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

DECLARATION OF STEVEN K. NEUFELD, M.D. IN SUPPORT OF PETITION FOR POST-GRANT REVIEW OF U.S. PATENT NO. 12,268,428

Paragon 28 v. Treace Medical Concepts
PGR2026-00020
Paragon Ex. 1003

I, Steven K. Neufeld, do hereby declare:

1. I am making this declaration (the "Declaration") at the request of Paragon 28, Inc. ("Paragon").

2. I am being compensated for my work in this matter, and I am being reimbursed at cost for any expenses. My compensation in no way depends upon the outcome of this proceeding.

3. In preparing this Declaration, I considered the following materials as well as any other documents or materials I discuss in this declaration:

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, *The Lapidus Procedure*, 13(3) CLINICS PODIATRIC MED. & SURGERY 486–496 (1996)

Exhibit No.	Description
1010	Paul W. Lapidus, *The author's bunion operation from 1931 to 1959,* 16 CLIN. ORTHOPAEDICS 119-135 (1960)
1011	Paul W. Lapidus, *Operative correction of the metatarsus varus primus in hallux valgus,* 58 J. SURGERY GYNECOLOGY & OBSTETRICS 183–191 (1934)
1012	James M. Cottom & Anand M. Vora, *Fixation of lapidus arthrodesis with a plantar interfragmentary screw and medial locking plate: a report of 88 cases*, 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")
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," Journal of Orthopedic Science, 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

Exhibit No.	Description
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., *One century of Kirschner wires and Kirschner wire insertion techniques: A historical review*, 76 Acta Orthopedic Belgium 1–6 (2010)
1028	Paul Dayton et al., *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*, 52(3) J. Foot & Ankle Surgery 348–354 (2013)
1030	Declaration of Sylvia Hall-Ellis, Ph.D.

I. BACKGROUND AND QUALIFICATIONS

A. Experience and Qualifications

4. I am an orthopedic surgeon by training and profession. My current CV is being submitted as Exhibit 1004.

5. In 1991, I received my Bachelor of Science degree in Industrial Engineering from the University of Pittsburgh in Pittsburgh, Pennsylvania. In 1995, I received my Doctor of Medicine degree from the Hahnemann University School of Medicine in Philadelphia, Pennsylvania.

6. From 1995 to 1996, I interned at the Ohio State University in the Department of General Surgery. From 1996 to 2000, I completed my residency at the Ohio State University in the Department of Orthopedics, during which I was trained in the use of various bunion correction technologies. Shortly thereafter, from 2000 to 2001, I completed my fellowship in foot and ankle surgery at Union Memorial Hospital in Baltimore, Maryland.

7. From 2001 to 2006, I was employed at Anderson Orthopedic Clinic in Arlington, Virginia. In 2006, I founded The Orthopedic Foot & Ankle Center of Washington in Washington, D.C., which is the first comprehensive foot and ankle center in Washington, D.C. and where I am currently employed and serve as the Medical Director.

8. I am also a member of the Inova Sports Medicine Institute and founder and Director of the Inova Health Total Ankle Replacement Program.

9. For over the past 20 years, I have performed between 500-600 surgeries per year, of which, roughly 150-200 per year involved bunion correction.

10. I am board certified in Orthopedic Surgery, a Fellow in the American Academy of Orthopedic Surgeons, a Board Member of the Centers for Advanced Orthopedics and a former Board Member of the American Orthopedic Foot & Ankle Society Foundation.

11. I have been a Clinical Instructor at Georgetown University's Department of Orthopedics in Washington, D.C. since 2005. From 2014 to 2016, I worked as a Clinical Professor in the Department of Orthopedic Surgery for Virginia Commonwealth University's Medical Center of the Medical College of Virginia. In these roles, I have taught numerous medical students, residents, and fellows, including about bunion correction. I have also served as a faculty member and lectured in many orthopedic conferences regarding bunion corrections and the use of plates and screws in foot and ankle reconstructions and fusions.

12. I am currently an editorial reviewer for several peer reviewed orthopedic journals including the prestigious Journal of Bone and Joint Surgery and the Journal of the American Academy of Orthopedic Surgeons.

13. I have co-authored many publications in the field of orthopedic medicine including peer-reviewed articles on bunion corrections and foot and ankle fusions.

14. Based on my engineering background and medical training and experience, by the mid-2000s, I began consulting in the design of methods and instrumentation used in foot and ankle surgery (including designing orthopedic implants used for fusions in the foot and ankle and bunion corrections). I have also consulted on education for the proper use of commercially available methods and systems.

15. I am a named inventor of several U.S. patents including a bunion correction plate device.

B. Relevant Legal Standards

16. I have been asked to provide my opinion as to whether the claims of the ’428 patent would have been obvious to a person of ordinary skill in the art (“POSA”) at the time of the alleged invention, in view of the prior art.

17. The opinions I am expressing in this Declaration are based on the application of my training and technical knowledge and experience to the evaluation of certain prior art to the ’428 patent.

18. I am not an expert in patent law. Attorneys from Morgan, Lewis & Bockius, LLP have provided me with guidance as to the applicable patent law in this

matter. The paragraphs below express my understanding of how I must apply current principles related to my analysis.

1. Claim Construction

19. I understand that claim construction is the process of determining the meaning of a term or phrase in a patent claim. I understand that the claims are construed before the Board using the same claim construction standard that applies in district courts, i.e., how a hypothetical POSA would have understood the term based on its use in the claims, specification, and file history of the patent. I have followed these principles in my analysis throughout this declaration.

20. The ’428 patent claims “instrumented surgical technique[s].” I understand that the order in which the steps of a method claim are written is not limiting unless the language of the claim or some other claim construction requires the steps to be performed in a particular order.

2. Obviousness

21. It is my understanding that in determining whether a patent claim is obvious in view of the prior art, the Patent Office construes the claim by giving the claim its ordinary and customary meaning ascribed to it by a person of ordinary skill in the art at the time of the invention, consistent with the specification. I also understand that in reading the claim, I must not import limitations from the specification into the claim terms; in other words, I must not narrow the scope of the

claim terms by implicitly adding disclosed limitations that have no express basis in the claims.

22. I understand that a claim is "obvious," and therefore unpatentable, if the claimed subject matter as a whole would have been obvious to a POSA at the time of the alleged invention. I also understand that an obviousness analysis takes into account the scope and content of the prior art, the differences between the claimed subject matter and the prior art, and the level of ordinary skill in the art at the time of the invention.

23. In determining the scope and content of the prior art, I understand that a reference is considered appropriate (e.g., analogous) prior art if it falls within the field of the inventor's endeavor.[1] In addition, a reference is relevant prior art if it is reasonably pertinent to the particular problem with which the inventor was involved. A reference is reasonably pertinent if it logically would have commended itself to an inventor's attention in considering their problem. If a reference relates to the same problem as the claimed invention, that supports use of the reference as prior art in an obviousness analysis.

24. To assess the differences between prior art and the claimed subject matter, I understand that the law requires the claimed invention to be considered as

[1] The '428 patent specification defines the "TECHNICAL FIELD" as "devices and methods for positioning and/or preparing bones." Ex.1001, 1:27-28. The '428 patent claims are directed to "instrumented surgical technique[s]." *Id.*, 26:8, 27:4, 28:54.

a whole. This "as a whole" assessment requires showing that a POSA at the time of alleged invention, confronted by the same problems as the inventor and with no knowledge of the claimed invention, would have been motivated to select the elements from the prior art and combine them in the claimed manner.

25. I further understand that the law recognizes several rationales for combining references or modifying a reference to show obviousness of claimed subject matter. Some of these rationales include: combining prior art elements according to known methods to yield predictable results; simple substitution of one known element for another to obtain predictable results; a predictable use of prior art elements according to their established functions; applying a known technique to a known device (method or product) ready for improvement to yield predictable results; choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success; and some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

26. I understand that a prior art reference may also suggest a limitation of the claims. In that case, even if the prior art reference does not explicitly or inherently disclose the limitation, the motivation to modify the prior art reference to include the limitation may exist within the prior art reference itself. Thus, the limitation would have been obvious over that prior art reference alone. This is the case if a person of

ordinary skill in the art would have had a simple design choice or a finite number of identified, predictable solutions, for example, and if the modification furthers the goals of the prior art reference.

27. I further understand that the obviousness analysis must be performed from the perspective of a person of ordinary skill in the art at the time of the alleged invention. This is to avoid using impermissible hindsight in the analysis. The claims of the patent must not be used to provide a road map for obviousness; instead, the claims would have been obvious if a person of ordinary skill in the art would have been motivated to combine the teachings of the prior art to arrive at the claimed invention and had a reasonable expectation of success in doing so.

28. I also understand that an obviousness analysis must consider whether there are additional factors that would indicate that the claimed invention would not have been obvious. These factors include whether there was: (i) a long-felt need in the industry; (ii) any unexpected results; (iii) skepticism of the invention; (iv) a teaching away from the invention; (v) commercial success; (vi) praise by others for the invention; and (vii) copying by other companies.

C. Person of Ordinary Skill in the Art

29. I understand that when evaluating the claims of the ’428 patent, I must do so based on the perspective of a POSA as of the relevant priority date. As

discussed below, I understand that the earliest possible priority date for the '428 patent is August 14, 2015.

30. I understand that in determining the level of ordinary skill in the art, several factors are considered. Those factors may include: (i) the type of problems encountered in the art; (ii) prior art solutions to those problems; (iii) the rapidity with which innovations are made; (iv) the sophistication of the technology; and (v) the educational level of active workers in the field. A person of ordinary skill in the art must have the capability of understanding the scientific and engineering principles applicable to the pertinent art.

31. The '428 patent describes devices and methods for positioning and cutting bones, and claims instrumented surgical techniques using instruments disclosed in the '428 patent specification. Ex.1001, 1:39-49, claim 1. The '428 patent thus includes both surgical procedures and mechanical devices for use in such procedures. Based on my review of the specification and claims of the '428 patent, the types of problems encountered in the art, the prior art solutions to the problems sought to be solved by the invention, the pace at which innovations are made in the art, the sophistication of the technology, and the educational level of those working in the field, it is my opinion that a POSA would be an orthopedic surgeon or podiatrist having at least three years of experience performing foot and ankle surgery. Such a surgeon/podiatrist might also work as part of a team or consult with

an engineer having a bachelor's degree in biomedical engineering, mechanical engineering, or a closely related discipline with experience designing surgical instrumentation, and who has at least three years of experience learning from these doctors about the use of such devices in foot and ankle surgeries.

32. For individuals with different engineering backgrounds, a person could still be of ordinary skill in the art if that person's additional experience, such as experience designing medical devices, compensates for any differences in that person's education.

33. Because the '428 patent includes both surgical procedures and mechanical devices, the hypothetical POSA would have a combination of the skill sets for surgical procedures and the design of mechanical devices. As described above, the consultation of a surgeon with an engineer would satisfy this combination of skill sets, as the surgeon would provide surgical know-how and the engineer would provide mechanical design know-how.

34. While I believe the above definition of a POSA is the correct one, my opinions in this Declaration are not dependent on this specific definition of the level of ordinary skill in the art. The claims of the '428 patent would have been obvious to any reasonably defined POSA.

35. I can make this assessment because I was at least a POSA by August 14, 2015 because by that time, I was an orthopedic surgeon with at least three years

of experience performing foot and ankle surgery, and I knew of an interacted with many other POSAs and had worked with many surgeons and engineer developers. Further, by August 2015, I had performed numerous surgeries (including bunion correction surgeries) and worked with many surgeons and engineer developers. Further, by August 2015, I had supervised and trained many surgeons in the field of orthopedic and podiatric surgery, including bunion surgery. By August 2015, the surgeons I worked with had the requisite knowledge to and did use the surgical methods and instruments as described in the specification and claims of the ’428 patent. Because I have worked with and supervised surgeons and engineers in the field, I know very well what their capabilities were prior to August 2015, how those surgeons and engineers would interpret and understand the ’428 patent and its claims, and how they would understand the disclosures in the prior art discussed herein.

36. Although my own experience may have exceeded that of a POSA, the opinions expressed herein are from the perspective of the POSA as of August 2015.

37. In my opinion, as set forth in more detail below, a POSA at the time of the invention would have considered the claimed methods of the ’428 patent to be obvious in view of the prior art. My conclusions that the claims of the ’428 patent would have been obvious would remain the same even if the invention date, field of endeavor, of level of ordinary skill were slightly different.

II. STATE OF THE ART

38. Bunion correction procedures and the use of bone cutting guides were well-known by August 2015. 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 such as bone cutting guides.

A. Relevant Human Foot Anatomy

39. The human foot has 26 bones, including the bones of the first ray—the first metatarsal, medial cuneiform, and associated joints. The below image depicts the bones of the human foot, with annotations identifying the relevant bones and joints:

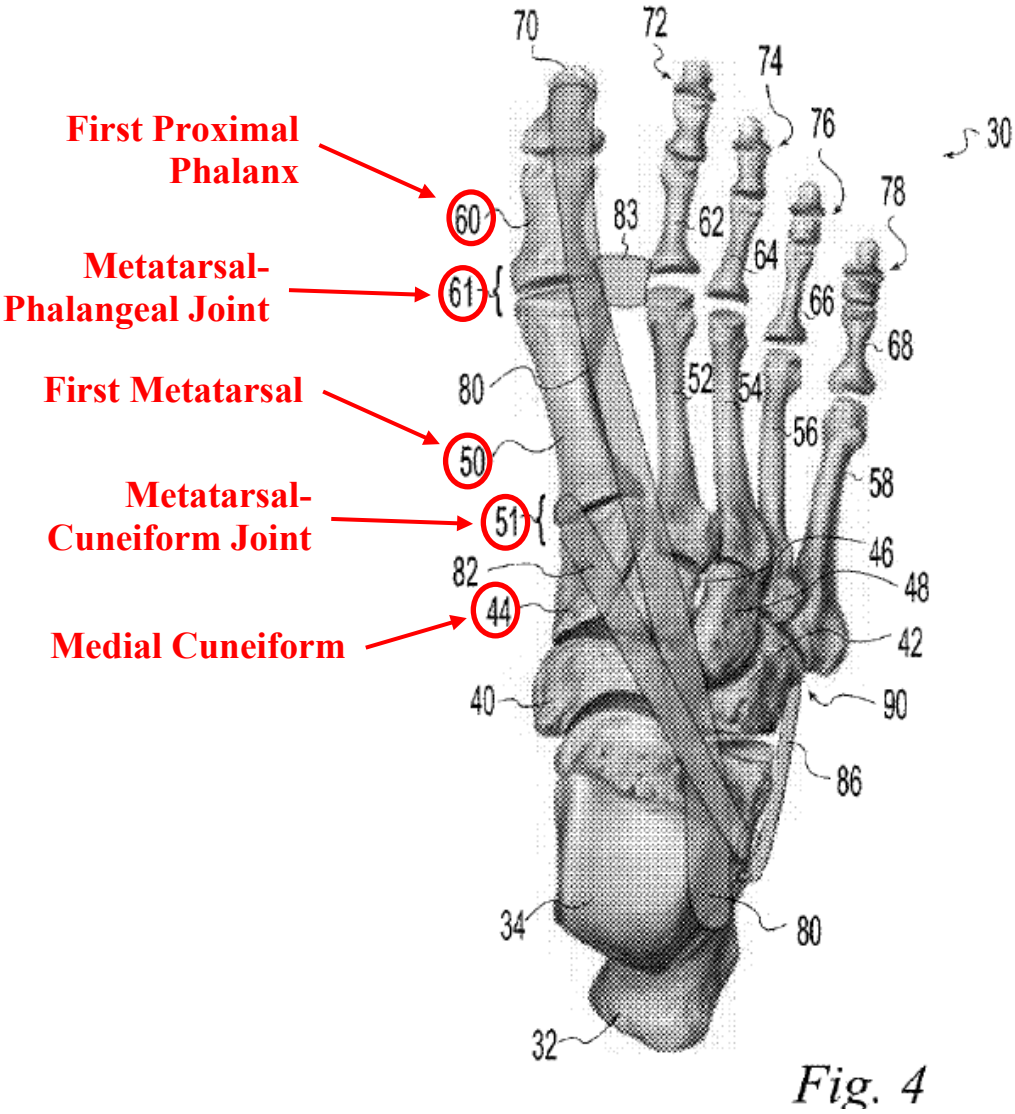


Fig. 4

Ex.1007, Fig. 4 (annotated).

40. In a healthy foot, the bones of the first ray are anatomically positioned in three-dimensional alignment from the medial cuneiform to first metatarsal through the hallux ("big toe"), which promotes normal function of the foot. The first metatarsal and medial cuneiform meet to form the metatarsal-cuneiform joint.

41. There are three anatomic reference planes for the foot—the sagittal, coronal, and transverse planes. The coronal plane is also called the frontal plane. These are shown below:

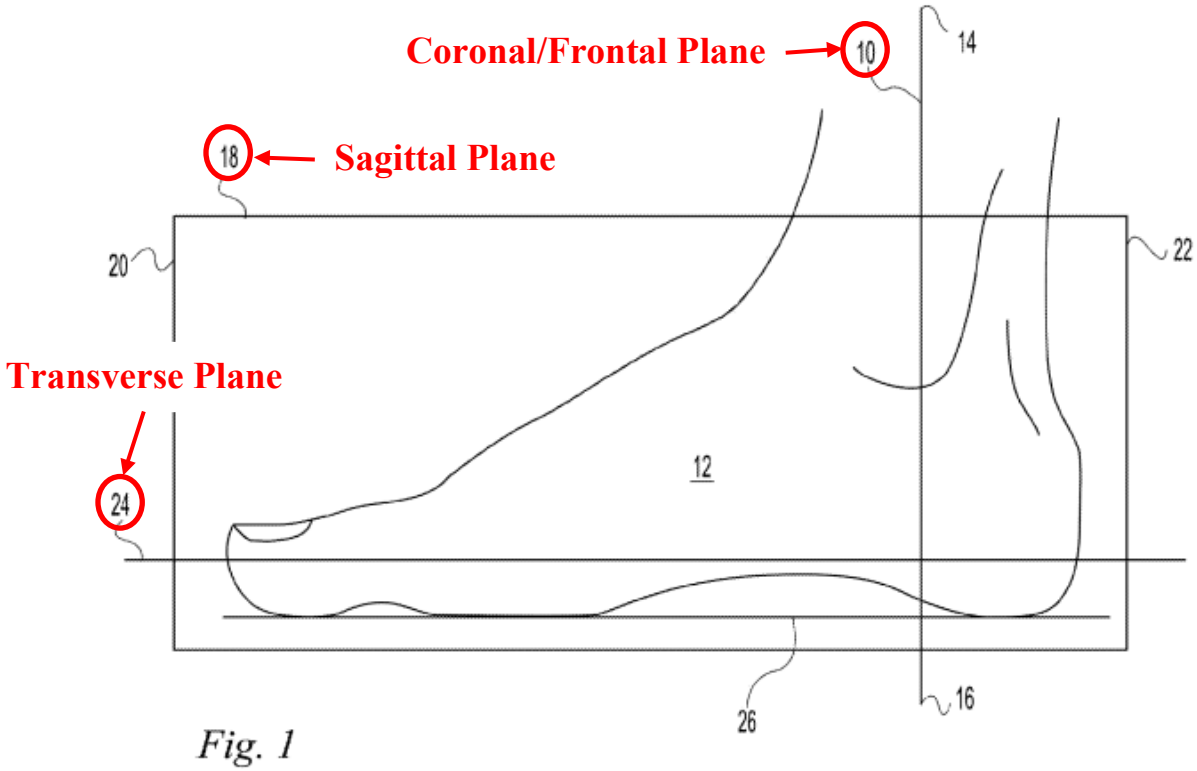


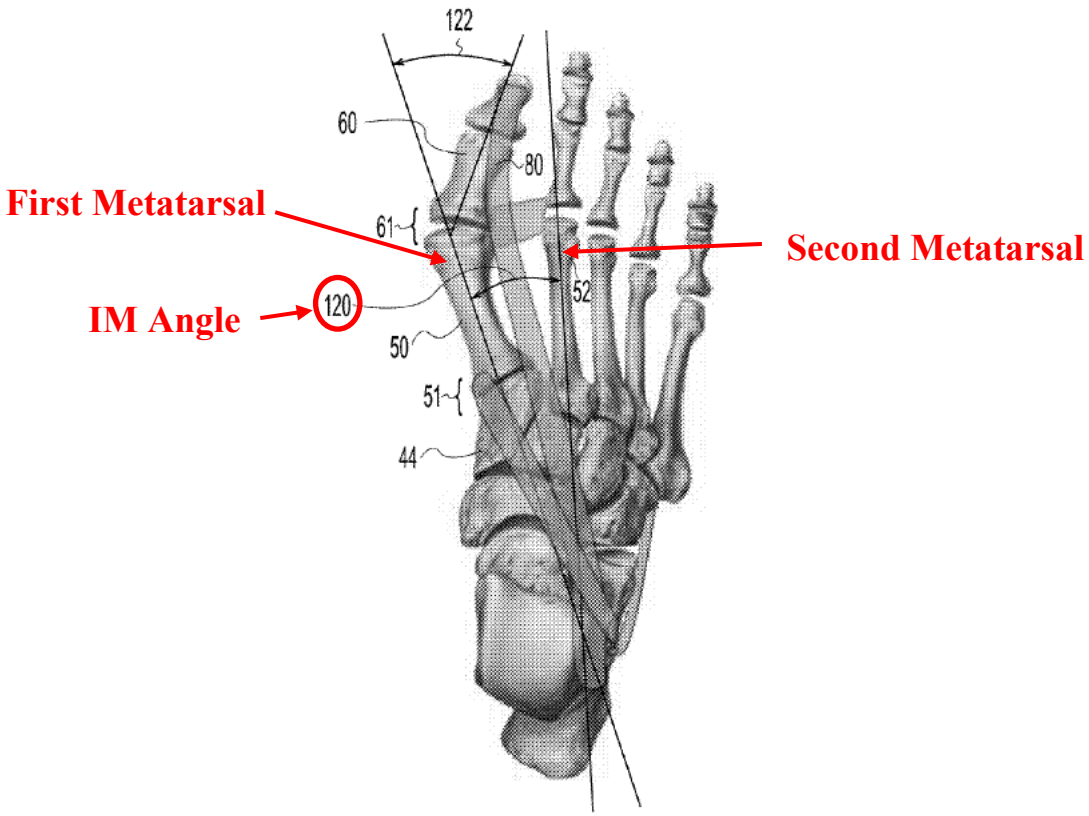
Fig. 1

Id., Fig.1 (annotated).

B. Bunion Deformity

42. One common deformity of the foot is a "bunion," which is also referred to medically as a hallux valgus deformity. *See* Ex.1007, [0047]. In a bunion deformity, the bones of the first ray (the medial cuneiform, the first metatarsal, and the phalanx) become misaligned. *Id.* The first metatarsal deviates medially (inwardly) and 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:



Ex.1007, Fig.11 (annotated). The phalanx deviates laterally (outwardly) and toward the second metatarsal. The deformity may also include mal-rotation of the first metatarsal and phalanx in one or more planes (e.g., adduction of the first metatarsal). Such misalignment causes a visible bump at the metatarso-phalangeal joint, which can impair foot function and cause pain.

