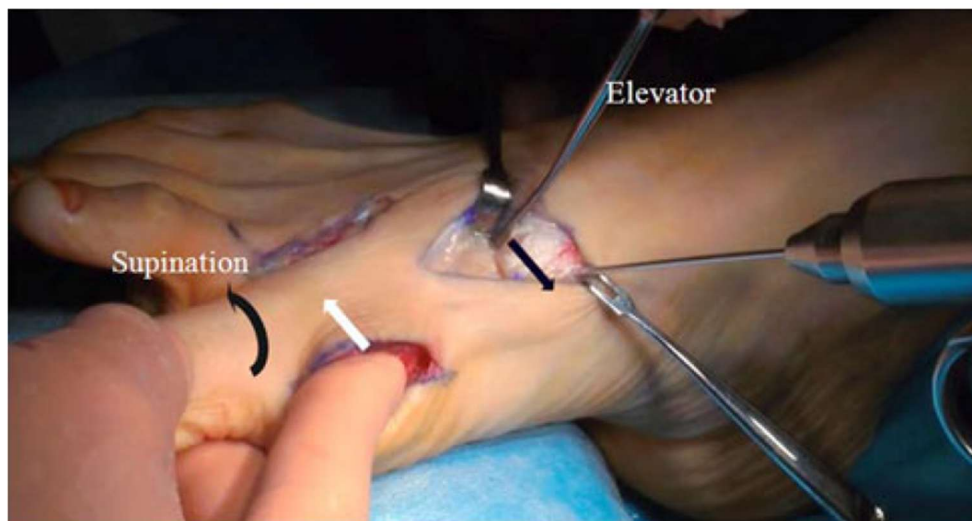


Id. (Fig.1.21) (top to bottom) (showing a Freer, Sayre, and Key elevators).

Like retractors, elevators are used to move bones and bone fragments during osteotomies in the foot. Ex.1003, ¶58. For example, Okuda discloses a bunion

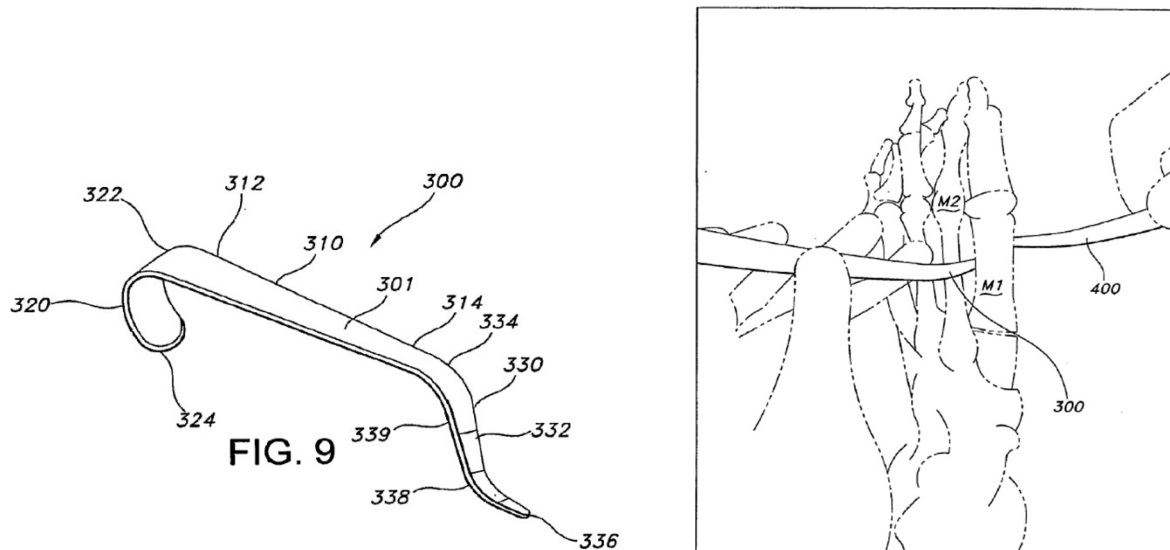
correction surgery where the first metatarsal is cut into two fragments and the fragments are repositioned to correct the bunion deformity. Ex.1016, 420. As shown below, Okuda uses an elevator (e.g., a Freer elevator) to push one of the metatarsal fragments in the medial direction and reposition it in a corrected position.

Id.



Id., Fig.1 (depicting “[t]he proximal fragment [being] pushed medially (black arrow) with a[n] elevator”).

Over the years, specialized retractors and elevators have been developed for podiatric surgery. For example, Davidson discloses retractors that are designed for the “unique shapes and contours of the human foot” and used in bunion correction surgery. Ex.1006, [0032], [0060]; Ex.1003, ¶59. Davidson describes its retractors as being used to move bones and protect the soft tissues. Ex.1006, [0057].



Id. (left to right) (Fig.9 – depicting Davidson’s retractor), (Fig.19 depicting the retractor 300 positioned between the metatarsal bones to move the first metatarsal M1).

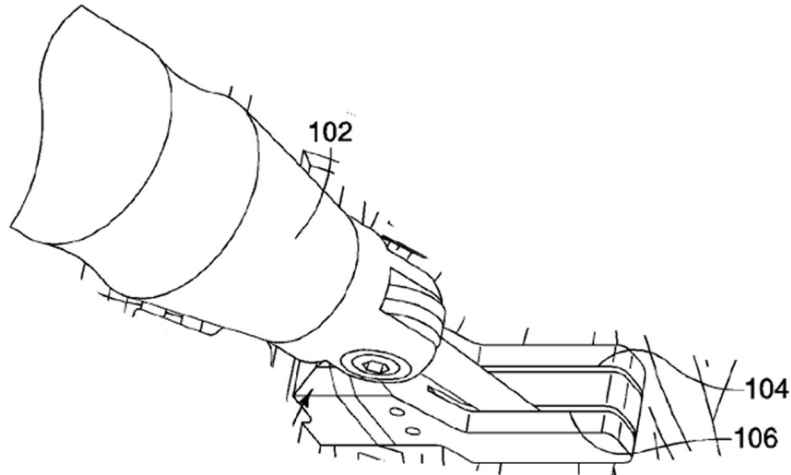
E. Known Bone Preparation Guides (Bone Cutting Guides)

Bone cutting guides, including those for metatarso-cuneiform arthrodesis, were well known by 2015.¹ Ex.1003, ¶¶60-62.

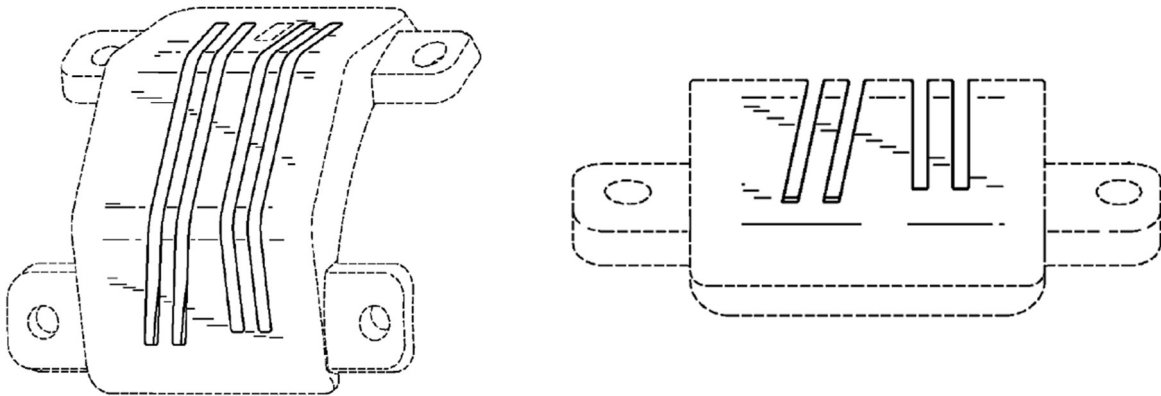
For example, Haddad discloses a cutting guide and a positioning jig usable “for a fusion application, [wherein] the jig likely would be secured to a metatarsal distally and a cuneiform proximally.” Ex.1015, [0058]. Haddad’s cutting guide includes slots 104/106 that allow a surgeon to use a surgical saw 102 “create two

¹ The term “bone preparation guide” as used in the ’428 patent is synonymous with “bone cutting guide.” Ex.1003, ¶¶60-62.

complimentary surfaces that will easily and effectively achieve unions through biological healing.” *Id.*, [0068].



Id., Fig.9 (excerpt). DaCosta-402 and Weinstein similarly disclose bone cutting guides for use in bunion correction surgeries:



Ex.1014, Figs.1, 5.

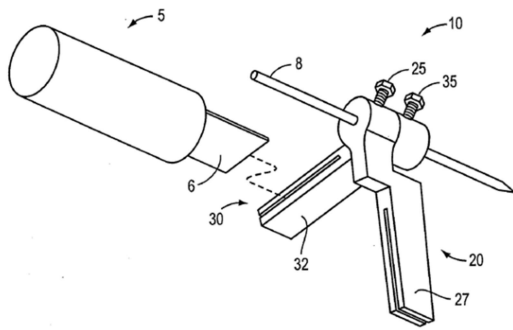


FIG. 3

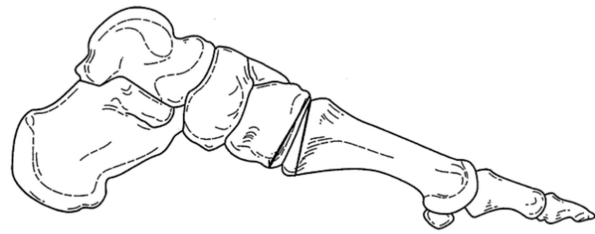


FIG. 13

Ex.1017, Figs.3, 13.

Fallin also discloses a bone cutting guide for use in a bunion correction surgery. Fallin describes “[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.1007, Abstract. Fallin further discloses an “an osteotomy guide 200” that achieves “more precision and repeatability in the relative orientation of the cuts” to the metatarsal and cuneiform. *Id.*, [0062].

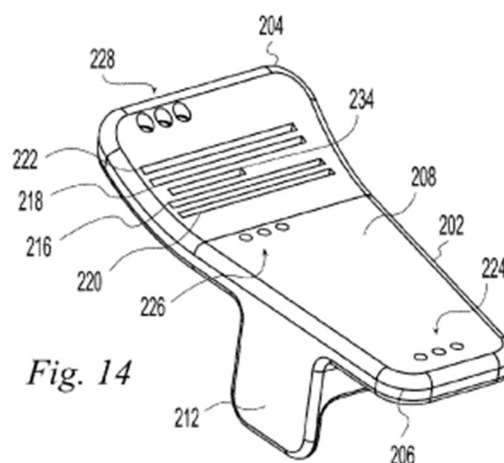


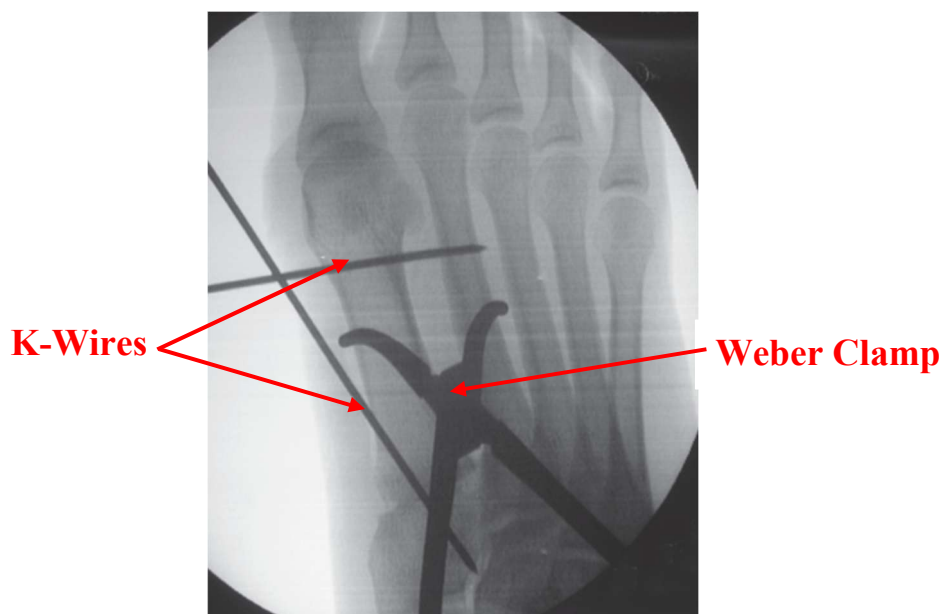
Fig. 14

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].

F. 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.1005, 324-27. Bone positioning guides that assist with this movement have long been known in the art. Ex. 1003, ¶¶63-64. For example, by 2013, McGlamry disclosed using a Weber clamp and K-wires to reposition the first metatarsal, as shown below.



Ex.1003, ¶63 (annotating Ex.1005, Fig.31.5).

Numerous bone positioning guides for use in bunion correction procedures were commercially available before 2015. For example, a Hintermann distractor may be pinned to the first and second metatarsals to reduce an abnormal IM angle and, after preparation of the metatarsocuneiform joint, pinned to the first metatarsal and medial cuneiform to compress the cut bones. Ex.1003, ¶64. Additional bone positioning guides include Weber clamps (Ex.1005, 325-326), reduction forceps/clamps (Ex.1012, 466), and joint distractors (Ex.1003, ¶64).

G. 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, ¶¶65-67. 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.*, ¶65; *see also* Ex.1009, 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.1009. 486-487. In 2013, McGlamry described the use of cortical screws and a “locking plate” as fixation devices in a bunion correction procedure, illustrated below. Ex.1005, 326.

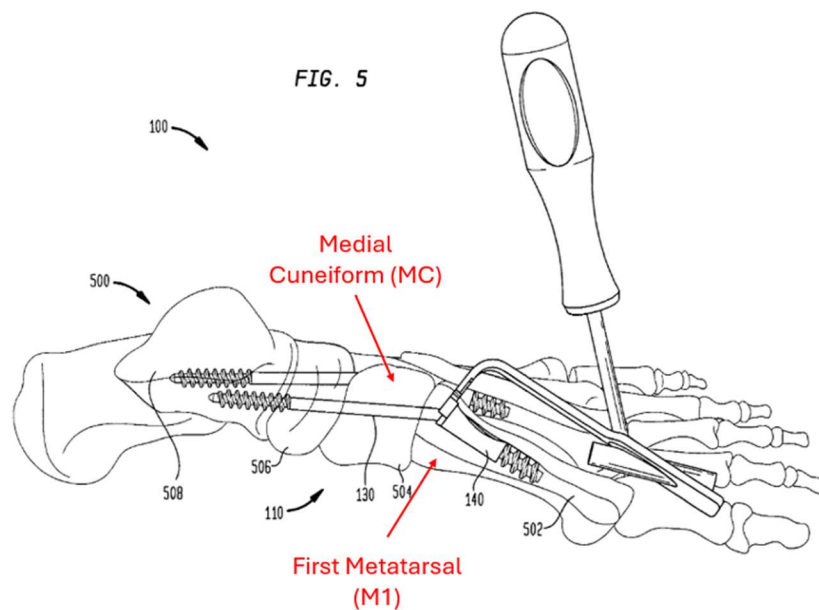


Figure 31.7 Postoperative AP radiograph demonstrating the “three solid cortical screw technique” with restoration of anatomical alignment.

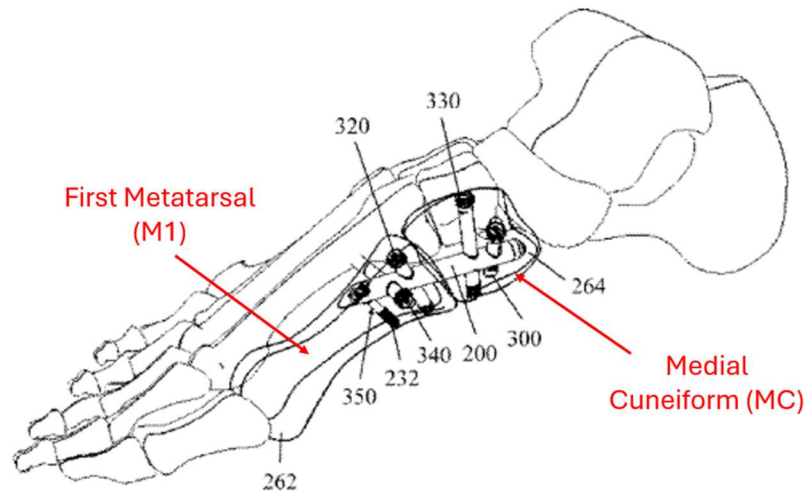


Id., Figs.31.7, 31.8.

Likewise, Tyber and DaCosta-219 disclose intramedullary implants used to fix the metatarsal and cuneiform during a bunion correction procedure. Ex.1008, 1:24-30, 2:27-29; Ex.1013, 3:22-24, 12:11-19.



Ex.1003, ¶67 (annotating Ex.1008, Fig.5).



Id., (annotating Ex. 1013, Fig.32).

III. THE '428 PATENT

A. Overview

The '428 patent purports to relate generally “to devices and methods for positioning and/or preparing bones” and describes procedures “to correct an alignment between a metatarsal ... and a second metatarsal and/or a cuneiform ... such as in a bunion correction surgery.” Ex.1001, 5:12-22; *see also* Ex. 1003, ¶¶84-85. The specification acknowledges that a Lapidus procedure is an example of such a procedure. *Id.*

The specification describes bone positioning operations in which an instrument is positioned between adjacent metatarsal bones. For example, in some embodiments the instrument is a fulcrum. The fulcrum can be a “surgical pin or rod, a screw driver head/shaft, an osteotome, or a retractor may be used as fulcrum 356.” Ex.1001, 17:40-42. The claims of the '428 patent recite “instrumented surgical

technique[s] for treating a bunion deformity.” The claims are listed in the Appendix to this Petition. Claims 1, 18 and 28 are independent. Claims 18 and 28 differ slightly from claim 1 and incorporate a bone preparation guide defining a cutting slot, among other things.

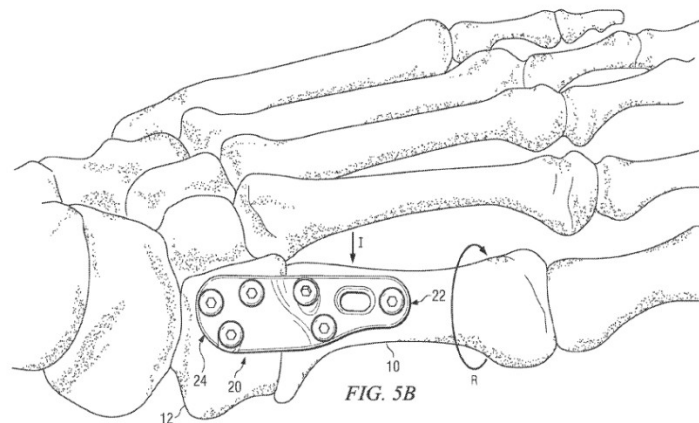
B. Prosecution History

The application which led to the ’428 patent was filed on April 25, 2024, along with a Track One Request, which was granted. Ex.1002, 202, 216-218; *see also* Ex.1003, ¶86. The application included claims 1-30 for examination. Ex.1002, 191-196.

A first office action was mailed on August 14, 2024. *Id.* In that office action, the Examiner indicated that, but for a double patenting rejection, claims 1-30 were allowable. *See id.*, 383-385. The Examiner explained the prior art discloses “inserting an instrument between [a first] metatarsal and a second metatarsal adjacent to the first metatarsal.” *Id.*, 383. This finding is consistent with the prosecution of one of the ’428 patent’s parent applications (App. No. 16/448,357) where the same examiner found—and the Applicant did not dispute—that the prior art (e.g., Davidson (Ex.1006)) discloses fulcrums used in bone realignment. *See* Ex.1018, 571-572, 725-731; *see also* Ex.1003, ¶87. But despite such instruments being disclosed in the prior art, the Examiner indicated that the claims of the ’428

patent were allowable because the prior art allegedly failed to disclose the steps of metatarso-cuneiform fusion. *See* Ex. 1002, 383.

The Examiner’s reasons for allowing the ’428 patent claims are inconsistent with his previous findings and call into question the patentability of the ’428 patent. For example, the Applicant cited U.S. Patent No. 9,107,715 (“Blitz”) during prosecution of the ’428 patent. *See* Ex.1001, 3. The Examiner was familiar with Blitz because he personally previously examined and allowed it as a patent. Ex.1019, 1 (listing Examiner Beccia as the primary examiner). Blitz claims priority to 2008 and describes—in the background section—a metatarso-cuneiform fusion surgery for correcting bunions, also known as a “Lapidus approach.” *Id.*, 2:29-3:4. Blitz claims “a method for fusing a metatarsocuneiform joint” which includes “laterally and inferiorly translating and rotating a metatarsal such that an end of the metatarsal abuts the cuneiform” and securing the cuneiform and metatarsal using a plate disclosed in the patent and shown below. *Id.*, claim 1.



Id., Fig.5B (showing movement of the metatarsal 10 in two planes (I and R) and fixation of the metatarsal 10 relative to the cuneiform 12). The Examiner acknowledged during Blitz’s prosecution that Blitz and/or the prior art disclosed these steps of metatarso-cuneiform fusion. Ex.1020, 21-23, 221-225.

The Examiner—having previously examined Blitz—nevertheless concluded in the prosecution of the ’428 patent that the prior art somehow does not disclose “moving the metatarsal in at least one plane” or “fixating a moved position of the first metatarsal relative to the medical cuneiform.” Ex.1002, 383. Thus, the Examiner’s allowance of the ’428 patent was contrary to prior art before him and his own findings regarding that same prior art. *See* Ex.1003, ¶88.

The Examiner was not provided with and did not consider the entirety of McGlamry. Chapters 1, 34, and 55 were not submitted by the Applicant nor considered by the Examiner. McGlamry’s Chapter 31, Davidson, Fallin, and Tyber were not applied by the Examiner during prosecution of the ’428 patent. *See generally* Ex.1002.

IV. LEVEL OF ORDINARY SKILL

The ’428 patent relates to devices and methods for positioning and/or preparing bones, and claims instrumented surgical techniques for treating bunion deformities. Ex.1001, 1:27-28, 26:8-29:30. A hypothetical person of ordinary skill in the art would have a combination of these two skill sets. Ex.1003, ¶33; *see also*

id., ¶¶29-37. Thus, a hypothetical person of ordinary skill in the art (“POSA”) would have had medical degree and at least 3 years of surgical experience with foot surgery. *Id.*, ¶31. Such person would have worked as part of a team and collaborated with a person having a degree in mechanical engineering or a similar engineering discipline, and experience with the design of surgical instrumentation. *Id.* For individuals with different engineering backgrounds, a person could still be of ordinary skill in the art provided that person’s additional experience compensates for any differences in that person’s education as stated above. *Id.*, ¶32.

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 a post grant review a claim “shall be construed using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. [§] 282(b).” 37 C.F.R. §42.100(b). Under this standard, claims “are generally given their ordinary and customary meaning,” as understood by a person of ordinary skill. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (citation omitted). Petitioner submits that the Board need not specially construe any claim terms. *Toyota Motor Corp. v. Cellport Sys., Inc.*, IPR2015-00633, Paper No. 11 at 16 (P.T.A.B. Aug. 14, 2015); *see also Vivid Techs., Inc. v. Am. Sci. & Eng’g*,

Inc., 200 F.3d 795, 803 (Fed. Cir. 1999) (“[O]nly those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy.”); *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017); *see* Ex.1003, ¶¶68. The claims are unpatentable under the plain and ordinary meaning of the claim language.

Petitioner also provides constructions under 35 U.S.C. §112(f) for completeness. Petitioner’s anticipation and obviousness showings apply under any reasonable construction consistent with the record.

A. “fulcrum”

The plain and ordinary meaning of the term “fulcrum” is a “mechanical instrument.” Ex.1003, ¶¶69-73.

The claims do not limit or define “fulcrum,” and instead they describe the fulcrum as an instrument about which the first metatarsal can pivot. Thus, the claims treat a “fulcrum” broadly as a mechanical instrument, without imposing any particular structural features or characteristics.

This interpretation is consistent with the specification, which describes the fulcrum in expansive terms. The specification explains that “any suitable mechanical instrument that maintains a spacing between adjacent bones can be used for the fulcrum.” Ex.1001, 17:14-16. For example, the fulcrum can be “a surgical pin or rod, a screw driver head/shaft, an osteotome, or a retractor.” *Id.*, 17:37-42.

The specification further makes clear that the instrument is also not limited to a particular shape or cross section, noting that “may have a variety of cross-sectional shapes.” *Id.*, 17:42-47.

The '428 patent discloses that the fulcrum merely “function[s] as a central point around which the proximal portion of the first metatarsal turns as the distal portion of the first metatarsal translates laterally.” *Id.*, 20:41-44. “As the first metatarsal pivots in the transverse plane toward the second metatarsal, closing the intermetatarsal space, a proximal portion of the first metatarsal may contact and press against the fulcrum, thereby causing the fulcrum to contact and press against a proximal portion of the second metatarsal. The fulcrum may function to maintain spacing between the proximal portion of the first metatarsal and proximal portion of the second metatarsal, e.g., such a spacing equal to the width of the fulcrum. This may help reduce or eliminate shifting or translation of the base of the first metatarsal toward the base of the second metatarsal during pivoting.” *Id.*, 20:48-59, 21:61-65 (“The use of fulcrum 356 can provide a pivot surface that also maintains a defined spacing between first metatarsal 210 and second metatarsal 292, potentially leading to a more anatomically correct realignment than when moving first metatarsal 210 without using the fulcrum.”)

Petitioner does not seek a construction of “fulcrum” beyond its plain and ordinary meaning, as the claims are unpatentable whether the term is expressly construed or afforded its ordinary meaning.

B. “bone positioning guide”

The plain and ordinary meaning of “bone positioning guide” is a “device that is designed to move bone(s).” Ex.1003, ¶¶74-78.

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

Function: “moving the first metatarsal relative to the second metatarsal in a transverse plane by applying a force to the first metatarsal...and thereby reducing an intermetatarsal angle between the first metatarsal and the second metatarsal” (Ex.1001, Claims 8, 21, 28) or “engage the first metatarsal and apply a force to the first metatarsal to move the first metatarsal in at least one plane” (*id.*, Claim 15, 26)

Corresponding Structure: The specification recites multiple structures that perform the claimed function. Examples of these structures include:

- “a tenaculum or tong structure,” which can include a “first shaft pivotably connected to a second shaft,” “[a] first end of each shaft can include an actuator, such as a handle,” “[a] second end of the first shaft can include a bone engagement member” (*id.*, 7:23-37);

- “[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.*, 5:40-48, Figs.1, 3B, 3C).

C. “bone fixation device”

The plain and ordinary meaning of “bone fixation device” is a “device that connects bones for fusion.” Ex.1003, ¶¶79-83.