C. Instrumented Bunion Correction

43. 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:

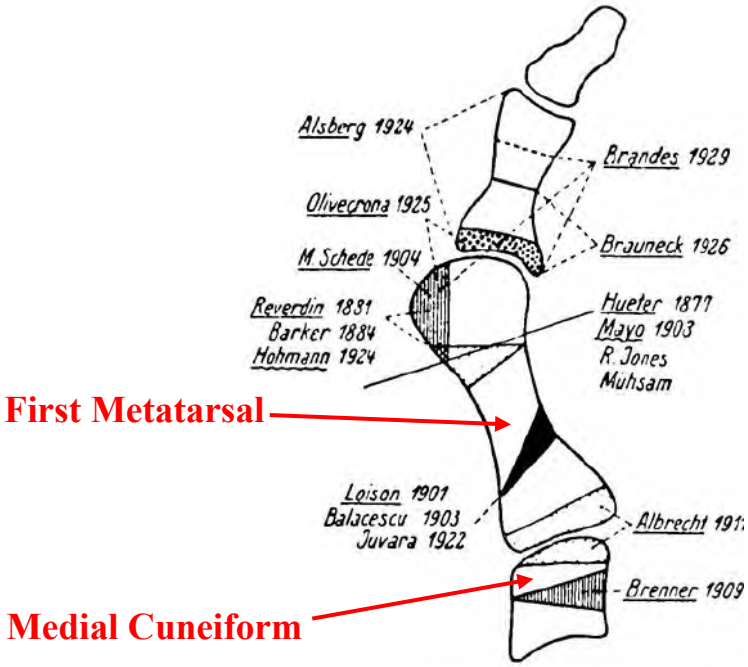


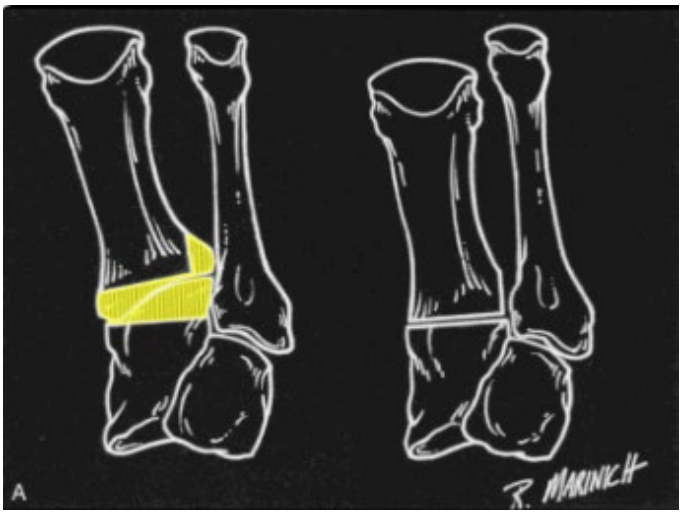
FIG. 3. Schematic drawing of various operative procedures devised for correction of bunion. The name of the author and the year of description of the operation are indicated. (Timmer, H.: Die Behandlung des Hallux valgus, Leipzig, Barth)

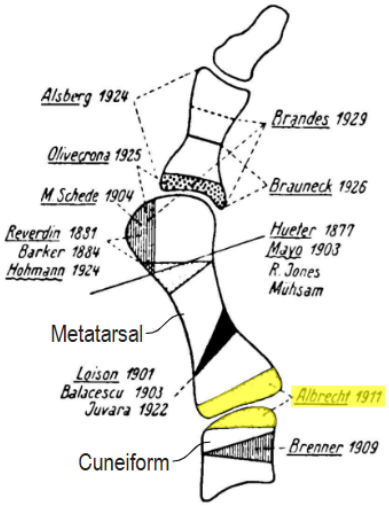
Ex.1010, 122.

44. One procedure for treating a bunion is a metatarso-cuneiform arthrodesis, which Dr. Paul Lapidus popularized a version of in 1934. *See generally* Ex. 1011. An arthrodesis is a surgical procedure in which the bones of a joint are permanently joined together through fusion. Ex.1005, 803 (referring to the "principles of arthrodesis" as the "principles for the fusion of joints"). An

arthrodesis procedure generally involves (1) the removal of material that will prevent the close approximation of raw bone masses for fusion, (2) the provision of an accurate and close-fitting boney construct for fusion, (3) optimal positioning of the bones for fusion, and (4) maintenance of the bones in an undisturbed fashion until fusion is complete. *Id.* Dr. Lapidus' arthrodesis procedure is now commonly referred to as a "Lapidus" procedure.

45. In a metatarso-cuneiform arthrodesis procedure, the first metatarsal and medial cuneiform are realigned in their natural positions, and fixed together for fusion. Ex.1005, 322 ("While many techniques have been described modifying the original Lapidus procedure, all use arthrodesis of the of the metatarsal-cuneiform joint."). Generally, this procedure involves the preparation of the joint for correction (e.g., by cutting the proximal end of the first metatarsal and distal end of the medial cuneiform, in one or more steps). *Id.*, 324. Joint preparation provides space for the correction and prepares the joint for fusion. *Id.* ("The joint preparation is extremely important in efforts to obtain a bony union and to avoid a delayed and nonunion."). The figures below illustrate these cuts providing space for correction.





Ex.1009, Fig.1A; Ex.1020, Fig.3 (color added).

46. As another step in the procedure, the surgeon corrects the position of the first metatarsal in one or more of the transverse, frontal, and sagittal planes. Ex.1009, 493 ("Inherent to this procedure is the ability to correct deformity in three planes."). *See generally* Ex.1005, 324-327; Ex.1009, 466 (describing correction of the first metatarsal's position in the transverse and sagittal planes); Ex. 1011, 187-188 ("the first metatarsal head can be abducted laterally, without much effort, bringing it closer to the second metatarsal head, and thereby easily correcting the metatarsus varus primus."). The purpose of this repositioning of the first metatarsal is to return the bone to its anatomically normal position. Ex.1005, 324-326 (describing desired "neutral" position of the first metatarsal in the frontal plane, reduction in the sagittal plane, and reduction of the IMA in the transverse plane).

47. Another step in the procedure is the use fixation devices—for example, a screw or plate—to fix the bones in their corrected position. Ex.1005, 326-327;

Ex.1009, 486-487, 490. Various fixation devices were known to surgeons for use bunion correction procedures. Ex.1009, 486-487 (describing known fixation methods for Lapidus procedures); Ex.1011, 467-468 (same). For example, McGlamry disclosed "three solid cortical screws" or a "cortical screw along with a medial based locking plate" for fixation. Ex.1005, 326-327.

48. When the bones are fixed relative to one another, the body will heal and form bone between the cut bone surfaces (referred to as bone "fusion") in the corrected orientation. Ex.1005, 808. The body treats the cut bones as a fracture and fuses them through the fracture healing process. In the weeks following the procedure, chondrogenesis takes places, creating a fibrocartilaginous network that spans the joint and links the two bones. Slowly the cartilage is ossified, transforming the soft cartilage into bone that fuses the first metatarsal and cuneiform. The fixation devices ensure that the two bones are maintained in the realigned position and facilitate fusion of the metatarsal and cuneiform in the corrected position. *Id*. ("While there are many different types of fixation that may be applied to the arthrodesis site (wire, screws, plates, etc.), it must be emphasized that the fixation is only to stabilize the arthrodesis site while the bone heals.").

D. Known Surgical Methods For Correcting Bunion Deformities

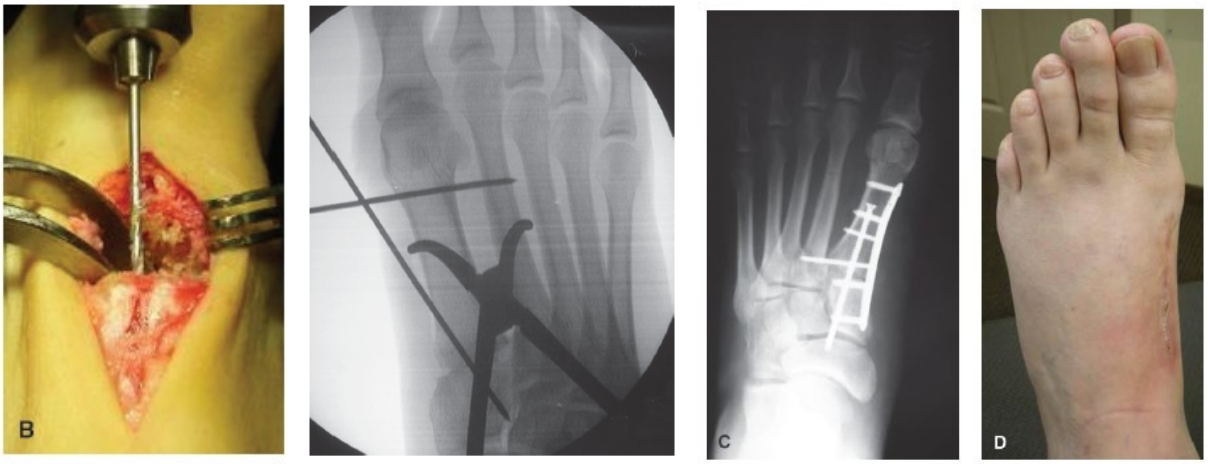
49. Metarso-cuneiform arthrodesis methods for bunion correction are described in most podiatric surgery textbooks. One such textbook is the 4th edition

of McGlamry's Foot and Ankle Surgery ("McGlamry"). McGlamry's "encompasses all aspects of foot and ankle surgery," and the fourth edition "places greater emphasis on an instructional approach so as to better help the surgeon, resident, or student *see* how the procedures are done." Ex.1005, xviii (Preface) (emphasis in original).

50. Chapter 31 of McGlamry walks through the steps of a metatarso-cuneiform arthrodesis bunion correction procedure. Ex.1005, 324-327. This chapter identifies the Lapidus procedure's origins and development, with the procedure first being described by Dr. Albrecht in 1911 and subsequently being modified by numerous surgeons. Ex.1005, 322. McGlamry discloses that its metatarso-cuneiform arthrodesis procedure is a "versatile procedure that can correct numerous pathologies," including bunions, because it "allows for triplanar correction of the first metatarsal pathology, increases the biomechanical advantage of the peroneus longus, and has the ability to stabilize the medial column." *Id.* McGlamry's bunion correction procedure is generally used to correct moderate to severe bunion deformities caused by a hypermobile first ray, including IMAs ranging from 14 to 30 degrees. *Id.*, 322-323.

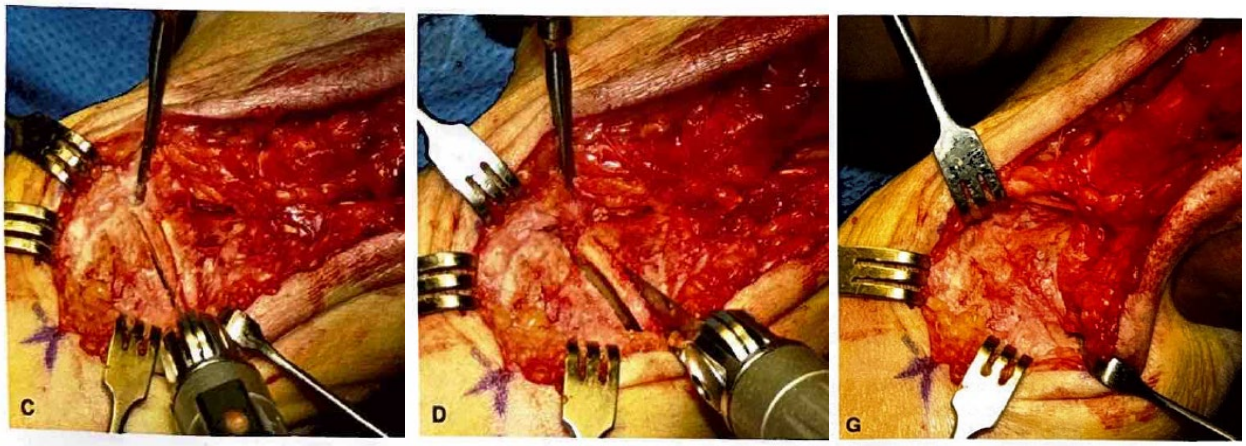
51. McGlamry describes in detail the traditional steps of the metatarso-cuneiform arthrodesis procedure, including (1) preparation of the metatarsal-cuneiform joint via the resection of the joint and cutting of the bones, (2) repositioning of the first metatarsal in each of the frontal, sagittal, and transverse

planes, and (3) fixation of the moved position of the first metatarsal relative to the medial cuneiform to promote fusion and healing of the bones. *See generally id.*, 324-327. McGlamry provides figures to guide the surgeon through each step of its bunion correction procedure, including the figures below:



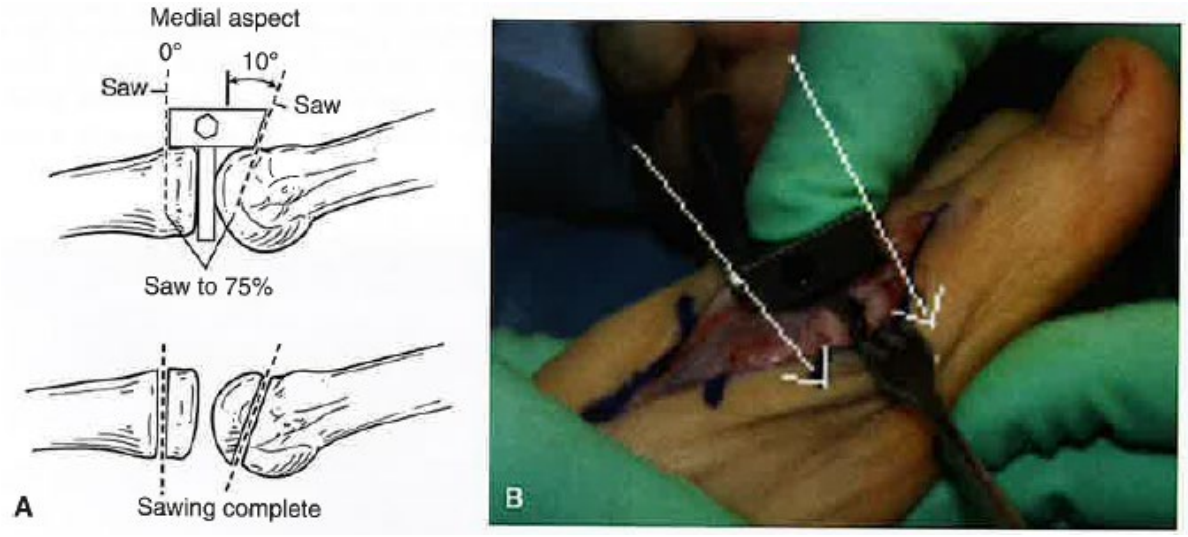
Id., Figs.31.3B (preparation of opposing ends of the first metatarsal and the medial cuneiform), 31.5 (temporary fixation of first metatarsal following bone repositioning using a clamp), 31.9C (x-ray showing fixation of the first metatarsal and cuneiform with screws and a plate), 31.9D (healed foot with corrected bunion) (left to right).

52. McGlamry also discloses "principles of arthrodesis" in Chapter 55 that apply to and are used in arthrodesis procedures like the metatarso-cuneiform arthrodesis procedure discussed in Chapter 31. Ex.1005, 803. In fact, McGlamry applies the arthrodesis principles to its Lapidus procedure, disclosing techniques for resection of the first metatarsal and cuneiform that provide a "close apposition of fusion surfaces." *Id.*, 807-809.



Id., 808-9 (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).

53. Chapters 1 and 34 of McGlamry identify instrumentation used in foot and ankle surgery, including bunion correction surgeries. For example, Chapter 34 of McGlamry describes using a bone cutting guide in podiatric surgery that "help[s] the surgeon resect the proper amount of bone and at the proper angles". Ex.1005, 381-383. The below image from McGlamry shows the bone cutting guide in use for resecting articular surfaces of a joint.



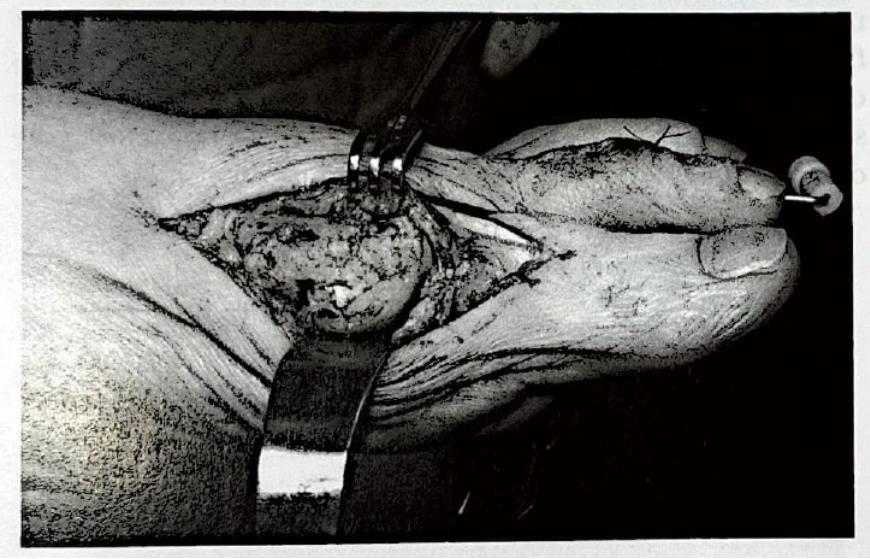
Id., Figs.34.27 (A and B) (describing "[i]nsertion of [a] primary resection guide [that] provides for a cutting guide for resection of the articular surfaces").

54. Likewise, Chapter 36 of McGlamry describes the various complications that can arise in bunion correction surgeries such as the metatarso-cuneiform arthrodesis procedure described in Chapter 31. *See* Ex.1005, 417-457. McGlamry discloses how complications can be diagnosed and corrected either through non-invasive means or in a follow up procedure. *Id.*

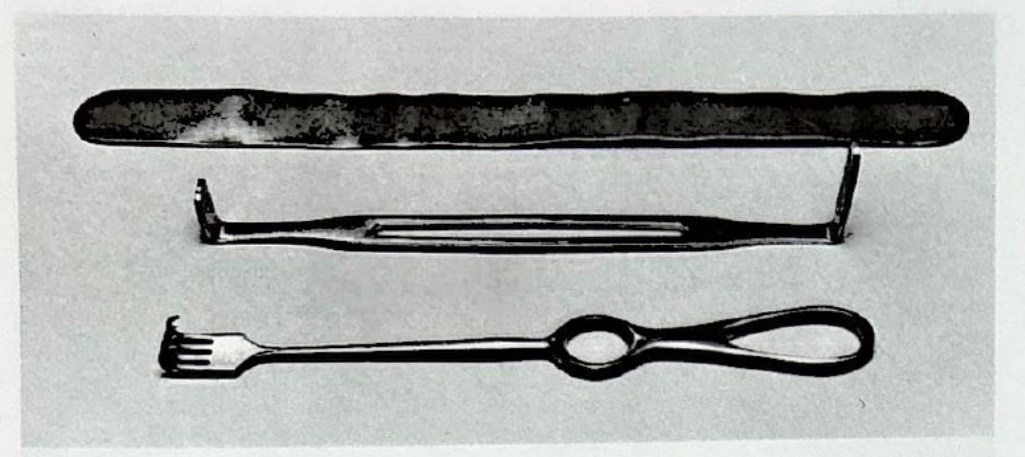
E. Known Use of Retractors and Elevators

55. Retractors and elevators were commonly used surgical instruments and part of "the basic set of podiatric surgical instruments." Ex.1005, 3. I regularly use retractors, such as the Hohman retractor (Ex.1005,324), when performing bunion correction surgeries.

56. "Retractors are used to hold tissues aside, thereby increasing exposure and protecting vital structures." *Id.*, 7. McGlamry discloses many different retractor designs. For example, McGlamry discloses a Seeburger malleable retractor that is placed on the plantar side of the first metatarsal. *See id.*, 7. The surgeon applies for to the handle, moving the metatarsal away from the soft tissues surrounding the distal end and allowing the distal end of the first metatarsal to be visualized. *See id.*

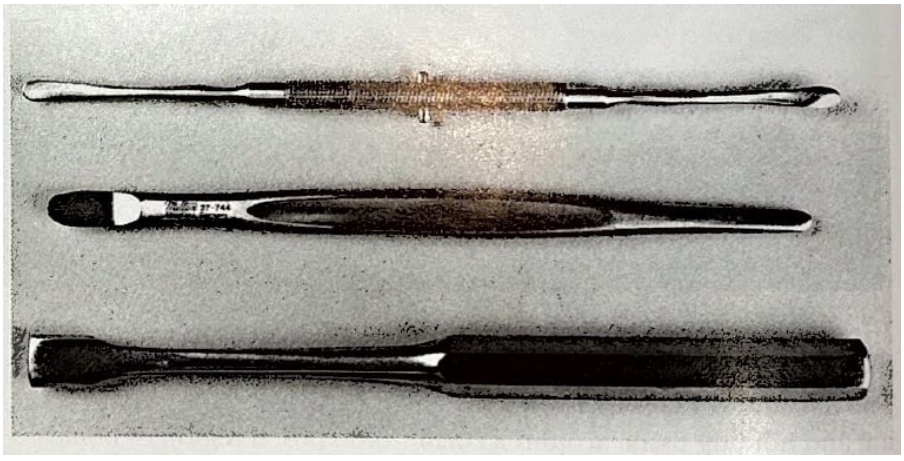


Id., 7 (Fig. 1.14). Large handheld retractors like those shown in Fig. 1.18 below "are helpful in providing full exposure." *Id.*



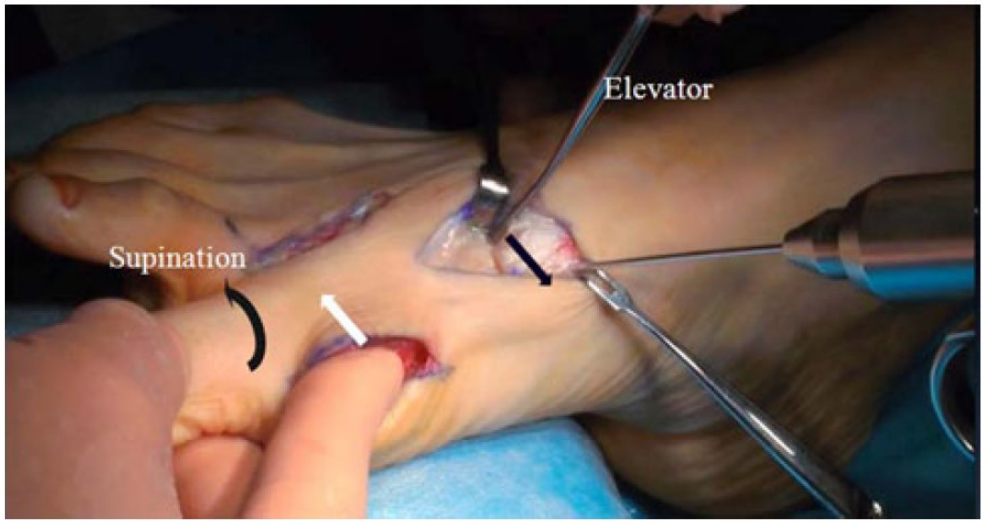
Id., 8 (Fig. 1.18).

57. Periosteal elevators are another tool regularly used in bunion correction surgeries. One use for periosteal elevators is to "separate periosteum from underlying bone." *Id.*, 8. The periosteum is a vascularized layer of tissue that surrounds bones like the metatarsal and is typically removed during osteotomies. Periosteal elevators are also used "to provide leverage for retracting deep fascia, ligaments, and periosteum" similar to retractors. *Id.*, 8. McGlamry discloses that the Freer elevator (shown below) is "ideal" for use with the metatarsals. *See id.*



Id. (Fig. 1.21) (top to bottom) (showing a Freer, Sayre, and Key elevators). I almost always use the elevators shown in Fig. 1.21 when performing metatarso-cuneiform arthrodesis procedures.

58. Retractors and elevators are used to move bones and bone fragments during bunion correction surgeries. *See id.* 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 inserts a Freer elevator between the first and second metatarsals to push a metatarsal fragment medially (inwardly) 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"). Like McGlamry, Okuda discloses using the elevator to

correct the bunion deformity in one or more planes (e.g., frontal plane rotation and reduction of the IMA). *See id.*; Ex.1005, 808-809.

59. 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." Ex.1006, [0032]. Davidson discloses that applications for the retractors include "osteotomy of the midtarsal bones and proximal first metatarsal," which includes first metatarso-cuneiform arthrodesis. *See id.*, [0060]. Davidson describes its retractors as being used to move bones and protect the soft tissues. Ex.1006, [0057].

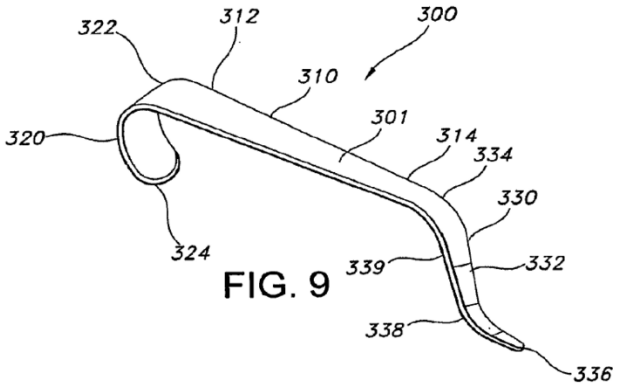
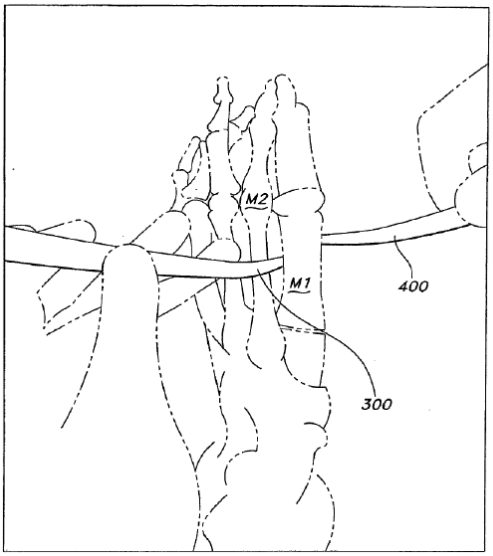


FIG. 9

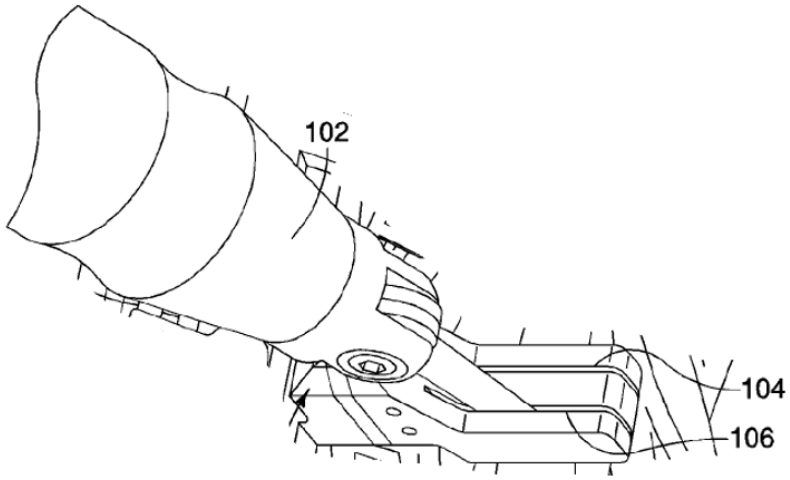


Id. (left to right) (Fig. 9) (depicting Davidson's retractor), (Fig. 19 depicting the retractor 300 positioned between the metatarsal bones to move the first metatarsal M1).

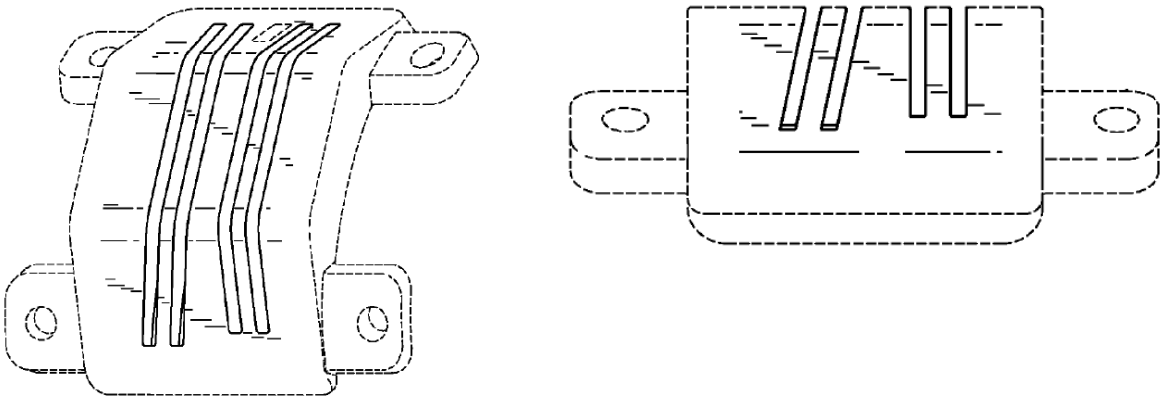
F. Known Bone Preparation Guides (Cutting Guides)

60. In metatarso-cuneiform arthrodesis for bunion correction, opposing ends of the first metatarsal and cuneiform are resected. Guides for preparing, i.e. cutting, the opposing surfaces of bones were well known by 2015, including cutting guides for performing metatarso-cuneiform arthrodesis.

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



Id., Fig.9 (excerpt). DaCosta and Weinstein similarly disclose bone cutting guides for use in metatarso-cuneiform arthrodesis to correct bunions:



Ex.1014, Figs.1, 5.

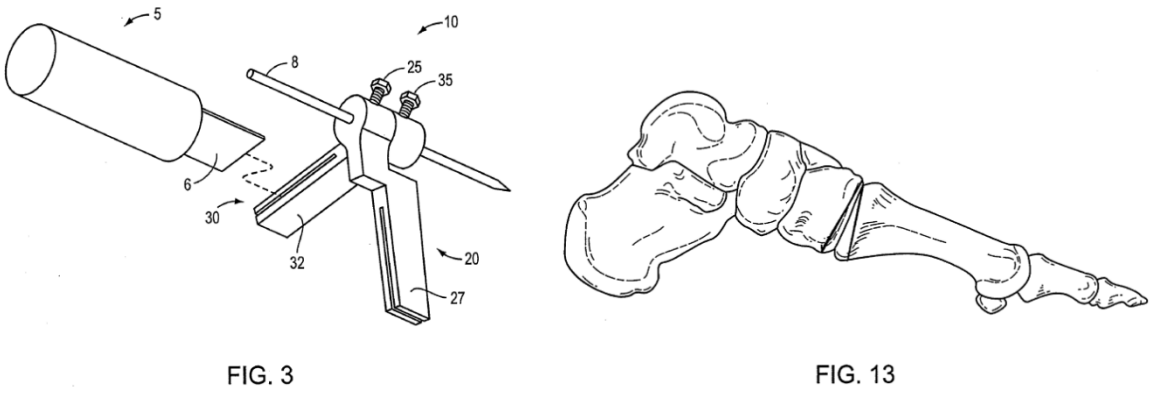


FIG. 3

FIG. 13

Ex.1017, Figs.3, 13.

62. Fallin also discloses a bone cutting guide for use in metatarso-cuneiform arthrodesis. Fallin discloses "[m]ethods and devices for performing an osteotomy," including "forming a fusion osteotomy at a metatarsocuneiform joint on the first ray of a human foot." Ex.1007, Abstract. Fallin discloses that its surgical method, which uses a bone cutting guide 200, can be used to correct bunions. *See* Ex.1007, [0057] (explaining that the disclosed methods can be used to "correct an angular deformity" of the first metatarsal and the cuneiform, e.g. a bunion). Fallin's

cutting guide provides "more precision and repeatability in the relative orientation of the cuts" to the metatarsal and cuneiform when compared to freehand resection. *Id*., [0062].

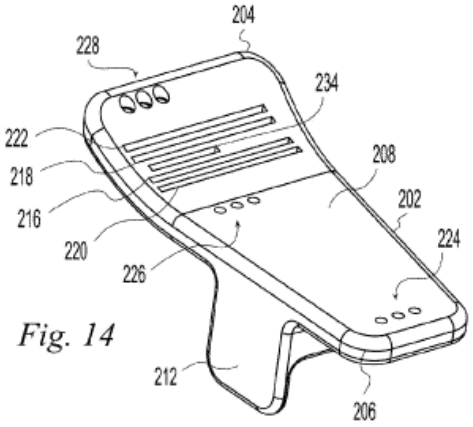


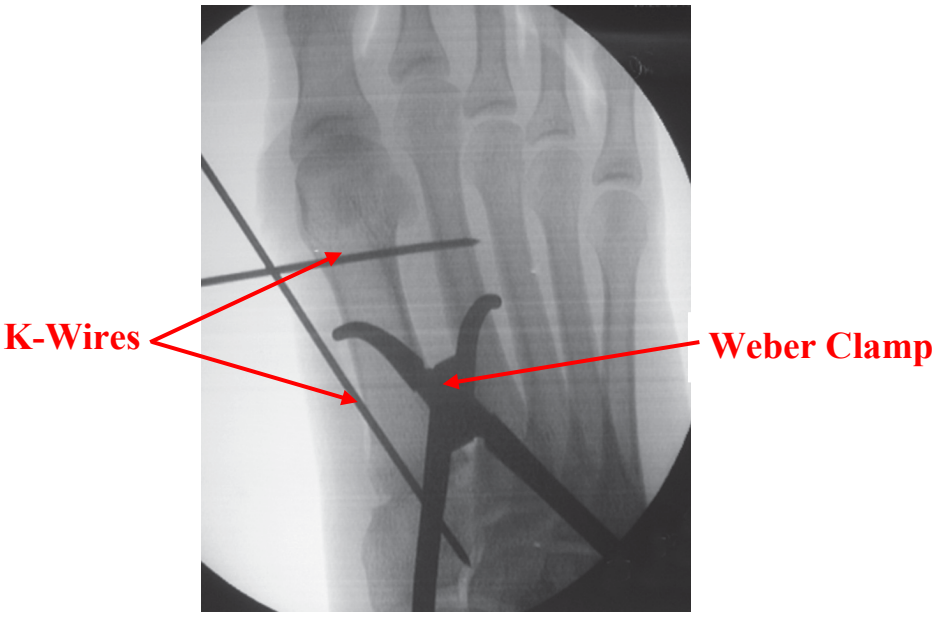
Fig. 14

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 metatarso-cuneiform joint such that a predetermined amount of bone is removed. *Id.*, [0055].

G. Known Bone Positioning Guides

63. As disclosed in McGlamry, one step in metatarso-cuneiform arthrodesis involves repositioning the first metatarsal in one or more planes (e.g., transverse, frontal, sagittal) to correct the bunion deformity. Ex.1005, 324-27. Bone positioning guides that assist with this movement have long been known in the art.

Ex.1005, 10-11 For example, by 2013, McGlamry disclosed using a Weber clamp and K-wires to reposition the first metatarsal, as shown below.



Id., Fig.31.5.

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

H. Known Fixation Devices

65. One of the final steps in metatarso-cuneiform arthrodesis for bunion correction is fixation of the first metatarsal and medial cuneiform to achieve a boney

fusion in the corrected position. 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. Ex.1009, 486-487, 490.

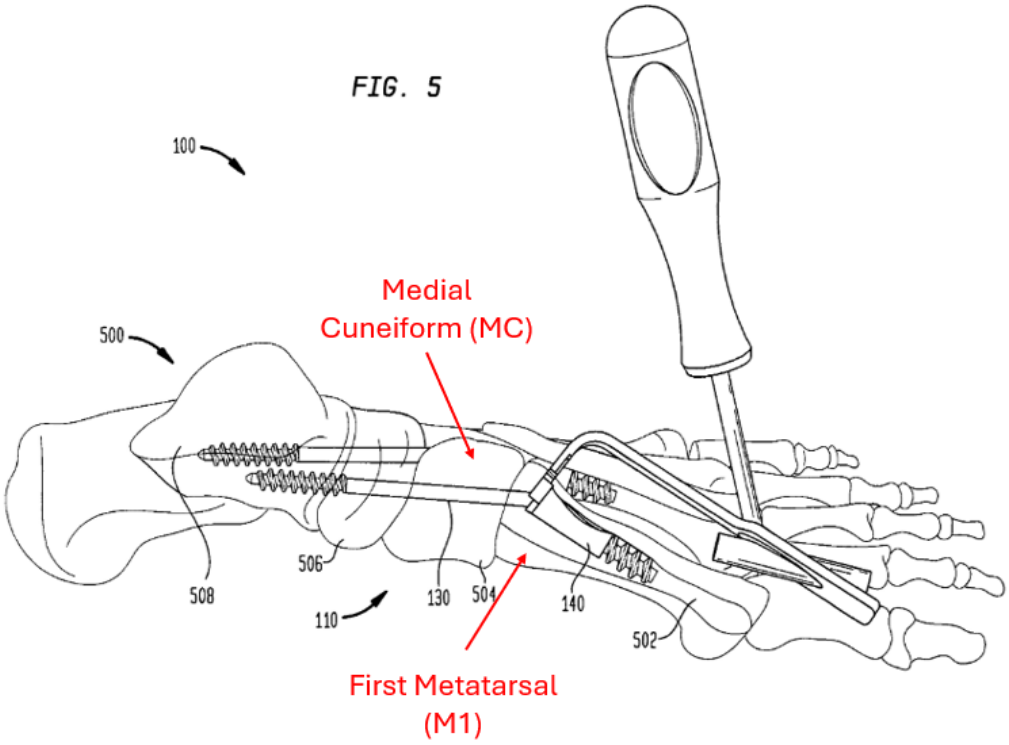
66. For example, in 1996, Hofbauer disclosed numerous fixation devices usable in this step, including K-wires, Steinman pins, compression screws, and plate/screw constructs. Ex.1009. 486-487. In 2013, McGlamry described the use of cortical screws and a "locking plate" as fixation devices in a bunion 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.

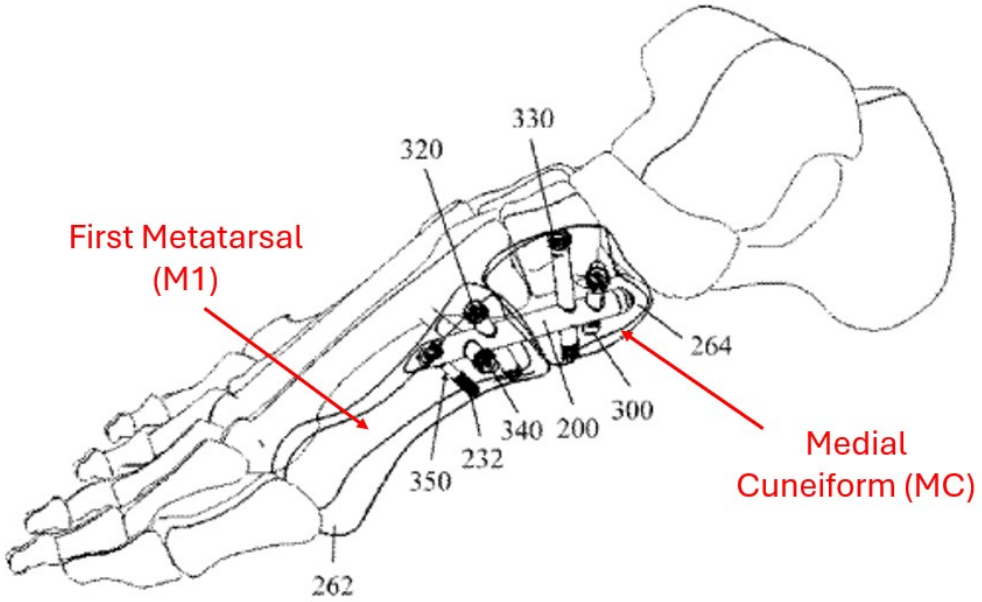
Id., Figs.31.7, 31.8.

67. Intramedullary implants for fixing the first metatarsal and medial cuneiform during a bunion correction surgery were also known at least as of August 2015. For example, 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.1008, Fig. 5 (annotated).



Ex. 1013, Fig. 32 (annotated).

III. CLAIM CONSTRUCTION

68. I was asked to apply constructions for certain claim terms under different assumptions but express no opinion herein on the proper construction of any claim term. I understand that claim terms are to be given their plain and ordinary meaning, as they would have been understood by a person of ordinary skill in the art at the time of the invention in view of the intrinsic record (patent claims, patent specification, and file history). I have applied the plain and ordinary meaning of the terms of the '428 patent throughout my analysis unless otherwise noted.

A. "fulcrum"

69. Claims 9 and 22 recite "the instrument is a fulcrum" and "moving the first metatarsal in the transvers plan comprises pivoting the first metatarsal about the fulcrum." Ex.1001, claims 9 and 22. It is my opinion that a person of ordinary skill in the art would have understood that the plain and ordinary meaning of the term "fulcrum" is a "mechanical instrument."

70. The claims describe the function of a fulcrum, e.g. an instrument about which the first metatarsal can pivot. The claims treat a "fulcrum" as a mechanical instrument without any specific features or characteristics.

71. The specification describes the mechanical instruments that can be used as "a fulcrum" broadly. 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." Ex.1001, 17:37-42. The instrument is also not limited to a particular shape or cross section. Id., 17:42-47 (describing how the instrument "may have a variety of cross-sectional shapes"). 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." Ex.1001, 20:41-44.

72. The specification also explains that "[a]s 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.")

73. I do not seek to specifically construe "fulcrum" in this proceeding as the claims would have been obvious whether the term is construed or is accorded a plain and ordinary meaning.

B. <u>"bone positioning guide"</u>

74. It is my opinion that a person of ordinary skill in the art would understand that the plain and ordinary meaning of "bone positioning guide" is a "device that is designed to move bone(s)." I do not seek to specifically construe "bone positioning guide" in this proceeding as the claims would have been obvious whether the term is construed or is accorded a plain and ordinary meaning.

75. To the extent the term is treated as a means-plus-function limitation, it should be construed as follows:

76. The claimed function of the "bone positioning guide" is "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. In other words, the claimed function of the "bone positioning guide" in other claims is "engage the first metatarsal and apply a force to the first metatarsal to move the first metatarsal in at least one plane." Ex.1001, Claim 15, 26.

77. The specification recites multiple structures that perform the claimed function of the bone positioning guide. 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." (Ex.1001, 7:23-37); and
- "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 (Ex.1001, 5:40-48, Figs. 1, 3B, 3C)

78. As discussed below, it is my opinion that the claims would have been obvious whether the term is construed as a means-plus-function limitation or is accorded a plain and ordinary meaning.

C. <u>"bone fixation device"</u>

79. It is my opinion that a person of ordinary skill in the art would have understood that the plain and ordinary meaning of "bone fixation device" is a "device that connects bones for fusion." I do not seek to specifically construe "bone fixation device" in this proceeding as the claims would have been obvious whether the term is construed or is accorded a plain and ordinary meaning

80. To the extent "bone fixation device" is construed as a means-plus-function limitation, it should be construed as follows:

81. The claimed function of the "bone fixation device" is "fixating a moved position of the first metatarsal relative to the medial cuneiform." Ex.1001, Claims 1, 18, 28.

82. The specification provides multiple examples of a bone fixation device, including: "compressing bone screw, bone plate, bone staple, external fixator, intramedullary implant or nail" (Ex.1001, 11:39-44) and "two bone plates positioned in different planes" (*id*. 14:26-30).

83. As discussed below, it is my opinion that the claims would have been obvious whether the term is construed as a means-plus-function limitation or is accorded a plain and ordinary meaning.

IV. THE '428 PATENT

A. Overview

84. 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. The specification acknowledges that a Lapidus procedure is an example of such a procedure. *Id.*

85. 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."

B. Prosecution History

86. I understand that the application which led to the '428 patent was filed on April 25,2024. Ex.1002, 202. I understand that a first office action was mailed on August 14, 2024, in which the Examiner indicated that, but for a double patenting rejection, claims 1-30 were allowable. *See id.*, 383-385.

87. In the office action, the Examiner explained that the prior art discloses "inserting an instrument between [a first] metatarsal and a second metatarsal adjacent to the first metatarsal." *Id.*, 384. The Examiner's statement in the '428 prosecution history is consistent with the prosecution of one of the '428 patent's parent applications (App. No. 16/448,357) where the same examiner found that Davidson (Ex.1006) discloses fulcrums for use in bone realignment. *See* Ex.1018, 571-572.

88. The Examiner decided 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, 383-385, 531. As I have explained in the sections above and below, the steps of metatarso-cuneiform arthrodesis and the use of various instruments to perform those steps were well-known before August 2015.