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

Function: “fixating a moved position of the first metatarsal relative to the medial cuneiform” (Ex.1001, Claims 1, 18, 28)

Corresponding Structure: The specification provides multiple examples of a bone fixation device, including: “compressing bone screw, bone plate, bone staple, external fixator, intramedullary implant or nail” (*id.*, 11:39-44) and “two bone plates positioned in different planes” (*id.*, 14:26-30).

VI. RELIEF REQUESTED

A. Grounds

Petitioner requests PGR for the following grounds of unpatentability:

Ground	Reference(s)	Claims	Basis
1	McGlamry	1-3, 6-8, 10-13, 16-17	§102
2	McGlamry	1-3, 6-8, 10-13, 16-17	§103
3	McGlamry and Davidson	1-3, 6-13, 16-17	§103
4	McGlamry and Fallin	4-5, 14-16, 17-21, 23-30	§103
5	McGlamry, Davidson, and Fallin	4-5, 14-15, 17-30	§103
6	McGlamry and Tyber	17	§103
7	McGlamry, Davidson, and Tyber	17	§103
8	McGlamry and DaCosta-219	17	§103
9	McGlamry, Davidson, and DaCosta-219	17	§103
10	Fallin and Davidson	1-7, 12-14, 16, 18-20, 25, 27	§103

In support of the Petition, Petitioner submits the expert declaration of Steven K. Neufeld, M.D. *See* Ex.1003, ¶¶1-28; *see also* Ex. 1004.

B. Asserted References

The '428 patent's earliest claimed priority date is August 14, 2015. Ex.1001.

The references² relied on are prior art for the following reasons:

Ex.	Reference(s)	Date	Art Type
1005	McGlamry	Published: 2013	§102(a)(1)
1006	Davidson	Published: Aug. 27, 2009	§§102(a)(1),(2)
1007	Fallin	Provisional Filed: Jan. 28, 2015	§102(a)(2)
1008	Tyber	Published: Dec. 11, 2012	§§102(a)(1),(2)
1013	DaCosta-219	Published: Sep. 25, 2014	§§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.1021, 11-57. Therefore, Fallin is “effectively filed” for those disclosures as of January 28, 2015 under 35 U.S.C. §102(d), and qualifies as prior art under §102(a)(2) as of that date.

The references are analogous art because they are from the same field as the ’428 patent, e.g., devices and methods for positioning and/or preparing bones.

² A declaration from a professional librarian is submitted to support the publication date and public accessibility of certain cited references. Ex.1030.

Ex.1003, ¶¶89-90; Ex.1001, 1:25-29, 5:1-22; *Unwired Planet, LLC v. Google Inc.*, 841 F.3d 995, 1000 (Fed. Cir. 2016). They are also pertinent to a problem the inventors were focused on, e.g., surgical techniques and instruments for correction of foot deformities. Ex.1003, ¶89.

VII. GROUNDS OF UNPATENTABILITY

A. Ground 1: McGlamry Anticipates Claims 1-3, 6-8, 10-13, and 16-17

1. Claim 1

a. Preamble

Claim 1’s preamble recites “an instrumented surgical technique for treating a bunion deformity.” To the extent the preamble is limiting, McGlamry discloses this. Ex.1003, ¶¶91-93.

McGlamry teaches a bunion correction surgery that includes cutting the medial end of the first metatarsal, cutting the distal end of the first cuneiform, correcting the position of the metatarsal in multiple planes, and fixing the medial portion of the moved first metatarsal to the distal portion of the cuneiform. *See* Ex.1005, 322-330, 808-809. McGlamry teaches using specific tools during the bunion surgery, e.g.:

- instruments to insert between the first and second metatarsals, for example a Freer elevator (*id.*, 808-809);

- a sagittal saw to cut the proximal end of the first metatarsal and the distal end of the medial cuneiform (*id.*, 808-809);
- weber clamps and/or K-wires to move the first metatarsal in one or more planes (*id.*, 325-326);
- K-wires to hold the first metatarsal in place prior to fixation (*id.*, 325-326); and
- various screws, locking plates, and drills to fix the metatarsal relative to the cuneiform and cause the bones to fuse (*id.*, 328-329).

As a single prior art reference, McGlamry describes a specific arthrodesis procedure across multiple chapters. Ex.1003, ¶¶92-93. In particular, McGlamry's Chapters 31 and 55 describe different aspects of the arthrodesis procedure and must be considered together as an example of the procedure. Chapters 31 and 55 are not directed to unrelated or mutually exclusive embodiments, but rather reflect different portions of a single reference addressing the same subject matter—first metatarsal-cuneiform arthrodesis—from complementary perspectives. *Id.*, ¶92; *see also* Ex.1005, 322-330, 808-809. Chapter 31 describes the specific surgical procedure, while Chapter 55 sets forth general arthrodesis principles intended to guide and inform such procedures. McGlamry explains that the principles described in Chapter 55 are broadly applicable across arthrodesis surgeries and are incorporated into common surgical practice to improve visualization, stability, and fusion outcomes.

A POSA reading McGlamry would therefore understand Chapter 31's procedure to be performed in accordance with the arthrodesis principles explained in Chapter 55. Ex.1003, ¶¶92-93. Treating Chapters 31 and 55 together does not require combining separate references or selecting among alternative embodiments, but instead reflects how McGlamry itself teaches and how a POSTA would naturally read and apply the disclosure, immediately enabling performance of a metatarso-cuneiform arthrodesis surgery in accordance with the principles of Chapter 55 as applied to the procedure of Chapter 31. *Id.*

b. Limitation 1[a]

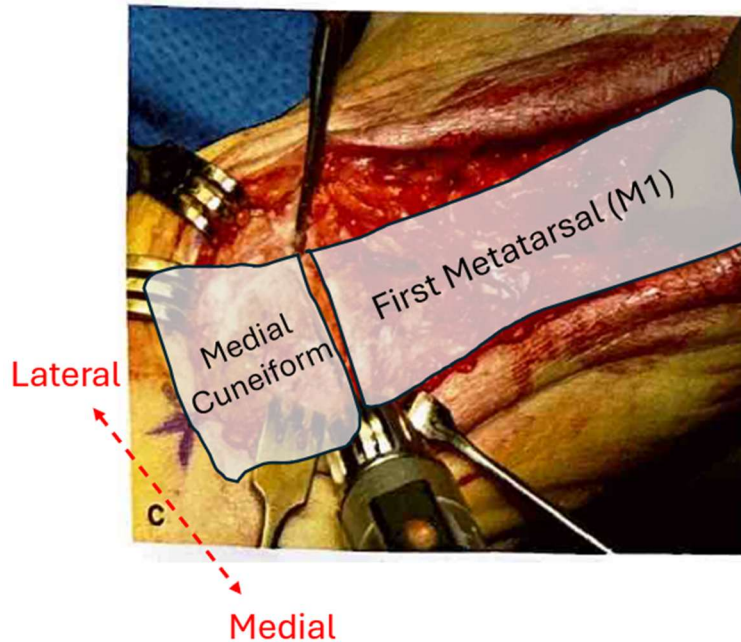
This limitation recites “inserting an instrument between a first metatarsal and a second metatarsal adjacent to the first metatarsal.” McGlamry discloses this. Ex.1003, ¶¶94-103. For example, McGlamry discloses inserting a surgical instrument such as a Freer elevator between the first and second metatarsals during the surgery. *Id.*, ¶¶100-101; Ex.1005, 808-809.

McGlamry describes a bunion correction technique with a dorsal approach (from the top side of the foot) where “an incision is made over the metatarsal-cuneiform joint.” Ex.1005, 324; *see generally id.*, 322-330, 808-809. The healed incision is shown below on the left, and on the right is the same photo with a post-operative x-ray overlayed by Dr. Neufeld:



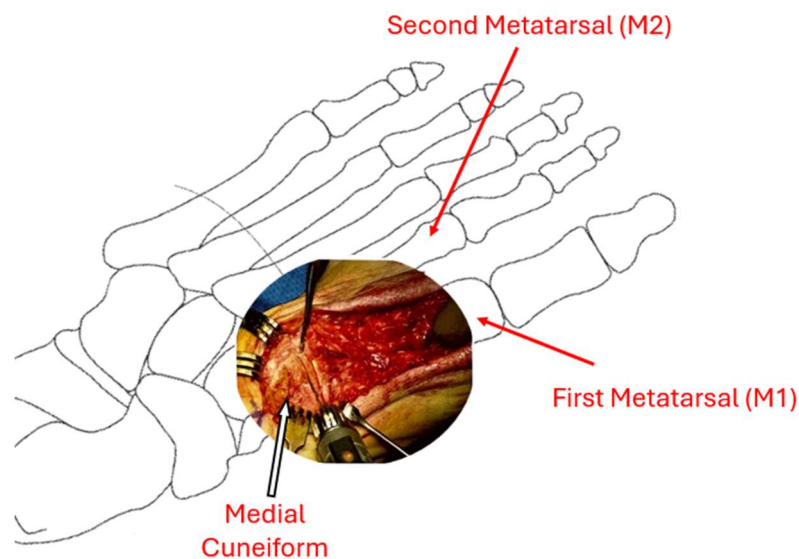
See Ex.1005 Figs.31.9D (left); Ex.1003, ¶¶95-96 (overlying McGlamry's Figs.31/9C-D).

During McGlamry's surgery, the metatarso-cuneiform joint is exposed using retractors, allowing the surgeon to visualize the joint. Ex.1005, 808. As shown below, the first metatarsal and medial cuneiform are in the immediate field of view. Ex.1003, ¶¶97-98, Ex.1005, 808. The first and second metatarsals are adjacent to one another, with the second metatarsal being disposed on the lateral side of the first metatarsal. Ex.1003, ¶98. In this image, the second metatarsal is above the first metatarsal because the image is taken from the medial side (inside) of the left foot. *Id.*, ¶¶98-99. The second metatarsal remains covered because dissection of those soft tissues is not necessary to fuse the first metatarsal and cuneiform. *Id.*



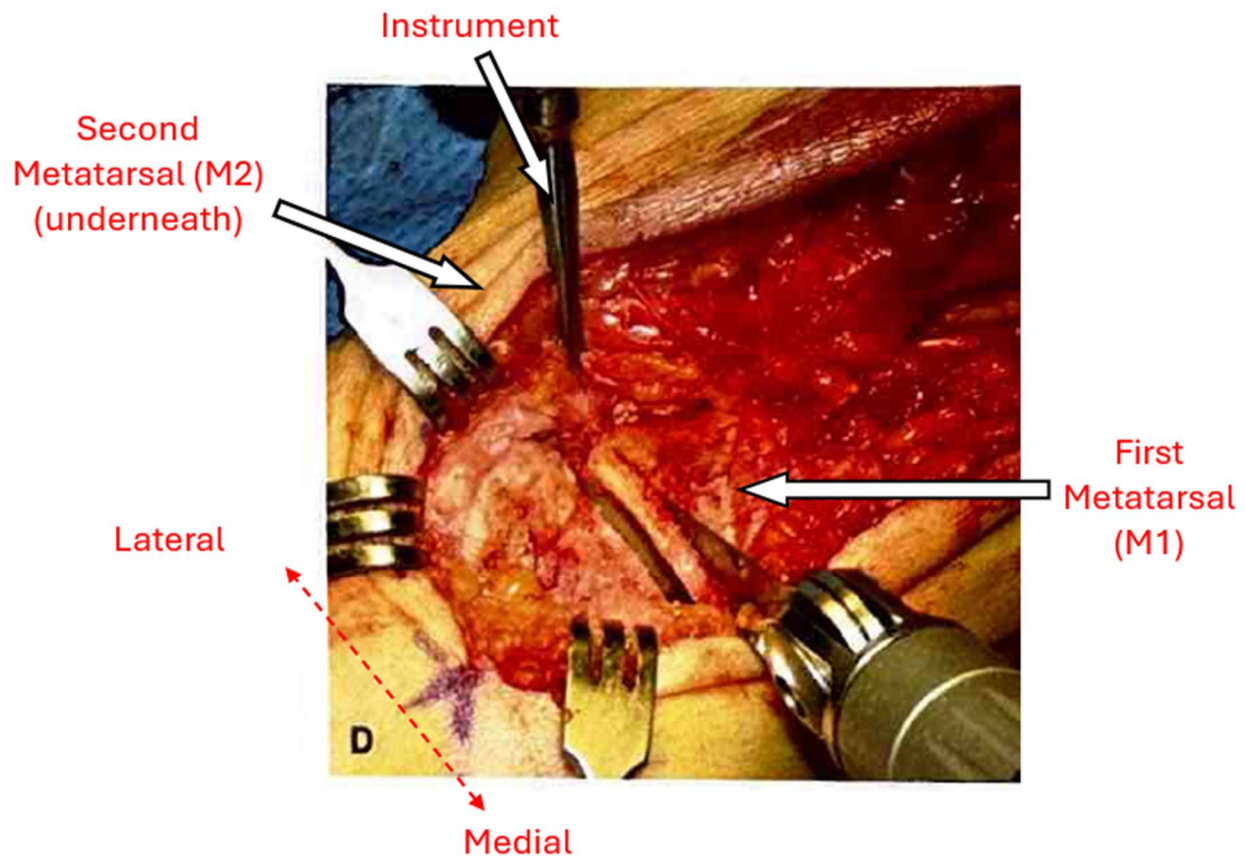
Ex.1003, ¶98 (annotating Ex.1005, Fig.55.7C).

Dr. Neufeld prepared the figure below to show the relative position of the first metatarsal, medial cuneiform, and instruments in Figures 55.7C-G relative to the other bones of the foot, including the second metatarsal. Ex.1003, ¶99.



Id. (overlying Fig.38 of the '428 patent with McGlamry Fig.55.7C).

As shown below, McGlamry discloses inserting an instrument on the lateral side of the first metatarsal and between the first and second metatarsals during the bunion correction surgery. Ex.1005, 808-809; Ex.1003, ¶100.

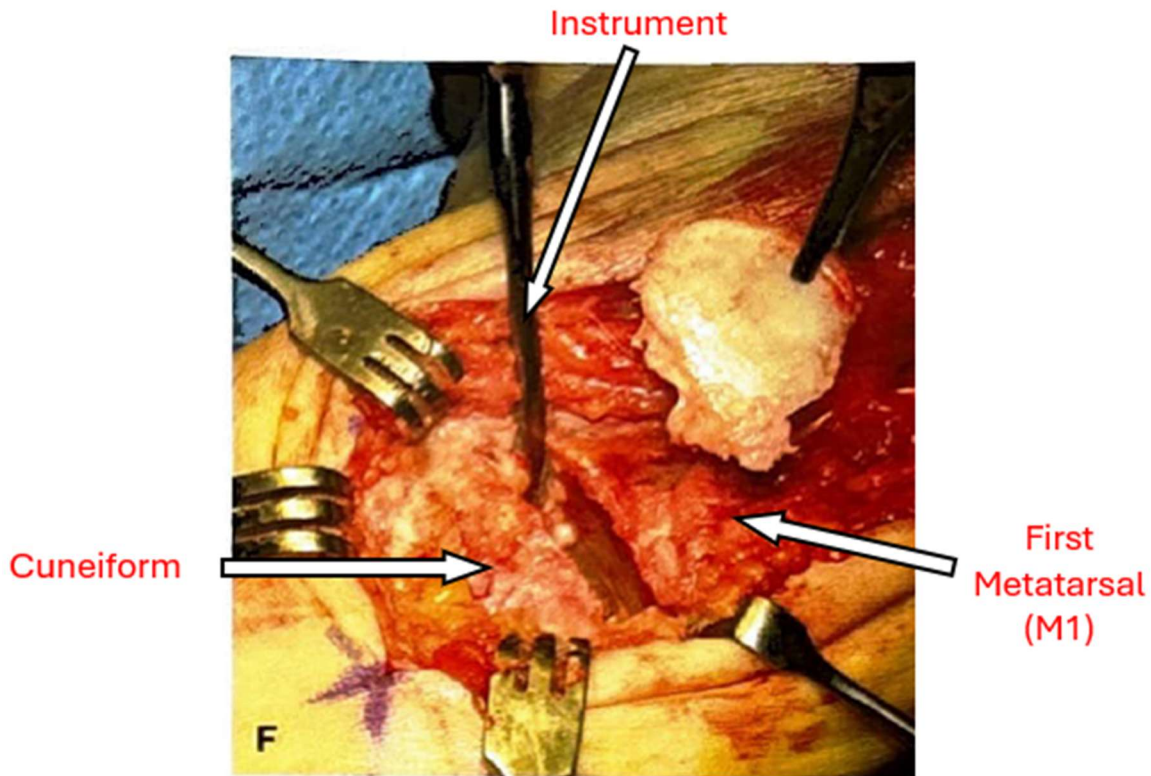


Ex.1003, ¶100 (annotating Ex.1005, Fig.55.7D).

McGlamry identifies this instrument between the metatarsals as a Freer elevator. *See id.*, 809; Ex.1003, ¶101. McGlamry also confirms that Freer elevators (shown below) are one of the “basic... podiatric surgical instruments.” Ex.1005, 3; *see also id.*, 8.



Ex.1005, Fig.1.21. Figure 55.7E depicts the depth of insertion of the end portion of McGlamry's instrument between the metatarsals. *See id.*, 809; Ex.1003, ¶101.



Ex.1003, ¶101 (annotating Fig.55.7F).

McGlamry's instrument is the same as those described in the embodiments of the '428 patent. Ex.1003, ¶¶102-103. For example, Figure 38 illustrates an instrument 356 inserted between a first metatarsal 210 and a second metatarsal 292. Ex.1001, 22:43-45. When Figure 38 is reoriented and reduced to the same field of view, McGlamry's figure and the '428 patent's Figure 38 show the same positioning of the instrument:

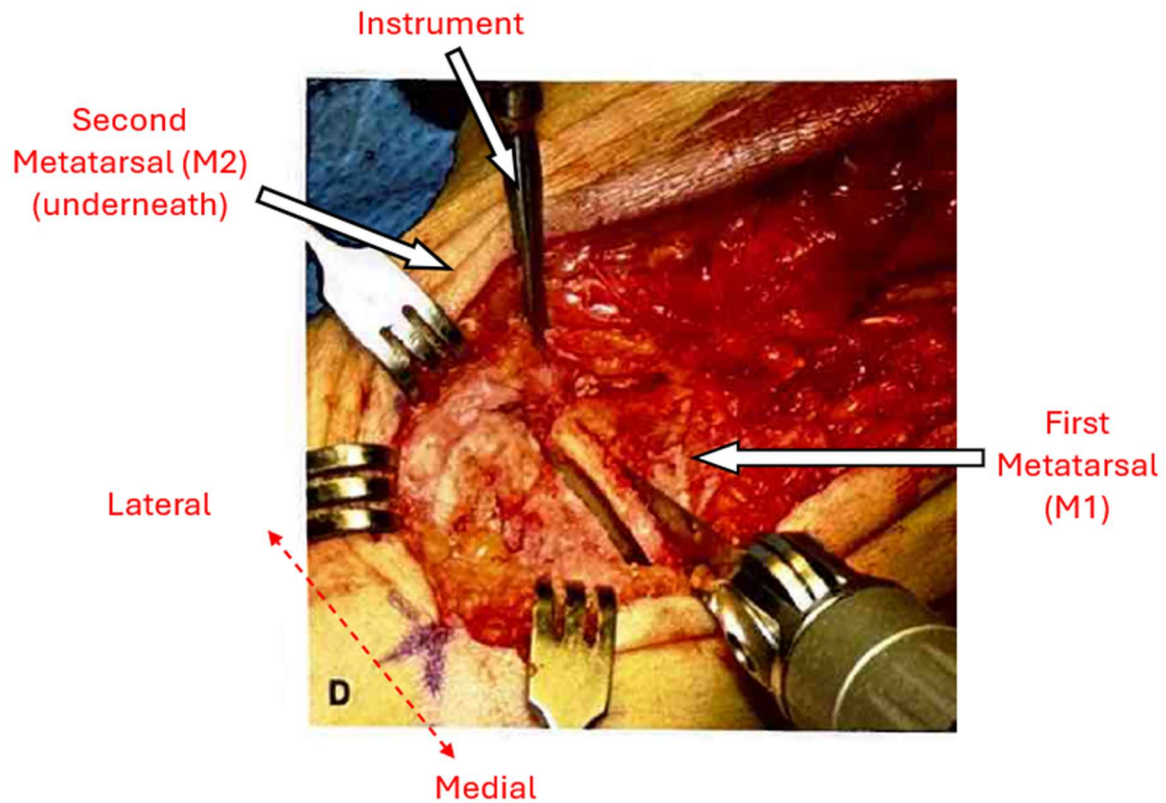


Fig. 55.7D of McGlamry (Annotated)

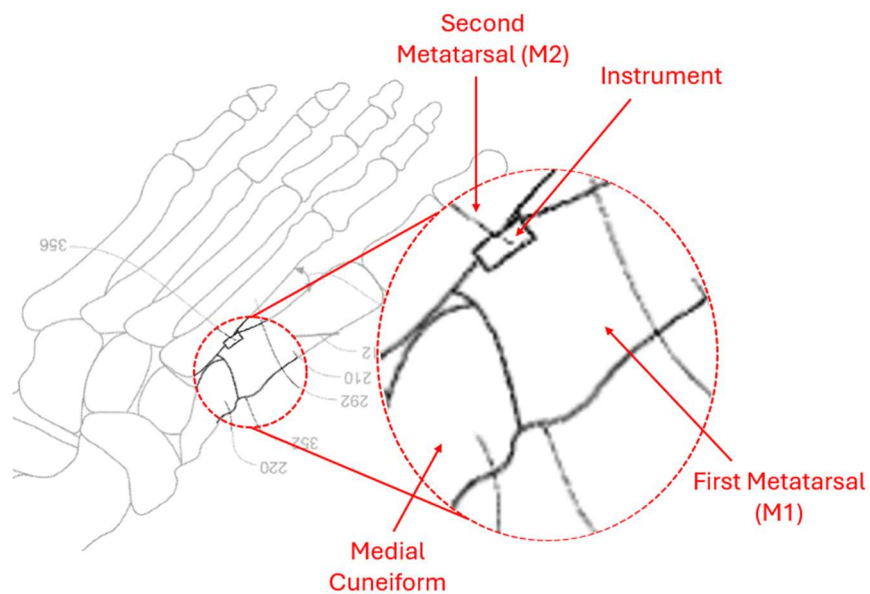
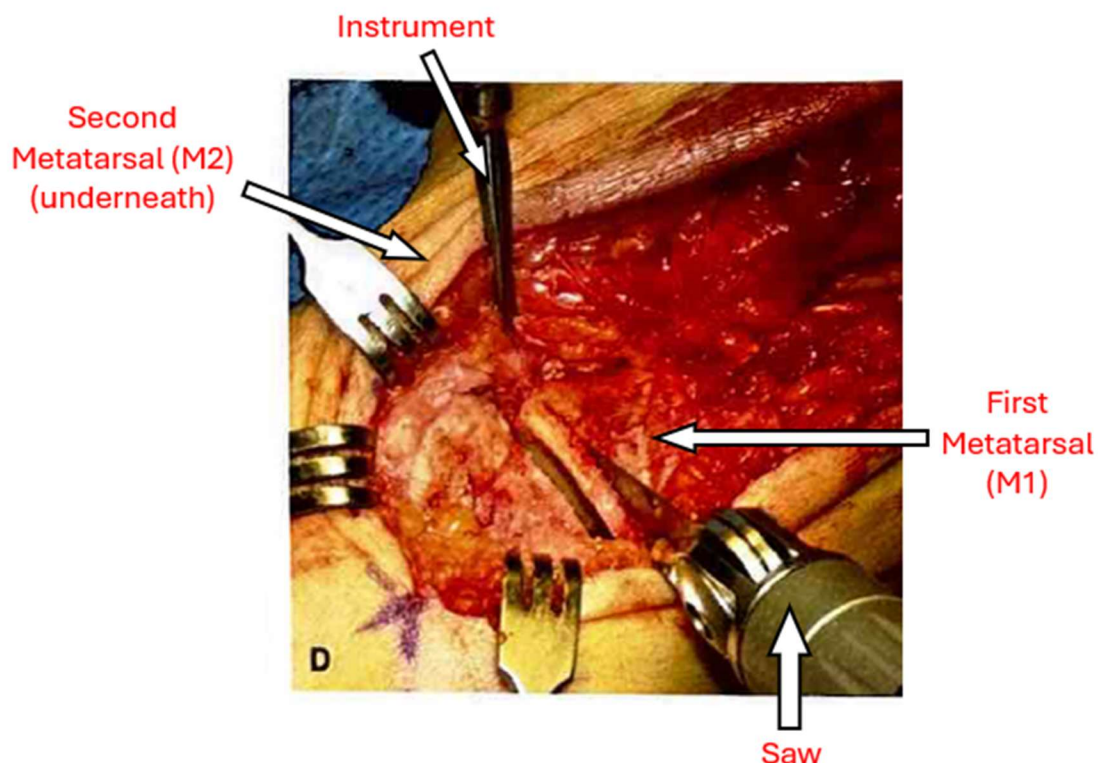


Fig. 38 of the '428 Patent (Reoriented and Annotated)

c. **Limitation 1[b]**

This limitation recites “with the instrument inserted between the first metatarsal and the second metatarsal, cutting an end of the first metatarsal.” McGlamry discloses this. Ex.1003, ¶104. For example, referring to Figure 55.7D, McGlamry describes “[r]emoval of the articular surface of the base of the first metatarsal.” Ex.1005, 808. As shown in Figure 55.7D below, the instrument (e.g., a Freer elevator) is positioned between the first and second metatarsals while the end of the first metatarsal adjacent to the cuneiform is cut with a sagittal saw. *Id.*; Ex.1003, ¶104.



Ex.1003, ¶104 (annotating Ex.1005, Fig.55.7D); *see also* Ex.1005, 324 (describing resection of the proximal end of the first metatarsal).