V. THE PRIOR ART

89. In this Declaration, I rely on several references that I understand are prior art to the '428 patent claims. These references include:

- McGlamry (McGlamry's Comprehensive Textbook of Foot and Ankle Surgery (4th edition)) (Ex.1005);
- Davidson (U.S. Publication No. 2009/0216089 to Davidson) (Ex.1006);
- Fallin (U.S. Publication No. 2016/0213384 to Fallin, et al.) (Ex.1007);
- Tyber (U.S. Patent No. 8,328,806 to Tyber et al.) (Ex.1008); and
- DaCosta-219 (International Patent App. Publ. No. 2014/152219 to DaCosta et al.) (Ex.1013).

90. These references are from the same field as the '428 patent, e.g., devices and methods for positioning and/or preparing bones. Ex.1001, 1:25-29, 5:1-22. These references are pertinent to a problem focused on by the inventors, e.g., surgical techniques and instruments for correction of foot deformities. Ex.1001, 1:39-2:14; *see also id.*, 26:8-9, 27:45-46, 28:54-55 (claims directed to a "instrumented surgical technique for treating a bunion deformity").

VI. MCGLAMRY ANTICIPATES CLAIMS 1-3, 6-8, 10-13, AND 16-17 OF THE '428 PATENT

A. Claim 1

1. Preamble

91. It is my understanding that the preamble is not considered limiting, but even if it were, McGlamry discloses "an instrumented surgical technique for treating a bunion deformity." Specifically, 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.*, 808-9);
- 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).

92. A POSA would have considered McGlamry as a single prior art reference and would know that the chapters describe a specific arthrodesis procedure

across the chapters. Specifically, chapters 31 and 55 are both directed to arthrodesis and both address metatarsal-cuneiform arthrodesis. Ex.1005, 322-330, 808-809. They describe different aspects of the arthrodesis procedure and would be considered together as providing an example of the procedure. Chapters 31 and 55 are not directed to unrelated or mutually exclusive embodiments, but instead describe different portions of a single reference addressing the same first metatarsal-cuneiform arthrodesis from complementary perspectives. Chapter 31 focuses specifically on metatarsal-cuneiform arthrodesis while Chapter 55 provides arthrodesis principles for all foot and ankle arthrodesis procedures. *See id.* The principles of Chapter 55 improve visualization, stability, and fusion outcomes. *Id.*, 803 (explaining that the principles were developed over time to "provide a more predictable fusion" and "greatly enhance surgical visualization and stability in arthrodesis" procedures). McGlamry discloses that the principles of Chapter 55 are applicable to all arthrodesis procedures including metatarsal-cuneiform arthrodesis. *Id.*, 803 ("From the proximal interphalangeal joint (PIPJ) for the correction of a digital contracture to a pantalar arthrodesis for the unstable Charcot foot and ankle, all podiatric surgeons need to be well versed in the principles for the fusion of joints."), 808-809 (applying the principles to metatarsal-cuneiform arthrodesis).

93. A POSA would have immediately been enabled to apply the principles and techniques of Chapter 55 to the procedure of Chapter 31 because Chapter 55

discloses how the principles are applied to a metatarsal-cuneiform arthrodesis. *Id.* 808-809.

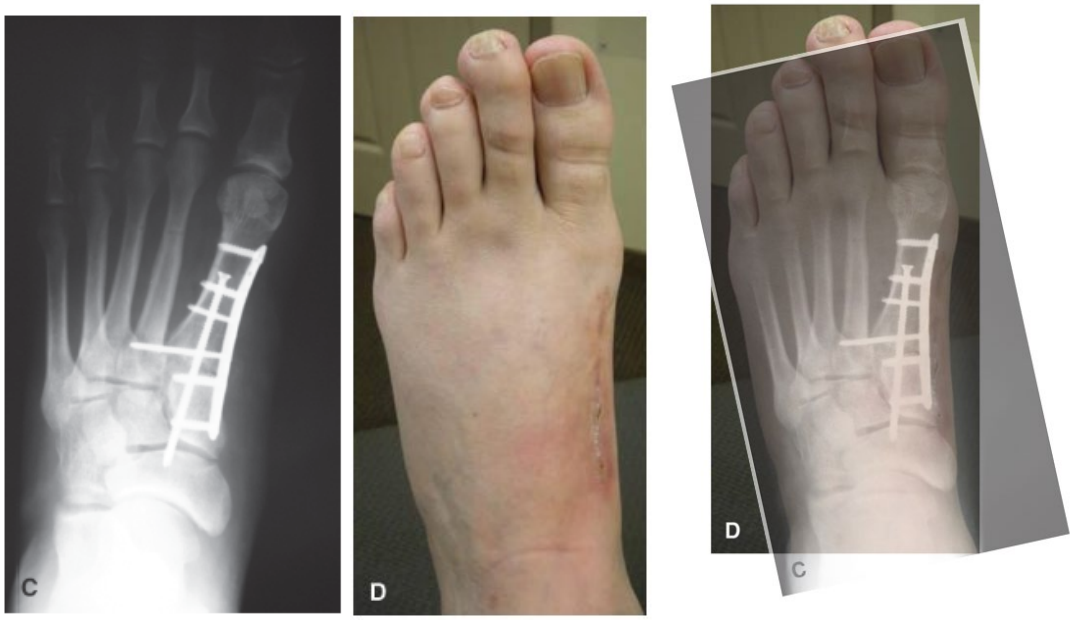
2. Limitation 1[a]

94. McGlamry discloses limitation 1[a] which is "inserting an instrument between a first metatarsal and a second metatarsal adjacent to the first metatarsal" as part of its bunion surgery technique.

95. McGlamry discloses 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 in Fig. 31.9C where the scar extends over the dorsal (top) side of the metatarsal-cuneiform joint.

Id., Fig. 31.9D (showing the healed incision from McGlamry's bunion correction surgery).

96. McGlamry also includes a post operative x-ray of the same foot in Fig. 31.9C. As shown below, the two figures can be overlayed to show the position of the incision relative to the metatarsals, medial cuneiform, and the metatarsal-cuneiform joint.

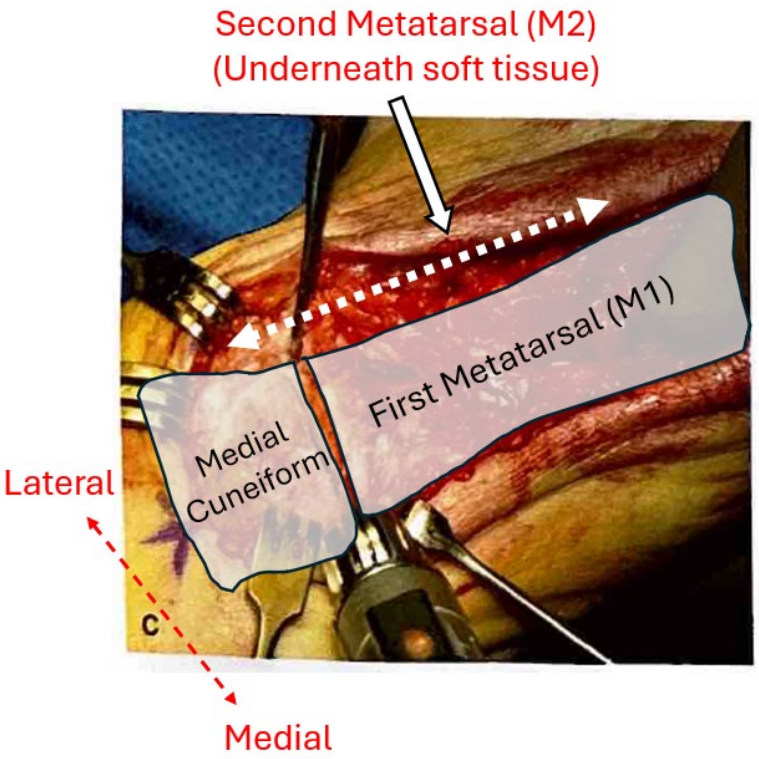


(left to right) (Fig. 31.9C – post operative x-ray) (Fig. 31.9D – post operative photo) (overlay of Figs. 31.9C and 31.9D).

97. During McGlamry's surgery, the metatarso-cuneiform joint is exposed using retractors, allowing the surgeon to visualize the joint and perform the procedure. Ex.1005, 808. Figs. 55.7C-G show the surgical field in McGlamry's bunion correction method from a left foot from a medial (inner) side. *See id.*, 808-809. The images depict the surgical field at various points in McGlamry's procedure, including "[r]emoval of the articular surface of the base of the first

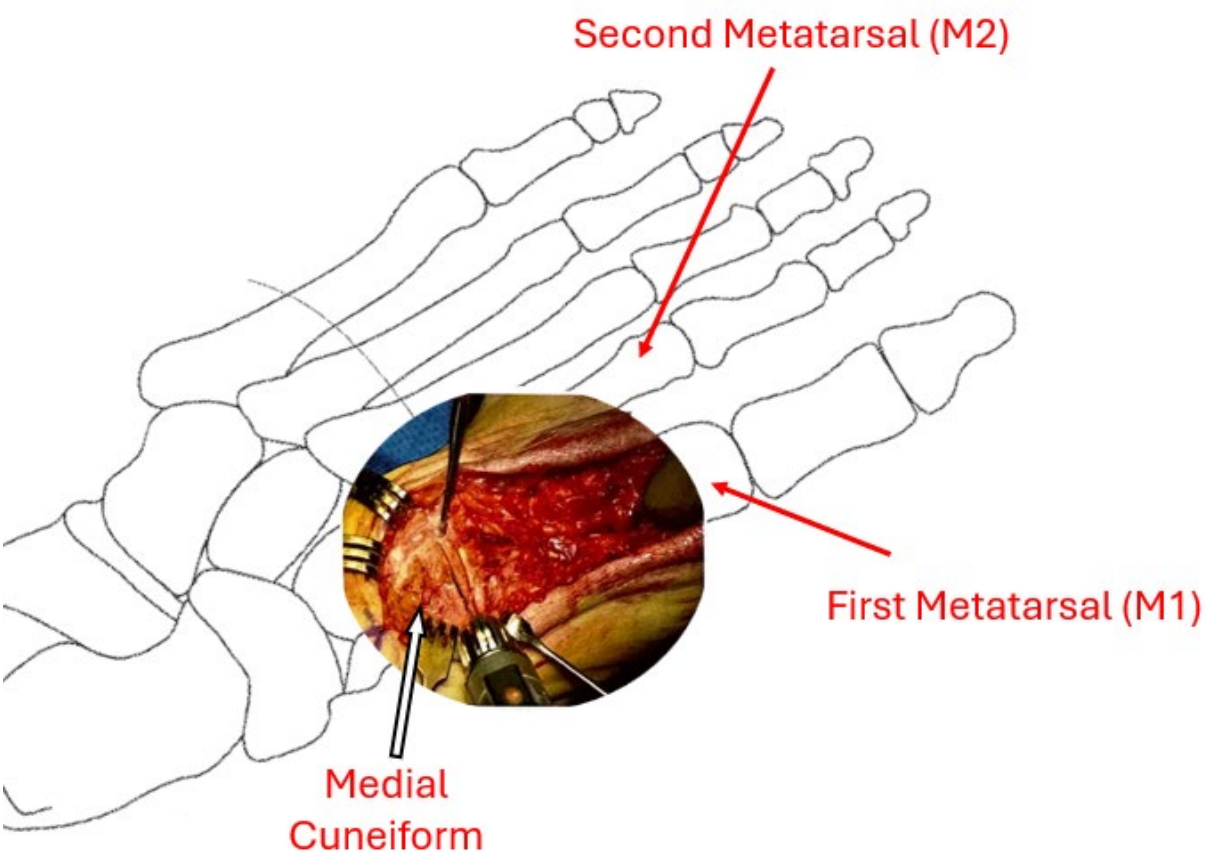
metatarsal" (Fig. 55.7D), "[r]esection of the articular surface of the medial cuneiform" (Fig. 55.7C), and the "[f]inal appearance of the first metatarsal cuneiform joint after planar resection" (Fig. 55.7G). *Id.*, 808-809.

98. A POSA would have understood and identified the bones and instruments shown in Figs. 55.7C-G. *See id.* 808-809 (identifying the step and bones in the figure descriptions). The first metatarsal and medial cuneiform are in the immediate field of view of Figs. 55.7C-G, as shown in the annotated version of Fig. 55.7C below. *See id.*, 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. *See id.* In Fig. 55.7C-G, the second metatarsal is above the first metatarsal because the image is taken from the medial side (inside) of the left foot. *See id.* The second metatarsal remains covered because dissection of those soft tissues surrounding the second metatarsal is not necessary to fuse the first metatarsal and medial cuneiform. *See id.*

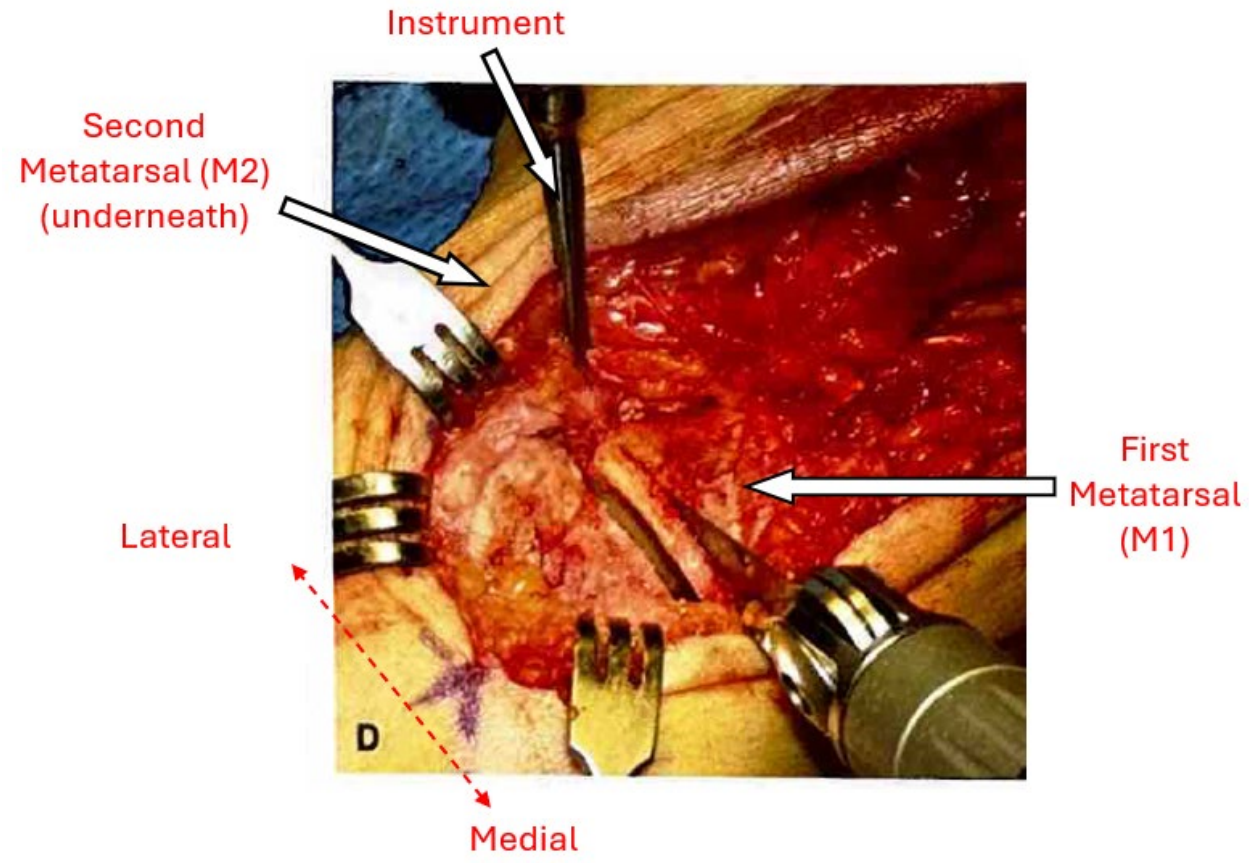


Ex.1005, Fig. 55.7C (annotated).

99. To help illustrate the context of Figs 55.7C-G, I overlayed Fig. 55.7C onto Fig. 38 of the '428 patent to show the relative position of the first metatarsal, medial cuneiform, and instruments relative to the other bones of the foot, including the second metatarsal.



100. A POSA would also be able to identify the instruments in Figs. 55.7C-G and their placement relative to the anatomy of the foot. 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.

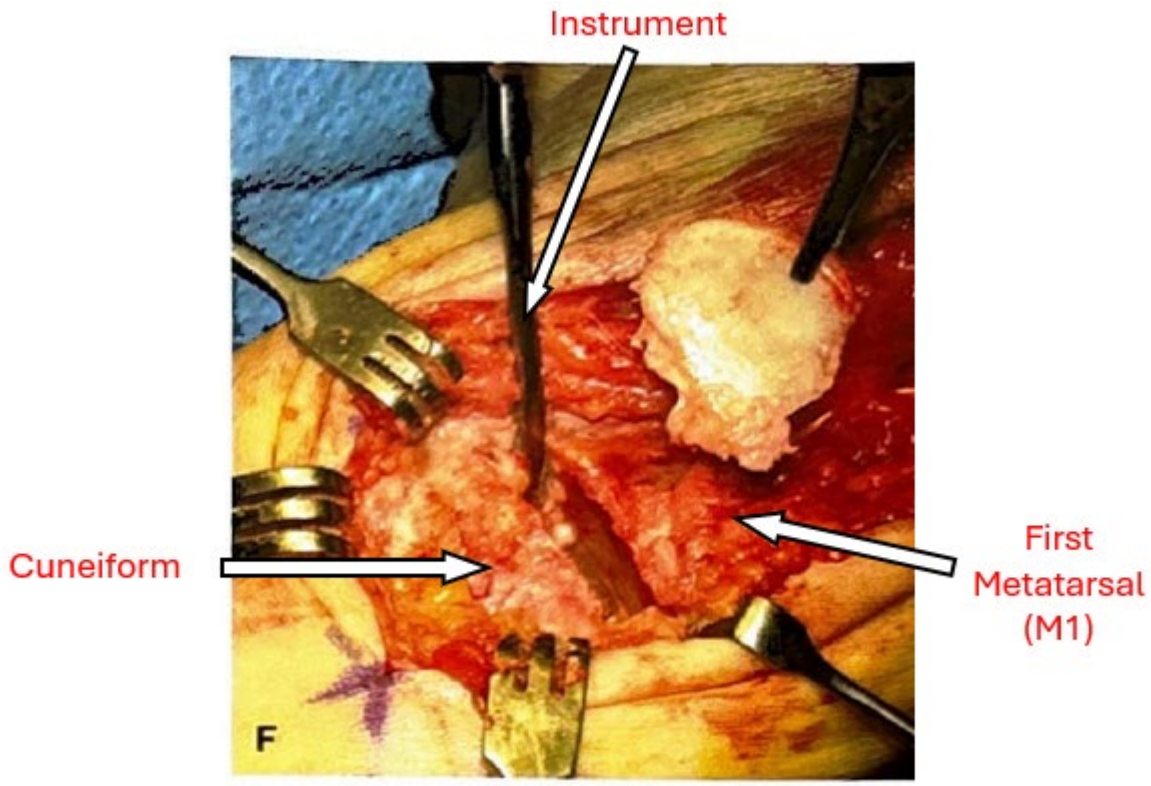


Ex.1005, Fig.55.7D (annotated).

101. McGlamry identifies the instrument between the metatarsals as a Freer elevator. *See id.*, 809 (identifying the instrument as a "Freer" in the figure descriptions). A POSA would have known that Freer elevators are one of the "basic… podiatric surgical instruments." *Id.*, 3; *see also id.*, 8. A Freer is shown below in Fig. 1.21 of McGlamry.

Ex.1005, Fig. 1.21. Fig. 55.7E depicts the metatarsal cuneiform joint as the resected portion of the metatarsal is being removed. *See id.*, 808. With the metatarsal

fragment removed, the end portion of the instrument inserted between the metatarsals is visible. *See id.*



Id., 809 (Fig. 55.7)

102. McGlamry's instrument between the metatarsals is identical to the embodiments shown in the '428 patent. For example, Fig. 38 illustrates "a perspective view of a foot showing an example position of a fulcrum during a bone correction procedure." Ex.1001, 4:37-39. In Fig. 38, an instrument 356 inserted between a first metatarsal 210 and a second metatarsal 292. *Id.*, 22:43-45. For comparison, I have created a modified version of Fig. 38. Original Fig. 38 is a lateral view, which I have rotated to show a medial view of the position of the instrument

below. Next, I created a cutout view of the position of the instrument 356 to limit the field of view.

103. As shown below, McGlamry discloses identical positioning of the instrument between the metatarsals as the '428 patent:

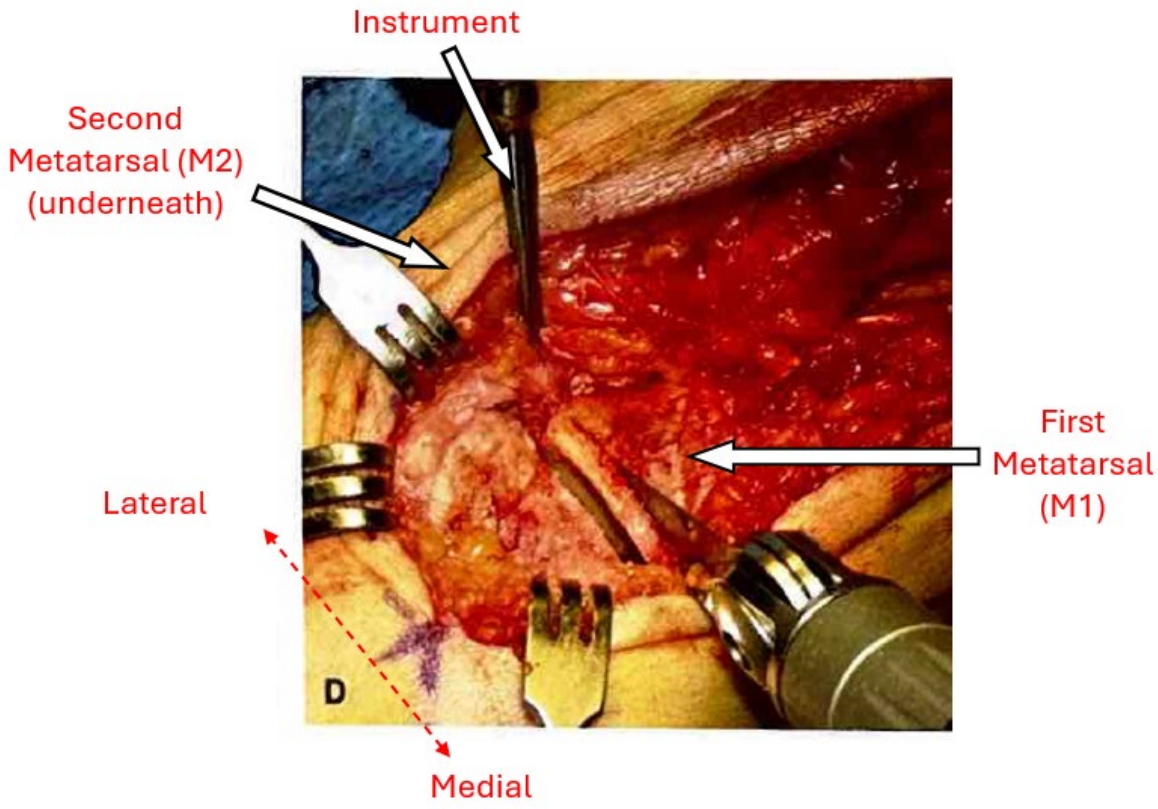


Fig. 55.7D of McGlamry (Annotated)

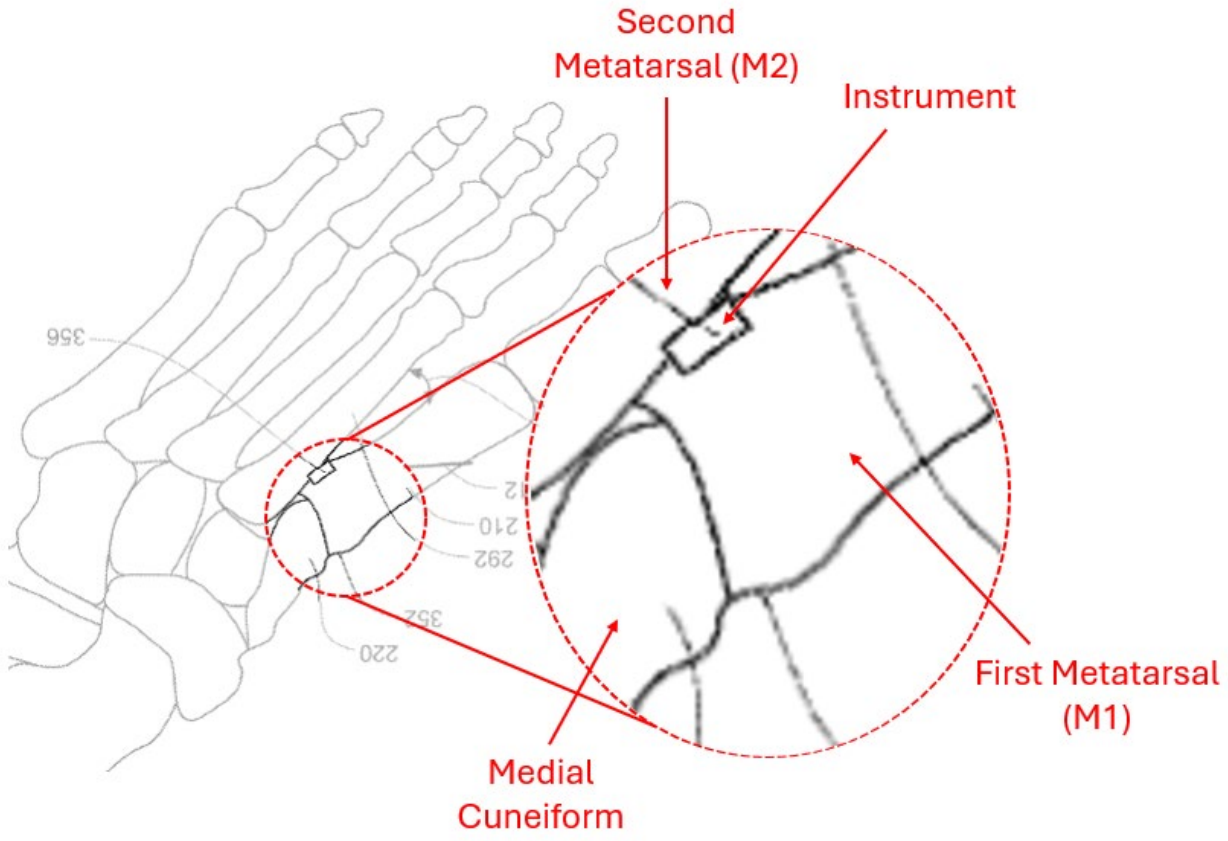
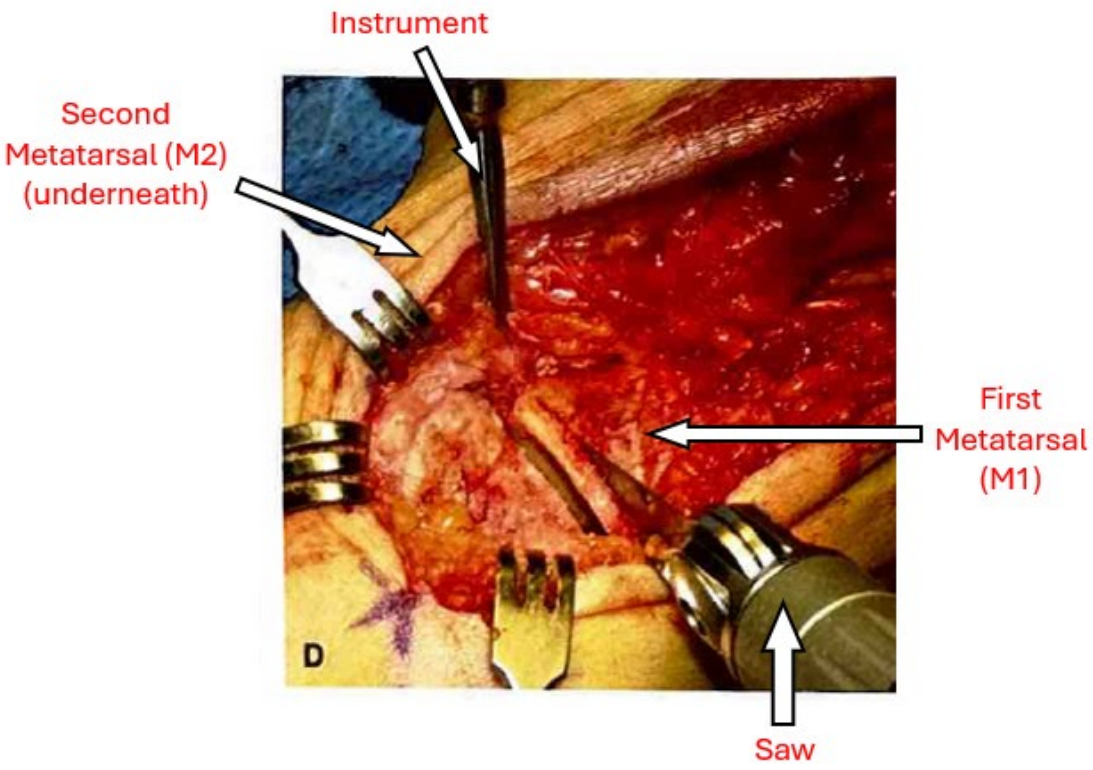


Fig. 38 of the '428 Patent (Reoriented and Annotated)

3. Limitation 1[b]

104. McGlamry discloses "with the instrument inserted between the first metatarsal and the second metatarsal, cutting an end of the first metatarsal" as part of its bunion surgery. For example, referring to Fig. 55.7D, McGlamry describes "[r]emoval of the articular surface of the base of the first metatarsal." Ex.1005, 808. As shown in Fig. 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.1005, Fig.55.7D (annotated); *see also* Ex.1005, 324 (describing resection of the proximal end of the first metatarsal).

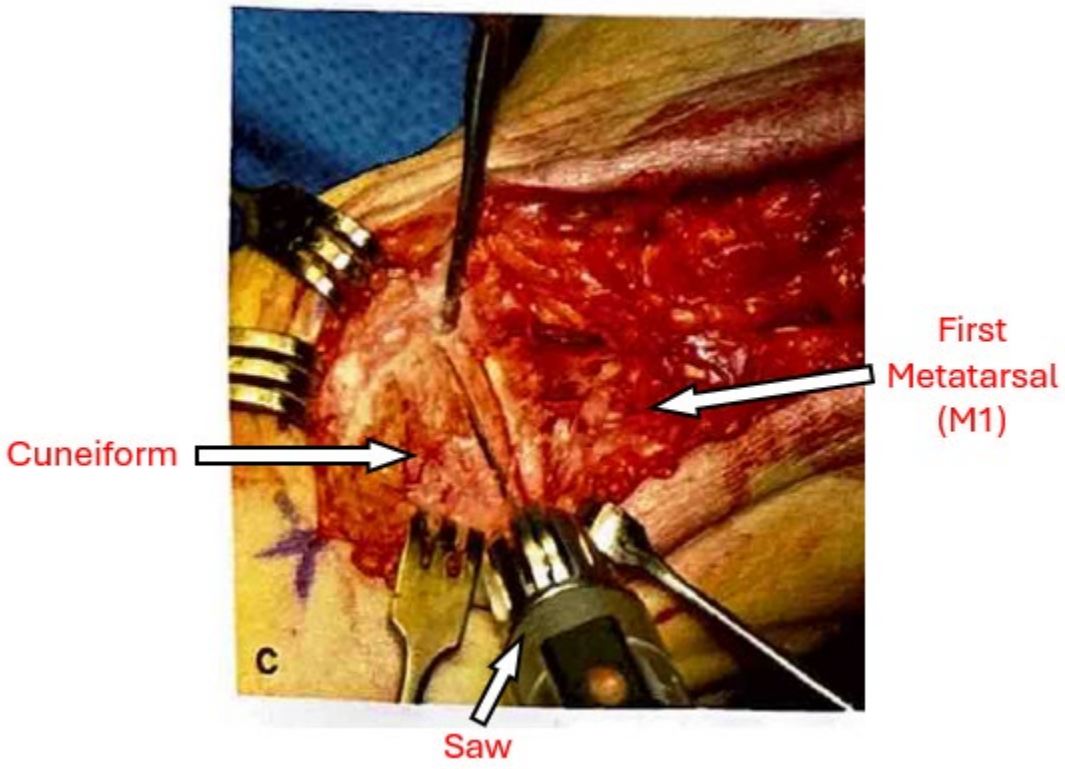
4. Limitation 1[c]

105. McGlamry discloses "moving the first metatarsal in at least one plane to treat the bunion deformity" as part of its bunion surgery. In fact, McGlamry discloses moving the first metatarsal in three anatomical planes to treat the bunion deformity, including the transverse, frontal, and sagittal planes. Ex.1005, 809 (showing movement of the metatarsal relative to the cuneiform); *see also id.*, 322 (discussing "triplanar correction of the first metatarsal pathology"), 324-325. 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.* Thus, McGlamry discloses moving the first metatarsal in at least one plane to treat bunion deformity.

5. Limitation 1[d]

106. McGlamry discloses "cutting an end of a medial cuneiform opposing the end of the first metatarsal" step as part of its bunion correction surgery. Ex.1005, 808-809; *see also id.*, 322-330. For example, McGlamry discloses that a "resection is made at the distal aspect of the convex-shaped cuneiform" during the bunion correction surgery. Ex.1005, 324. The distal end of the cuneiform is the end that opposes the end of the first metatarsal. Fig. 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.1005, Fig.55.7C (annotated).

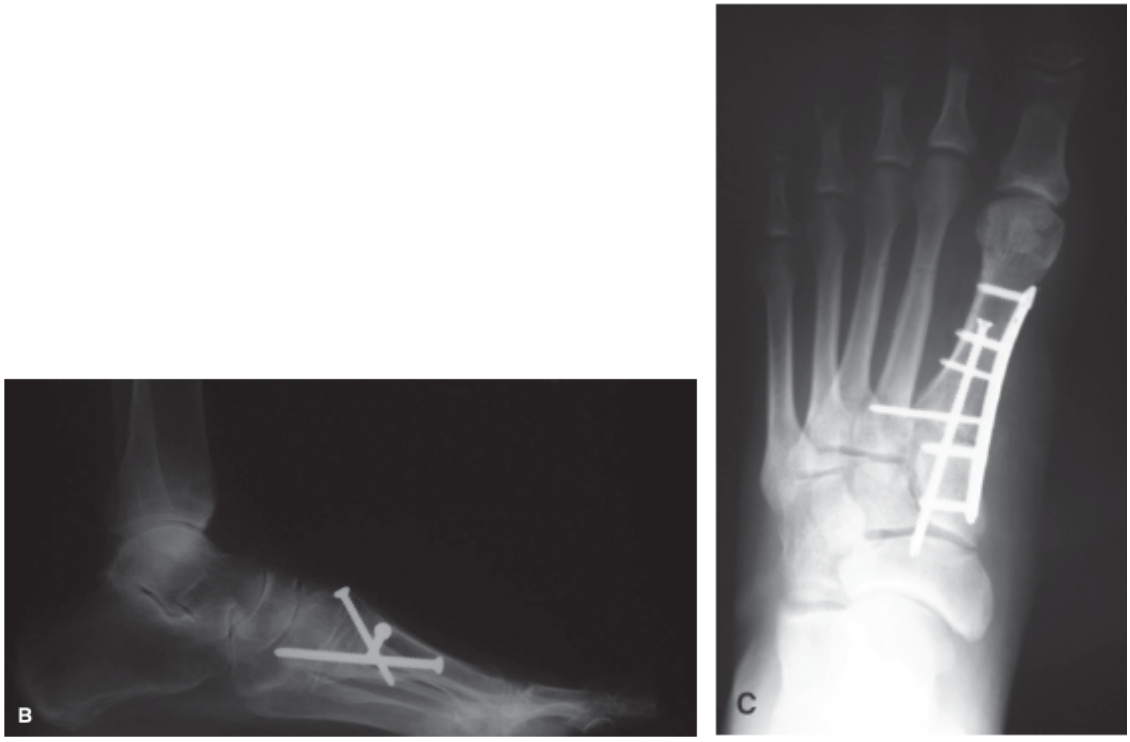
6. Limitation 1[e]

107. McGlamry 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."

108. 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.

109. 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*

§VI.A.4, *supra*. After moving the metatarsal to the new 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 Figs. 31.6B, and 31.9C:



Id., Fig. 31.6B (left) (depicting a lateral x-ray showing the placement of a homerun screw and two additional screws to fix the metatarsal relative to the cuneiform); Fig.

31.9C (right) (depicting screws and a medial locking plate for fixing the metatarsal relative to the cuneiform).

110. McGlamry's disclosure satisfies "fixation device" under the plain and ordinary meaning discussed above in Section III.C. If a means-plus-function construction were applied, McGlamry would still satisfy this limitation. The screws and/or plates disclosed by McGlamry are positioned across the metatarsal-cuneiform joint and are the same types of structures disclosed by the '428 patent. Ex.1005, 326-327; Ex.1001, 11:39-44 (disclosing fixation devices include "compressing bone screw, bone plate, …"). Thus, the fixation devices disclosed by McGlamry constitute corresponding structures (or equivalents) for fixing the moved metatarsal relative to the cuneiform for fusion. *Id.*

111. McGlamry discloses each limitation of Claim 1. Thus, Claim 1 is anticipated by McGlamry.

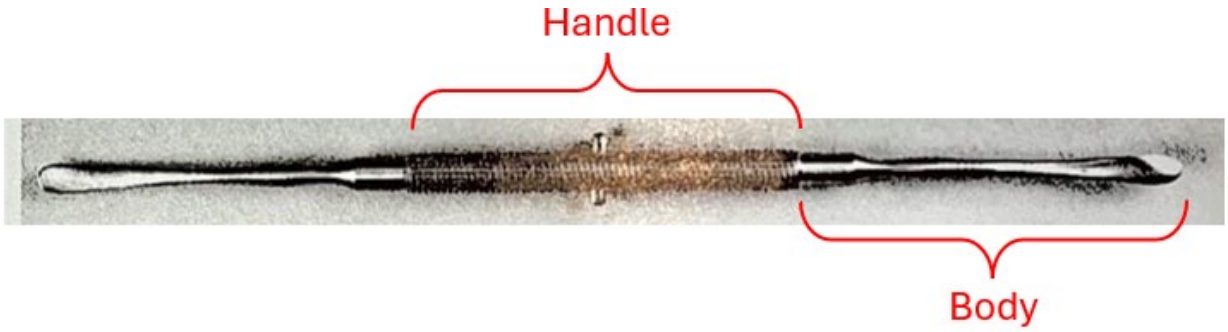
B. Claim 2

112. Claim 2 depends from claim 1 and recites "wherein [a] the instrument has a body and a handle operatively connected to the body; [b] the handle extends from the body; and [c] 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 of claim 2 and is used in the recited manner.

1. Limitations 2[a] and 2[b]

113. 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. *See* Ex.1005, 8 ("One end of the Freer elevator is semisharp, whereas the other is blunt."). The middle of the Freer elevator has a textured handle that extends from the body portion. *See id*.

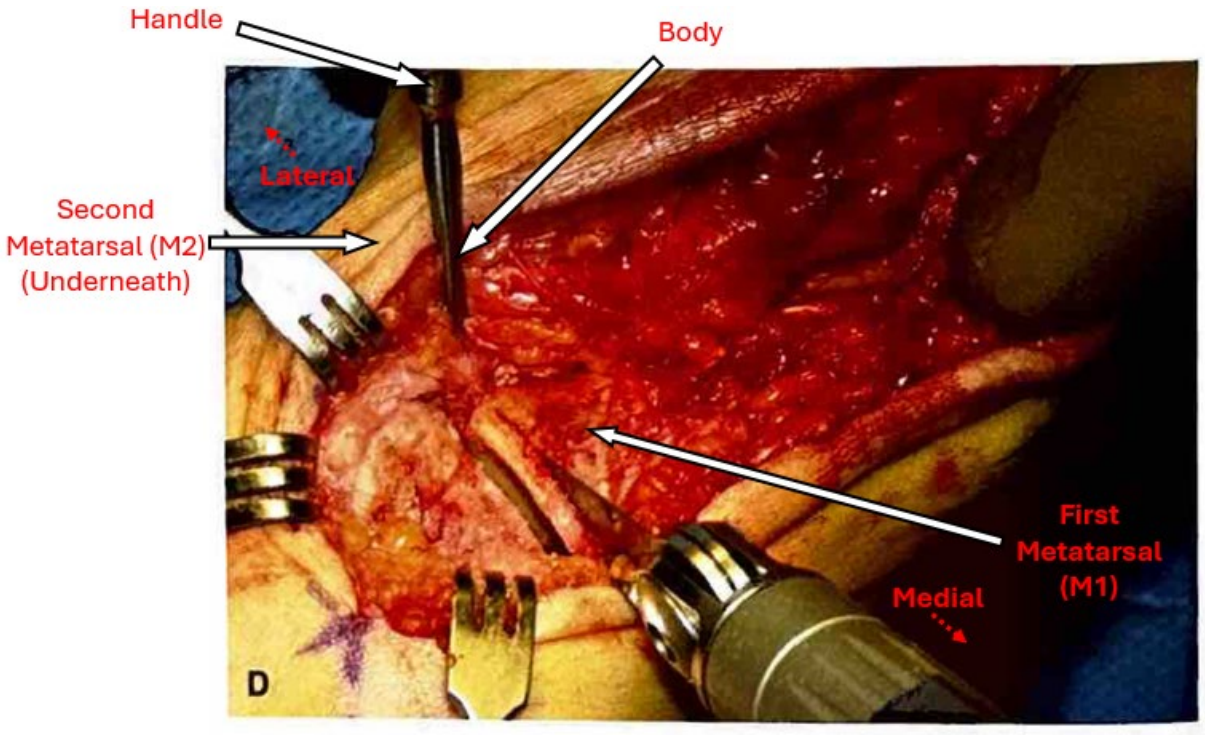


Id. (Fig.1.21, annotated).

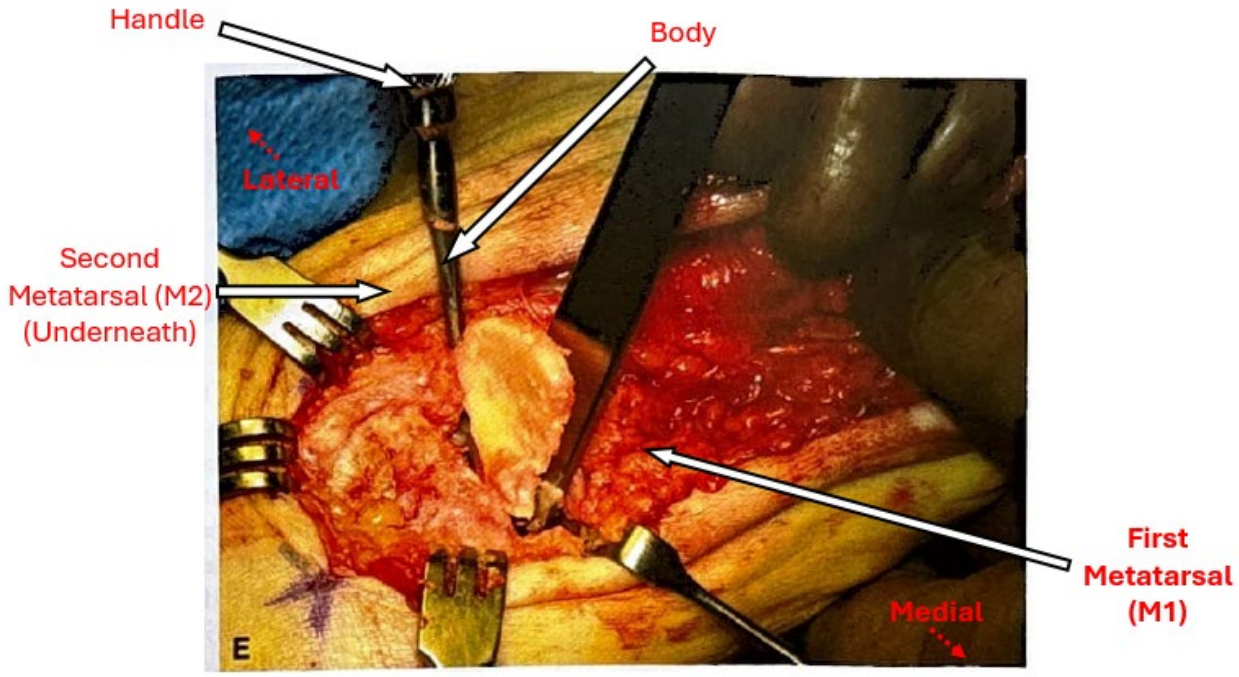
2. Limitation 2[c]

114. As shown below in Figs. 55.7D-F, the body portion of McGlamry's Freer elevator instrument is inserted between the first and second metatarsals. As discussed above, the second metatarsal is disposed adjacent to the first metatarsal underneath the soft tissue in Figs. 55.7D-F. *See* §VI.A.1, *supra*. The Freer elevator is inserted between the metatarsals from the lateral side of the first metatarsal such that the handle of the Freer (the bottom of which is shown in Figs. 55.7D-F) extends

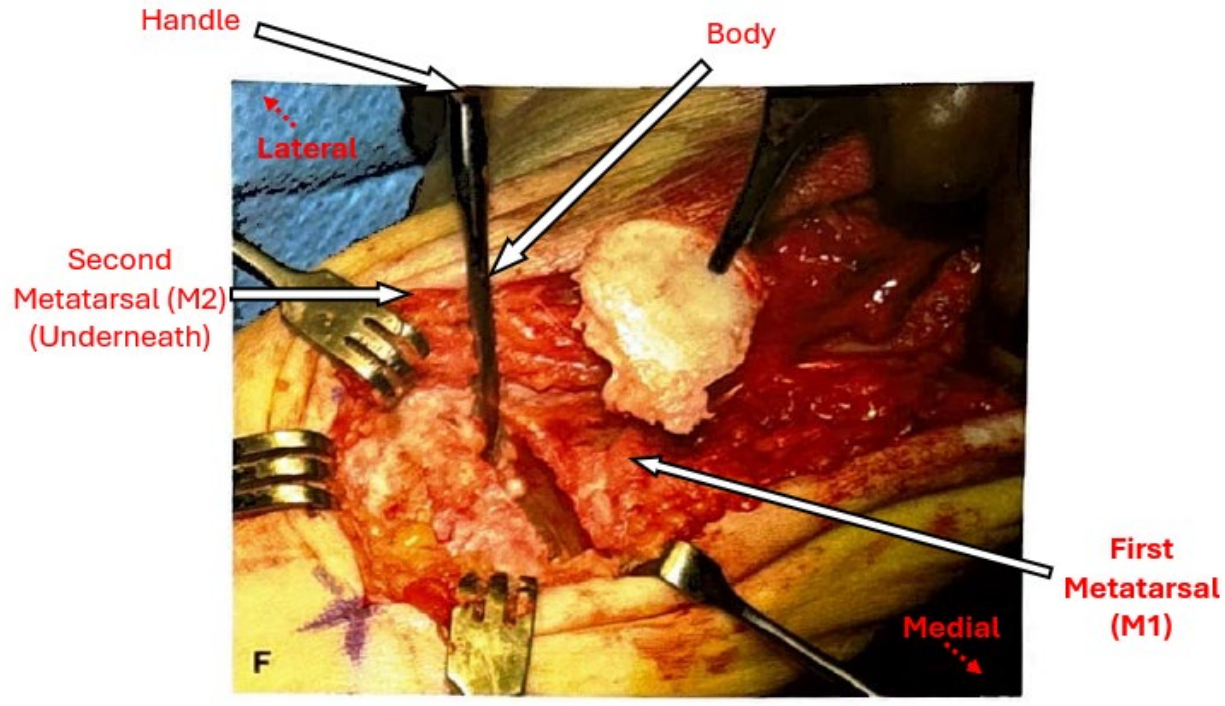
laterally, i.e. over the dorsal surface of the second metatarsal. *See* Ex.1005, 808-809 (Fig. 55.7D-F). The position of the handle over the second metatarsal is evinced in part by the pressure applied to the skin by the Freer, indicating the handle is extending laterally. *See id.*



Ex.1005, 808 (Fig.55.7D) (annotated).