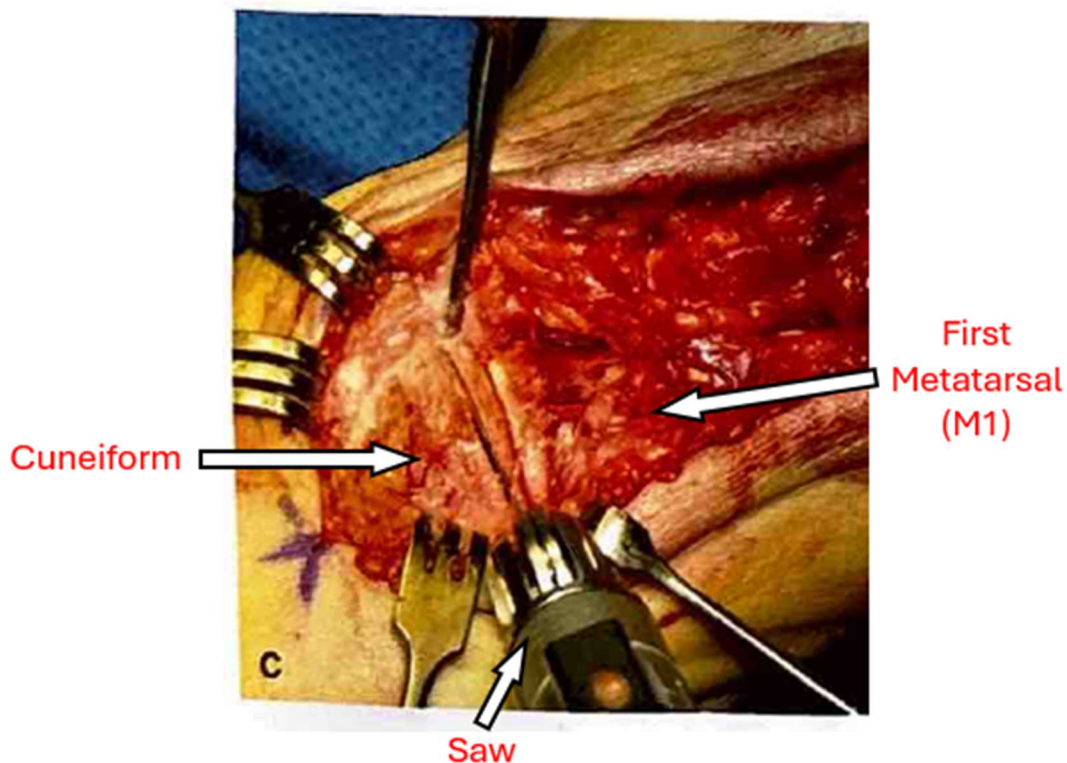
d. Limitation 1[c]

This limitation recites “moving the first metatarsal in at least one plane to treat the bunion deformity.” McGlamry discloses this. Ex.1003, ¶105. In fact, McGlamry discloses moving the first metatarsal in three anatomical planes to treat the bunion deformity. Ex.1005, 809 (Fig.55.7G, showing movement of the metatarsal); *see also id.*, 322 (discussing “tripplanar correction of the first metatarsal pathology”), 324-325; Ex.1003, ¶105. McGlamry explains that the first ray, including the metatarsal, is moved in the frontal plane by “derotat[ing] the hallux [big toe] out of valgus in order to get the nail plate to be parallel with the ground. 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.1005, 324. McGlamry also discloses movement of the first metatarsal in the sagittal plane toward the bottom of the foot “to a natural occurring level, parallel with the lesser metatarsals.” *Id.*, 325. McGlamry further describes correcting the position of the first metatarsal in the transverse plane by “reduc[ing] the first intermetatarsal angle.” *Id.*

e. Limitation 1[d]

This limitation recites “cutting an end of a medial cuneiform opposing the end of the first metatarsal.” McGlamry discloses this. Ex.1003, ¶106; Ex.1005, 809-809; *see also* Ex.1005, 322-330. For example, McGlamry discloses that a “resection

is made at the distal aspect of the convex-shaped cuneiform.” Ex.1005, 324. The distal end of the cuneiform is the end that opposes the end of the first metatarsal. Ex.1003, ¶106. Figure 55.7C below shows the “[r]esection of the articular surface of the medial cuneiform with the sagittal saw” at the end of the medial cuneiform opposing the end of the first metatarsal. Ex.1005, 808.



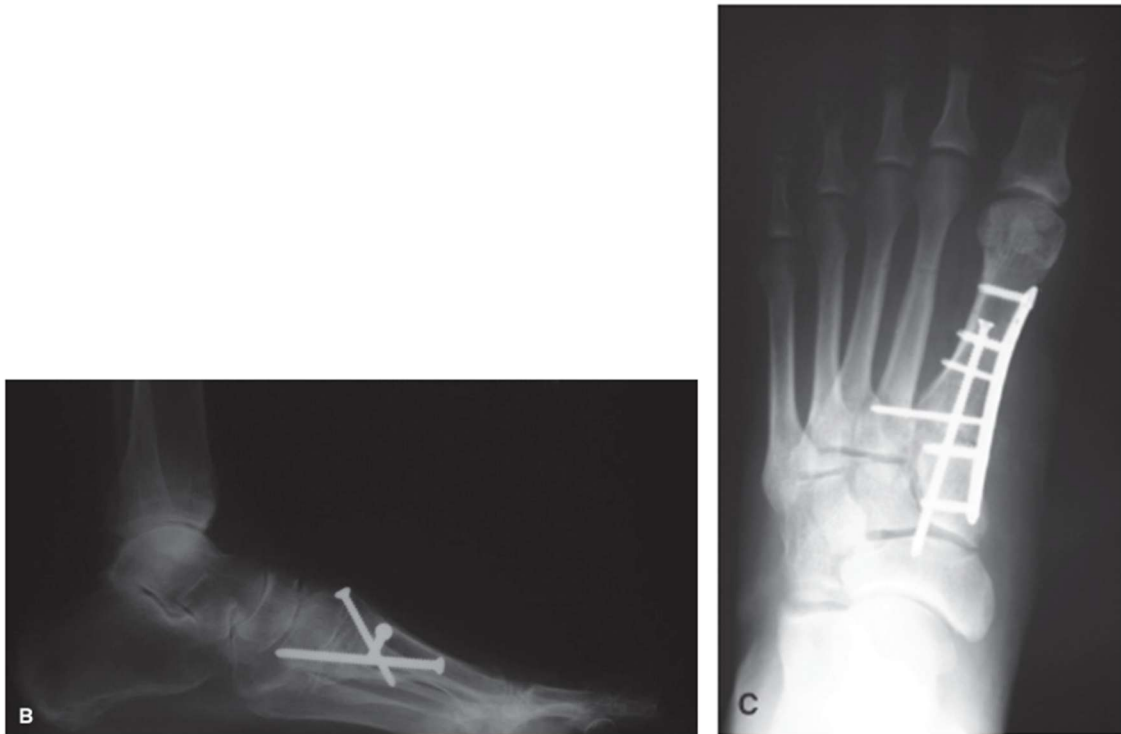
Ex.1003, ¶106 (annotating Ex.1005, Fig.55.7C).

f. Limitation 1[e]

This limitation recites “after moving the first metatarsal in at least one plane to treat the bunion deformity, fixating a moved position of the first metatarsal relative to the medial cuneiform using at least one bone fixation device.”

The '428 patent states that “the position of the bones can be fixed with one or more bone fixation devices (e.g., compressing bone screw, bone plate, bone staple, external fixator, intramedullary implant or nail)....” Ex.1001, 11:41-44.

McGlamry discloses this limitation. Ex.1003, ¶¶107-111. McGlamry discloses moving the first metatarsal in at least one plane to treat the bunion deformity, as explained above with respect to limitation 1[c]. *See* §VII.A.1.d. After moving the metatarsal to the moved position, McGlamry discloses fixating the first metatarsal relative to the medial cuneiform with a bone fixation device. Ex.1005, 808; *see also id.*, 326-327. For example, McGlamry explains that “interfragmentary compression of three solid cortical screws or an interfragmentary compression of solid cortical screw along with a medial based locking plate” can be used to fix the metatarsal and cuneiform. *Id.* Examples of McGlamry’s bone fixation devices fixating the metatarsal relative to the medial cuneiform are shown below in Figures 31.6B and 31.9C:



Id., Fig.31.6B (left) (depicting three cortical screws); Fig.31.9C (right) (depicting screws and a medial locking plate).

This disclosure satisfies “fixation device” under its plain and ordinary meaning discussed in Section V.C. Ex.1003, ¶110. Under §112(f), McGlamry’s across-joint screws and/or plate are the same types of fixation structures identified in the ’428 patent (e.g., screws/plates) and thus constitute the corresponding structure (or at least an equivalent) for fixing the moved position for fusion. *Id.*

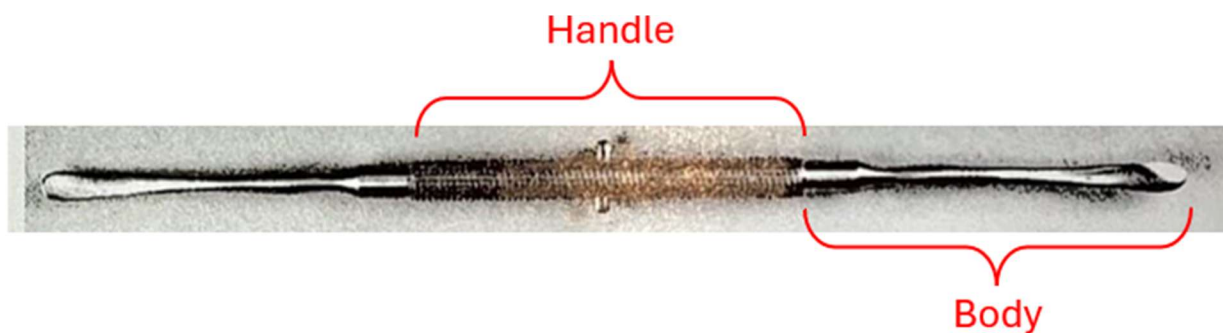
Because McGlamry discloses each limitation of claim 1, McGlamry anticipates claim 1.

2. Claim 2

Claim 2 depends from claim 1 and recites: “wherein: [2a] the instrument has a body and a handle operatively connected to the body; [2b] the handle extends from the body; and [2c] inserting the instrument between the first metatarsal and the second metatarsal comprises inserting the body between the first metatarsal and the second metatarsal and thereby positioning the handle extending laterally over a dorsal surface of the second metatarsal.” McGlamry’s discloses an instrument that meets these structural limitations and is used in this manner as part of its bunion correction surgery. Ex.1003, ¶¶112-115.

a. Limitations 2[a]-2[b]

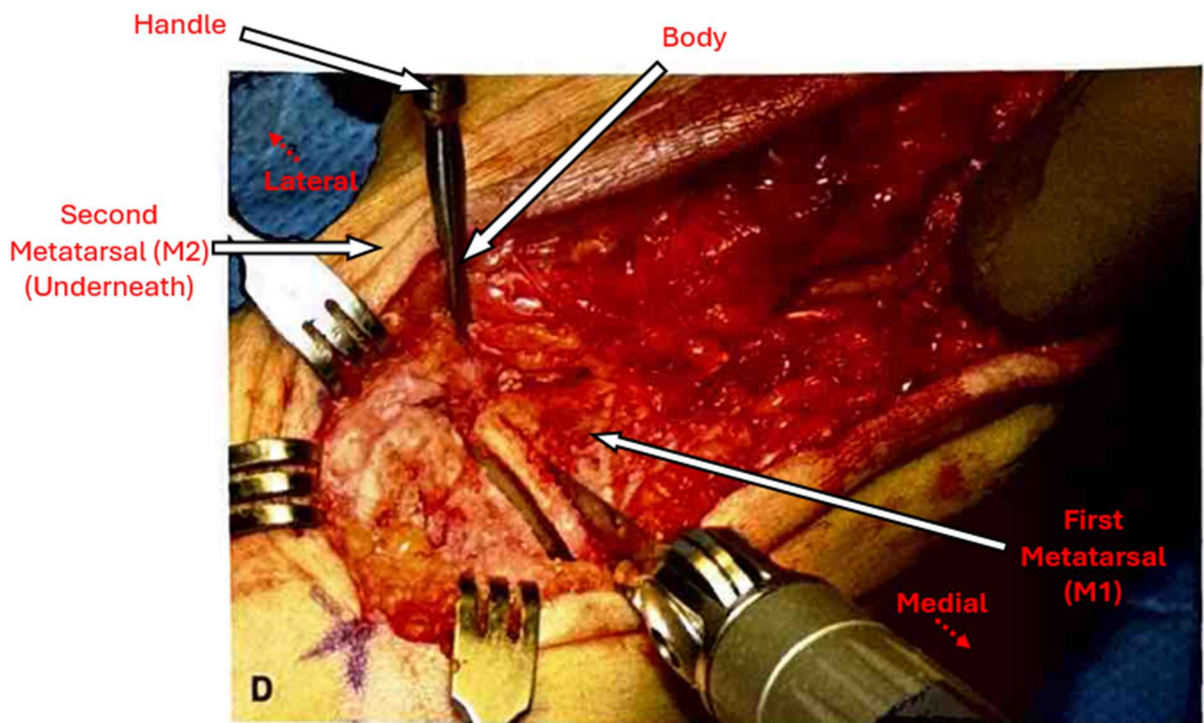
McGlamry’s discloses that the Freer elevator instrument positioned between the metatarsals has a body with a handle that is operatively connected to the body and extending from the body. Ex.1003, ¶113; Ex.1005, 8 (“One end of the Freer elevator is semisharp, whereas the other is blunt.”). *Id.* The middle of the Freer elevator has a textured handle that extends from the body portion, which is inserted between the bones as shown below. *Id.*; Ex.1003, ¶113.



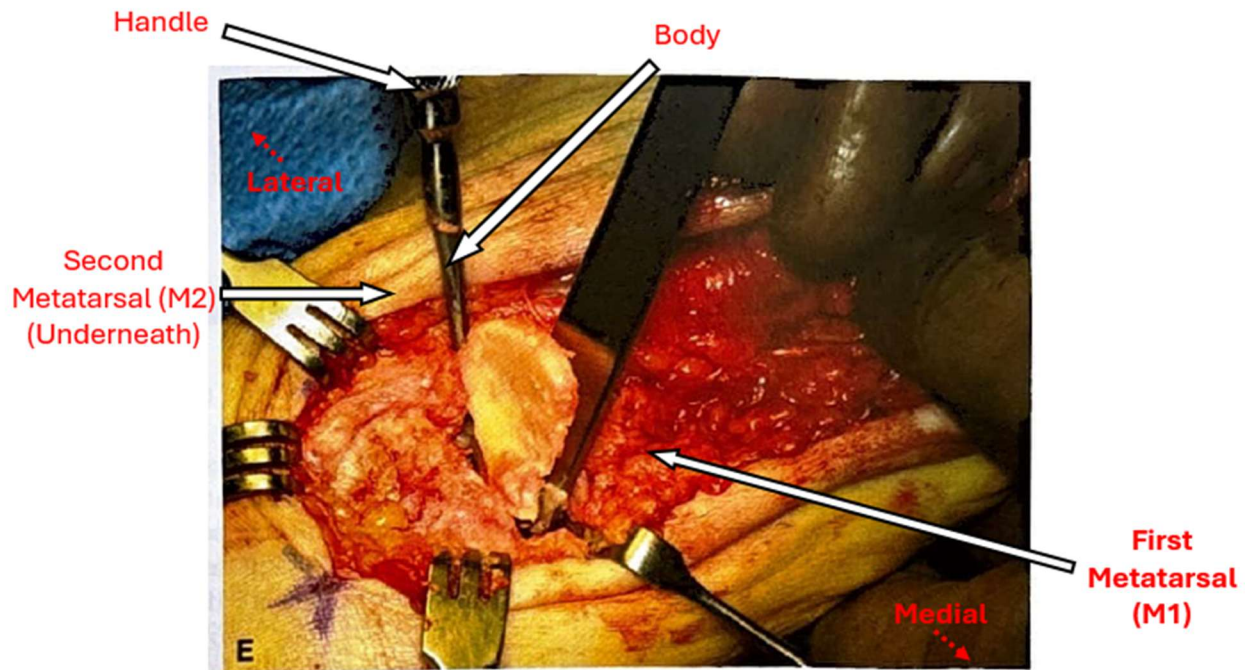
Ex.1003, ¶113 (annotating Ex.1005, Fig.1.21).

b. Limitation 2[c]

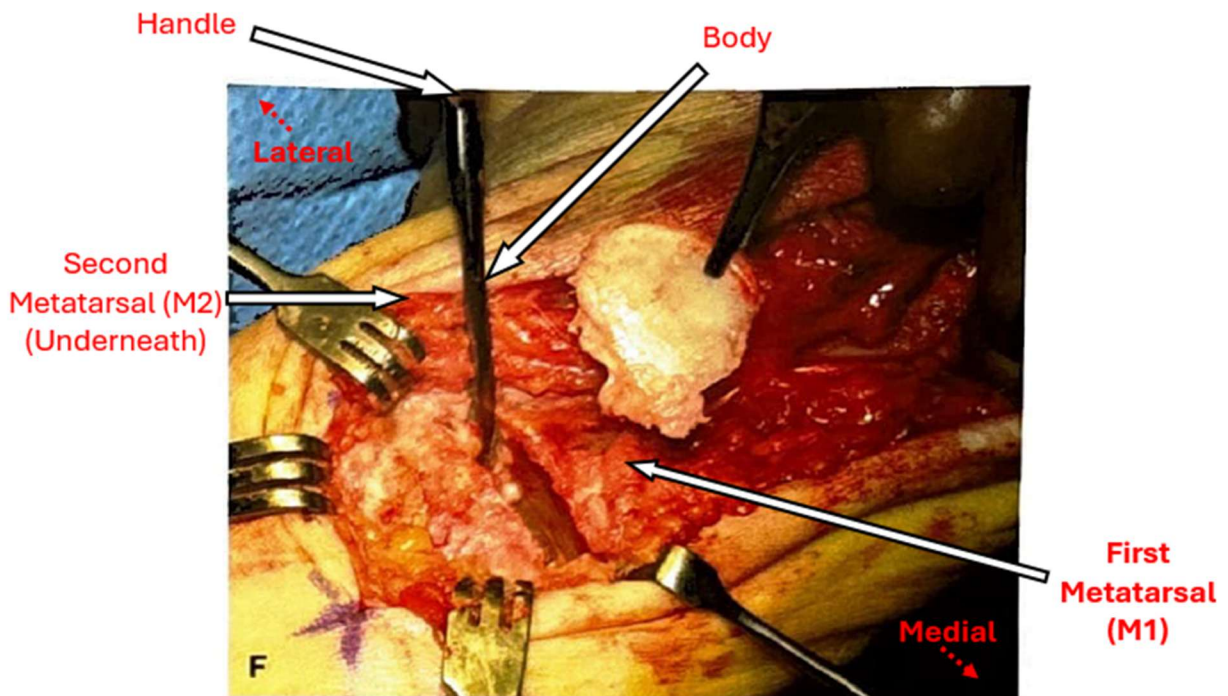
As shown below in Figures 55.7D-F, the body portion of McGlamry's Freer elevator instrument is inserted between the first and second metatarsals. Ex.1003, ¶114. As discussed, the second metatarsal is disposed adjacent to the first metatarsal underneath the soft tissue. *See* §VII.A.1.b, *supra*. As shown below, the Freer elevator is inserted from the lateral side such that the handle of the Freer (the bottom of which is shown in Figure 55.7D) extends laterally over a dorsal (top) surface of the second metatarsal. Ex.1005, 808-809; Ex.1003, ¶114.



Ex.1003, ¶114 (annotating Ex.1005, Fig.55.7D).



Id., ¶114 (annotating Ex.1005, Fig.55.7E)



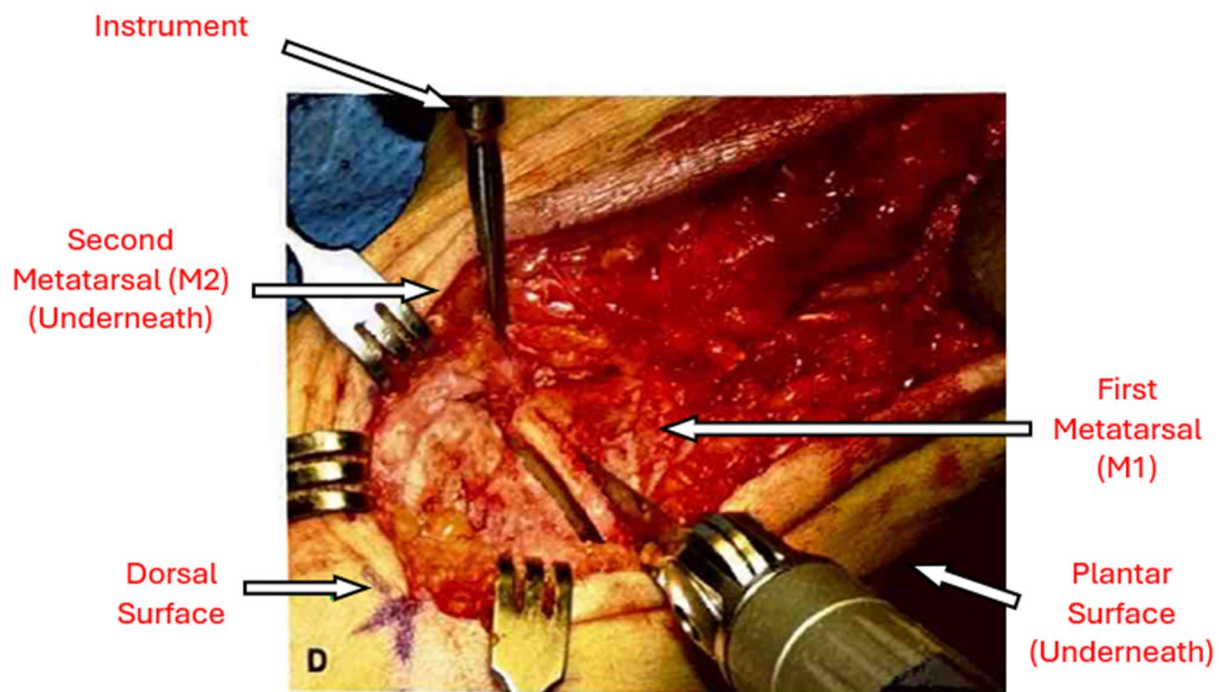
Id., ¶114 (annotating Ex.1005, Fig.55.7F).

Thus, McGlamry's anticipates claim 2.

3. Claim 3

Claim 3 depends from claim 2 and recites: “wherein inserting the body between the first metatarsal and the second metatarsal comprises inserting the body from a dorsal side of a foot toward a plantar side of the foot.”

McGlamry discloses this additional limitation. Ex.1003, ¶¶116-118. As discussed above, McGlamry discloses a dorsal approach to bunion correction procedures. *See* §VII.A.1.b, *supra*. An incision is made on the dorsal (top) surface of the foot, and the instruments are inserted toward the plantar (bottom) surface of the foot. *Id.* McGlamry also discloses inserting the Freer elevator instrument through the incision on the dorsal (top) side of the foot toward the plantar (bottom) side, as shown in Figure 55.7D below. Ex.1003, ¶117.



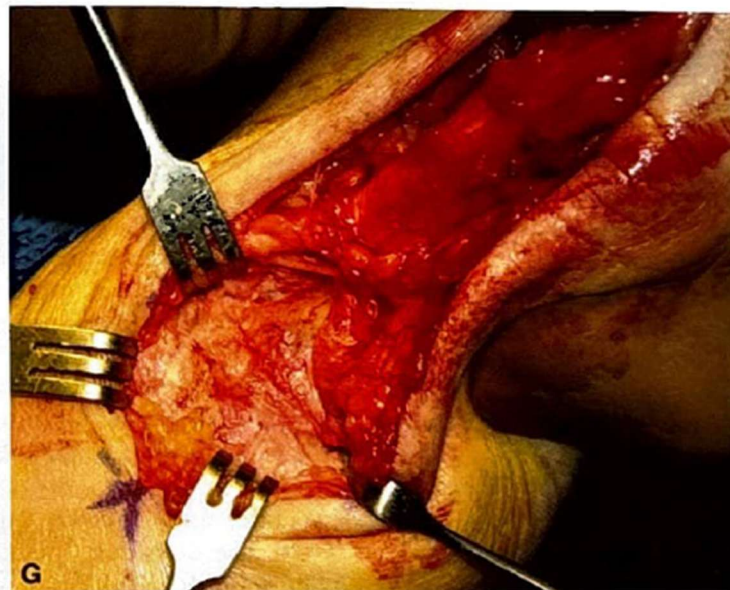
Id. (annotating Ex.1005, Fig.55.7D).

Thus, McGlamry anticipates claim 3.

4. Claim 6

Claim 6 depends from claim 1 and recites: “further comprising, after cutting the end of the first metatarsal, removing the instrument from between the first metatarsal and the second metatarsal.”

McGlamry discloses this additional limitation. Ex.1003, ¶¶119-120. As explained above, McGlamry discloses cutting the end of the first metatarsal while the instrument is positioned between the first and second metatarsals. *See* §VII.A.1.c, *supra*. After the metatarsal is cut and the bone fragment is removed, the instrument is removed. Ex.1003, ¶120; Ex.1005, 808-809. Figure 55.7G below depicts the “final appearance of the first metatarsal cuneiform joint after planar resection,” with the instrument shown in Figures 55.7C-F removed from between the first and second metatarsals.

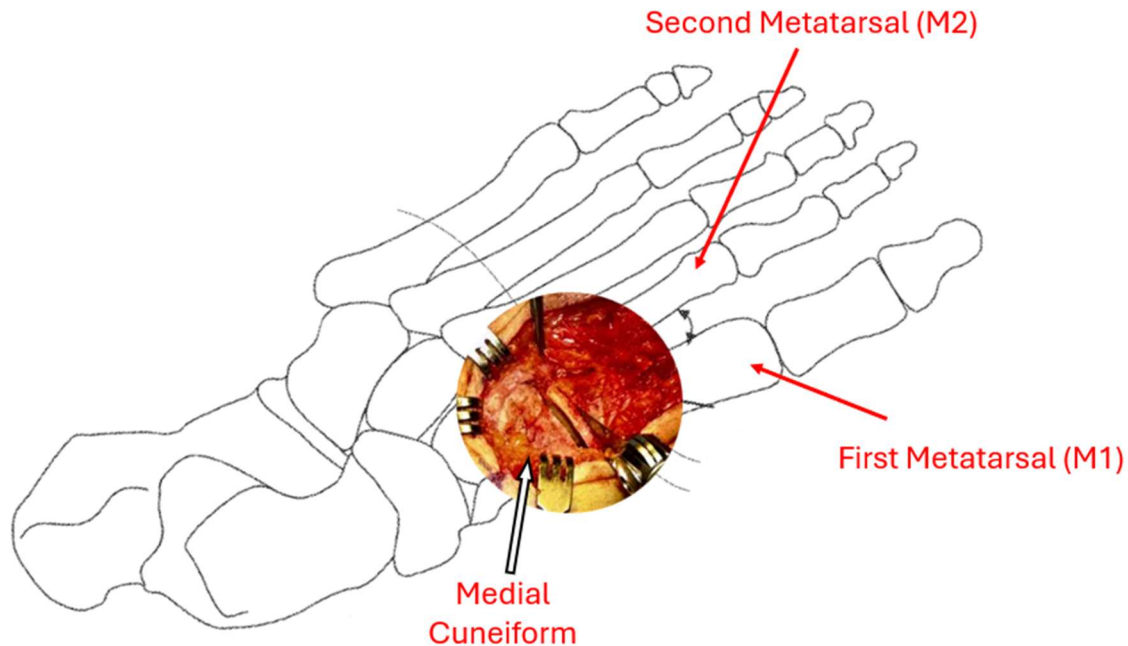


Ex.1005, Fig.55.7G.