Id., 809 (Fig. 55.7E) (annotated)



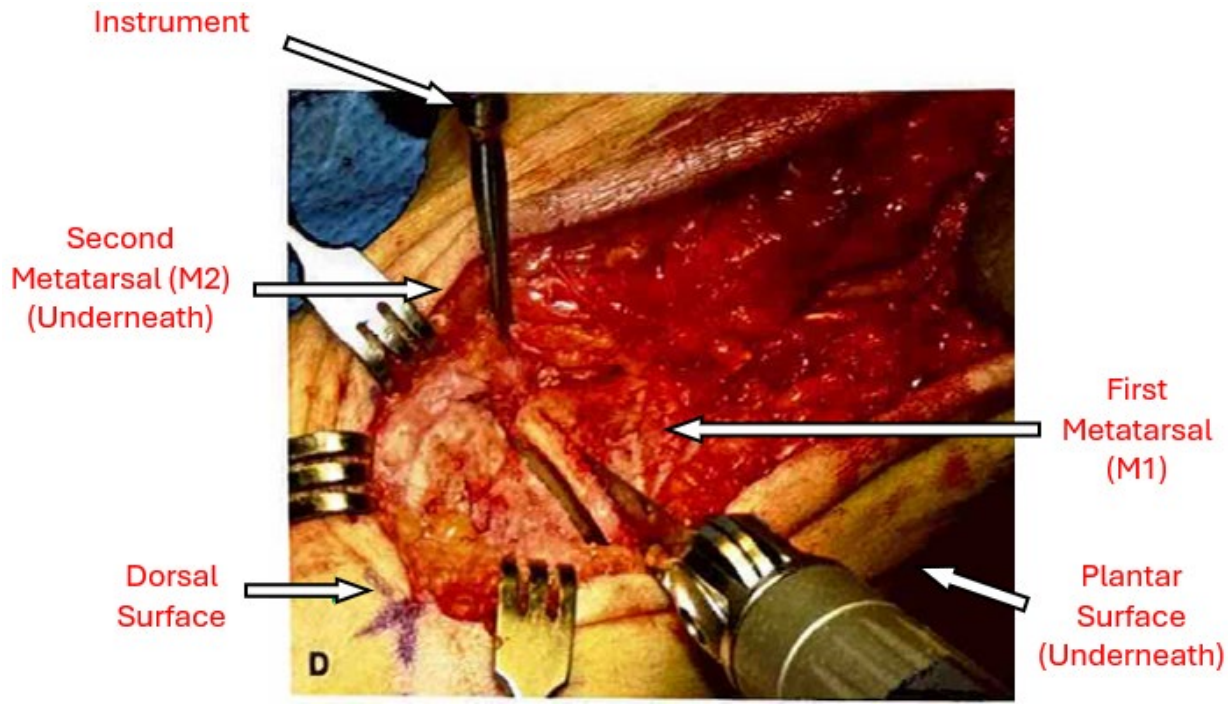
Id., 809 (Fig. 55.7F) (annotated).

115. Thus, McGlamry's discloses each of the limitations and anticipates Claim 2.

C. Claim 3

116. 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."

117. As discussed above, McGlamry discloses a dorsal approach to Lapidus procedures. *See* §VI.A.1, *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 Fig. 55.7D below. Ex. 1005, 808-809.



Ex.1005, Fig.55.7D (annotated).

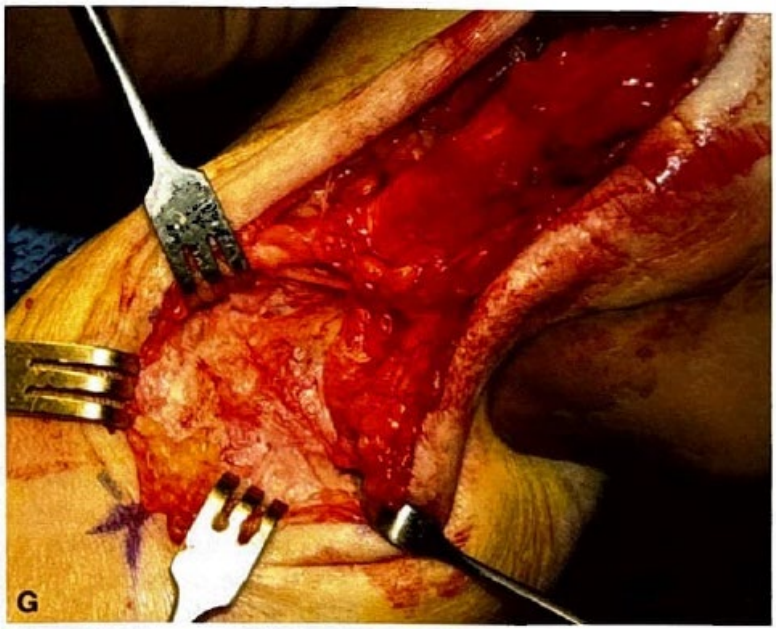
118. Therefore, McGlamry anticipates Claim 3.

D. Claim 6

119. 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."

120. McGlamry discloses this limitation. For example, McGlamry discloses cutting the end of the first metatarsal while the instrument is positioned between the first and second metatarsals. *See* §VI.A.3, *supra*. After the metatarsal is cut and the bone fragment is removed, the instrument is removed. Ex.1005, 808-809. Fig.55.7G below depicts the "final appearance of the first metatarsal cuneiform joint after

planar resection" where the instrument in Figs.55.7C-F has been removed from between the first and second metatarsals. *Id.*, 809. A POSA would understand that prior to closing the incision, all instruments (including the Freer) must be removed from their intraoperative positions.



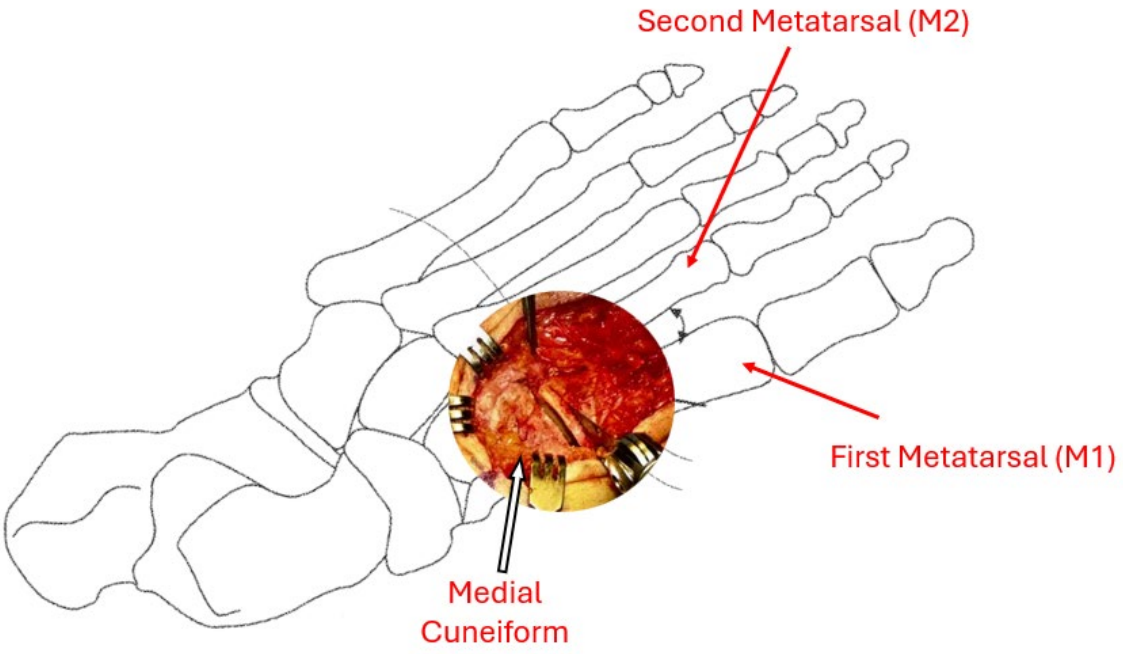
Id., 809, Fig.55.7G. Thus, McGlamry anticipates claim 6.

E. Claim 7

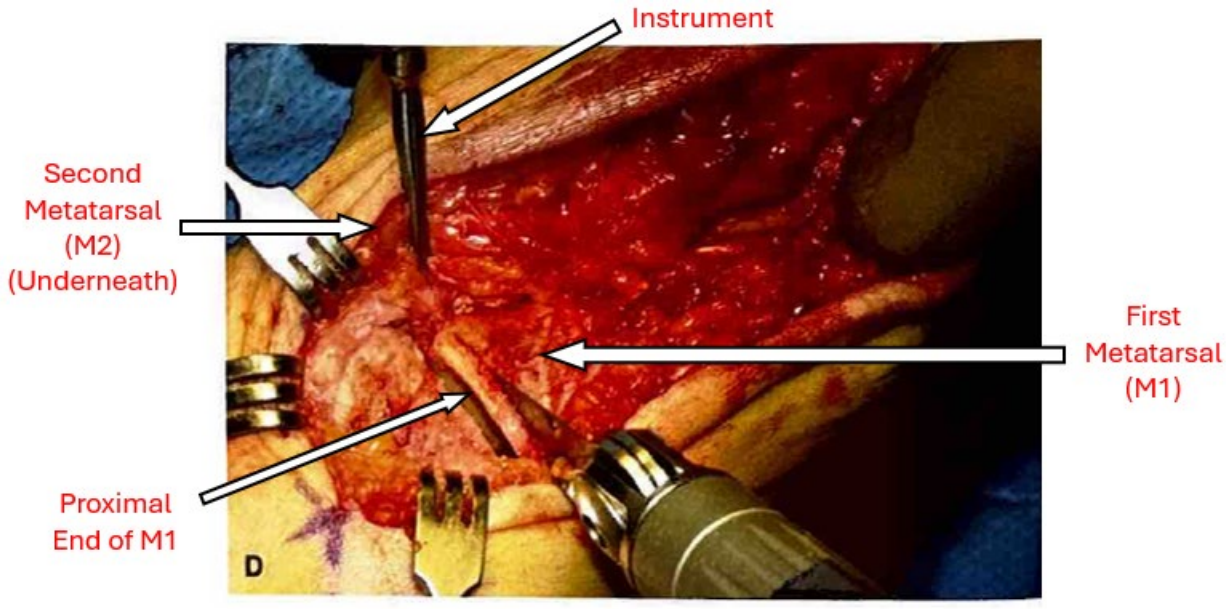
121. Claim 7 depends from claim 1 and recites "wherein positioning the instrument between the first metatarsal and the second metatarsal comprises positioning the instrument between a proximal-most third of the first metatarsal and a proximal-most third of the second metatarsal."

122. As discussed above, the first and second metatarsals are adjacent to one another, including the proximal thirds of each of the metatarsals. As shown in the

overlay of McGlamry's Fig. 55.7D on Fig. 38 of the '428 patent, McGlamry's resection of the metatarsal is positioned with the proximal third of the first and second metatarsals.



123. McGlamry discloses positioning the Freer elevator between the proximal thirds of the first and second metatarsals. Ex.1005, 808-809. As shown below, McGlamry positions the instrument at the proximal end of the first metatarsal, which is between the proximal-most third of each of the two metatarsals.



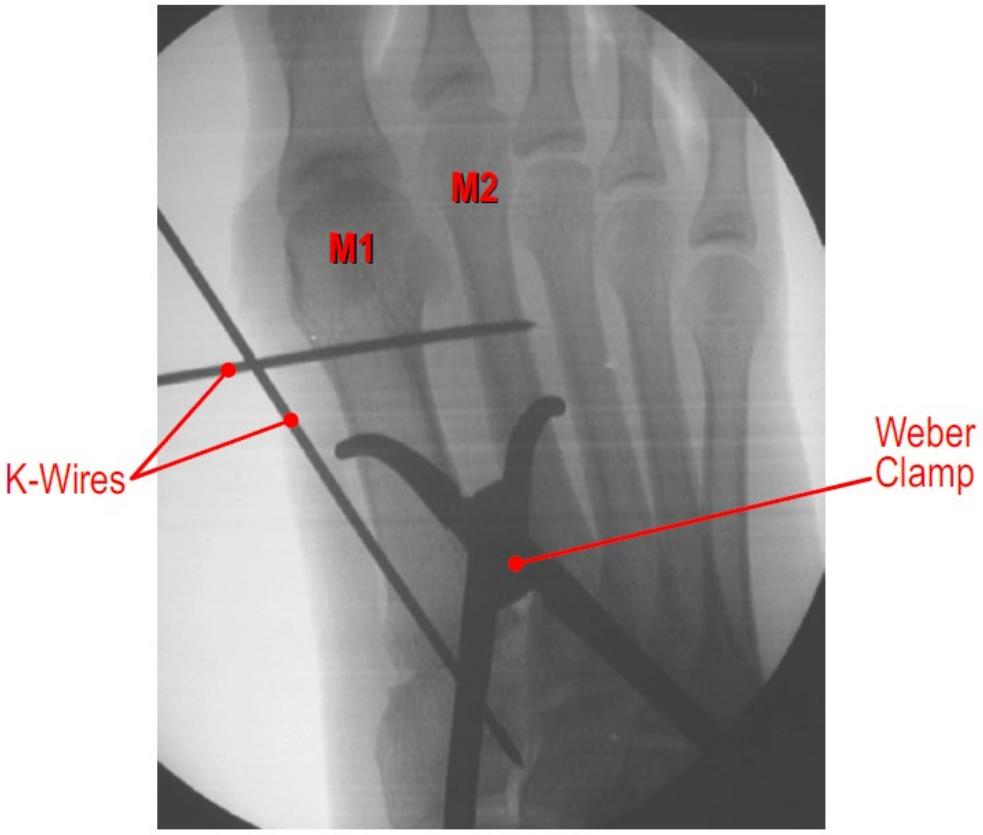
Ex.1005, 808. Thus, McGlamry discloses each of the limitations and anticipates claim 7.

F. Claim 8

124. 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."

125. 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 in Claim 1. *See* §VI.A.4, *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. 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. McGlamry's Fig.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." Ex.1005, 326. One of the tongs is placed on the lateral aspect of the second metatarsal, and the other tong is placed on the medial aspect of the first metatarsal. *See id.* The clamp is then used to reduce the intermetatarsal angle, i.e. move the first metatarsal laterally toward the second metatarsal in the transverse plane. Ex.1005, 326.



Id., Fig.31.5.

126. A POSA would understand that clamps, like the Weber clamp, are basic surgical instruments used in bunion correction surgeries. *See* Ex.1005, 10. Bone holding clamps, such as the Weber clamp, are "basic [] podiatric surgical instruments" used to position bones relative to one another. Ex.1005, 3. Clamps are used in many podiatric surgeries, including bunion correction surgeries, to "grasp bone[s] and hold bony fragments together." *Id.*, 10. 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.

Use of clamps to move the metatarsal in the transverse plane was common at least as of August 2015. *See id.*, 325-326.

127. Thus, under the ordinary meaning of bone positioning guide, McGlamry's Weber clamp is a device designed to move bones. Moreover, if a means-plus-function construction is applied, McGlamry's Weber clamp moves the first metatarsal in the transverse plane, reducing the intermetatarsal angle and maintaining the first metatarsal in the corrected position. Ex.1005, 325-326. McGlamry's Weber clamp is also identical (or at least equivalent) to the structures of the bone positioning guide identified by the '428 patent. Ex. 1005, 325-326; Ex.1001, 7:23-37. McGlamry's Weber clamp includes two shafts (e.g., tongs) that are pivotally connected. Ex.1005, 325-326. A first end of each of the tongs include a handle, and the second end of at least the first tong includes a bone engagement member. *Id.*

128. Thus, McGlamry anticipates claim 8 under either construction.

G. Claim 10

129. 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."

130. McGlamry discloses moving the first metatarsal in a frontal plane. *See* §VI.A.4, *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* Ex.1005, 325 ("[t]he primary surgeon must ensure that the first metatarsal is in the desired position, which is essentially rotated out of valgus"). Thus, McGlamry anticipates claim 10.

H. Claim 11

131. Claim 11 depends from claim 10 and further 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."

132. McGlamry 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. McGlamry discloses that a K-wire is inserted into the first metatarsal. Ex.1005, 326. A K-wire is a type of pin used in surgeries, including podiatric surgeries. 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 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).

133. 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…." Ex.1005, 326. "Once the K-wire penetrates 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.* McGlamry discloses that the K-wire is used in additional to other means of repositioning the metatarsal, such as the Weber clamp. Thus, McGlamry anticipates claim 11.

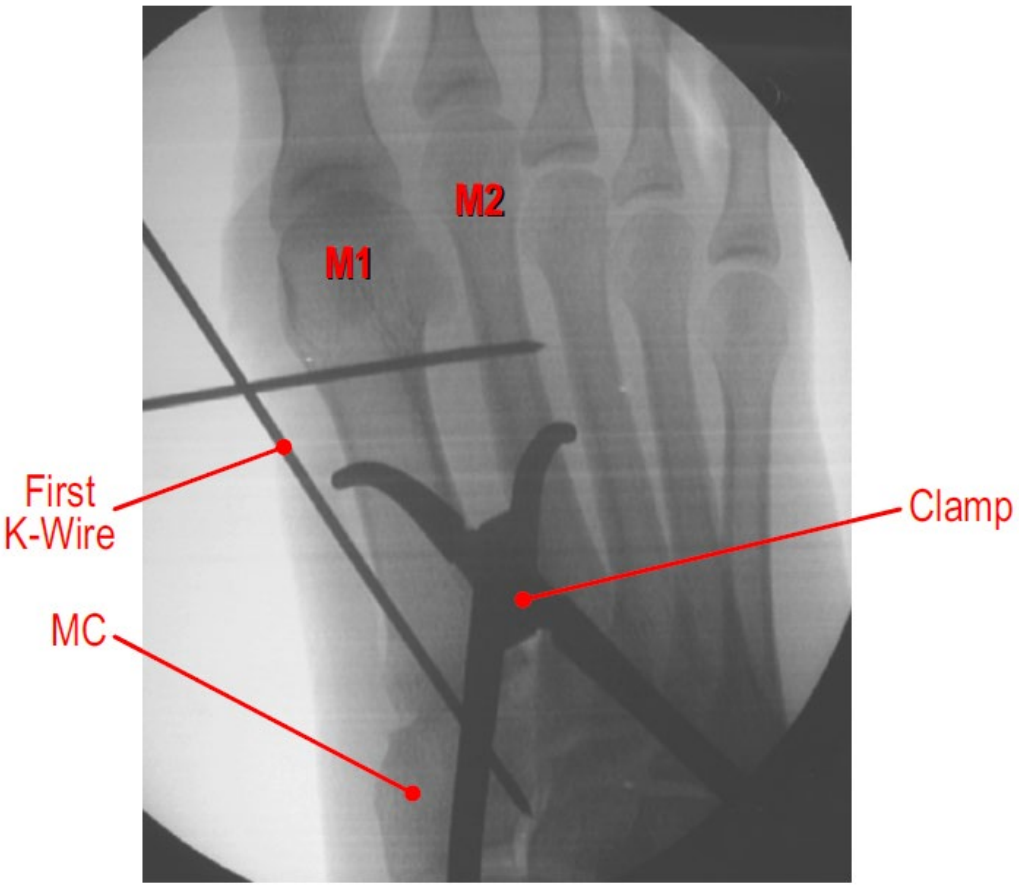
I. Claim 12

134. Claim 12 depends from claim 1 and recites "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."

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

136. McGlamry discloses this limitation. 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 as shown below in Fig.31.5. *Id.*, 326. A POSA would understand that insertion of the K-wire in this manner applies a force to the metatarsal in the sagittal plane, compressing the metatarsal against the cuneiform.



Ex.1005, Fig.31.5C (annotated).

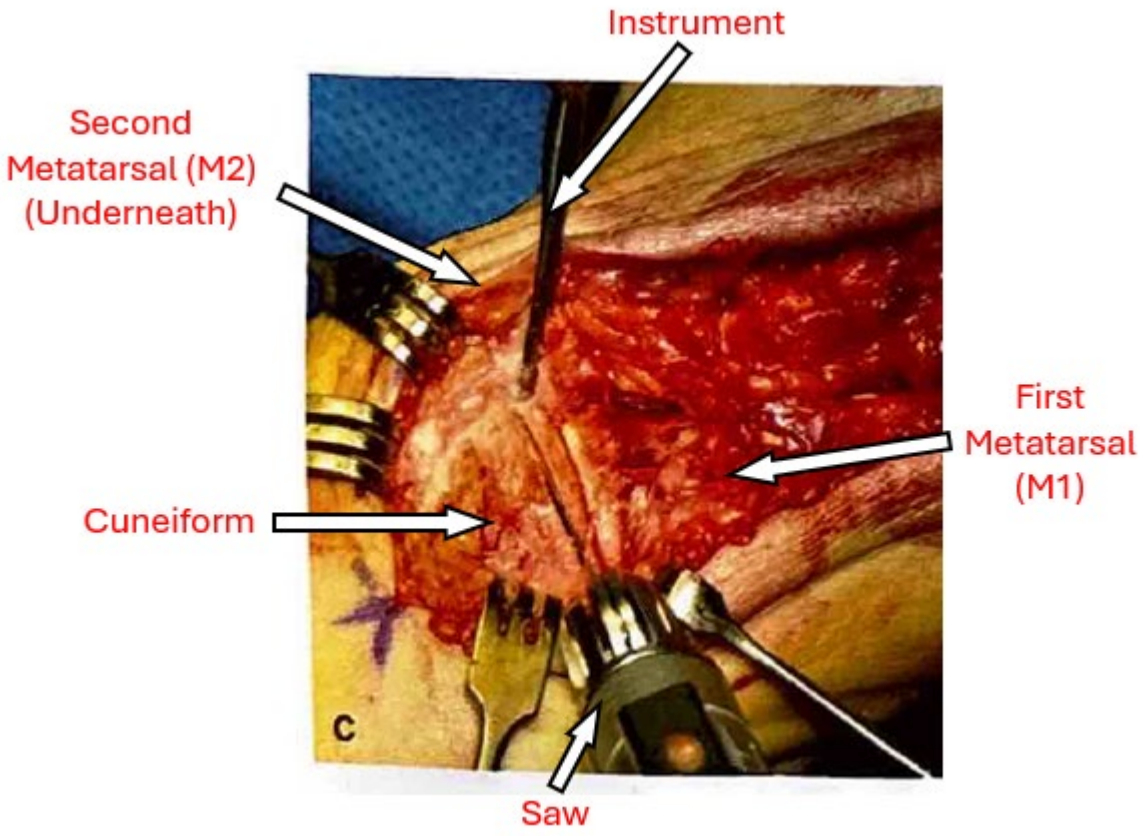
137. After "acceptable alignment" of the bones is confirmed, a "homerun screw" is placed into the metatarsal and cuneiform, securing and compressing the bones. *See* Ex.1005, 324 (describing resection of the first metatarsal and cuneiform at the joint), 326 (describing compression of the metatarsal and cuneiform occurring after preparation). The homerun screw is inserted through the first metatarsal and into the medial cuneiform to "provide[] interfragmentary compression and leverage" as the bones fuse together. *Id.*, 326. Similarly, McGlamry's describes installing a plate or screws (fixation devices) after the placement of the "homerun screw": "[f]ollowing 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. Thus, McGlamry anticipates claim 12.

J. Claim 13

138. 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."

139. McGlamry discloses cutting the end of the medial cuneiform with the Freer elevator instrument inserted between the first and second metatarsals. For

example, Fig. 55.7C depicts "[r]esection of the articular surface of the medial cuneiform with the sagittal saw." Ex.1005, 809. In Fig.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. *See id.*, 808.



Id., Fig.55.7C (annotated). Thus, McGlamry anticipates claim 13.

K. Claim 16

140. 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."

141. McGlamry discloses bone fixation devices that comprise 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."). Thus, McGlamry anticipates claim 16.

L. Claim 17

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

143. McGlamry discloses bone fixation devices comprise three intramedullary screws. Ex.1005, 326 ("[F]ixation techniques consist of interfragmentary compression of three solid cortical screws…."). A POSA would understand the three intramedullary screws to be intramedullary implants because they are inserted into the intramedullary canal(s) of at least the first metatarsal and medial cuneiform. *Id.*

VII. MCGLAMRY RENDERS CLAIMS 1-3, 6-8, 10-13 AND 16-17 OBVIOUS

144. A POSA would have understood that Chapters 31 and 55 of McGlamry both relate to the same metatarso-cuneiform arthrodesis procedure which is used to correct a bunion deformity. Ex.1005, 322-330, 803, 808-809. A POSA would not think that Chapters 31 and 55 are different procedures or separate disclosures that require combining. *See* §VI.A.1, *supra* (explaining the same). However, I have been asked to evaluate whether it would have been obvious to combine the teachings of these two chapters to arrive at the claimed technique.

145. A POSA would recognize that these two chapters describe the same procedure (metatarsal-cuneiform arthrodesis) with Chapter 55 providing more detail regarding certain steps. *Id.* 322-330, 808-809. McGlamry's Chapter 55 supplies principles that are implemented in arthrodesis procedures, including the metatarso-cuneiform arthrodesis of Chapter 31. *See id.*, 322-330, 808-809. Chapter 55 explains that those principles "greatly enhance surgical visualization and stability in arthrodesis," providing a more predictable fusion of the bones. *See id.* 803. Chapter 55 discloses applying the principles to metatarso-cuneiform arthrodesis procedure depicted in Chapter 55 includes similar steps and more detail regarding the procedure discussed in Chapter 31. Ex.1005, 322-330, 808-809.

146. A POSA would have recognized that application of Chapter 55's principles would improve fusion and reduce known complications disclosed in Chapter 31, including delayed union, nonunion, malunion, or loss of correction. *See id.* 803; *see also id.*, 324 (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"). Chapter 55 describes resection approaches that promote close-fitting apposition of the fusion surfaces, and applies those principles to a metatarsal-cuneiform arthrodesis. *See* Ex.1005, 804-806, 808-809. Chapter 55 also describes surgical strategy and exposure techniques designed to improve

visualization and facilitate proper positioning and stable fixation of the joint. *Id.*, 803-805, 808-809. A POSA would have recognized that increased visualization would allow the surgeon to more accurately and predictably correct the position of the metatarsal and fix the bones. *See id.* Chapter 31 likewise identifies accurate repositioning and fixation as important for achieving union and avoiding complications in the metatarsal-cuneiform arthrodesis context. *See* Ex.1005, 324, 329.A POSA would have recognized that combining the teachings of Chapters 31 and 55 constitutes nothing more than application of known arthrodesis principles and techniques to a known first metatarsal-—cuneiform arthrodesis procedure to improve fusion and reduce complications. *See* Ex.1005, 803, 808-809.

147. A POSA would have recognized that combining Chapters 31 and 55 also merely constitutes predictable use of Chapter 55's arthrodesis principles and techniques in Chapter 31's arthrodesis procedure. Chapter 55 discloses that it's principles and technique can be applied to metatarso-cuneiform arthrodesis procedures like the procedure disclosed in Chapter 31. Ex.1005, 808-809.

148. A POSA would have a reasonable expectation of success applying Chapter 55's principles to the procedure of Chapter 31 because Chapter 55 describes applying the principles to the specific arthrodesis procedure disclosed in Chapter 31. *Id.*, 808-809. For example, Chapter 31 demonstrates that a Freer elevator is a standard, suitable instrument in the same operative setting by expressly using a Freer

elevator during periosteal freeing/exposure for calcaneal bone graft harvest in the bunion correction procedure. Ex.1005, 803. And Chapter 55 underscores the routine nature of the periosteal/subperiosteal approach, emphasizing tissue-plane dissection principles and cautioning against periosteal shredding (*id*., 803)—considerations that align with Chapter 31's concern for limiting periosteal stripping.

149. Thus, McGlamry renders Claims 1-3, 6-8, 10-13, and 16-17 obvious.

VIII. MCGLAMRY AND DAVIDSON RENDER CLAIMS 1-3, 6-13 AND 16-17 OBVIOUS

150. Even if McGlamry did not anticipate or render obvious claims 1-3, 6-8, 10-13, and 16-17 as I explained in Sections VI and VII (*see* §§VI, VII, *supra*), these claims would have been obvious over McGlamry and Davidson. McGlamry and Davidson also render claim 9 obvious.

151. As discussed in Section VII, a POSA would have recognized that the principles of Chapter 55 of McGlamry could be applied to the metatarsal-cuneiform arthrodesis procedure of Chapter 31. *See* §VII, *supra*. That motivation carries through to the following analysis.

A. Claim 1

152. McGlamry discloses each of the limitations of Claim 1 as explained above in Section VI. *See* §VI.A, *supra*. Like McGlamry, Davidson discloses an instrument that satisfies the related claim limitations. As discussed below, a POSA

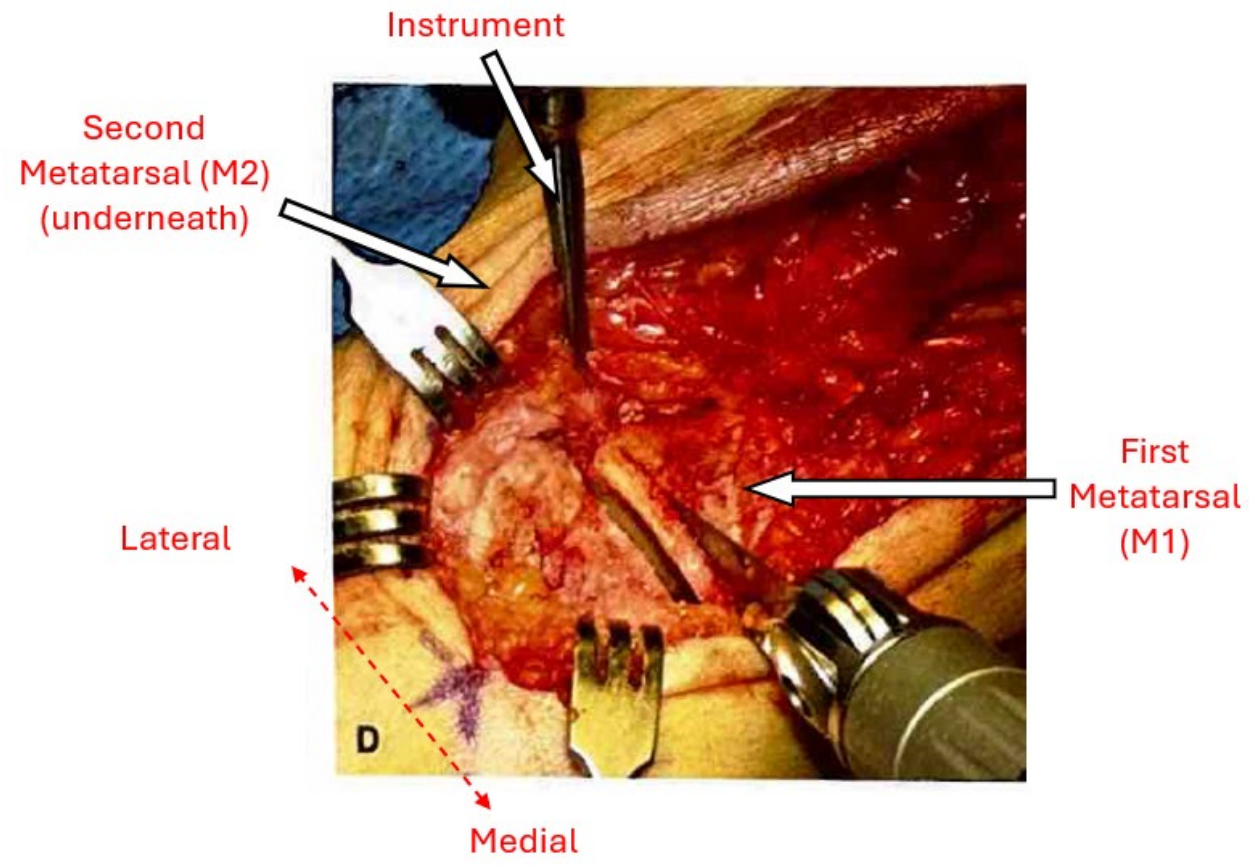
would have recognized that Davidson's retractor could be used in McGlamry's bunion correction surgery to enhance safety and reduce the risk of complications. Thus, McGlamry in view of Davidson renders claim 1 obvious.

1. Preamble

153. To the extent the preamble is limiting, McGlamry discloses "an instrumented surgical technique for treating a bunion deformity." *See* §VI.A.1 *supra*.

2. Limitation 1[a]

154. McGlamry discloses "inserting an instrument between a first metatarsal and a second metatarsal adjacent to the first metatarsal." *See* §VI.A.2, *supra*. For example, McGlamry discloses inserting a Freer elevator between the metatarsals during a bunion correction surgery as shown below. *Id.*



Ex.1005, 808 (Fig. 55.7D annotated).

155. Davidson also discloses "inserting an instrument between a first metatarsal and a second metatarsal adjacent to the first metatarsal." For example, Davidson discloses retractors designed for use in podiatric surgery, including "osteotom[ies] of the midtarsal bones and proximal first metatarsal." Ex.1006, [0060]. McGlamry's bunion correction surgery is a metatarso-cuneiform arthrodesis procedure, which is an osteotomy of a midtarsal bone (the medial cuneiform) and the first metatarsal. *See* Ex.1005, 322-330. Thus, Davidson discloses that its

retractor is used in bunion correction surgeries like McGlamry's. *See* Ex.1006, [0060].

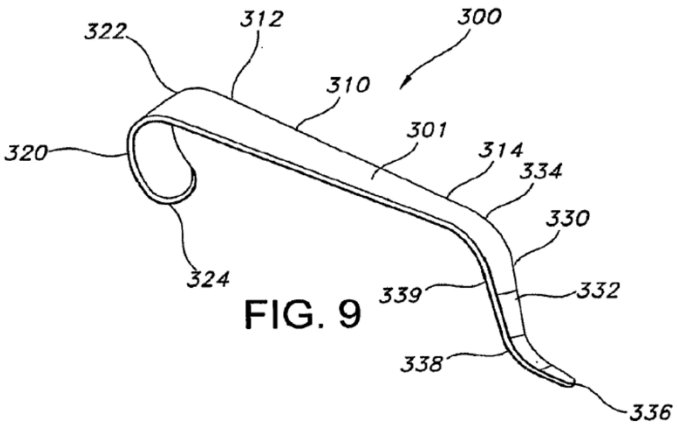


FIG. 9

Ex.1006, Fig. 9.

156. 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.

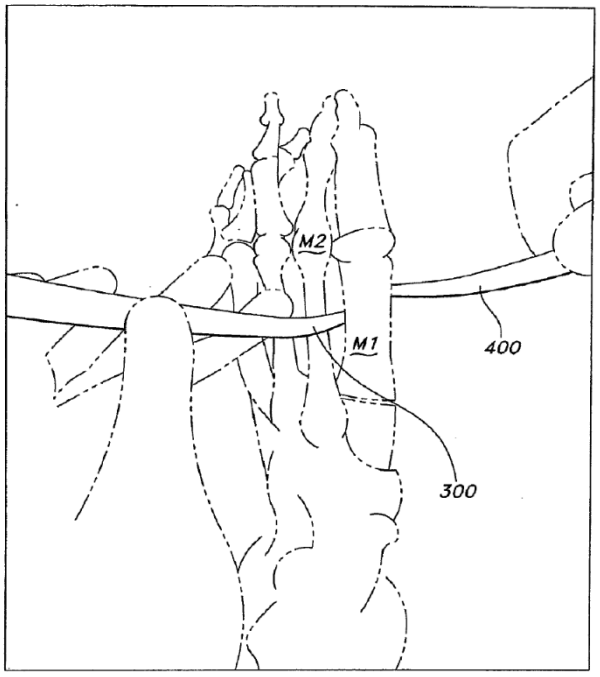


FIG. 19

Ex.1006, Fig.19.

157. A POSA would have recognized that Davidson's retractor provides advantages and benefits over a Freer elevator because Davidson's retractors are specialized for use in podiatric surgery. 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." Ex.1006, [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].

158. However, Davidson's retractor is structurally configured for retraction in the foot: an elongated body with handle and a blade portion extending at about 90º 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. *See* Ex.1005, 7-8. A POSA would recognize 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 because Davidson's discloses that its retractors are designed to retract soft tissues around foot bones and fit in small spaces. *Id.*, Ex.1006, [0032]. A POSA would further recognize that 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.

159. A POSA would have recognized that McGlamry's and Davidson's techniques are similar and their instruments are interchangeable. McGlamry teaches

that surgical instruments such as elevators (like McGlamry's Freer elevator discussed in Section VI) and retractors (like Davidson's retractor described below) are among the "basic set of podiatric surgical instruments." Ex.1005, 3. Retractors have similar structures to and are used in a similar manner as periosteal elevators. *See* Ex.1005, 7 (disclosing the uses for retractors like Davidson's), 8 (disclosing the uses for periosteal elevators like the Freer elevator).

160. A POSA would have had a reasonable expectation of success using Davidson's retractor in McGlamry's procedure. Davidson's retractors are engineered for the same anatomical and procedural context in which McGlamry uses a Freer elevator. Ex.1005, 7-8; Ex.1006, [0057]-[0058], Fig. 19. 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*.

161. Thus, McGlamry in view of Davidson renders limitation 1[a] obvious.

3. Limitation 1[b]

162. McGlamry discloses cutting an end of the first metatarsal with the instrument inserted between the first metatarsal and the second metatarsal. *See* Section §§VI.A.2-3, *supra*. A POSA using Davidson's retractor in McGlamry's

bunion correction surgery would similarly position the retractor instrument between the metatarsals just as McGlamry discloses positioning a Freer elevator in that location. Ex.1005, 808-809. Davidson discloses that the retractors are designed for insertion into the intermetatarsal space and sized to protect the soft tissues on the opposite side of resections. *See* Ex.1006, [0003], [0032], [0055]-[0058], Fig. 19. Thus, McGlamry in view of Davidson renders limitation 1[b] obvious.

4. Limitation 1[c]

163. McGlamry's discloses Limitation 1[c]. *See* §VI.A.4, *supra*. Thus, McGlamry in view of Davidson renders limitation 1[c] obvious.

5. Limitation 1[d]

164. McGlamry's discloses Limitation 1[d]. *See* §VI.A.5, *supra*. Thus, McGlamry in view of Davidson renders limitation 1[d] obvious.

6. Limitation 1[e]

165. McGlamry's discloses Limitation 1[e]. *See* §VI.A.6, *supra*. McGlamry in view of Davidson renders limitation 1[e] obvious. Thus, Claim 1 is rendered obvious by McGlamry's in view of Davidson.

B. Claim 2

1. Limitation 2[a]

166. Davidson discloses these limitations. As shown below, Davidson discloses retractors that includes a body (blue) that is inserted between the metatarsals. Ex.1006, [0057]-[0058], Figs. 18-19. The retractor also includes a

handle (yellow) that the surgeon grasps during surgery. *See* Ex.1006, [0044], [0057]-[0058], Figs. 18-19. Davidson's retractors also include "[a] handle 320 extends from proximal end 312." *Id.*

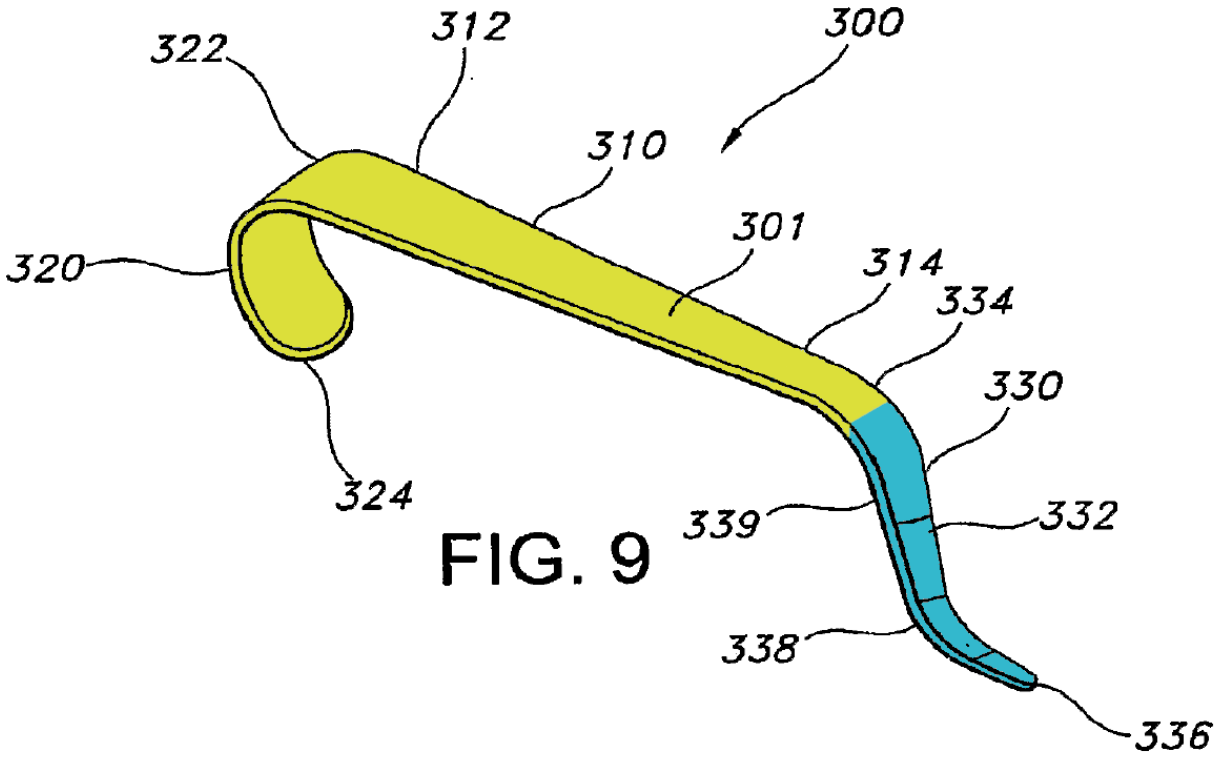


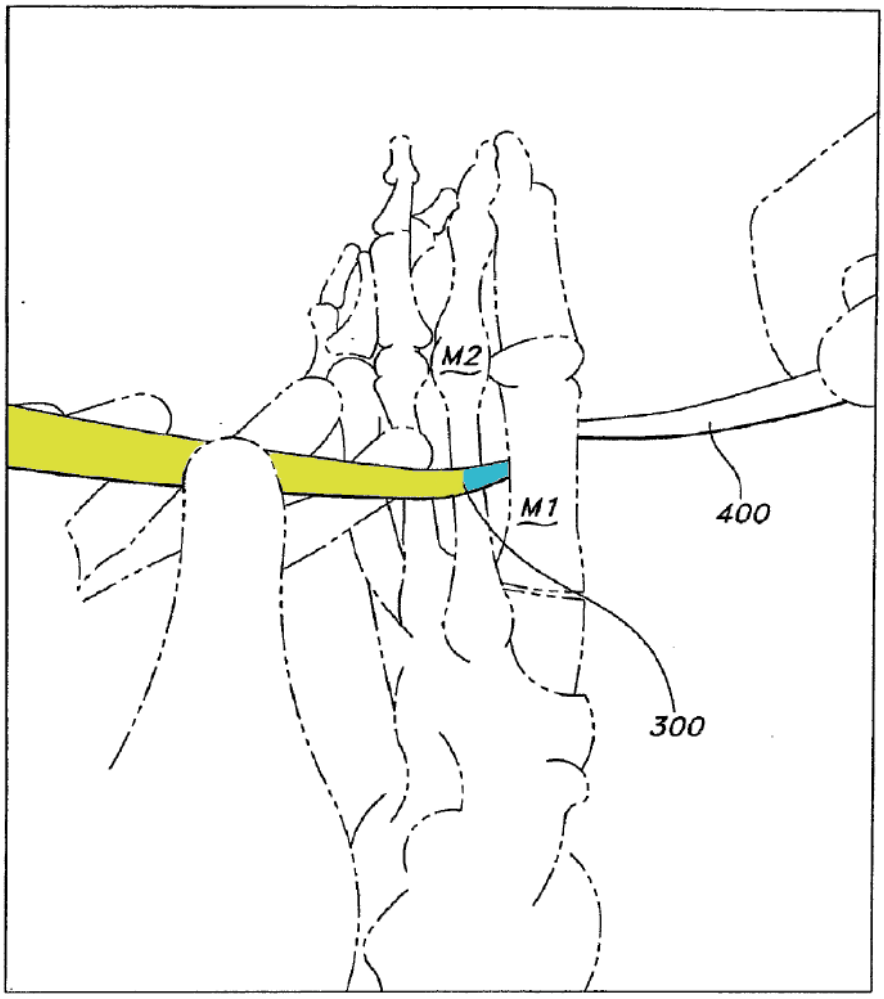
FIG. 9

Id., Fig.9 (annotated).