5. Claim 7

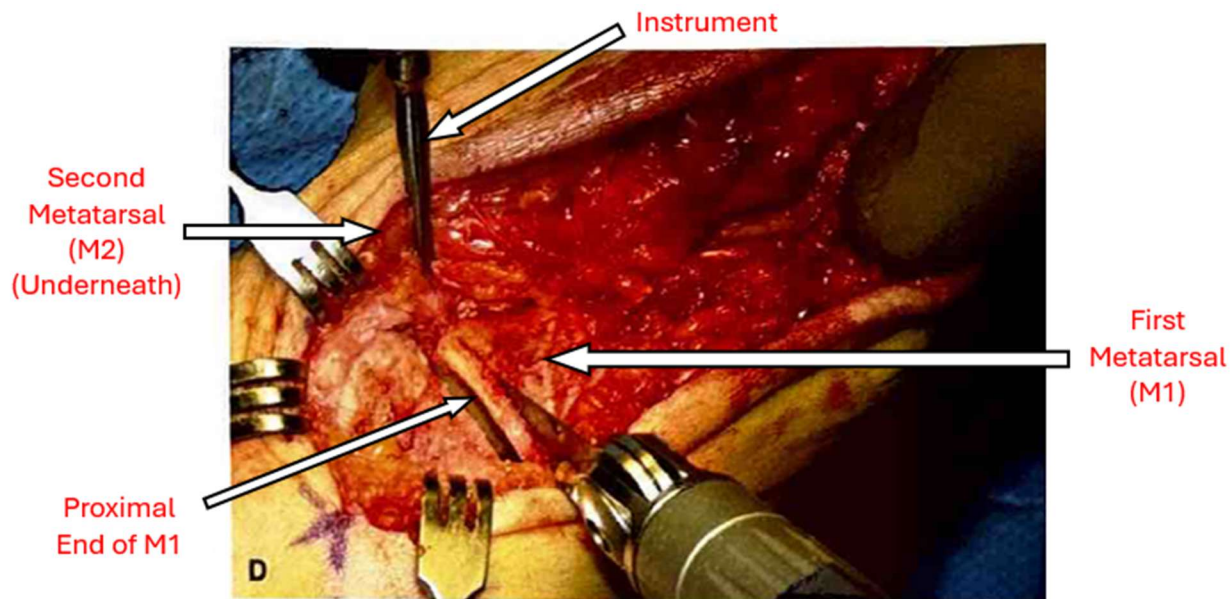
Claim 7 depends from claim 1 and recites: “wherein positioning the instrument between the first metatarsal and the second metatarsal comprises positioning the instrument between a proximal-most third of the first metatarsal and a proximal-most third of the second metatarsal.”

McGlamry discloses this additional limitation. Ex.1003, ¶¶121-123. For example, McGlamry discloses positioning the Freer elevator between the first and second metatarsals at the proximal end of the first metatarsal, within the proximal-most third of each metatarsal. Ex.1005, 808-809; Ex.1003, ¶¶122-123. Figure 55.7D shows resection of the proximal end of the first metatarsal, which is disposed within the proximal third of the second metatarsal as shown below.



Ex.1003, ¶123.

This placement situates the instrument between the proximal-most thirds of the first and second metatarsals. Ex.1005, 808-809; Ex.1003, ¶123.



Ex.1003, ¶123 (annotating Ex.1005, Fig.55.7D).

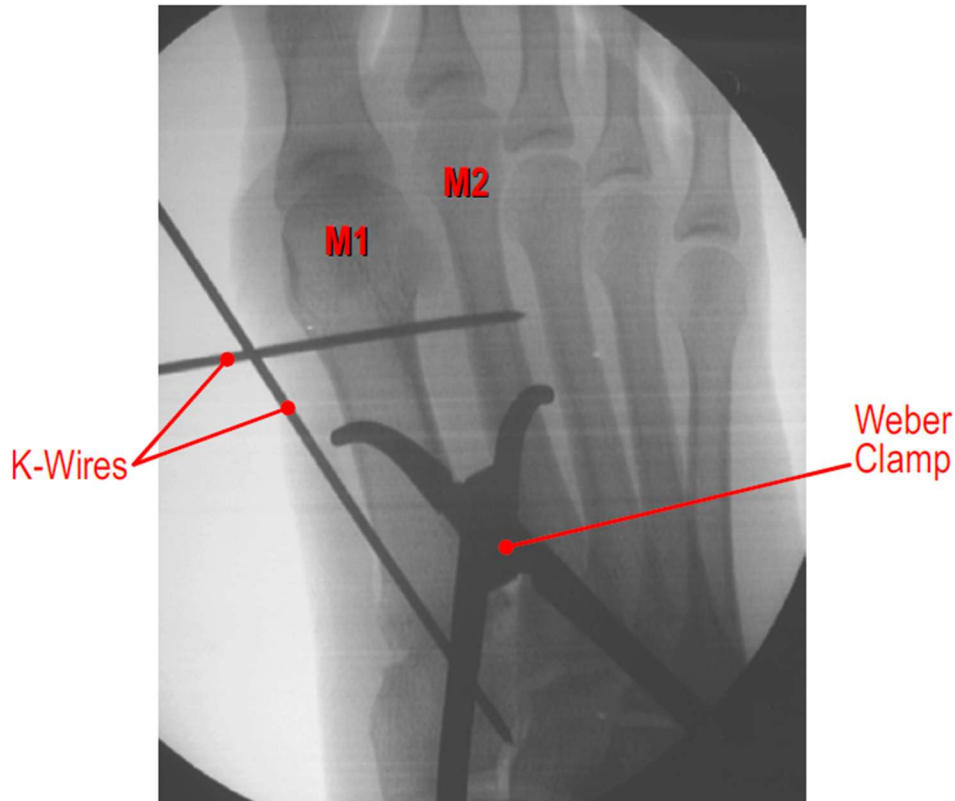
Thus, McGlamry anticipates claim 7.

6. Claim 8

Claim 8 depends from claim 1 and recites: “wherein moving the first metatarsal in at least one plane comprises moving the first metatarsal relative to the second metatarsal in a transverse plane by applying a force to the first metatarsal with a bone positioning guide and thereby reducing an intermetatarsal angle between the first metatarsal and the second metatarsal.”

McGlamry discloses this additional limitation. Ex. 1003, ¶¶124-128. McGlamry discloses moving the first metatarsal in at least one plane relative to the second metatarsal, including movement in a transverse plane to reduce the first intermetatarsal angle, as explained above for claim 1. *See* §VII.A.1.d, *supra*; Ex.1005, 325 (“[T]he surgeon can use his or her thumb against the first metatarsal to manually reduce the first intermetatarsal angle in the transverse plane”), 809 (Fig.55.7G). McGlamry also discloses using instruments to move the first metatarsal in one or more planes, including the transverse plane. *See* Ex.1005, 325-326; Ex.1003, ¶125. For example, McGlamry explains that “a large Weber clamp may be used to assist, increase, or maintain the reduction” of the first metatarsal. Ex.1005, 325; Ex.1003, ¶125. McGlamry’s Figure 31.5 (below) is an x-ray depicting “a case in which a large Weber clamp was used for reduction of a large

[intermetatarsal] angle,” i.e. used to move the first metatarsal toward the second metatarsal in the transverse plane to reduce the angle. Ex.1005, 326.



Ex.1003, ¶125 (annotating Ex.1005, Fig.31.5).

The use of bone holding clamps to move the first metatarsal in the transverse plane during bunion correction surgery was common among surgeons before the earliest claimed priority date of the '428 patent. Ex.1003, ¶126. Bone holding clamps, such as the Weber clamp, are “basic [] podiatric surgical instruments” used to position bones relative to one another. Ex.1005, 3, 10 (describing how clamps are used to “grasp bone[s] and hold bony fragments together”); Ex.1003, ¶126. McGlamry discloses that clamps (e.g., Weber clamps) and tenaculum are both used

for similar purposes and would be considered the same class of instruments by a POSA. *See* Ex.1005, 10; Ex.1003, ¶126.

McGlamry’s Weber clamp is a bone positioning guide under any construction discussed in Section V.B, as it is a type of tenaculum and is used to position bones, including moving the metatarsal in the transverse plane. Ex.1003, ¶127. Under §112(f), McGlamry’s Weber clamp is identical or at least equivalent to structures identified in the ’428 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.*

Thus, McGlamry anticipates claim 8.

7. Claims 10-11

Claim 10 depends from claim 8 and recites: “wherein moving the first metatarsal in at least one plane further comprises moving the first metatarsal in a frontal plane.” Claim 11 depends from claim 10 and recites: “wherein moving the first metatarsal in the frontal plane comprises imparting a force to a pin inserted into

the first metatarsal to adjust an alignment of the first metatarsal in the frontal plane to treat the bunion deformity.”

McGlamry discloses these additional limitations. Ex.1003, ¶¶129-133. McGlamry discloses moving the first metatarsal in a frontal plane, as explained for limitation [1c]. *See* §VII.A.1.d, *supra*. McGlamry further discloses that “the frontal plane is addressed [by] derotat[ing] the hallux out of valgus in order to get the nail plate to be parallel with the ground. 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.1005, 324 (emphasis added), *see also id.*, 325 (“[t]he primary surgeon must ensure that the first metatarsal is in the desired position, which is essentially rotated out of valgus”); Ex.1003, ¶130.

McGlamry also discloses the use of a pin inserted into the first metatarsal to rotate and adjust the alignment of the first metatarsal in the frontal plane. Ex.1003, ¶¶131-133. For example, McGlamry explains that “[i]f the surgeon feels a need to obtain more correction in the frontal plane, the K-wire can be inserted into the first metatarsal medial and lateral cortex...”³ Ex.1005, 326. “Once the K-wire penetrates

³ A K-wire is a pin. Ex.1003, ¶132; *see also* Ex.1027, 1 (“A century ago, in 1909, Martin Kirschner (1879-1942) introduced a smooth pin, presently known as the Kirschner wire (K-wire).”). In a bunion correction procedure, K-wires and other

the far cortex of the metatarsal, the K-wire can be used as a rotation device and rotate the metatarsal into more of a neutral position.” *Id.* By applying force to the K-wire, the surgeon adjusts the metatarsal in the frontal plane. *See id.*; Ex.1003, ¶133. McGlamry’s K-wire “rotation device” is used in addition to—not instead of—other means of repositioning the metatarsal, such as the Weber clamp. Ex.1003, ¶133.

McGlamry thus anticipates claims 10-11.

8. Claim 12

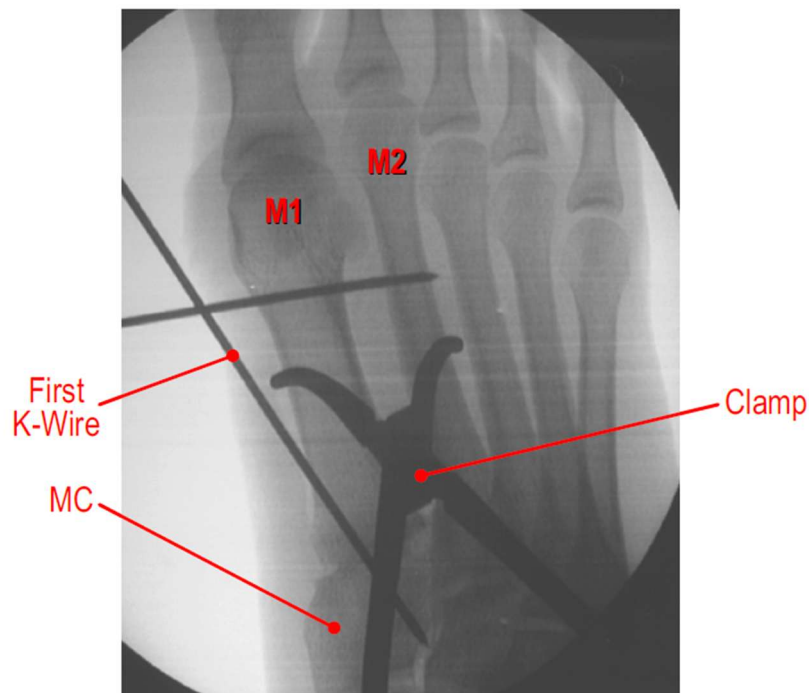
Claim 12 depends from claim 1 and recites: “further comprising compressing the first metatarsal together with the medial cuneiform prior to fixing the moved position of the first metatarsal relative to the medial cuneiform using the at least one bone fixation device.”

The ’428 patent discloses that “[a]fter preparation, the ends of the two bones can be placed in apposition and optionally compressed together by provisionally fixating the joint.” Ex. 1001, 14:3-5. For example, “a compression pin, such as a threaded olive pin, is inserted through the first metatarsal and into the medial

pins (e.g., Steinman pins) are used interchangeably for temporary fixation. *See, e.g.*, Ex.1010, 487 (disclosing temporary fixation by K-wire or Steinman pin in a bunion correction procedure); Ex.1028, 349 (interchangeable use of pins and wires).

cuneiform to provide compression and provisional fixation between the first metatarsal and the medial cuneiform.” *Id.*, 21:25-30.

McGlamry discloses this additional limitation. Ex.1003, ¶¶134-137. For example, McGlamry discloses that the surgeon places the metatarsal in a corrected position against the medial cuneiform and then inserts K-wires to “stabilize the position.” *See* Ex.1005, 325-326. A K-wire is inserted through the proximal end of the metatarsal and into the cuneiform and used to assist in compressing the bones together in the moved position, as shown below in Figure 31.5. *Id.*, 326; Ex.1003, ¶136.



Ex.1003, ¶136 (annotating Ex.1005, Fig.31.5C).

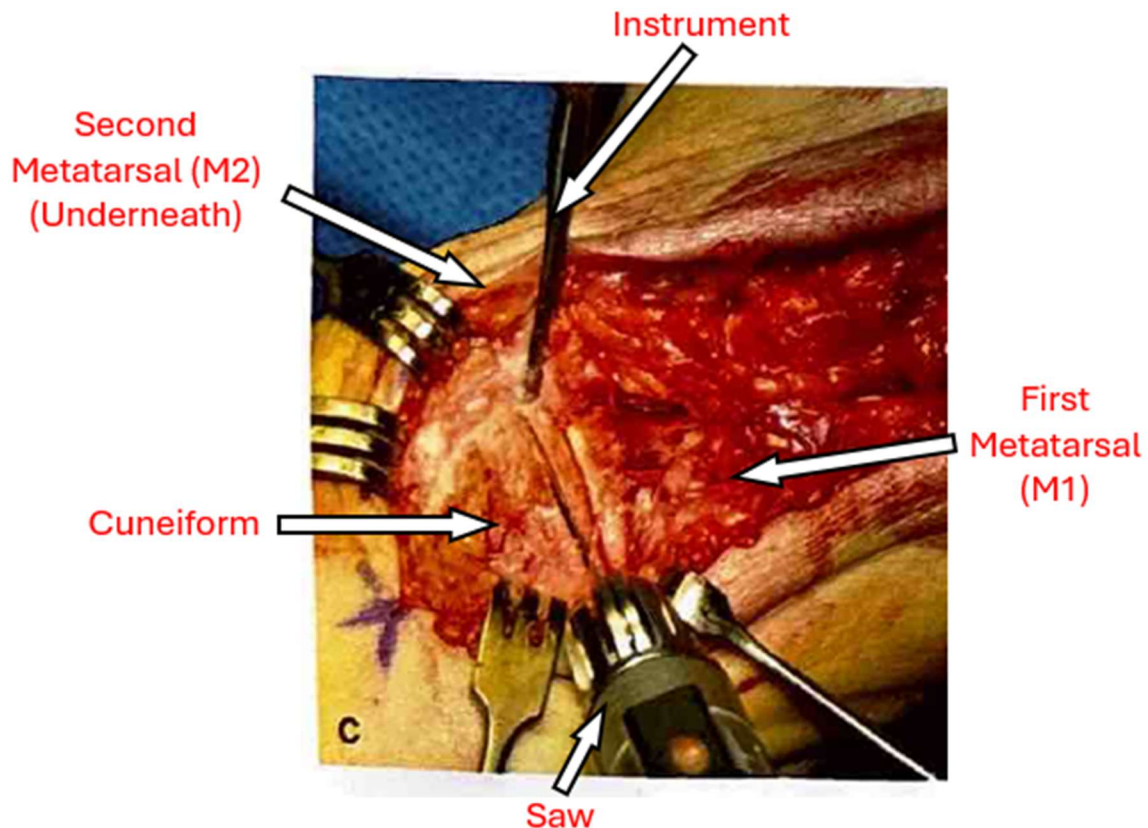
After “acceptable alignment” of the bones is confirmed, a “homerun screw” is further placed into the metatarsal and cuneiform, securing and compressing the bones. *See* Ex.1005, 324 (describing joint preparation), 326 (describing compression occurring after preparation); Ex.1003, ¶137. McGlamry’s describes installing a plate or screws (fixation devices) after the placement of the “homerun screw”: “Following the insertion of the homerun screw, the initial screws are placed proximal in the medial cuneiform of the plate in combination of lock and nonlocking screws. The distal screws are placed into the metatarsal with a combination of locking and nonlocking screws.” Ex.1005, 327; Ex.1003, ¶137. Thus, McGlamry anticipates claim 12.

9. Claim 13

Claim 13 depends from claim 1 and recites: “wherein cutting the end of the medial cuneiform comprises cutting the end of the medial cuneiform with the instrument inserted between the first metatarsal and the second metatarsal.”

McGlamry discloses this additional limitation. Ex.1003, ¶¶138-139. McGlamry discloses cutting the end of the medial cuneiform with the Freer elevator instrument inserted between the first and second metatarsals. *Id.*, ¶139. For example, Figure 55.7C depicts “[r]esection of the articular surface of the medial cuneiform with the sagittal saw.” Ex.1005, 809. In Figure 55.7C, the instrument

(e.g., Freer elevator) is shown inserted between the first and second metatarsals while the sagittal saw is shown cutting the cuneiform. *Id.*, 808; Ex.1003, ¶139.



Ex.1003, ¶139 (annotating Ex.1005, Fig.55.7C).

McGlamry thus anticipates claim 13.

10. Claim 16

Claim 16 depends from claim 1 and recites: “wherein the at least one bone fixation device comprises at least one of a screw and a plate.”

McGlamry discloses this additional limitation. Ex.1003, ¶¶140-141. McGlamry discloses bone fixation devices including at least one of a screw and a

plate. Ex.1005, 326 (“[F]ixation techniques consist of ... an interfragmentary compression of solid cortical screw along with a medial based locking plate.”); Ex.1003, ¶141.

Thus, McGlamry anticipates claim 16.

11. Claim 17

Claim 17 depends from claim 1 and recites: “wherein the at least one bone fixation device comprises an intramedullary implant.”

McGlamry discloses this additional limitation. Ex.1003, ¶¶142-143. McGlamry discloses bone fixation devices including three intramedullary screws. Ex.1005, 326 (“[F]ixation techniques consist of interfragmentary compression of three solid cortical screws....”). A POSA would understand the screws to be intramedullary implants. Ex.1003, ¶143.

B. Ground 2: McGlamry Renders Claims 1-3, 6-8, 10-13, and 16-17 Obvious

To the extent Treace argues that the McGlamry disclosures identified in Ground 1 reflect “separate” embodiments—i.e., that Chapter 31 and Chapter 55 should not be read together or that their teachings therefore cannot anticipate the claim limitations—it also would have been obvious to combine these disclosures. Ex.1003, ¶¶144-149. Chapter 55 is expressly directed to general “Principles of Arthrodesis” and explains that those principles have been adopted and integrated into common surgical practice to “greatly enhance surgical visualization and

stability in arthrodesis,” providing a more predictable fusion of the bones. *See* Ex.1005, 803, 322-30; Ex.1003, ¶¶145-146. Those principles are not limited to a single joint or single procedure; rather, they are applicable across arthrodesis surgeries, including the first metatarsal-cuneiform arthrodesis described in Chapter 31. Ex.1005, 803, 808-809; Ex.1003, ¶145.

A POSA would have been motivated to apply the Chapter 55 arthrodesis principles to the Chapter 31 procedure to improve fusion reliability and reduce known complications such as delayed union, nonunion, malunion, or loss of correction. *See* Ex.1005, 803 (describing principles that enhance visualization and stability in arthrodesis), 324 (Chapter 31 emphasizing that “[j]oint preparation is extremely important in efforts to obtain a bony union and to avoid a delayed and nonunion” and recommending surgeons devote a “substantial period of time...preparing this [metatarsal-cuneiform] joint”); Ex.1003, ¶146. Consistent with that objective, Chapter 55 describes resection approaches that promote close-fitting apposition of the fusion surfaces—principles directly relevant to a metatarsal-cuneiform fusion. *See* Ex.1005, 804-806, 808-809; Ex.1003, ¶146. Chapter 55’s surgical strategy and exposure techniques are designed to improve visualization and facilitate proper positioning and stable fixation—again, considerations that Chapter 31 identifies as important for achieving union and avoiding complications in the

metatarsal-cuneiform arthrodesis context. *See* Ex.1005, 803-805, 324, 329; Ex.1003, ¶146.

Combining the teachings of Chapters 31 and 55 constitutes nothing more than application of known arthrodesis principles and techniques to a known first metatarsal-medial cuneiform arthrodesis procedure to improve fusion reliability and reduce complications. Ex.1003, ¶147; *KSR* 550 U.S. 398, 417. Applying the arthrodesis principles of Chapter 55 in the context of the Chapter 31 procedure represents a predictable use of established surgical techniques in their intended setting. Ex.1003, ¶147; *KSR*, 550 U.S. at 417. A POSA would have had a reasonable expectation of success because this combination involves no more than applying a conventional, expressly taught arthrodesis resection and exposure principles from a “principles” chapter (Chapter 55) to the specific arthrodesis procedure described in Chapter 31. Ex.1003, ¶148.

Therefore, McGlamry renders claims 1-3, 6-8, 10-13, and 16-17 obvious. *Id.*, ¶¶144-149.

C. Ground 3: McGlamry and Davidson Render Claims 1-3, 6-13, and 16-17 Obvious

Even if McGlamry had not anticipated or rendered obvious claims 1-3, 6-8, 10-13, and 16-17 as explained in Grounds 1-2 (*see* §VII.A.1, *supra*), these claims would have been obvious over McGlamry and Davidson. Ex. 1003, ¶150. McGlamry and Davidson also render claim 9 obvious.

As discussed in Ground 2, a POSA would have been motivated to read and apply the teachings of McGlamry’s different chapters together. *See* §VII.B, *supra*; Ex. 1003, ¶151. That motivation carries through the following analysis.

1. Claim 1

McGlamry discloses each limitation of claim 1 as explained in Ground 1. *See* §VII.A.1, *supra*. Even if McGlamry did not disclose the instrument in the method steps of claim 1, Davidson discloses an instrument satisfying the related claim limitations, and Davidson’s instrument would have been obvious to use in McGlamry’s procedure. Thus, the combination of McGlamry and Davidson renders claim 1 obvious. Ex.1003, ¶¶152-165.

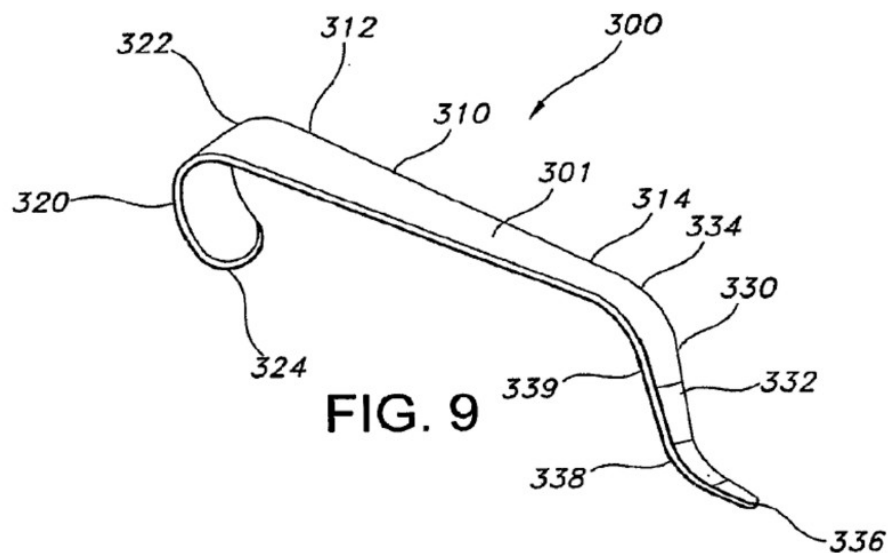
a. Preamble

To the extent this preamble is limiting, McGlamry discloses the preamble. *See* §VII.A.1.a, *supra*; Ex.1003, ¶153.

b. Limitation 1[a]

McGlamry discloses “inserting an instrument between a first metatarsal and a second metatarsal adjacent to the first metatarsal.” *See* Section §VII.A.1.b, *supra*. Even if McGlamry did not disclose this limitation, Davidson does. Ex.1003, ¶¶154-156. For example, Davidson discloses retractors designed for use in podiatric surgery, including metatarso-cuneiform fusion surgeries like McGlamry’s bunion

correction surgery. Ex.1006, [0060] (“Applications for this type of procedure include...osteotomy of the midtarsal bones and proximal first metatarsal.”).



Id., Fig.9. Davidson discloses that the retractor 300 is be placed between the first metatarsal (M1) and second metatarsal (M2) during a corrective osteotomy. *Id.*, [0058], [0060], Figs.18-19; Ex.1003, ¶156.

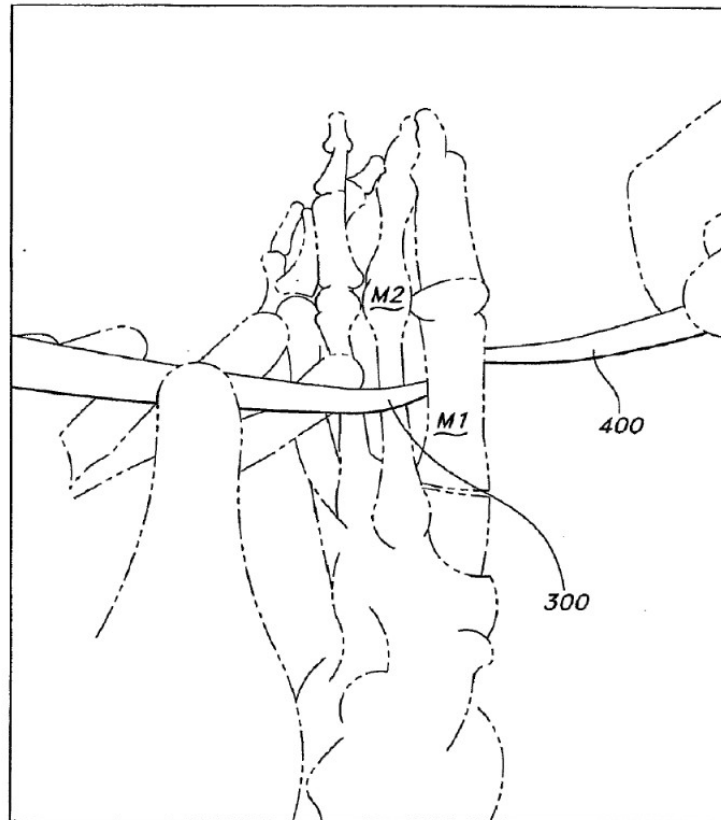


FIG. 19

Ex.1006, Fig.19. Davidson's retractor "permit[s] isolation and exposure of individual...metatarsal bones for corrective osteotomy, and protect[s] soft tissues (arteries, veins, nerves, muscles, etc) on the deep side of the foot bones from damage from sharp saws, osteotomes and displaced bone fragments." *Id.*, [0057]; *see* Ex.1003, ¶¶155-156. Thus, among other uses, Davidson's retractor provides a stop which prevents McGlamry's saw from cutting the second metatarsal or soft tissues on the lateral side of the first metatarsal.

A POSA would have recognized that Davidson’s retractor provides advantages and benefits because Davidson’s retractors are specialized for use in podiatric surgery. Ex.1003, ¶¶157-158. According to Davidson, “[e]xisting devices do not hook around bones, are prone to slipping out of position, and create operating fields that are awkward to work in, such as are found in the foot.” Ex.1006, [0003]. Davidson’s retractors “are designed specifically to optimize retraction of the soft tissues around the unique shapes of the bones of the foot while maintaining the assistant’s hands comfortably outside of the operating field.” *Id.*, [0032]. Davidson’s retractors are designed for insertion into the intermetatarsal space, sized to protect the soft tissues on the opposite side of resections, and shaped to fit around and grip the bones of the foot. *Id.* [0003], [0032], [0055]-[0057]; Ex.1003, ¶¶157-158.

It would have been obvious to use Davidson’s retractor in McGlamry’s bunion correction surgery, and a POSA would have been motivated to do so. *See* Ex.1003, ¶¶157-160. A POSA would have recognized that McGlamry’s and Davidson’s techniques are similar and that their instruments are interchangeable. *Id.*, ¶159. In fact, McGlamry teaches that surgical instruments such as elevators (like McGlamry’s Freer elevator discussed in Ground 1) and retractors (like Davidson’s retractor) are among the “basic set of podiatric surgical instruments.” Ex.1005, 3; Ex.1003, ¶159.

Davidson’s retractor is structurally configured for retraction in the foot: an elongated body with handle and a blade portion extending at about 90° with a curvature and tapered tip. Ex.1006, [0046] (“Straight portion 339 extends...at an angle of approximately 90 degrees from plane P3.”). That geometry is consistent with an instrument a POSA would use to (i) retract and protect soft tissue adjacent bone and (ii) maintain exposure in narrow operative corridors typical of foot arthrodesis approaches. Ex.1003, ¶158. Davidson’s disclosure that its retractors are designed to retract soft tissues around foot bones and fit in small spaces confirms that using Davidson’s retractor in McGlamry’s exposure/dissection steps is a straightforward substitution of one known tool (McGlamry’s Freer elevator) for another (Davidson’s retractor) to accomplish the same overarching goal: safe, effective exposure. *Id.*; *KSR Intern. Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007) (claims are obvious if they “involve [nothing] more than the simple substitution of one known element for another.”); *see also* Ex.1005, 7 (disclosing the uses for retractors like Davidson’s), 8 (disclosing the uses for periosteal elevators like the Freer elevator). Further, a POSA would have been motivated to adopt Davidson’s retractor in McGlamry’s procedure because it is designed to “hook[] around bones,” resist “slipping out of position,” and “creat[ing] operating fields that are [not] awkward to work in”—precisely the types of exposure and handling concerns encountered during bunion correction surgery like McGlamry’s. Ex.1003, ¶158.

Because Davidson’s retractors are designed for and disclosed as providing the functions of the Freer elevator, a POSA would have had a reasonable expectation of success when using the Freer elevator in place of a retractor. *Id.*, ¶160. Davidson’s retractors are engineered for the same anatomical and procedural context in which McGlamry uses a Freer elevator. *Id.* A POSA would have reasonably expected that a foot-specific retractor like Davidson’s could be introduced and manipulated to maintain tissue planes and exposure, thereby supporting McGlamry’s periosteal-preservation goals. *Id.* Any minor technique adjustments (e.g., angle of approach, hand position) would have been routine surgical judgement. *Id.*

c. Limitation 1[b]

McGlamry discloses cutting an end of the first metatarsal with the instrument inserted between the first metatarsal and the second metatarsal. *See* §VII.A.1.c, *supra*. A POSA using Davidson’s retractor in McGlamry’s bunion correction surgery would similarly position the retractor between the metatarsals while cutting the metatarsals, just as McGlamry describes positioning a Freer elevator in that location. Ex.1003, ¶162. Indeed, Davidson’s retractors are designed for insertion into the intermetatarsal space and sized to protect the soft tissues on the opposite side of resections. Ex.1006, [0003], [0032], [0055]-[0057]; Ex.1003, ¶162. This confirms that Davidson’s retractors are well suited for use during McGlamry’s cutting step. Ex.1003, ¶162.

d. Limitations 1[c]-1[e]

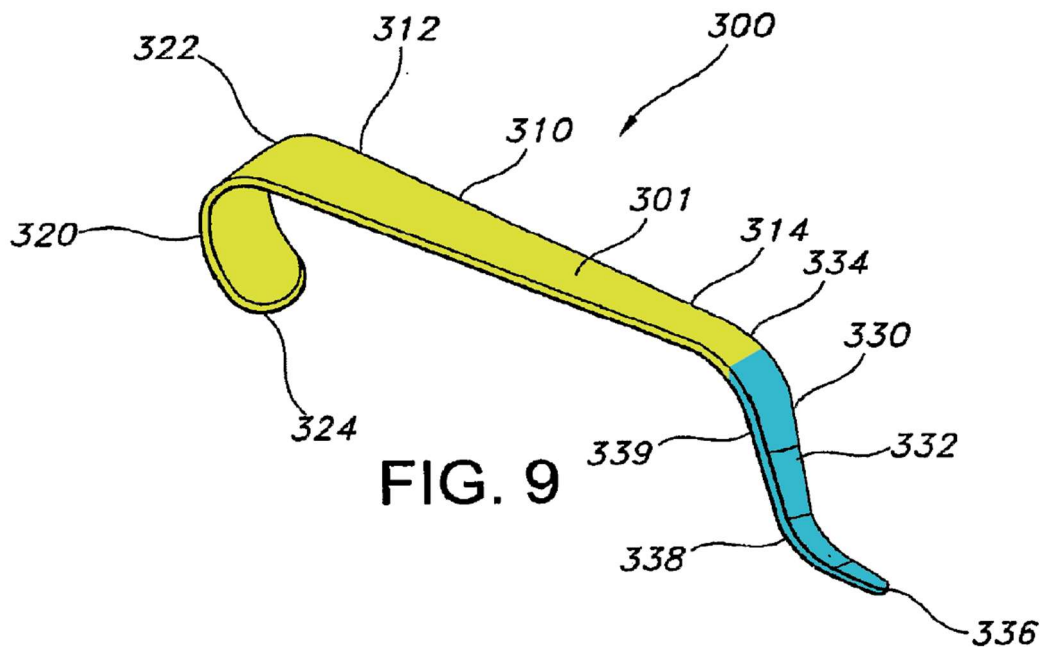
McGlamry's discloses limitations 1[c]-1[e] as explained for Ground 1. *See* §§VII.A.1.d, VII.A.1.e, VII.A.1.f, *supra*; Ex.1003, ¶¶163-165.

Thus, claim 1 is rendered obvious by McGlamry in view of Davidson.

2. Claim 2

a. Limitations 2[a]-2[b]

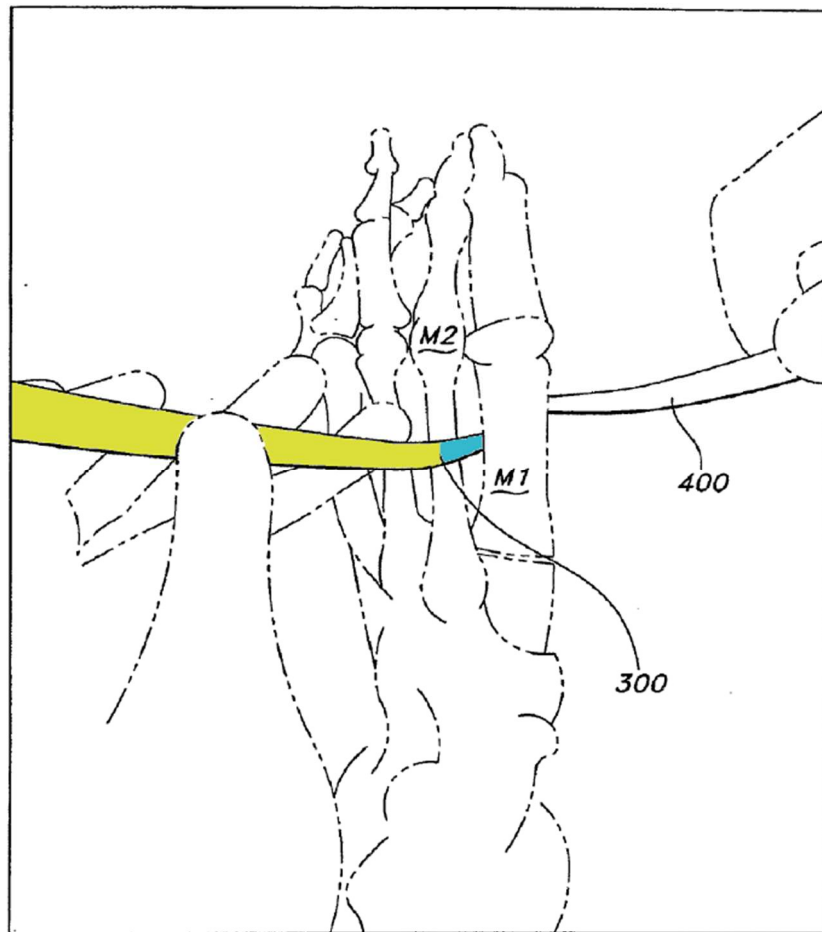
Davidson discloses these limitations. Ex.1003, ¶166. As shown below, Davidson discloses a retractor that includes a body (blue) configured for insertion into the operative site and a handle (yellow) configured to be grasped by a surgeon during surgery. *See* Ex.1006, [0044], [0057]-[0058], Figs.18-19; *see also id.*, [0044] (describing “[a] handle 320 extend[ing] from proximal end 312”).



Ex.1003, ¶166 (annotating Ex.1006, Fig. 9).

b. Limitation 2[c]

Even if McGlamry somehow did not disclose this limitation, Davidson does. Davidson discloses inserting its retractor body (blue) between the first and second metatarsals (M1 and M2, respectively), with the retractor handle (yellow) extending laterally over a dorsal (top) surface of the second metatarsal, as shown below in Figure 19. Ex.1006, Fig.19; Ex.1003, ¶167.



Ex.1006, Fig.19; Ex.1003, ¶167. McGlamry discloses positioning an instrument between the first and second between the first and second metatarsals during bunion

correction surgery, and a POSA would understand that the orientation of Davidson's retractor would remain the same when used in McGlamry's procedure. Ex.1003, ¶168.

Thus, McGlamry and Davidson render claim 2 obvious.

3. Claim 3

As shown below, Davidson discloses that the retractor 300 is inserted between the first metatarsal (M1) and second metatarsal (M2) from the dorsal (top) side of the foot and “worked under metatarsal M1” toward a plantar side of the foot. Ex.1006, [0058]; Ex.1003, ¶169.

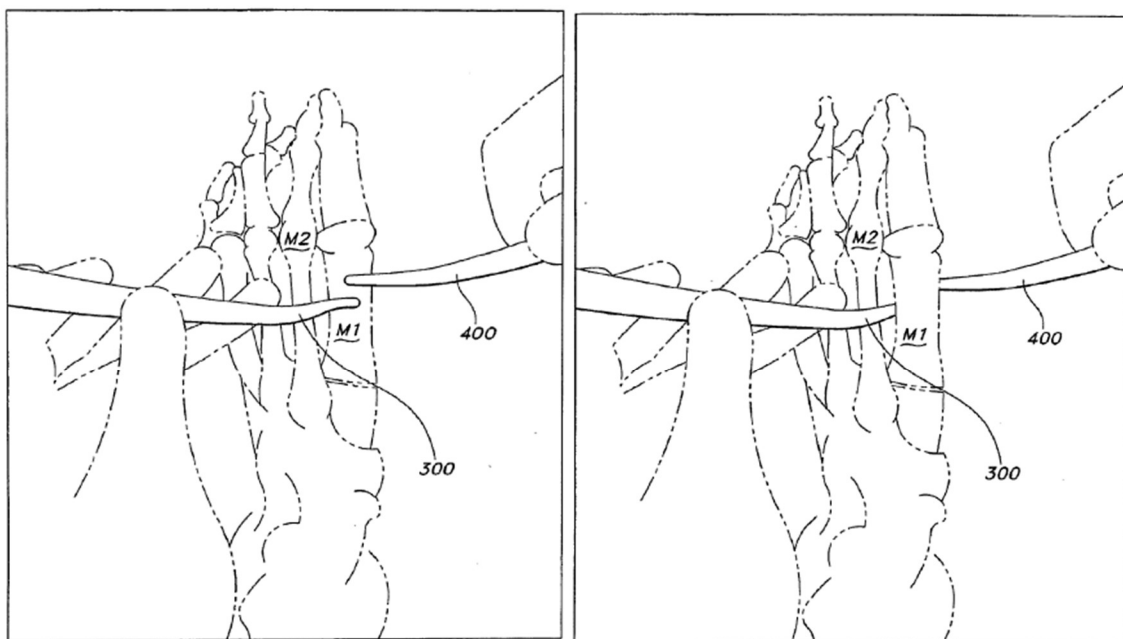


FIG. 18

FIG. 19

Ex.1006, Figs.18-19. A POSA would have understood that this same manner of insertion would be used when using Davidson's retractor in McGlamry's procedure,

because both references involve sim an instrument within the intermetatarsal space to retract tissue adjacent the first metatarsal. Ex.1003, ¶169.

Thus, McGlamry and Davidson render claim 3 obvious.

4. Claim 6

As explained in Ground 1, McGlamry discloses the limitations of claim 6. *See* §VII.A.4, *supra*. When Davidson’s retractor is used in McGlamry’s bunion correction procedure, a POSA would remove the retractor after completion of cutting the end of the first metatarsal, consistent with McGlamry’s disclosed surgical sequence. Ex.1003, ¶170.

5. Claim 7

As explained for claim 7 in Ground 1, McGlamry discloses positioning its instrument between the first and second metatarsals at the proximal-most third of the first metatarsal. *See* §VII.A.5, *supra*; Ex.1003, ¶¶171-172. When using Davidson’s retractor in McGlamry’s bunion correction procedure, it would have been obvious to place the retractor in the same position. Ex.1003, ¶172. That placement allows Davidson’s retractor to protect the soft tissues of the second metatarsal while also serving as a physical stop that limits advancement of McGlamry’s saw. *Id.* Thus, McGlamry and Davidson render claim 7 obvious.

6. Claim 8

McGlamry discloses the additional limitations of claim 8 as explained in Ground 1. *See* §VII.A.6, *supra*. Using an instrument such as Davidson’s retractor in McGlamry’s procedure would not change the manner in which force is applied by the bone positioning guide to the first metatarsal. Ex.1003, ¶173. Thus, McGlamry and Davidson render claim 8 obvious.

7. Claim 9

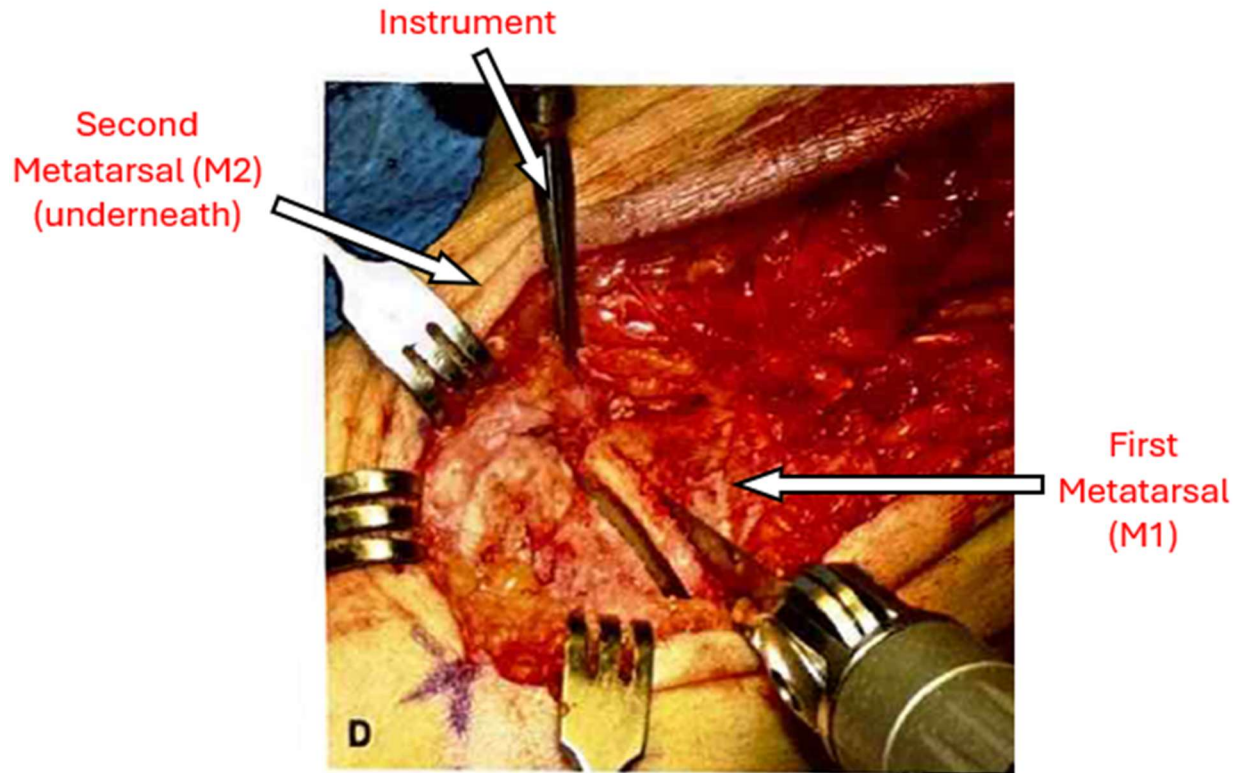
Claim 9 depends from claim 8 and recites: “wherein the instrument is a fulcrum; and moving the first metatarsal in the transverse plane comprises pivoting the first metatarsal about the fulcrum.”

The ’428 patent describes a fulcrum broadly, explaining that “any suitable mechanical instrument that maintains a spacing between adjacent bones” may be a fulcrum. Ex.1001, 17:14-16, 17:41-42 (including standard surgical instruments such as a “surgical pin or rod, a screw driver head/shaft, an osteotome, or a retractor”).

McGlamry and Davidson render this additional limitation obvious. Ex.1003, ¶¶174-183. As explained for limitation 1[a] in Ground 1, McGlamry discloses inserting an instrument between the first and second metatarsals during bunion correction surgery. *See* §VII.A.1.b, *supra*.

As shown in Figures 55.7C-F of McGlamry, the instrument is positioned in this intermetatarsal space such that it necessarily maintains a separation between the

metatarsals equal to the instrument's thickness. Ex.1005, 808-809; Ex.1003, ¶¶176-177.



Ex.1003, ¶176 (annotating Ex.1005, Fig.55.7D). In this configuration, the instrument functions as a fulcrum within the meaning the meaning of the '428 patent because any lateral moment of the first metatarsal toward the second metatarsal occurs by rotation about the instrument positioned between the bones. Ex.1003, ¶177.

Davidson discloses the same mechanical relationship. Davidson explains that the retractor 300 “engages second metatarsal M2 proximate to attached end 334[, and] [s]econd metatarsal M2 is used as a fulcrum to assist in retracting the first

metatarsal M1.” Ex.1006, [0058]. As shown in Figure 19 below, the retractor is wedged/engaged between the first and second metatarsals such that movement of the first metatarsal toward the second metatarsal occurs as pivoting about the retractor-bone interface. Ex.1003, ¶178.

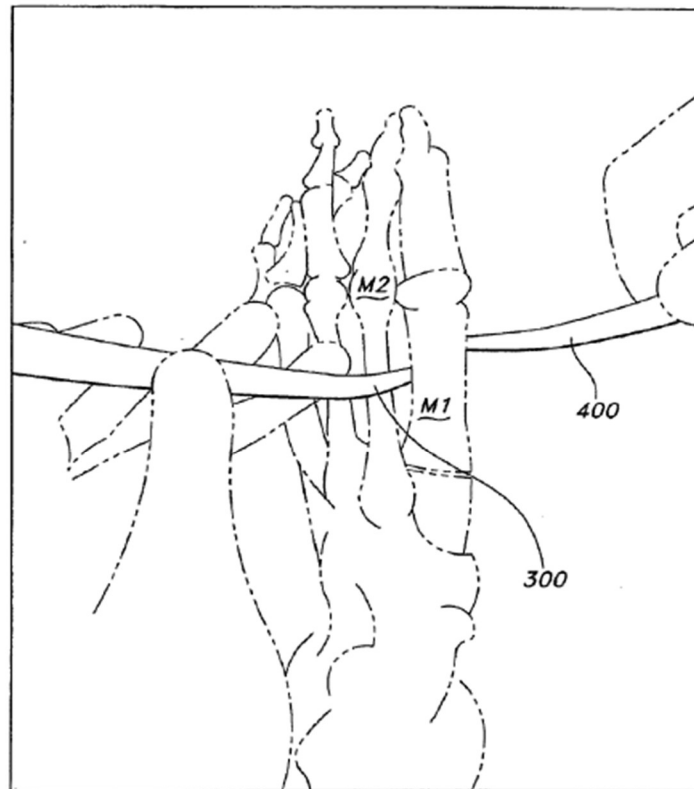


FIG. 19

Ex.1006, Fig.19. In this configuration, as the surgeon manipulates the first metatarsal using a second instrument 400, the first metatarsal pivots about the retractor 300, which serves as the fulcrum. Ex.1003, ¶178.

It would have been obvious to use Davidson’s retractor as the fulcrum during the repositioning step of McGlamry’s bunion correction surgery. Davidson’s

retractors are designed to “fit the unique shape and contours of the human foot and to accommodate the varied locations between bones and small spaces in the foot.” Ex.1006, [0032]. A POSA would have recognized that placing Davidson’s retractor between the first and second metatarsals—where McGlamry already teaches positioning an instrument—would provide predictable mechanical advantage, stability, and control when repositioning the first metatarsal in the transverse and sagittal planes. Ex.1003, ¶179 (citing Ex.1016, 420). This use does not change the fundamental technique disclosed by McGlamry, but uses a known retractor designed for intermetatarsal placement to perform the same mechanical function.

A POSA also would have understood that using Davidson’s retractor as the fulcrum would protect soft tissues between the metatarsals from injury during metatarsal manipulation, an expected benefit from retractors and one taught by Davidson. *Id.*, ¶¶180-181 (citing Ex.1006, Ex.2022); Ex.1006, [0057], [0061].

Using Davidson’s retractor as a fulcrum in McGlamry’s procedure would therefore have been nothing more than the predictable use of a known surgical instrument in a known anatomical location to perform its expected mechanical function. *KSR*, 550 U.S. at 417. A POSA would have a reasonable expectation of success because Davidson discloses using its retractor during Lapidus-type procedures like Fallin’s and positioning the retractor between the first and second

metatarsals to protect anatomy during corrective osteotomy. Ex.1006, [0060], [0057]-[0058], Fig.19; Ex.1003, ¶182.

This understanding is consistent with how the USPTO previously treated Davidson's retractor during prosecution of one of the '428 patent's parent applications, where the Examiner mapped Davidson's retractor as a fulcrum. Ex.1018, 571-572. Treace did not contest this mapping, including the identification of the retractor as a fulcrum. *Id.*, 730-731. Instead, Treace amended the claims to include additional features not recited in the '428 patent claims. *Id.*, 726-729. Thus, both the Examiner and the Patent Owner understood that Davidson's retractor is a fulcrum about which the metatarsal can rotate. Ex.1003, ¶183.

Thus, the combination of McGlamry and Davidson renders claim 9 obvious. Ex.1003, ¶¶174-183.

8. Claims 10-12

McGlamry's discloses the additional limitations of claim 10-12 as explained in Ground 1. *See* §§VII.A.7, VII.A.8, *supra*. Using an instrument such as Davidson's retractor in McGlamry's procedure would not change how or when these limitations would be performed during the procedure. Ex.1003, ¶184. Thus, the combination of McGlamry and Davidson renders claims 10-12 obvious. *Id.*

9. Claim 13

McGlamry discloses the additional limitations of claim 13. *See* §VII.A.9, *supra*. When using Davidson’s retractor in McGlamry’s procedure, it would have been obvious to position the retractor between the metatarsals while cutting the cuneiform, as disclosed by McGlamry. Ex.1003, ¶185. Using Davidson’s retractor for McGlamry’s disclosed instrument would not alter the manner in which the cuneiform-cutting step is performed and would predictable provide the same spacing and tissue protection during that step. *Id.* Thus, McGlamry and Davidson render claim 13 obvious. *Id.*

10. Claim 16

McGlamry discloses the additional limitations of claim 16. *See* §VII.A.10, *supra*. Thus, McGlamry and Davidson render claim 16 obvious. Ex.1003, ¶186.

11. Claim 17

McGlamry discloses the additional limitations of claim 17. *See* §VII.A.11, *supra*. Thus, McGlamry and Davidson render claim 17 obvious. Ex.1003, ¶187.

D. Ground 4: McGlamry and Fallin Render Claims 4-5, 14-15, 17-21, and 23-30 Obvious

Even if McGlamry had not anticipated or rendered obvious claim 17 as explained in Grounds 1-2 (*see* §VII.A.1, *supra*), this claim would have been obvious over McGlamry and Fallin. McGlamry and Fallin also render claims 4-5, 14-15, 17-21, and 23-30 obvious. Ex.1003, ¶188.

As discussed in Ground 2, a POSA would have been motivated to read and apply the teachings of McGlamry’s different chapters together. *See* §VII.B, *supra*; Ex.1003, ¶189. That motivation carries through the following analysis.

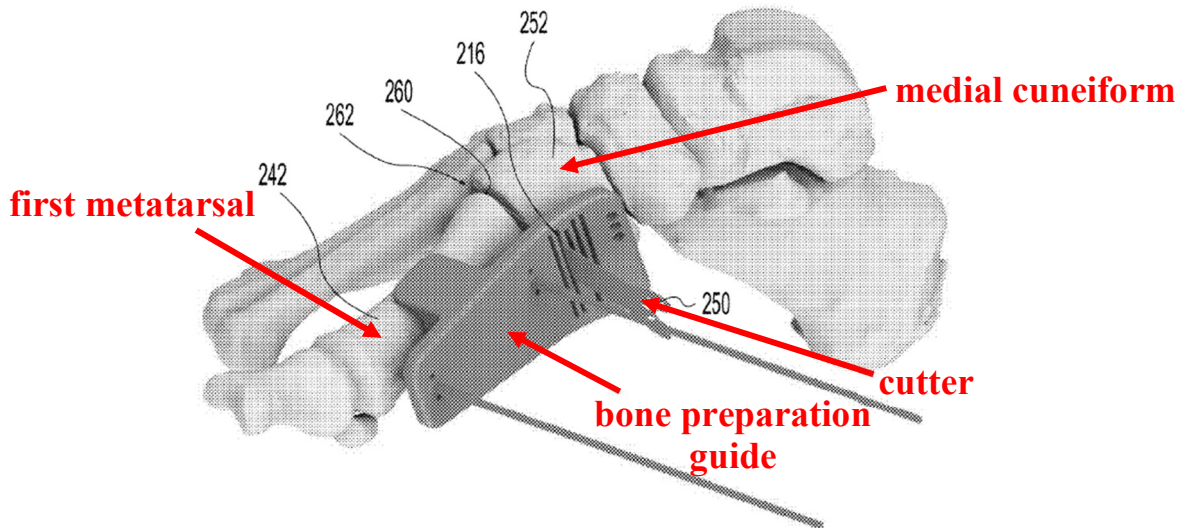
1. Claim 4

Claim 4 depends from claim 1 and recites: “further comprising positioning a bone preparation guide defining a cutting slot over the first metatarsal, wherein cutting the end of the first metatarsal comprises guiding a saw blade through the cutting slot to cut the end of the first metatarsal.” The combination of McGlamry and Fallin renders claim 4 obvious. Ex.1003, ¶¶190-208.

McGlamry discloses an instrumented technique for bunion correction surgery that includes cutting the proximal end of the first metatarsal, as explained for claim 1 in Ground 1. *See* §VII.A.1.d *supra*. McGlamry emphasizes the important nature of bone cutting, describing it as a “vital portion of the procedure.” Ex.1005, 324. McGlamry further notes that “[j]oint preparation is extremely important in efforts to obtain a bony union and to avoid a delayed and nonunion,” recommending that surgeons devote a “substantial period of time...preparing this [metatarsal-cuneiform] joint.” *Id.* McGlamry also warns that imprecise cutting can lead to complications such as “significant shortening” of the first metatarsal, delayed unions, non-unions, and malunions. *Id.*, 329.

McGlamry also describes “freehand” bone resection (Ex.1005, 324), which depends on the surgeon’s skill and may lead to complications (Ex.1023, 1:31-34). A POSA would recognize that freehand resection is “very difficult to perform and can be rather imprecise.” *Id.*, 1:31-37. Inaccuracies during freehand resection “lead to complications such as nerve damage, poor quality bone healing, bone resorption,...increased operating time and increased blood loss.” *Id.*, 1:45-50.

Fallin discloses positioning a bone preparation guide defining a cutting slot over the first metatarsal through which a saw blade is guided to cut the end of the first metatarsal. Ex.1007, [0051]-[0056]; *see also id.*, claim 24; Ex.1003, ¶¶192-195.



Ex.1003, ¶195 (annotating Ex.1007, Fig.22). According to Fallin, “[t]he guide body 202 [of the bone preparation guide] includes...a first slot 216 and a second slot 218.” Ex.1007, [0052]. “[G]uide slots 216, 218 are positioned so that with the joint

alignment slot 234 aligned with the metatarsocuneiform joint, a cutter guided by the guide slots 216, 218 will remove a predetermined, and relative thin, portion of bone from the articulating ends of the metatarsus and cuneiform,” respectively. *Id.*, [0056]. Fallin further discloses “a saw blade 250 in a powered handpiece...is guided in one of the distal guide slots 216 to remove bone from the proximal end of the metatarsus 242.” *Id.*, [0065].

It would have been obvious to use Fallin’s cutting guide in the cutting steps of McGlamry’s procedure. Ex.1003, ¶¶196-208. Fallin’s cutting guide simplifies and standardizes the cutting steps in McGlamry’s procedure. *Id.*, ¶198. *See also* §II.E, *supra*; Ex.1023, 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....”). “There are numerous prior art devices for precision cutting of bones in the appendicular skeleton,” including the feet. Ex.1023, 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.1005, 381-83. Fallin likewise discloses that cutting guides can be used to “remove a predetermined, and relatively thin, portion of bone from the articulating ends of the metatarsus and cuneiform.” Ex.1007, [0056]. Further, rather than spending “a substantial amount of time” on freehand joint preparation (Ex.1005, 324), Fallin’s

cutting guide would make preparation predictable and repeatable, thereby simplifying and shortening the procedure. Ex.1003, ¶¶198-199. Shorter and simpler surgical procedures typically mean less time under anesthesia and less time with a tourniquet applied, which benefits the patient. *Id.*, ¶199. 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.*, ¶200.

Fallin’s cutting guide also mitigates complications identified by McGlamry. For example, McGlamry’s identifies “significant shortening” of the metatarsal as a potential complication. Ex.1005, 329. Shortening refers to excessive removal of bone that alters foot biomechanics and can result in pain, deformities, and other complications. Ex.1003, ¶¶201-202. Fallin’s cutting guide “results in more precision and repeatability in the relative orientation of the cuts [to the metatarsal and cuneiform].” Ex.1007, [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, ¶¶202-203.

Fallin’s cutting guide also reduces the risk of delayed unions, non-unions, and malunions identified by McGlamry. Ex.1005, 324. These complications can occur when the cut ends of the metatarsal and cuneiform do not correctly fit together after the metatarsal is repositioned. Ex.1003, ¶204. The use of cutting guides in metatarsal-cuneiform fusion procedures was a known technique for “easily and

effectively achiev[ing] unions through biological healing.” Ex.1015, [0068]. Fallin’s cutting guide promotes effective unions because it prepares complementary joint surfaces. *See, e.g.*, Ex.1007, [0058] (“the cuneiform may be cut to create a second cut surface in predetermined relationship (as determined by the cut guide feature) to the first cut surface.”).

Using Fallin’s cutting guide in McGlamry’s bunion correction surgery would have been nothing more than the use of a known technique to solve a known problem using prior art elements according to their established functions. Ex.1003, ¶205; *NuVasive, Inc. v. Hirshfeld*, 2021 WL 3661208, at *4-5 (Fed. Cir. 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 Intern. Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007) (claims are obvious if they apply “a known technique to a piece of prior art ready for the improvement”). It also would have been obvious to use Fallin’s cutting guide in McGlamry’s procedure because this would have been nothing more than using a known technique used to improve a similar method in the same way. Ex.1003, ¶205; *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, ¶206; *see also, e.g.*, Ex.1023, 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, ¶206; Ex.1015, [0057]-[0058] (describing how the jig and guide can be used in multiple metatarsal procedures and other anatomies, such as the hand); Ex.1024, 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.”).

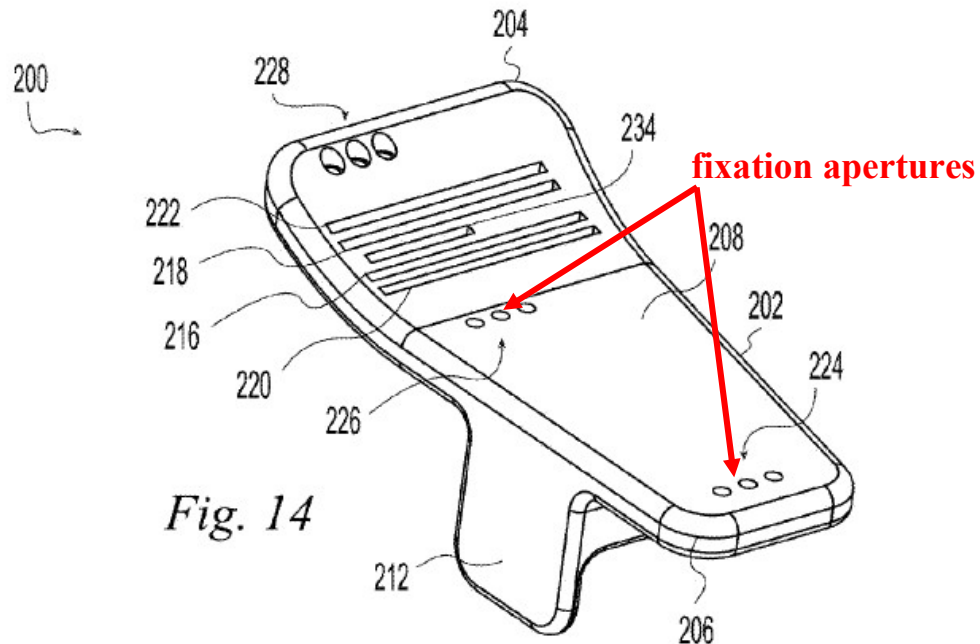
The relevant portions of the surgical procedures described in McGlamry and Fallin are nearly identical. *See* §VII.D.5, *infra*; Ex.1003, ¶207. Both involve bunion correction procedures in which the proximal end of the first metatarsal and the distal end of the cuneiform are cut, and the first metatarsal is repositioned relative to the cuneiform. Ex.1005, 324-26; Ex.1007, [0056]-[0058], [0065]-[0068]. Fallin discloses that its cut guide is readily substituted for freehand resection and provides the advantages of such a cut guide. Ex.1007, [0062] (“A method according to the invention may be performed freehand or with the use of an osteotomy guide. The use of an osteotomy guide...results in more precision and repeatability in the relative orientation of the cuts.”). A POSA therefore would have had a reasonable expectation of success. *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).

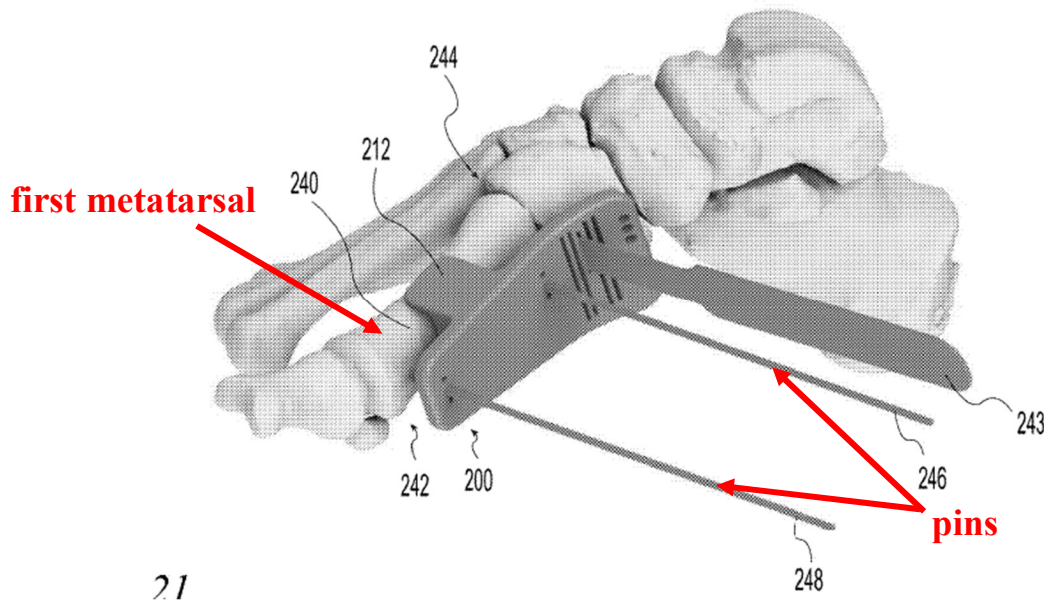
2. Claim 5

Claim 5 depends from claim 4 and recites: “wherein the bone preparation guide comprises at least one fixation aperture, and further comprising securing the bone preparation guide to the first metatarsal with at least one fixation pin inserted into the first metatarsal and extending through the at least one fixation aperture of the bone preparation guide.” McGlamry and Fallin render claim 5 obvious. Ex.1003, ¶¶209-211.

Fallin discloses that its bone preparation guide (osteotomy guide 200) includes at least one fixation aperture. As shown in Figure 14, Fallin’s guide body 202 includes “two sets of holes 224, 226 are provided distal to the guide slots 216, 218, 220, 222.” Ex.1007, [0053].



Ex.1003, ¶210 (annotating Ex.1007, Fig.14). Fallin explains that at least one fixation pin is inserted through the holes 224, 226 to secure the guide to the first metatarsal. Specifically, Fallin teaches that “[p]ins 246, 248 are placed through the fixation holes 224, 226 to fix the guide 200 to the metatarsus 242.” Ex.1007, [0064]; *see also id.*, [0056].



Ex.1003, ¶211 (annotating Ex.1007, Fig.21). It would have been obvious to secure Fallin’s bone preparation guide to the first metatarsal when performing McGlamry’s procedure by inserting at least one fixation pin into the first metatarsal through at least one fixation aperture of the guide, as taught by Fallin. Ex.1003, ¶211.

3. Claim 14

Claim 14 depends from claim 1 and recites: “wherein cutting the end of the medial cuneiform comprises cutting the end of the medial cuneiform after cutting the end of the first metatarsal and after moving the first metatarsal in the at least one plane to treat the bunion deformity.”

The ’428 patent acknowledges that the order of surgical steps is not critical and identifies no particular order imparting an advantage over another. Ex.1001, 20:30-33 (“The first metatarsal can be moved relative to the second metatarsal before and/or after preparing the end of the first metatarsal and/or the opposed end of the

medial cuneiform.”). The ’428 patent further confirms that “unless otherwise indicated, the steps described need not be carried out in the order described.” *Id.*, 11:48-49

McGlamry and Fallin render claim 14 obvious. Ex. 1003, ¶¶212-218. McGlamry identifies that steps in its bunion correction procedure may be performed in different orders. *See* Ex.1005, 324, 808-809. Like the ’428 patent, McGlamry does not identify any technical significance to the order of its cutting and adjusting steps relative to each other. Ex.1003, ¶¶213-214.

Fallin discloses cutting the first metatarsal, repositioning the first metatarsal relative to the medial cuneiform in at least one plane, and then cutting the medial cuneiform. Ex.1007, [0065]-[0068]. A POSA using Fallin’s guide in McGlamry’s procedure would have found it obvious to cut the metatarsal, adjust the metatarsal position, and then cut the cuneiform, as this sequence naturally accommodates Fallin’s guided correction technique while achieving the same surgical endpoint. Ex.1003, ¶¶215-216.

Furthermore, there are only two options for the timing of cutting the cuneiform relative to the metatarsal repositioning—before or after adjustment. *Id.* Both options were known in the art prior to August 2015. *Id.* Selecting Fallin’s disclosed order represents nothing more than choosing between known alternatives. *Id.*

Reordering of steps constitutes a predictable variation and is insufficient to confer patentability. *KSR Intern. Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007) (claims are obvious when they “involve [nothing] more than the simple substitution of one known element for another.”). Substituting one of two known alternatives for the other is obvious where the result is predictable. *KSR*, 550 U.S. at 416-18; *Uber Techs., Inc. v. X One, Inc.*, 957 F.3d 1334, 1340 (Fed. Cir. 2020) (holding substitution of one of two alternatives for the other “is obvious because it would have been a ‘predictable variation.’”).

Because Fallin’s order of steps produces the same clinical and structural outcome as McGlamry’s disclosed techniques, a POSA would have had a reasonable expectation of success in performing bunion correction by first adjusting the position of the metatarsal and then cutting the cuneiform. Ex.1003, ¶217.

4. Claim 15

Claim 15 depends from claim 14 and recites: “further comprising, prior to inserting the instrument between the first metatarsal and the second metatarsal, obtaining the instrument from a sterile kit that also includes (1) a bone positioning guide configured to engage the first metatarsal and apply a force to the first metatarsal to move the first metatarsal in at least one plane and (2) a bone preparation guide defining a cutting slot configured to be positioned over an end of the first

metatarsal to be cut.” McGlamry and Fallin render claim 15 obvious. Ex.1003, ¶¶219-225.

As explained regarding claim 1, McGlamry discloses an instrumented surgical procedure for correcting a bunion. *See* §VII.A.1.a, *supra*. 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.1005, 12. 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. *Id.*, 12-14; Ex.1003, ¶221. Thus, McGlamry discloses the use of sterile kits for surgical procedures. Ex.1003, ¶221.

It would have been obvious to a POSA to include the claimed bone positioning guide and the claim bone preparation guide in a sterile kit for McGlamry’s procedure. As explained for claim 8 in Ground 1, McGlamry discloses using such a bone positioning guide to engage and reposition the first metatarsal during bunion correction. *See* §VII.A.6, *supra*. As explained for claim 4 in this ground, it further would have been obvious to use Fallin’s cutting guide in the cutting steps of McGlamry’s procedure. *See* §VII.D.1, *supra*

Packaging these instruments together in a sterile kit would have been a routine and predictable application of known surgical practice. With a sterile kit, both the bone positioning guide and the bone preparation guide would have been readily available, sterile, and ready for use at the start of the procedure. Ex.1003, ¶222. 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.* (citing Ex.1025, [0260], [0264], [0266] and Ex. 1026 [0002], [0010]). 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, ¶223. 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 performed with a cutting guide) that was ready for such modification. *Id.*, ¶224.

5. Claim 17

McGlamry discloses these limitations for the reasons explained for claim 17 in Ground 1. *See* §VII.A.11, *supra*. Thus, McGlamry and Fallin render claim 17 obvious. Ex.1003, ¶226.

6. Claim 18

Independent claim 18 recites substantially the same limitations as independent claim 1 and dependent claims 4-5 (using and securing a cutting guide), 7 (proximal instrument positioning), and 12 (compressing the metatarsal and cuneiform). The combination of McGlamry and Fallin renders claim 18 obvious. Ex.1003, ¶227.

a. Preamble

McGlamry discloses “[a]n instrumented surgical technique for treating a bunion deformity.” *See* §VII.A.1.a, *supra*; Ex.1003, ¶228.

b. Limitation 18[a]

This limitation recites “positioning a bone preparation guide defining a cutting slot over a first metatarsal with at least one fixation pin inserted into the first metatarsal and extending through at least one fixation aperture of the bone preparation guide.” McGlamry and Fallin render the limitation obvious. Ex.1003, ¶¶229-232.

As explained for claims 4-5 in this ground, Fallin discloses limitation 18[a]. *See* §§VII.D.1-2, *supra*. It would have been obvious, for the reasons previously explained, to use Fallin’s cutting guide in McGlamry’s bunion correction procedure and to secure the cutting guide to the first metatarsal using a fixation pin as recited. *See id.* Moreover, a POSA would have had a reasonable expectation of success in the combination for the same reasons. *Id.*

c. Limitation 18[b]

This limitation recites “inserting an instrument between a proximal portion of the first metatarsal and a proximal portion of a second metatarsal adjacent to the first metatarsal.” McGlamry and Fallin render the limitation obvious. Ex.1003, ¶¶233-234.

As explained for limitation 1[a] and claim 7 in Ground 1, McGlamry discloses limitation 18[b]. *See* §§VII.A.2, VII.5, *supra*.

d. Limitation 18[c]

This limitation recites “with the instrument inserted between the first metatarsal and the second metatarsal, guiding a saw blade through the cutting slot to cut an end of the first metatarsal.” McGlamry and Fallin render the limitation obvious. Ex.1003, ¶¶235-236.

As explained for limitation 1[b] in Ground 1, McGlamry discloses limitation 18[c] other than expressly describing use of a cutting guide with a cutting slot. *See* §VII.A.3, *supra*. As explained for claim 4, Fallin discloses guiding a saw blade through a cutting guide’s cutting slot. *See* §VII.A.1.c, *supra*. It would have been obvious, for the reasons previously explained, to use Fallin’s cutting guide with its cutting slot to cut the end of the first metatarsal in McGlamry’s bunion correction procedure. *See* §VII.D.1, *supra*.

e. Limitation 18[d]

This limitation recites “moving the first metatarsal in at least one plane to treat the bunion deformity.” McGlamry and Fallin render the limitation obvious. Ex.1003, ¶¶237-238.

As explained for limitation 1[c] in Ground 1, McGlamry discloses limitation 18[d]. *See* §VII.A.1.d, *supra*. Fallin also discloses “the bones may be repositioned in one or more planes” during a bunion correction surgery, including the frontal, sagittal, and transverse planes. Ex.1007, [0058]; *see also id.*, [0066] (“the metatarsus 242 is repositioned relative to the cuneiform 252 to change their relative position in one or more planes.”).

f. Limitation 18[e]

This limitation recites “cutting an end of a medial cuneiform opposing the end of the first metatarsal.” McGlamry and Fallin render the limitation obvious. Ex.1003, ¶¶239-240.

As explained for limitation 1[d], McGlamry discloses limitation 18[e]. *See* §VII.A.1.e, *supra*. Fallin also discloses cutting an end of a medial cuneiform opposing the end of the first metatarsal using its cutting guide. Ex.1007, [0067].

g. Limitation 18[f]

Limitation 18[f] recites “compressing the first metatarsal together with the medial cuneiform.” McGlamry and Fallin render the limitation obvious. Ex.1003, ¶¶241-243.

As explained for claim 12 in Ground 1, McGlamry discloses this limitation. *See* §VII.A.8, *supra*. Fallin also discloses this limitation. Fallin describes that “[t]he...cut surfaces [of the first metatarsal and cuneiform] may be brought together” before they are fixed for fusing the joint in the new position. Ex.1007, [0058]. Fallin further explains that “compression may be facilitated by using a forceps or clamp, e.g. a towel clamp, to press the bone portions together.” *Id.*, [0075].

h. Limitation 18[g]

This limitation recites “after moving the first metatarsal in at least one plane to treat the bunion deformity and after compressing the first metatarsal together with the medial cuneiform, fixating a moved position of the first metatarsal relative to the medial cuneiform for fusion using at least one bone fixation device.” McGlamry and Fallin render the limitation obvious. Ex.1003, ¶¶244-247.

As explained for limitation 1[e] and claim 12, McGlamry discloses limitation 18[g]. *See* §§ VII.A.1.f, VII.A.8, *supra*. Fallin also discloses this limitation. For example, Fallin discloses using a bone fixation device to fixate the first metatarsal and cuneiform after moving and compressing the bones. Ex.1007, [0075] (“[T]he

bones [are held] in the reduced position while fixation such as one or more pins, plates, screws, rods or other suitable fixation is applied.”); *see also id.*, [0058], [0065]-[0068], [0073]-[0075].

Thus, claim 18 is rendered obvious by McGlamry and Fallin.

7. Claim 19

Claim 19 depends from claim 18 and recites the additional limitations as claim 6. McGlamry discloses these limitations for the reasons explained for claim 6 in Ground 1. *See* §VII.A.4, *supra*. Thus, McGlamry and Fallin render claim 19 obvious. Ex.1003, ¶248.

8. Claim 20

Claim 20 depends from claim 18 and recites the additional limitations as claim 2. McGlamry discloses these limitations for the reasons explained for claim 2 in Ground 1. *See* §VII.A.2, *supra*. Thus, McGlamry and Fallin render claim 20 obvious. Ex.1003, ¶249.

9. Claim 21

Claim 21 depends from claim 18 and recites the additional limitations of claim 8. McGlamry discloses these limitations for the reasons explained for claim 8 in Ground 1. *See* §VII.A.6, *supra*. Thus, McGlamry and Fallin render claim 21 obvious. Ex.1003, ¶250.

10. Claim 23

Claim 23 depends from claim 21 and recites the additional limitations of claim 10. McGlamry discloses these limitations for the reasons explained for claim 10 in Ground 1. *See* §VII.A.7, *supra*. Fallin also discloses the additional limitations. Ex.1007, [0058] (“...the metatarsus may be...rotated in the coronal plane to correct abnormal pronation/supination...”). Thus, McGlamry and Fallin render claim 23 obvious. Ex.1003, ¶251.

11. Claim 24

Claim 24 depends from claim 18 and recites the additional limitations of claim 11. McGlamry discloses these limitations for the reasons explained for claim 11 in Ground 1. *See* §VII.A.7, *supra*. Thus, McGlamry and Fallin render claim 24 obvious. Ex.1003, ¶252.

12. Claim 25

Claim 25 depends from claim 18 and recites the additional limitations of claim 14. McGlamry and Fallin render these limitations obvious for the reasons explained for claim 14 in this ground. *See* §VII.D.3, *supra*. Thus, McGlamry and Fallin render claim 25 obvious. Ex.1003, ¶253.

13. Claim 26

Claim 26 depends from claim 18 and recites the additional limitations of claim 15. McGlamry and Fallin render these limitations obvious for the reasons explained

for claim 15 in this ground. *See* §VII.D.4, *supra*. Thus, McGlamry and Fallin render claim 26 obvious. Ex.1003, ¶254.

14. Claim 27

Claim 27 depends from claim 18 and recites: “wherein the at least one bone fixation device comprises one or more of a screw, a plate, and an intramedullary implant.” McGlamry discloses these additional limitations for the reasons explained for claim 16 in Ground 1. *See* §VII.A.10, *supra*. Thus, McGlamry and Fallin render claim 27 obvious. Ex.1003, ¶255.

15. Claim 28

The combination of McGlamry and Fallin renders independent claim 28 obvious. Ex.1003, ¶¶256-261.

a. Preamble

McGlamry discloses “[a]n instrumented surgical technique for treating a bunion deformity.” *See* §VII.A.1.a, *supra*; Ex.1003, ¶256.

b. Limitations 28[a]-28[c]

These limitations are the same as limitations 18[a]-18[c]. McGlamry and Fallin render limitations 28[a]-28[c] obvious for the same reasons as limitations 18[a]-18[c]. *See* §§VII.D.6.b-d, *supra*; Ex.1003, ¶257.

c. Limitation 28[d]

This limitation recites “engaging a bone positioning guide with the first metatarsal and using the bone positioning guide to move the first metatarsal relative to the second metatarsal in a transverse plane to reduce an intermetatarsal angle between the first metatarsal and the second metatarsal to treat the bunion deformity.” McGlamry and Fallin render this limitation obvious for the reasons explained for claims 21 and 26 in this ground. *See* §§VII.D.9, VII.D.13, *supra*; Ex.1003, ¶258.

d. Limitation 28[e]

This limitation recites “imparting a force to a pin inserted into the first metatarsal to adjust an alignment of the first metatarsal in a frontal plane to treat the bunion deformity.” McGlamry and Fallin render this limitation obvious for the reasons explained for claim 24 in this ground. *See* §VII.D.11, *supra*; Ex.1003, ¶259.

e. Limitations 28[f]-28[g]

These limitations are the same as limitations 18[e]-18[f]. McGlamry and Fallin render limitations 28[f]-28[g] obvious for the same reasons as limitations 18[e]-18[f]. *See* §§VII.D.6.e-g, *supra*; Ex.1003, ¶260.

f. Limitations 28[h]

This limitation recites “fixating a moved position of the first metatarsal relative to the medial cuneiform for fusion using at least one bone fixation device.”

McGlamry and Fallin render this limitation obvious for the reasons explained for claim 18[g] in this ground. *See* §VII.D.6.h, *supra*; Ex.1003, ¶261.

Thus, claim 28 is rendered obvious by McGlamry and Fallin. Ex.1003, ¶¶256-262.

16. Claim 29

Claim 29 depends from claim 28 and recites the additional limitations as claim 20. McGlamry and Fallin render these limitations obvious for the reasons explained for claim 20 in this ground. Ex.1003, ¶263; *see* §VII.D.6, *supra*.

17. Claim 30

Claim 30 depends from claim 28 and recites the additional limitations of claim 19. McGlamry and Fallin render claim 30 obvious for the reasons explained for claim 19. Ex.1003, ¶264; *see* §VII.D.7, *supra*.

E. Ground 5: McGlamry, Davidson, and Fallin Render Claims 4-5, 14-15, and 17-30 Obvious

1. Claims 4-5, 14-15, 17-21, and 23-30

The combination of McGlamry, Davidson, and Fallin renders each of claims 4-5, 14-15, 17-21, and 23-30 obvious for the reasons explained with respect to each of these corresponding claims in Ground 4, which addressed the combination of McGlamry and Fallin. As explained in Ground 4, it would have been obvious to use Fallin's cutting guide in the cutting steps in McGlamry's procedure. *See* §VII.D.1, *supra*. As explained in Ground 3, it would have been obvious to perform

McGlamry's procedure using Davidson's retractor to provide exposure and access during the procedure. *See* §VII.C.1, *supra*.

The addition of Fallin's cutting guide to McGlamry's procedure as performed with Davidson's retractor represents a straightforward combination of known, compatible surgical tools used according to their established functions. Ex.1003, ¶265. Fallin's cutting guide is complementary to McGlamry's procedure and does not interfere with the use of Davidson's retractor. *Id.*, ¶266. Accordingly, a POSA would have had a reasonable expectation of success in combining McGlamry, Davidson, and Fallin for the same reasons supporting the McGlamry-Fallin combination. *Id.*, ¶266; *see* §§ VII.C.1, VII.D.1, *supra*.

2. Claim 22

Claim 22 depends from claim 21 and recites the additional limitations of claim 9. The combination of McGlamry, Davidson, and Fallin renders claim 22 obvious. Ex.1003, ¶¶267-272.

As explained in Ground 3, McGlamry and Davidson render the additional limitations of claim 9 obvious. Ex.1003, ¶268; *see* §VII.C.7, *supra*. As explained in Ground 4, McGlamry and Fallin render claim 21 obvious. Ex.1003, ¶268; *see* §VII.D.9, *supra*.

It would have been obvious to use Fallin's cutting guide in McGlamry's procedure as performed using Davidson's retractor. Ex.1003, ¶¶269-270. As

explained in Ground 3 and this ground, Davidson’s retractor provides exposure and access during bunion correction procedures and is compatible with both McGlamry’s surgical technique and Fallin’s cutting guide. *Id.*; see §VII.C.7, *supra*.

The combination of McGlamry’s procedure, Davidson’s retractor, and Fallin’s cutting guide—where Davidson’s retractor serves as a fulcrum about which the first metatarsal is moved in the transverse plate—represents a straightforward combination of known, compatible surgical tools used according to their established functions. Ex.1003, ¶270. Accordingly, a POSA would have had a reasonable expectation of success in combining McGlamry, Davidson, and Fallin for the same reasons supporting the McGlamry-Davidson combination. *Id.*, ¶271; see §§VII.C.7, VII.D.1, *supra*.

F. Ground 6: McGlamry and Tyber Render Claim 17 Obvious

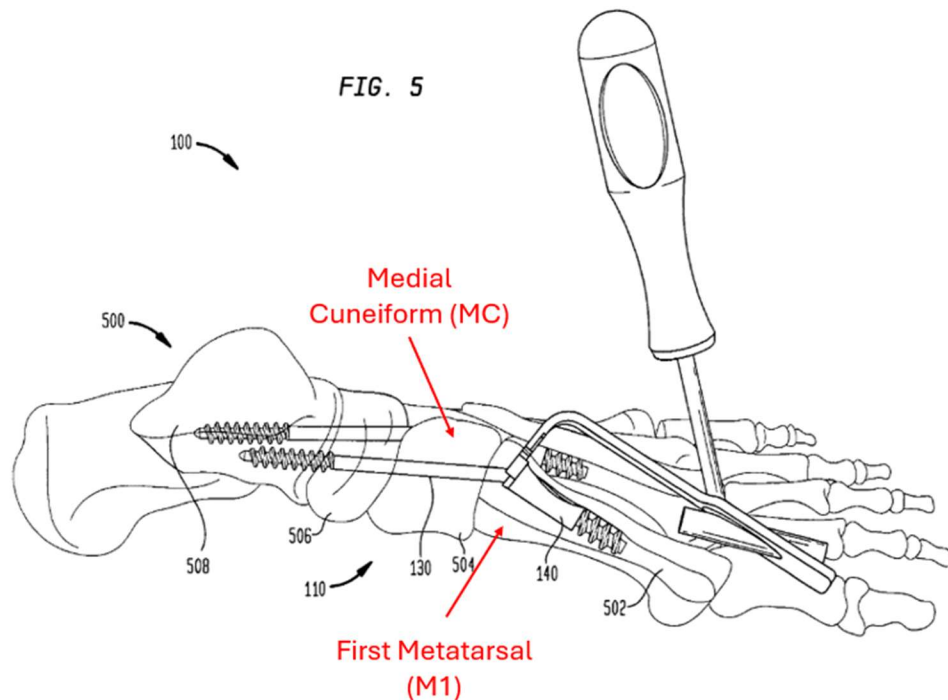
Claim 17 depends from claim 1 and recites: “wherein the at least one bone fixation device comprises an intramedullary implant.” The combination of McGlamry and Tyber renders claim 17 obvious. Ex.1003, ¶¶273-278

As explained for limitation 1[e] in Grounds 1-2, McGlamry discloses and renders obvious surgical techniques for correcting the bunion deformity, including fixation of the first metatarsal relative to the cuneiform with a bone fixation device. See §VII.A.1.f, *supra*. McGlamry’s further describes that “there are many different types of fixation that may be applied to the arthrodesis site (wires, screws, plates,

etc.),” and that regardless of the fixation selected, “the arthrodesis site must be held in close, stable apposition until full healing across the fusion site has occurred.” Ex.1005, 808.

Tyber discloses an “intramedullary fixation assembly that may be utilized to treat bones in a mid-foot and forefoot regions.” Ex.1008, 2:27-29. Tyber explains that its intramedullary implant may be used to treat podiatric deformities, including “hallux valgus deformities,” i.e. bunions. *Id.*, 1:24-30. Tyber discloses an intramedullary implant including a proximal screw 130 and a distal screw 140 configured for placement within bone. *Id.*, 5:15-18.

As shown in Figure 5, “the intramedullary assembly is coupled to the medullary canals of the first metatarsal 502, medial cuneiform 504, navicular, and talus bones 508,” thereby fixing the first metatarsal relative to the cuneiform. *Id.*, 7:36-39.



Ex.1003, ¶275 (annotating Ex.1008, Fig.5). Tyber further teaches inserting the intramedullary fixation assembly through the joint selected for fusion, such that rigid coupling of the components maintains alignment of the bones during healing. Ex.1008, 7:30-8:50.

It would have been obvious to use an intramedullary implant like Tyber's as the fixation device in McGlamry's bunion correction procedure to fix the first metatarsal relative to the medial cuneiform. Ex.1003, ¶276. McGlamry recognizes that multiple fixation options are suitable for achieving stable fixation across the joint, and that the fixation selected must hold the bones in close, stable apposition until fusion occurs. Ex.1005, 808.

Tyber provides a known alternative fixation approach that achieves the same objective—maintaining close, stable apposition across the fusion site—using an intramedullary fixation configuration. *See, e.g.,* Ex.1008, 1:44-46, Figs. 5-6. A POSA would have understood Tyber’s intramedullary fixation to be a suitable substitute for one of McGlamry’s disclosed fixation devices for stabilizing the first metatarsal relative to the medial cuneiform during healing. Ex.1003, ¶¶276-277. Substituting Tyber’s intramedullary implant for one of McGlamry’s fixation devices therefore constitutes nothing more than the substitution of one known fixation element for another to achieve predictable results. *KSR*, 550 U.S. at 416-18.

Accordingly, a POSA would have had a reasonable expectation of success in using an intramedullary implant such as Tyber’s in McGlamry’s bunion correction procedure, rendering claim 17 obvious. Ex.1003, ¶278.

G. Ground 7: McGlamry, Davidson, and Tyber Render Claim 17 Obvious

The combination of McGlamry, Davidson, and Tyber renders claim 17 obvious. Ex.1003, ¶¶279-280. As explained for claim 1 in Ground 3, it would have been obvious to perform McGlamry’s procedure using Davidson’s retractor to provide exposure and access during the procedure. *See* §VII.C.1, *supra*. As explained for claim 17 in Ground 7, it further would have been obvious to use Tyber’s intramedullary implant as the fixation device in McGlamry’s procedure. *See* §VII.F, *supra*.

The addition of Tyber’s intramedullary implant to McGlamry’s procedure as performed with Davidson’s retractor represents a straightforward combination of known, compatible surgical tools used according to their established functions. Ex.1003, ¶280. Tyber’s intramedullary implant is complementary to McGlamry’s procedure and does not interfere with the use of Davidson’s retractor. *Id.* Accordingly, a POSA would have had a reasonable expectation of success in combining McGlamry, Davidson, and Tyber for the same reasons supporting the McGlamry-Tyber combination. *Id.*; see §§VII.C.1, VII.F, *supra*.

H. Ground 8: McGlamry and DaCosta-219 Render Claim 17 Obvious

The combination of McGlamry and DaCosta-219 renders claim 17 obvious. Ex.1003, ¶¶281-288.

As explained for limitation 1[e] in Grounds 1-2, McGlamry discloses and renders obvious surgical techniques for correcting the bunion deformity, including fixation of the first metatarsal relative to the cuneiform with a bone fixation device. *See* §VII.A.1.f, *supra*.

DaCosta-219 discloses “intramedullary nail fixation guides, devices, and methods” specifically designed for fixation of prepared joint surfaces in the foot. Ex.1013, 1:22-24; *see also id.*, 1:26-30. For example, DaCosta-219 discloses an “intramedullary nail 200 [that] includes a body 202 with a closed end 204, a fastening end 206, and four openings 208, 210, 212, 214.” *Id.*, 10:16-18.

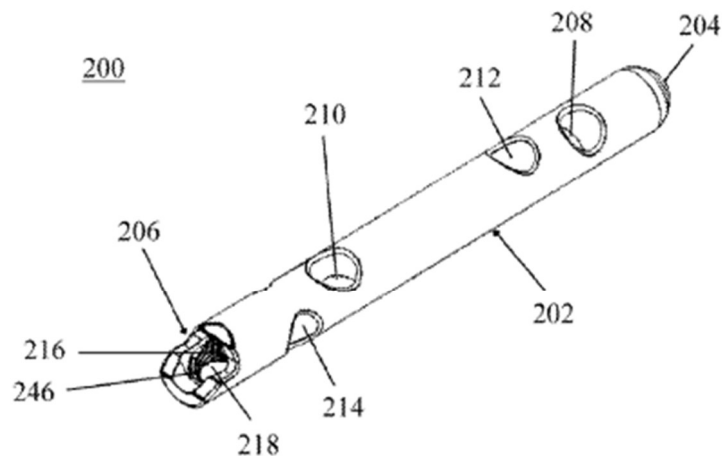
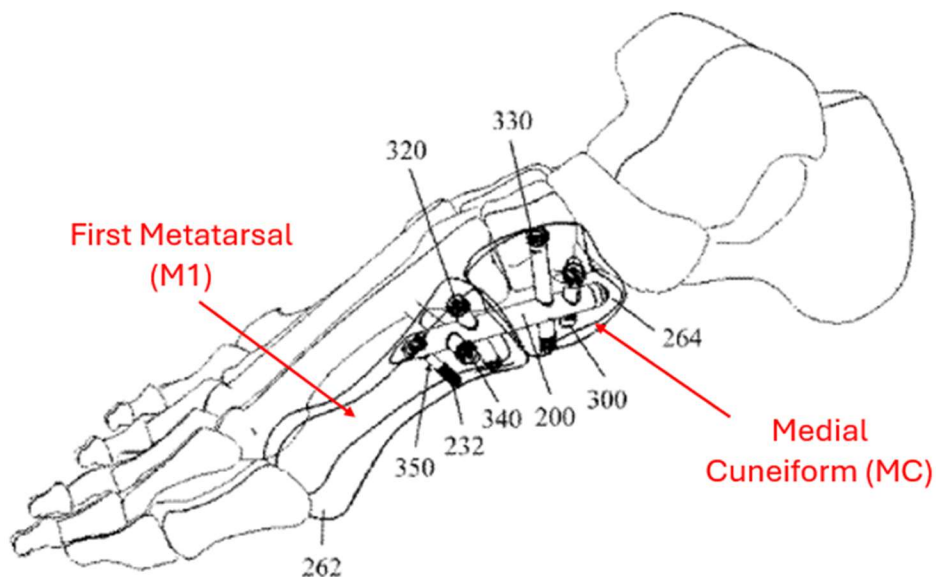


FIG. 9

Id., Fig.9. As illustrated by Figure 32, DaCosta-219 describes methods for fixing “a proximal tarsal-metatarsal joint,” e.g. the first metatarso-cuneiform joint, using the intramedullary implant 200. *Id.*, 12:11-19. *See generally id.*, 12:1-23:13, Figs. 13-32.



Ex.1003, ¶283 (annotating Ex.1013, Fig.32). The intramedullary implant 200 is secured via fasteners through openings, thereby resisting longitudinal and rotational movement. *See* Ex.1013, 10:18-21, 14:22-15:24, Fig.32.

A POSA would have understood DaCosta-219's intramedullary fixation to be a suitable alternative to McGlamry's disclosed fixation devices because both achieve the same stated objective: maintaining close, stable apposition across an arthrodesis site to promote predictable fusion. *See* Ex.1005, 326-327, 808; Ex.1013, 1:22-24, 10:19-21

It would have been obvious to use DaCosta-219's intramedullary implant in McGlamry's bunion correction procedure. Ex.1003, ¶¶284-287. McGlamry discloses arthrodesis of the first metatarsal-cuneiform joint to correct bunion deformity and emphasizes the importance of stable internal fixation to prevent non-union or malunion. Ex.1006, 322-325. DaCosta-219 provides an express motivation for substituting intramedullary fixation for traditional plates and screws in precisely this anatomical location. DaCosta-219 explains that prior art plates and screws cause soft-tissue irritation and "gapping" at the plantar surface of a metatarso-cuneiform joint, thereby compromising fusion. *See* Ex.1013, 1:12-21. DaCosta-219 further discloses that intramedullary implant overcomes these problems by improving compression and stability across the joint. *Id.*, 1:22-24.

DaCosta-219 also discloses its intramedullary implant reduces longitudinal and rotational movement across the fusion site through the placement of multiple fixation openings, thereby increasing construct stability. *Id.*, 10:19-21. With increased stability, patients may engage in earlier weight-bearing activities, reducing complications like delayed union or non-union. *See id.*; Ex.1003, ¶286.

Substituting DaCosta-219’s intramedullary implant for McGlamry’s fixation devices therefore represents nothing more than the predictable substitution of one known fixation element for another to achieve the same result—stable arthrodesis with improved biomechanical performance. Ex.1003, ¶287; *KSR*, 550 U.S. at 416-18.

Accordingly, a POSA would have had a reasonable expectation of success in using DaCosta-219’s intramedullary implant in McGlamry’s procedure, particularly because DaCosta-219 discloses fixation of the metatarsal relative to the cuneiform using the same implant. Ex.1003, ¶288; *see also* Ex.1013, 12:1-23:13, Figs. 13-32.

I. Ground 9: McGlamry, Davidson, and DaCosta-219 Render Claim 17 Obvious

The combination of McGlamry, Davidson, and DaCosta-219 renders claim 17 obvious. Ex.1003, ¶¶289-290. As explained for claim 1 in Ground 3, it would have been obvious to perform McGlamry’s procedure using Davidson’s retractor to provide exposure and access during the procedure. *See* §VII.C.1, *supra*. As explained for claim 17 in Ground 9, it further would have been obvious to use

DaCosta-219's intramedullary implant as the fixation device in McGlamry's procedure. *See* §VII.H, *supra*.

The addition of DaCosta-219's intramedullary implant to McGlamry's procedure as performed with Davidson's retractor represents a straightforward combination of known, compatible surgical tools used according to their established functions. Ex.1003, ¶290. DaCosta-219's intramedullary implant is complementary to McGlamry's procedure and does not interfere with the use of Davidson's retractor. *Id.* Accordingly, a POSA would have had a reasonable expectation of success in combining McGlamry, Davidson, and DaCosta-219 for the same reasons supporting the McGlamry-Tyber combination. *Id.*; *see* §§VII.C.1, VII.H, *supra*.

J. Ground 10: Fallin and Davidson Render Claims 1-7, 12-14, 16, 18-20, 25, and 27 Obvious

1. Claim 1

a. Preamble

To the extent the preamble is limiting, Fallin discloses “an instrumented surgical technique for treating a bunion deformity.” Ex.1007, [0047]-[0049], [0057]; Ex.1003, ¶¶291-292. Fallin describes a bunion correction surgery that includes: cutting a proximal portion of the first metatarsal, moving the first metatarsal in multiple planes, cutting a distal portion of the first cuneiform, and fixing the first metatarsal to the first cuneiform to promote fusion of the joint. Ex.1007, [0058]. For example, Fallin discloses that:

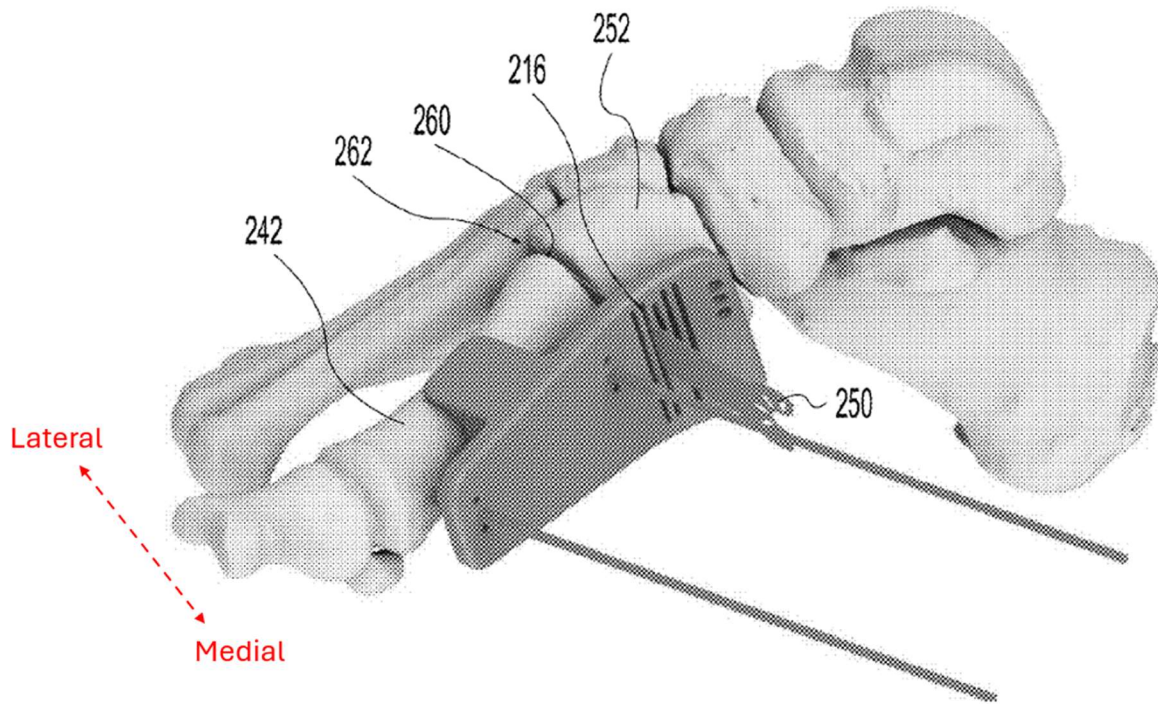
a first cut may be made on one of the metatarsus and cuneiform to remove a portion of bone creating a first cut surface The bones may then be repositioned in one or more planes. For example, the metatarsus may be rotated laterally in the transverse plane ... rotated in the coronal plane ... and rotated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

Id., [0058]. Fallin further discloses that “bone portions can be fixed together relative to one another to promote healing with fixation elements such as pins, plates, screws, rods, or other suitable fixation elements.” *Id.*, [0060].

b. Limitation 1[a]

During Fallin’s bunion correction surgery, the metatarso-cuneiform joint is exposed, and a cutting guide 200 is applied on the medial side of the joint. Ex.1007, Figs.21-25, [0063]-[0064]; Ex.1003, ¶294. During the cutting step, a saw is inserted into the slots 216 of the cutting guide laterally, i.e. toward the second metatarsal. Ex.1007, [0065].

In these embodiments, Fallin does not disclose any structure that physically limits the depth of the saw blade or shields anatomy on the lateral (blind) side of the cut. As a result, the saw blade may inadvertently contact the second metatarsal or tissues in the blade path, such as the tissues shown in Figures 4-5 of Fallin. Ex.1003, ¶¶295-296.



Ex.1003, ¶295 (annotating Ex.1007, Fig.22).

It would have been obvious to use Davidson’s retractor during Fallin’s bunion correction surgery to protect anatomy in the path of the saw (e.g., the second metatarsal, nerves, blood vessels) from inadvertent damage. Ex.1003, ¶297. Davidson discloses using its retractors during “osteotom[ies] of the midtarsal bones and proximal first metatarsal,” e.g. metatarso-cuneiform fusion. Ex.1006, [0060]. Davidson further discloses that its retractors “permit[] isolation and exposure of individual...bones for corrective osteotomy, and protect[] the soft tissues (arteries, veins, nerves, muscles, etc.) on the deep side of the foot bones from damage from sharp saws.” Ex.1006, [0057]. In particular, Davidson discloses placing the

retractor between the first and second metatarsals to isolate the first metatarsal and protect adjacent anatomy during corrective osteotomy. *Id.*, [0056]-[0058].

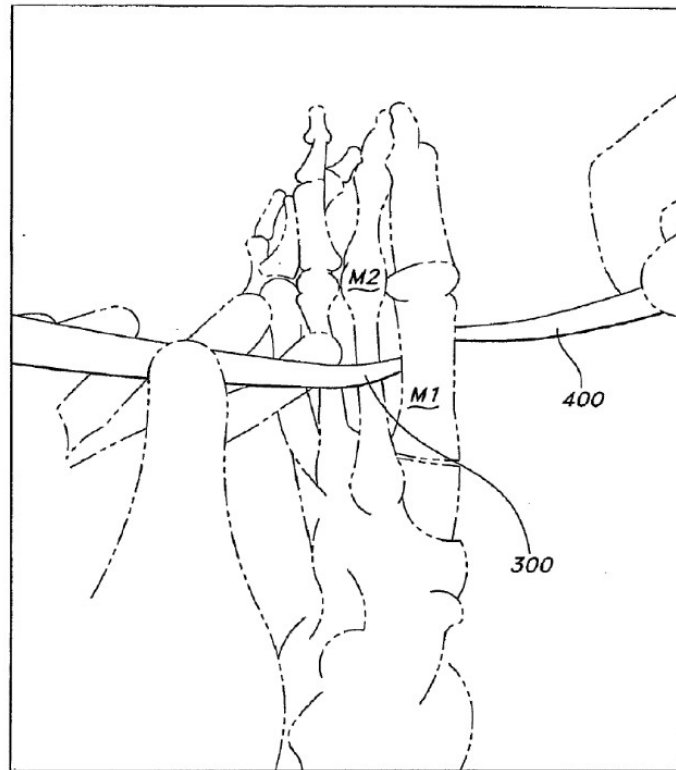


FIG. 19

Id., Fig.19. With Fallin’s cutting guide positioned on the medial side of the first metatarsal, it would have been obvious to insert Davidson’s retractor on the lateral side—between the first and second metatarsal as taught in Davidson—to physically interpose a rigid barrier between the saw blade and the opposing second metatarsal and surrounding tissues during Fallin’s cutting step. Ex.1003, ¶295.

Placing Davidson’s retractor between the metatarsals during Fallin’s procedure would have been nothing more than the use of a known surgical technique

to solve a known problem using prior-art elements according to their established functions. Ex.1003, ¶¶295, 299; *see NuVasive*, 2021 WL 3661208, at *4-5 (use of a known nerve-monitoring technology to avoid a known surgical complication was nothing “more than the predictable use of prior art elements according to their established functions”); *see also Intel Corp. v. PACT XPP Schweiz AG*, 61 F.4th 1373, 1380 (Fed. Cir. 2023); *KSR*, 550 U.S. 398, 417 (claims are obvious if they apply “a known technique to a piece of prior art ready for the improvement”). A POSA would have a reasonable expectation of success because Davidson discloses using its retractor during Lapidus-type procedures like Fallin’s and positioning the retractor between the first and second metatarsals to protect anatomy during corrective osteotomy. Ex.1003, ¶297; *see* Ex.1006, [0060], [0057]-[0058], Fig.19.

It also would have been obvious to use Davidson’s retractor during Fallin’s procedure to reposition the first metatarsal. Ex.1003, ¶298. Fallin discloses repositioning the metatarsal relative to the cuneiform in one or more planes after an initial cut to correct deformity. *See* Ex.1007, [0058], [0075]. Davidson’s retractors are designed to “fit the unique shape and contours of the human foot and to accommodate the varied locations between bones and small spaces in the foot.” Ex.1006, [0032]. A POSA would have recognized that placing Davidson’s retractor between the first and second metatarsals—as taught by Davidson—would provide predictable mechanical advantage and control when repositioning the first metatarsal

in the transverse and sagittal planes, as performed during Fallin’s procedure. Ex.1003, ¶298.

Using Davidson’s retractor for repositioning would have involved nothing more than applying a known surgical instrument to perform its established function—providing leverage and control of a bone—in the same anatomical location and during the same type of corrective procedure disclosed in both references. Ex.1003, ¶¶298-299; *see KSR*, 550 U.S. 398, 417 (claims are obvious if they apply “a known technique to a piece of prior art ready for the improvement”). Davidson discloses using its retractor in Lapidus-type procedures and positioning it between the first and second metatarsals to manipulate the first metatarsal during corrective surgery. Accordingly, a POSA would have had a reasonable expectation of success in using Davidson’s retractor to assist with repositioning the first metatarsal during Fallin’s bunion correction surgery. Ex.1003, ¶300.

Thus, Fallin and Davidson render this limitation obvious. *Id.*, ¶¶293-301.

c. Limitation 1[b]

Fallin discloses that “a saw blade 250 in a powered handpiece...is guided in one of the distal guide slots 216 to remove bone from the proximal end of the metatarsus 242.” Ex.1007, [0065]. During the cutting step, the saw advances laterally toward adjacent anatomy, including the second metatarsal and intervening soft tissues. Ex.1003, ¶303.

For the reasons explained for limitation 1[a], it would have been obvious to place Davidson’s retractor between the metatarsals while performing Fallin’s cutting steps. *See* §VII.J.1.b, *supra*. Doing so would predictably protect tissues and opposing bone in the path of the saw by physically interposing a rigid barrier on the blind (lateral) side of the cut, consistent with Davidson’s teachings regarding use of its retractor during corrective osteotomy procedures. *Id.*

Thus, Fallin and Davidson render this limitation obvious. Ex.1003, ¶¶302-304.

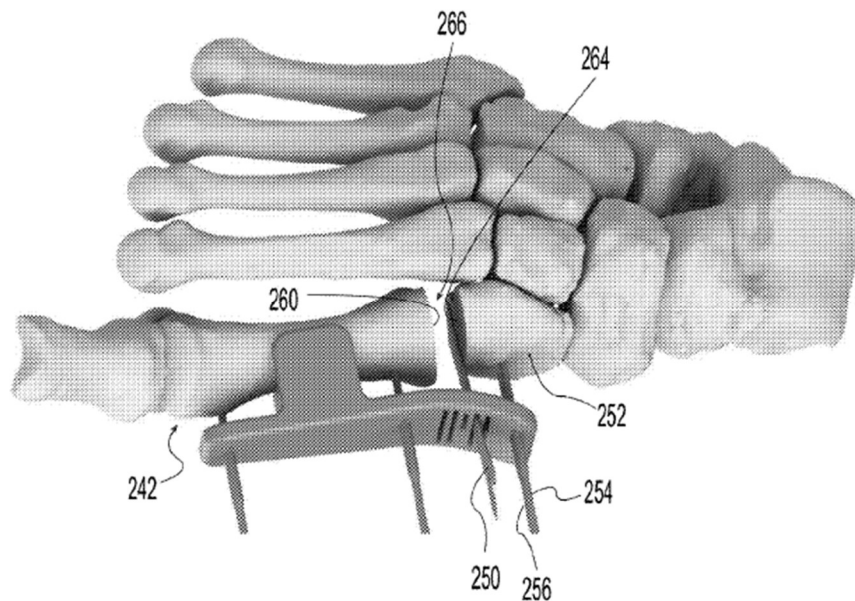
d. Limitation 1[c]

Fallin discloses moving the first metatarsal in at least one plane to treat a bunion deformity as part of its bunion surgery. Ex.1007, [0066] (“[T]he metatarsus 242 is repositioned relative to the cuneiform 252 to change their relative position in one or more planes.”); Ex.1003, ¶305. Specifically, Fallin describes moving the metatarsal three anatomical planes to treat the bunion deformity. Ex.1007, [0057]. “For example, the metatarsus may be rotated laterally in the transverse plane to correct an MIN deformity, rotated in the coronal plane to correct abnormal pronation/supination, and rotated in the sagittal plane to adjust plantar/dorsal flexion.” *Id.*, [0058].

Thus, Fallin and Davidson render this limitation obvious. Ex.1003, ¶¶305-306.

e. Limitation 1[d]

Fallin discloses cutting an end of a medial cuneiform opposing the end of the first metatarsal step as part its bunion correction surgery. Ex.1007, [0067]; Ex.1003, ¶307. For example, Fallin discloses “[a] saw blade 250 is guided in one of the proximal guide slots 218 to remove bone from the distal end of the cuneiform 252. Ex.1007, [0067]. “This creates a second planar cut surface 264 on the cuneiform 252 in predetermined relationship to the first planar cut surface 260 on the metatarsus 242 and a gap 266 between the bones having a predetermined shape,” as shown in Figure 25. *Id.*



Id., Fig.25.

Thus, Fallin and Davidson render this limitation obvious. Ex.1003, ¶¶307-308.

f. Limitation 1[e]

Fallin discloses, after moving the first metatarsal in at least one plane to treat the bunion deformity, fixating a moved position of the first metatarsal relative to the medial cuneiform using at least one bone fixation device. Ex.1003, ¶309. Fallin explains that “[t]he first and second cut surfaces may be brought together and fixed so that they heal together fusing the joint in the new position.” Ex.1007, [0058]. According to Fallin, the bones may be fixed with at least one bone fixation device “such as pins, plates, screws, rods or other suitable fixation elements.” *Id.*, [0060].

This disclosure satisfies “fixation device” under its plain and ordinary meaning discussed in Section V.C. Ex.1003, ¶310. Under §112(f), Fallin’s across-joint pins, plates, screws, etc. are the same types of fixation structures identified in the ’428 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, the combination of Fallin and Davidson renders claim 1 obvious. Ex.1003, ¶¶291-312.

2. Claim 2

Davidson discloses the additional limitations of claim 2 as explained in Ground 3. *See* §VII.C.2, *supra*. Incorporating Davidson’s retractor into Fallin’s procedure would not alter the disclosed configuration or placement of the retractor, including positioning the handle laterally over the second metatarsal, because

Davidson teaches that configuration independent of the particular corrective osteotomy being performed. Ex.1003, ¶¶313-314. Thus, Fallin and Davidson render claim 2 obvious. *Id.*

3. Claim 3

Davidson discloses the additional limitations of claim 3 as explained in Ground 3. *See* §VII.C.3, *supra*. Davidson teaches dorsal insertion of its retractor, and that manner of insertion would not change when the retractor is used in Fallin’s procedure. Ex.1003, ¶315. Thus, Fallin and Davidson render claim 3 obvious. *Id.*

4. Claim 4

Fallin discloses the additional limitations of claim 4 as explained in Ground 4. *See* §VII.D.1, *supra*. Thus, Fallin and Davidson render claim 4 obvious. Ex.1003, ¶316.

5. Claim 5

Fallin discloses the additional limitations of claim 5 as explained in Ground 4. *See* §VII.D.2, *supra*. Thus, Fallin and Davidson render claim 5 obvious. Ex.1003, ¶317.

6. Claim 6

Fallin and Davidson render this claim obvious. Ex.1003, ¶¶318-319.

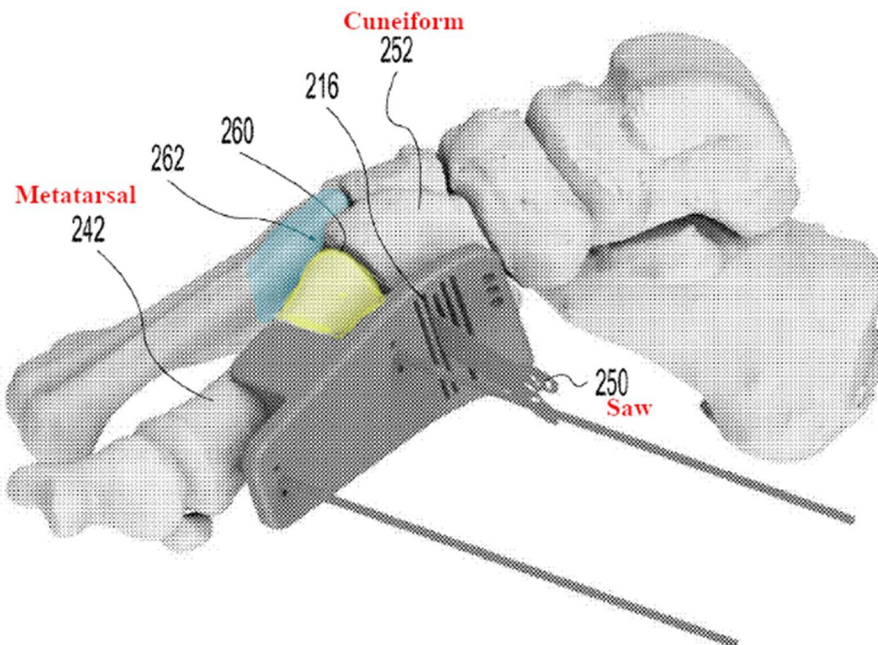
As explained for limitation 1[b] in this ground, it would have been obvious to place Davidson’s retractor between the metatarsals while cutting the first metatarsal

as disclosed by Fallin. *See* §VII.J.1.c, *supra*. Fallin further discloses that the osteotomy guide 200 is removed from the metatarsal after cutting the metatarsal, repositioning the bones, and cutting the cuneiform. Ex.1007, [0068]. A POSA would understand that Davidson’s retractor—used during the cutting to protect intervening tissues—would likewise be removed after completion of the cutting. Ex.1003, ¶319; *see also* Ex.1007,[0055] (Retractors are used “during surgery.”).

7. Claim 7

Fallin and Davidson render this claim obvious. Ex.1003, ¶¶320-323.

Fallin discloses cutting the proximal end of the first metatarsal, with the cutting location falling within the proximal third of the first metatarsal (yellow) and the second metatarsal (blue), as shown below. Ex.1007, [0065]; Ex.1003, ¶321*.



Ex.1003, ¶321 (annotating Ex.1007, Fig.22).

As explained for limitation 1[a] in this ground, it would have been obvious to place Davidson’s retractor between the metatarsals on the opposite side of Fallin’s metatarsal resection to protect anatomy in the path of the saw. *See* §VII.J.1.c, *supra*. Because Fallin’s resection is performed at the proximal third of the first metatarsal, a POSA would have positioned Davidson’s retractor between the proximal third of the first and second metatarsals—i.e., at the same anatomical location where the resection occurs—to physically interpose the retractor between the saw blade and adjacent tissues and bone. *See* Ex.1007, [0065]; Ex.1003, ¶322.

8. Claim 12

Fallin discloses “[t]he...cut surfaces [of the first metatarsal and cuneiform] may be brought together and fixed so that they heal together fusing the joint in the new position.” Ex.1007, [0058]. Fallin further discloses that “compression may be facilitated by using a forceps or clamp, e.g. a towel clamp, to press the bone portions together.” *Id.*, [0075]. Thus, Fallin and Davidson render claim 12 obvious. Ex.1003, ¶¶324-325.

9. Claim 13

Fallin and Davidson render this claim obvious. Ex.1003, ¶¶326-327.

As explained for limitation 1[a] in this ground, Davidson’s retractor would have been used not only for protection during cutting, but also to provide control and leverage of the first metatarsal during subsequent steps of Fallin’s procedure. *See*

§VII.J.1.b, *supra*. Because Fallin discloses repositioning the first metatarsal relative to the cuneiform before and during cutting of the cuneiform, it would have been obvious to leave Davidson’s retractor positioned between the first and second metatarsals to maintain control and stabilization of the first metatarsal in the corrected position while the medial cuneiform is cut. Ex.1003, ¶327; Ex.1006, [0057]. In this configuration, the retractor need not function as a physical stop for the cuneiform cut, but instead serves its established function of providing leverage, isolation, and positional control during the cuneiform resection. Ex.1003, ¶327.

10. Claim 14

Fallin discloses performing the steps in the order recited by claim 14 as explained for claim 14 in Ground 4. *See* §VII.D.3, *supra*. Thus, Fallin and Davidson render claim 14 obvious. Ex.1003, ¶328.

11. Claim 16

Fallin discloses that its fixation device is one or more of “pins, plates, screws, rods or other suitable fixation is applied.” Ex.1007, [0075]. Thus, Fallin and Davidson render claim 16 obvious. Ex.1003, ¶329.

12. Claim 18

Independent claim 18 recites substantially the same limitations as independent claim 1 and dependent claims 4-5 (using and securing a cutting guide), 7 (proximal instrument positioning), and 12 (compressing the metatarsal and cuneiform). Thus,

Fallin and Davidson render obvious these limitations as explained for claims 1, 4-5, 7, and 12 in this ground. Ex.1003, ¶330; *see* §§VII.J.1, VII.J.4-5, VII.J.7, VII.J.8, *supra*.

13. Claim 19

Fallin and Davidson render the additional limitations of claim 19 obvious for the reasons explained for claim 6 in this ground. Ex.1003, ¶331; *see* §VII.J.6, *supra*.

14. Claim 20

Fallin and Davidson render the additional limitations of claim 20 obvious for the reasons explained for claim 2 in this ground. Ex.1003, ¶332; *see* §VII.J.2, *supra*.

15. Claim 25

Fallin and Davidson render the additional limitations of claim 25 obvious for the reasons explained for claim 14 in this ground. Ex.1003, ¶333; *see* §VII.J.10, *supra*.

16. Claim 27

Fallin discloses that “the bone portions may be fixed relative to one another to promote healing with fixation elements such as pins, plates, screws, rods or other suitable fixation elements.” Ex.1007, [0060]; *see also id.*, [0075]. Thus, Fallin and Davidson render claim 27 obvious. Ex.1003, ¶¶334-335.

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 (Dist. Del), any invalidity ground against the challenged claims of the '428 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 ’428 patent against Petitioner in the district court litigation. Treace has also asserted U.S. Patent No. 12,268,397 (“the ’397 patent”) in the district court litigation, and the ’397 patent is currently the subject of PGR Review No. IPR2026-00017.

C. Lead and Backup Counsel and Service Information (37 C.F.R. §42.8(b)(3)-(4))

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

Lead Counsel	Back-up Counsel
Ali S. Razai (Reg. No. 60,771) <i>ali.razai@morganlewis.com</i>	Benjamin J. Everton (Reg. No. 60,659) <i>ben.everton@morganlewis.com</i>
<u>Postal and Hand-Delivery Address:</u> MORGAN, LEWIS & BOCKIUS LLP 600 Anton Boulevard, Suite 1800 Costa Mesa, CA 92626-7653 Tel.: (714) 830-0600 Fax: (714) 830-0700	Jacob L. Peterson (Reg. No. 65,096) <i>jacob.peterson@morganlewis.com</i> Zachary Messick (Reg. No. 77,839) <i>zachary.messick@morganlewis.com</i> <u>Postal and Hand-Delivery Address:</u> MORGAN, LEWIS & BOCKIUS LLP 600 Anton Boulevard, Suite 1800 Costa Mesa, CA 92626-7653 Tel.: (714) 830-0600 Fax: (714) 830-0700

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

Please direct all correspondence to lead counsel and back-up counsel at the addresses shown above. Petitioner also consents to electronic service by email to MLB-P28-PGR-428@morganlewis.com.

E. Standing

The '428 patent is available for PGR and no bar or estoppel applies.

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

The Office may charge any fees to Deposit Account No. 50-0310. Review of thirty claims is requested.

XI. CONCLUSION

Petitioner respectfully requests that the Board institute PGR and cancel claims 1–30 of the '428 patent.

Dated: December 23, 2025 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. 12,268,428	
Claim 1 ⁶	
[1pre]	An instrumented surgical technique for treating a bunion deformity, the instrumented surgical technique comprising:
[1a]	inserting an instrument between a first metatarsal and a second metatarsal adjacent to the first metatarsal;
[1b]	with the instrument inserted between the first metatarsal and the second metatarsal, cutting an end of the first metatarsal;
[1c]	moving the first metatarsal in at least one plane to treat the bunion deformity;
[1d]	cutting an end of a medial cuneiform opposing the end of the first metatarsal; and
[1e]	after moving the first metatarsal in at least one plane to treat the bunion deformity, fixating a moved position of the first metatarsal relative to the medial cuneiform using at least one bone fixation device.
Claim 2	
[2pre]	The instrumented surgical technique of claim 1, wherein:
[2a]	the instrument has a body and a handle operatively connected to the body;
[2b]	the handle extends from the body; and
[2c]	inserting the instrument between the first metatarsal and the second metatarsal comprises inserting the body between the first metatarsal and the second metatarsal and thereby positioning the

	handle extending laterally over a dorsal surface of the second metatarsal.
Claim 3	
--	The instrumented surgical technique of claim 2, wherein inserting the body between the first metatarsal and the second metatarsal comprises inserting the body from a dorsal side of a foot toward a plantar side of the foot.
Claim 4	
--	The instrumented surgical technique of claim 1, further comprising positioning a bone preparation guide defining a cutting slot over the first metatarsal, wherein cutting the end of the first metatarsal comprises guiding a saw blade through the cutting slot to cut the end of the first metatarsal.
Claim 5	
--	The instrumented surgical technique of claim 4, wherein the bone preparation guide comprises at least one fixation aperture, and further comprising securing the bone preparation guide to the first metatarsal with at least one fixation pin inserted into the first metatarsal and extending through the at least one fixation aperture of the bone preparation guide.
Claim 6	
--	The instrumented surgical technique of claim 1, further comprising, after cutting the end of the first metatarsal, removing the instrument from between the first metatarsal and the second metatarsal.

Claim 7	
--	The instrumented surgical technique of claim 1, wherein positioning the instrument between the first metatarsal and the second metatarsal comprises positioning the instrument between a proximal-most third of the first metatarsal and a proximal-most third of the second metatarsal.
Claim 8	
--	The instrumented surgical technique of claim 1, wherein moving the first metatarsal in at least one plane comprises moving the first metatarsal relative to the second metatarsal in a transverse plane by applying a force to the first metatarsal with a bone positioning guide and thereby reducing an intermetatarsal angle between the first metatarsal and the second metatarsal.
Claim 9	
[9pre]	The instrumented surgical technique of claim 8, wherein:
[9a]	the instrument is a fulcrum; and
[9b]	moving the first metatarsal in the transverse plane comprises pivoting the first metatarsal about the fulcrum.
Claim 10	
--	The instrumented surgical technique of claim 8, wherein moving the first metatarsal in at least one plane further comprises moving the first metatarsal in a frontal plane.
Claim 11	
--	The instrumented surgical technique of claim 10, wherein moving the first metatarsal in the frontal plane comprises imparting a force to a pin inserted into the first metatarsal to adjust an alignment of

	the first metatarsal in the frontal plane to treat the bunion deformity.
Claim 12	
--	The instrumented surgical technique of claim 1, further comprising compressing the first metatarsal together with the medial cuneiform prior to fixing the moved position of the first metatarsal relative to the medial cuneiform using the at least one bone fixation device.
Claim 13	
--	The instrumented surgical technique of claim 1, wherein cutting the end of the medial cuneiform comprises cutting the end of the medial cuneiform with the instrument inserted between the first metatarsal and the second metatarsal.
Claim 14	
--	The instrumented surgical technique of claim 1, wherein cutting the end of the medial cuneiform comprises cutting the end of the medial cuneiform after cutting the end of the first metatarsal and after moving the first metatarsal in the at least one plane to treat the bunion deformity.
Claim 15	
--	The instrumented surgical technique of claim 1, further comprising, prior to inserting the instrument between the first metatarsal and the second metatarsal, obtaining the instrument from a sterile kit that also includes (1) a bone positioning guide configured to engage the first metatarsal and apply a force to the first metatarsal to move the first metatarsal in at least one plane and (2) a bone

	preparation guide defining a cutting slot configured to be positioned over an end of the first metatarsal to be cut.
Claim 16	
--	The instrumented surgical technique of claim 1, wherein the at least one bone fixation device comprises at least one of a screw and a plate.
Claim 17	
--	The instrumented surgical technique of claim 1, wherein the at least one bone fixation device comprises an intramedullary implant.
Claim 18	
[18pre]	An instrumented surgical technique for treating a bunion deformity, the instrumented surgical technique comprising:
[18a]	positioning a bone preparation guide defining a cutting slot over a first metatarsal with at least one fixation pin inserted into the first metatarsal and extending through at least one fixation aperture of the bone preparation guide;
[18b]	positioning a bone preparation guide defining a cutting slot over a first metatarsal with at least one fixation pin inserted into the first metatarsal and extending through at least one fixation aperture of the bone preparation guide;
[18c]	with the instrument inserted between the first metatarsal and the second metatarsal, guiding a saw blade through the cutting slot to cut an end of the first metatarsal;
[18d]	moving the first metatarsal in at least one plane to treat the bunion deformity;

[18e]	cutting an end of a medial cuneiform opposing the end of the first metatarsal;
[18f]	compressing the first metatarsal together with the medial cuneiform; and
[18g]	after moving the first metatarsal in at least one plane to treat the bunion deformity and after compressing the first metatarsal together with the medial cuneiform, fixating a moved position of the first metatarsal relative to the medial cuneiform for fusion using at least one bone fixation device.
Claim 19	
--	The instrumented surgical technique of claim 18, further comprising, after cutting the end of the first metatarsal, removing the instrument from between the first metatarsal and the second metatarsal.
Claim 20	
[20pre]	The instrumented surgical technique of claim 18, wherein:
[20a]	the instrument has a body and a handle operatively connected to the body;
[20b]	the handle extends from the body; and
[20c]	inserting the instrument between the first metatarsal and the second metatarsal comprises inserting the body between the first metatarsal and the second metatarsal and thereby positioning the handle extending laterally over a dorsal surface of the second metatarsal.

Claim 21	
--	The instrumented surgical technique of claim 18, wherein moving the first metatarsal in at least one plane comprises moving the first metatarsal relative to the second metatarsal in a transverse plane by applying a force to the first metatarsal with a bone positioning guide and thereby reducing an intermetatarsal angle between the first metatarsal and the second metatarsal.
Claim 22	
[22pre]	The instrumented surgical technique of claim 21, wherein:
[22a]	the instrument is a fulcrum; and
[22b]	moving the first metatarsal in the transverse plane comprises pivoting the first metatarsal about the fulcrum.
Claim 23	
--	The instrumented surgical technique of claim 21, wherein moving the first metatarsal in at least one plane comprises moving the first metatarsal in a frontal plane.
Claim 24	
--	The instrumented surgical technique of claim 23, wherein moving the first metatarsal in the frontal plane comprises imparting a force to a pin inserted into the first metatarsal to adjust an alignment of the first metatarsal in the frontal plane to treat the bunion deformity.
Claim 25	
--	The instrumented surgical technique of claim 18, wherein cutting the end of the medial cuneiform comprises cutting the end of the medial cuneiform after cutting the end of the first metatarsal and

	after moving the first metatarsal in the at least one plane to treat the bunion deformity.
Claim 26	
--	The instrumented surgical technique of claim 18, further comprising, prior to inserting the instrument between the first metatarsal and the second metatarsal, obtaining the instrument from a sterile kit that also includes (1) a bone positioning guide configured to engage the first metatarsal and apply a force to the first metatarsal to move the first metatarsal in at least one plane and (2) the bone preparation guide.
Claim 27	
--	The instrumented surgical technique of claim 18, wherein the at least one bone fixation device comprises one or more of a screw, a plate, and an intramedullary implant.
Claim 28	
[28pre]	An instrumented surgical technique for treating a bunion deformity, the instrumented surgical technique comprising:
[28a]	positioning a bone preparation guide defining a cutting slot over a first metatarsal with at least one fixation pin inserted into the first metatarsal and extending through at least one fixation aperture of the bone preparation guide;
[28b]	inserting an instrument between a proximal portion of the first metatarsal and a proximal portion of a second metatarsal adjacent to the first metatarsal;

[28c]	with the instrument inserted between the first metatarsal and the second metatarsal, guiding a saw blade through the cutting slot to cut an end of the first metatarsal;
[28d]	engaging a bone positioning guide with the first metatarsal and using the bone positioning guide to move the first metatarsal relative to the second metatarsal in a transverse plane to reduce an intermetatarsal angle between the first metatarsal and the second metatarsal to treat the bunion deformity;
[28e]	imparting a force to a pin inserted into the first metatarsal to adjust an alignment of the first metatarsal in a frontal plane to treat the bunion deformity;
[28f]	cutting an end of a medial cuneiform opposing the end of the first metatarsal;
[28g]	compressing the first metatarsal together with the medial cuneiform; and
[28h]	fixating a moved position of the first metatarsal relative to the medial cuneiform for fusion using at least one bone fixation device.
Claim 29	
[29pre]	The instrumented surgical technique of claim 28, wherein:
[29a]	the instrument has a body and a handle operatively connected to the body;
[29b]	the handle extends from the body; and
[29c]	inserting the instrument between the first metatarsal and the second metatarsal comprises inserting the body between the first metatarsal and the second metatarsal and thereby positioning the

	handle extending laterally over a dorsal surface of the second metatarsal.
Claim 30	
--	The instrumented surgical technique of claim 28, further comprising, after cutting the end of the first metatarsal, removing the instrument from between the first metatarsal and the second metatarsal.

CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. § 42.24(d), the undersigned certifies that this PETITION FOR POST GRANT REVIEW OF U.S. PATENT NO. 12,268,428 contains 18,699 words according to the word-processing program used to prepare this paper. The foregoing word count complies with the 18,700-word type-volume limit specified by 37 C.F.R. § 42.24(a)(1).

Dated: December 23, 2025 By: / Ali S. Razai/
Ali S. Razai (Reg. No. 60,771)
MORGAN, LEWIS & BOCKIUS LLP

CERTIFICATE OF SERVICE

The undersigned hereby certifies that on the date below a copy of this **PETITION FOR POST GRANT REVIEW OF U.S. PATENT NO. 12,268,428, PETITIONER’S POWER OF ATTORNEY, AND EXHIBITS 1001-1028 AND 1030**, were served by FedEx on the Patent Owner at the correspondence address of record for the subject patent as follows:

FREDRIKSON & BYRON, P.A.
INTELLECTUAL PROPERTY GROUP
60 SOUTH SIXTH STREET, SUITE 1500
MINNEAPOLIS, MN 55402
UNITED STATES

A courtesy copy is being sent by email on this day to Patent Owner’s counsel of record in the Litigation as follows:

Nimalka Wickramasekera (NWickramasekera@winston.com)
Robert T. Vlasik III (RVlasik@winston.com)
Michael A. Meneghini (MMeneghini@winston.com)

Dated: December 23, 2025 By: /Ali S. Razai/
Ali S. Razai (Reg. No. 60,771)
MORGAN, Lewis & BOCKIUS LLP