2. Limitation 2[c]

167. McGlamry discloses placing the instrument between the metatarsals such that the handle extends laterally over the second metatarsal. *See* §VI.B.2, *supra*. Even if McGlamry did not disclose this limitation, Davidson discloses inserting the retractor body (blue) between the first metatarsal (M1) and the second metatarsal (M2) such that the retractor handle (yellow) extends laterally over a dorsal surface of the second metatarsal as shown below in Fig.19. The body of the retractor

300 is inserted between the metatarsals, and the handle extends over the second metatarsal (M2). Ex.1006, Fig. 19.



Ex.1006, Fig.19.

168. McGlamry and Davidson both disclose the positioning of the body of the instrument between the metatarsals and the handle of the instrument extending laterally over the second metatarsal. *Id.*; Ex.1005, 808-809 (Figs. 55.7C-G). A POSA would understand that the orientation of Davidson's retractor would remain the same as Fig. 19 when the instrument is inserted between the metatarsals in

McGlamry's procedure. Thus, McGlamry in view of Davidson renders claim 2 obvious.

C. Claim 3

169. As discussed above, McGlamry discloses the additional limitations of claim 3. *See* §VI.C, *supra*. Even if McGlamry did not disclose the additional limitations of claim 3, Davidson does. Figs. 18 and 19 below show a dorsal (top) view of the foot. Ex.1006, Figs. 18-19. Davidson also 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 toward a plantar (bottom) side of the foot as shown in Fig. 19. *See* Ex.1006, [0058] (disclosing that the retractor is "worked under metatarsal M1").

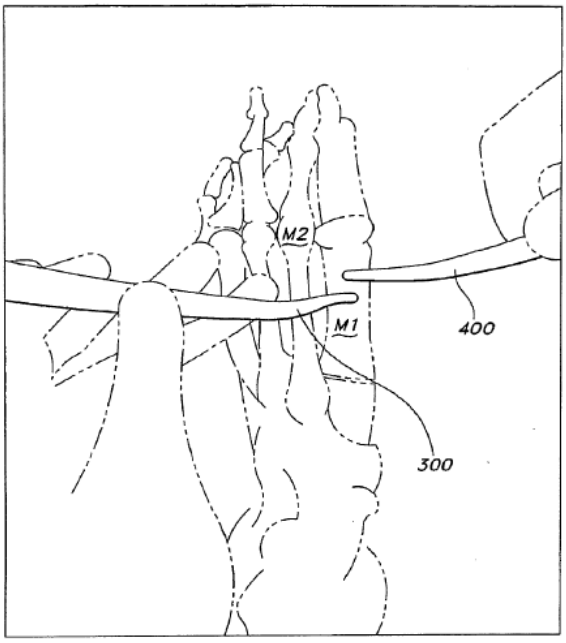


FIG. 18

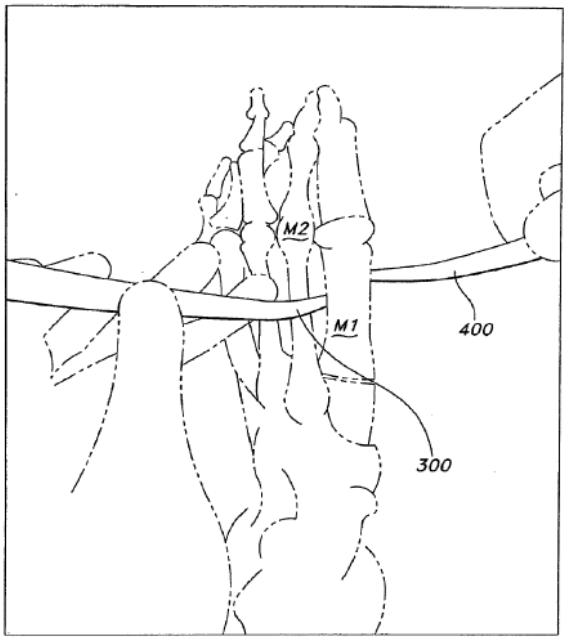


FIG. 19

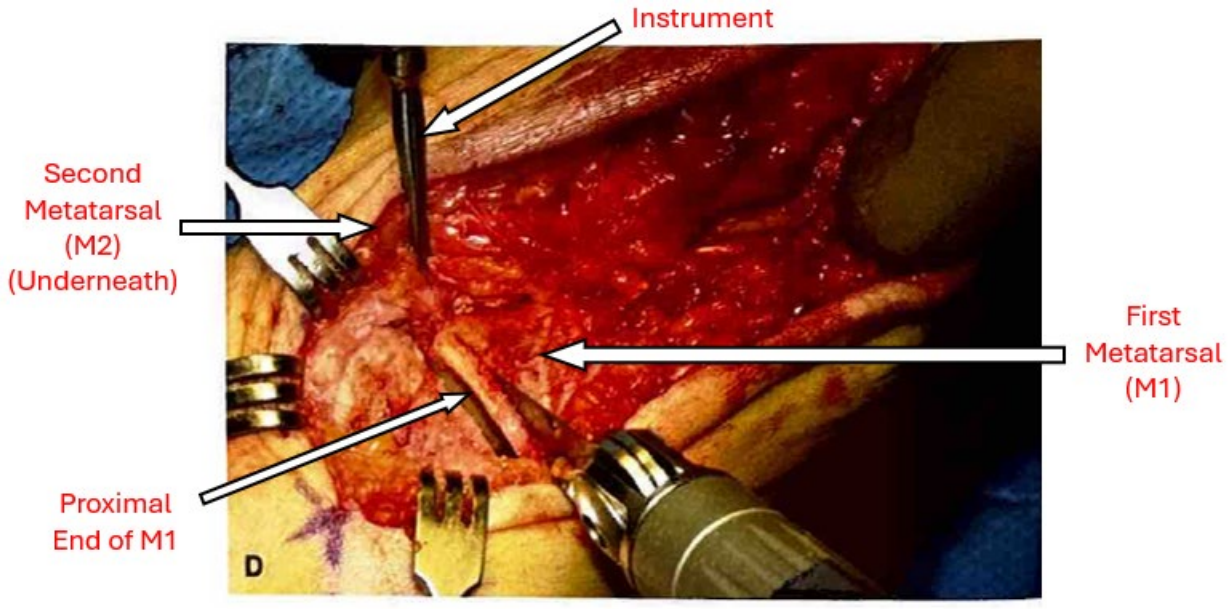
Ex.1006, Figs. 18-19. This insertion would not change when using Davidson's retractor in McGlamry's procedure because both references disclose inserting the instrument in the same manner and McGlamry discloses a dorsal approach in its bunion correction surgery. Thus, McGlamry in view of Davidson renders claim 3 obvious.

D. Claim 6

170. As discussed above, McGlamry discloses the additional limitations of claim 6, which recites removing the instrument after cutting the first metatarsal. *See* §VI.D, *supra*. A POSA would have recognized that Davidson's retractor would need to be removed from its intraoperative position. *See id.* When using Davidson's retractor in McGlamry's bunion correction surgery, the retractor would be removed after cutting the first metatarsal like the other instrumentation. *See id.* Thus, McGlamry in view of Davidson renders claim 6 obvious.

E. Claim 7

171. As discussed above, McGlamry discloses the additional limitations of claim 7. *See* §VI.E, *supra*). As shown below, McGlamry positions the instrument between the first and second metatarsals at the proximal end of the first metatarsal (adjacent the cuneiform), which is between the proximal-most third of the two metatarsals.



Ex.1005, 808 (Fig. 55.7D).

172. When using Davidson's retractor in McGlamry's bunion correction surgery, the placement retractor would not change. McGlamry discloses resecting a proximal portion of the first metatarsal. A POSA would have recognized that Davidson's instrument should be placed between the proximal third of the metatarsals to protect the tissues in the path of the saw from damage and serve as a physical stop for the saw. *See* Ex.1005, 808; Ex.1006, [0032]. Thus, McGlamry in view of Davidson renders claim 7 obvious.

F. Claim 8

173. McGlamry discloses the additional limitations of Claim 8. *See* §VI.F, *supra*. Using an instrument like Davidson's retractor in McGlamry's procedure would not change the use of the bone positioning guide. For example, the bone

positioning guide would still be positioned over the shafts of the metatarsals as disclosed by McGlamry and used to reposition the metatarsal. Ex.1005, 325. Thus, McGlamry in view of Davidson render Claim 8 obvious.

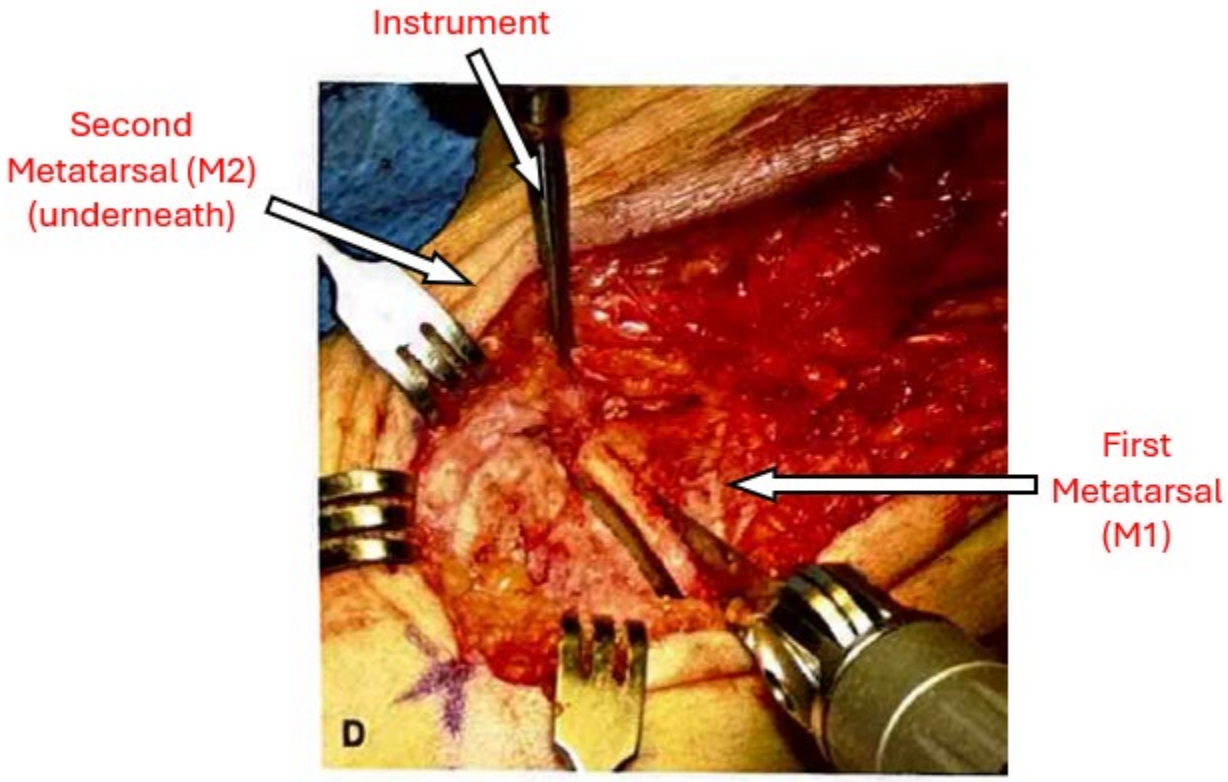
G. Claim 9

174. 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."

175. The '428 patent describes a fulcrum broadly, explaining that "any suitable mechanical instrument that maintains a spacing between adjacent bones" can 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").

176. McGlamry discloses that the instrument inserted between the first metatarsal and the second metatarsal is a fulcrum about which the first metatarsal can pivot. As explained in limitation 1[a] in Section VI, McGlamry discloses inserting an instrument between the first and second metatarsals during the bunion correction surgery. *See* Section §VI.A.2, *supra*. The instrument has a width to its body, which prevents the first and second metatarsals from touching while the instrument is inserted, thereby maintaining a separation between the bones. *See* Ex.1005, 808-809 (Figs. 55.7C-F). As shown in Figs. 55.7C-F, the instrument

maintains a space between the first and second metatarsals equal to the size of the instrument. *See* Ex.1005, 808-809.



Ex.1005, 809 (Fig.55.7 D) (annotated).

177. A POSA would have understood that McGlamry's instrument functions as a fulcrum—as described by the '428 patent—because lateral movement of the first metatarsal would occur with rotation about McGlamry's instrument. For example, in a left foot, a lateral movement of the first metatarsal with the instrument between the metatarsals as disclosed by McGlamry would cause the metatarsal to pivot counterclockwise on the instrument. *See, e.g.*, *id.*, 808.

178. Davidson also discloses a fulcrum inserted between the first and second metatarsals that provides the same mechanical relationship. Davidson discloses 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 below, the retractor is engaged between the first and second metatarsals such that lateral movement of the first metatarsal toward the second metatarsal occurs as pivoting about the retractor where it interfaces with the first metatarsal.

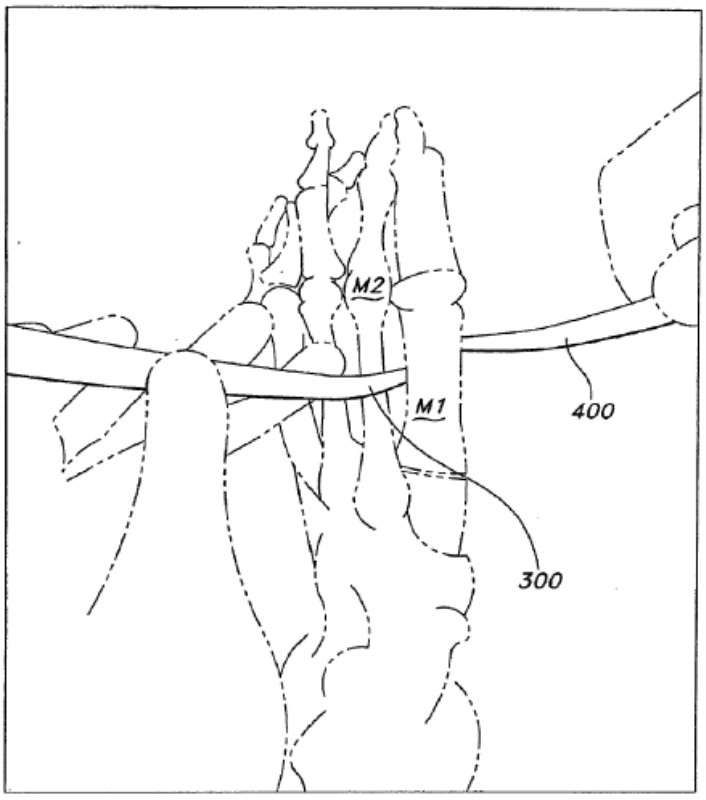


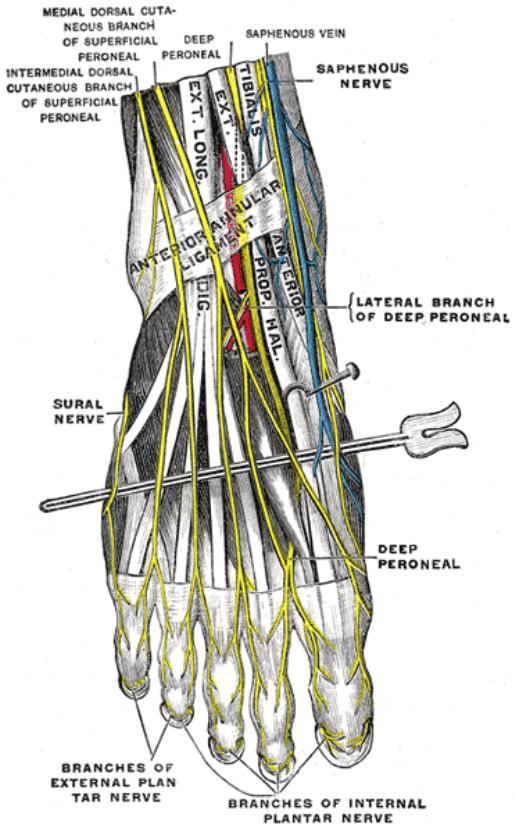
FIG. 19

Ex.1006, Fig. 19. In this configuration, the surgeon manipulates the first metatarsal using a second instrument 400, causing the first metatarsal to pivot about the retractor 300 at the retractor-bone interface. *Id.*; *see also id.*, [0057]-[0058].

179. A POSA would have recognized that placing Davidson's retractor between the first and second metatarsals would provide predictable mechanical advantage, stability, and control when repositioning the first metatarsal in the transverse and sagittal planes. 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]. Unlike a surgeon's finger, Davidson's retractors are capable of fitting between the metatarsals and providing additional leverage and control. *See id.* A POSA would recognize that Davidson's retractor also provides a second point of contact to control the repositioning the metatarsal in the transverse plane. *See* Ex.1016, 420 (disclosing use of a Freer to move metatarsal fragments in addition to a surgeon's hand).

180. A POSA would have also recognized that using Davidson's retractor as a fulcrum would protect soft tissues between the metatarsals from injury during repositioning of the metatarsals. Davidson discloses that the retractors protect soft tissues (e.g., nerves, arteries) from injury from "displaced bone fragments" such as the first metatarsal as it is being displaced laterally to its corrected position. Ex.1006, [0057]. For example, Davidson discloses in another related foot procedure that the

retractor "prevents medial displacement of bone fragments which can lead to recurrence, pain, and soft tissue damage." *Id.*, [0061]. A POSA would have understood that there are soft tissues (e.g., nerves, blood vessels, etc.) between the metatarsals, some of which are shown below.



Dorsal digital nerves of foot, WIKIPEDIA (https://en.wikipedia.org/wiki/Dorsal_digital_nerves_of_foot), last accessed December 23, 2025

181. A POSA would recognize that Davidson's retractor would be used as a fulcrum in McGlamry's to similarly protect soft tissues between the metatarsals as the first metatarsal is repositioned laterally. *See* Ex.1006, [0057], [0061]. For

example, the third edition of McGlamry's (Ex.1022) discloses that "[p]roper tissue handling" can decrease the risk of disruption of the nerves in the first interspace. *See* Ex.1022, 552.

182. 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.

183. 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. Thus, McGlamry in view of Davidson renders claim 9 obvious. My patentability opinions are consistent with the prosecution history of one of the parent applications of the '428 patent. *See generally* Ex.1018. There, the Examiner determined that Davidson's retractor is a fulcrum. Ex.1018, 571-572. Treace did not argue against the Examiner's mapping of Davidson to claims, including the retractor as a fulcrum. *Id.*, 730-731. Thus, both the Examiner and Treace understood that Davidson's retractor is a fulcrum about which the metatarsal can rotate.

H. Claim 10, 11, and 12

184. McGlamry's discloses the additional limitations of Claim 10, 11, and 12. *See* Section §§VI.G, VI.H, VI.I, *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. Thus, McGlamry in view of Davidson renders claims 10, 11 and 12 obvious.

I. Claim 13

185. McGlamry discloses the additional limitations of Claim 13. *See* §VI.J, *supra*. When using Davidson's retractor in McGlamry's procedure, it would have been obvious to place the retractor between the metatarsals while cutting the cuneiform, as disclosed by McGlamry. Ex.1005, 808. A POSA would have recognize that Davidson's retractor would protect the soft tissues between the metatarsals during the cuneiform cutting step of McGlamry's bunion correction surgery. *See* Ex.1006, [0057]. Thus, McGlamry in view of Davidson renders claim 13 obvious.

J. Claim 16

186. McGlamry discloses the additional limitations of Claim 16. *See* §VI.K, *supra*. Thus, McGlamry in view of Davidson renders claim 16 obvious.

K. Claim 17

187. McGlamry discloses the additional limitations of Claim 17. *See* §VI.L, *supra*. Thus, McGlamry in view of Davidson renders claim 17 obvious.

IX. MCGLAMRY AND FALLIN RENDER CLAIMS 4-5, 14-15, 17-21, AND 23-30 OBVIOUS

188. Even if McGlamry had not anticipated or rendered obvious claim 17 as explained in Sections VI and VII (*see* §§VI.L, VII, *supra*), this claim would have been obvious over McGlamry and Fallin. McGlamry in view of Fallin also renders claims 4-5, 14-15, 17-21, and 23-30 obvious.

189. As discussed in Section VII, a POSA would have been motivated to read and apply the teachings of McGlamry's different chapters together. *See* §VII, *supra*. That motivation carries through the following analysis.

A. Claim 4

190. 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.

191. McGlamry discloses a bunion correction surgery that includes cutting the proximal end of the first metatarsal and the distal end of the medial cuneiform. *See* §§VI.A.3, VI.A.5., *supra*.

192. Fallin also discloses a system for correcting a metatarsal bunion. *See* Ex.1005, [0003] ("The present invention provides improved osteotomy and arthrodesis methods, implants, and instruments."); *see also id.*, [0047]-[0049]

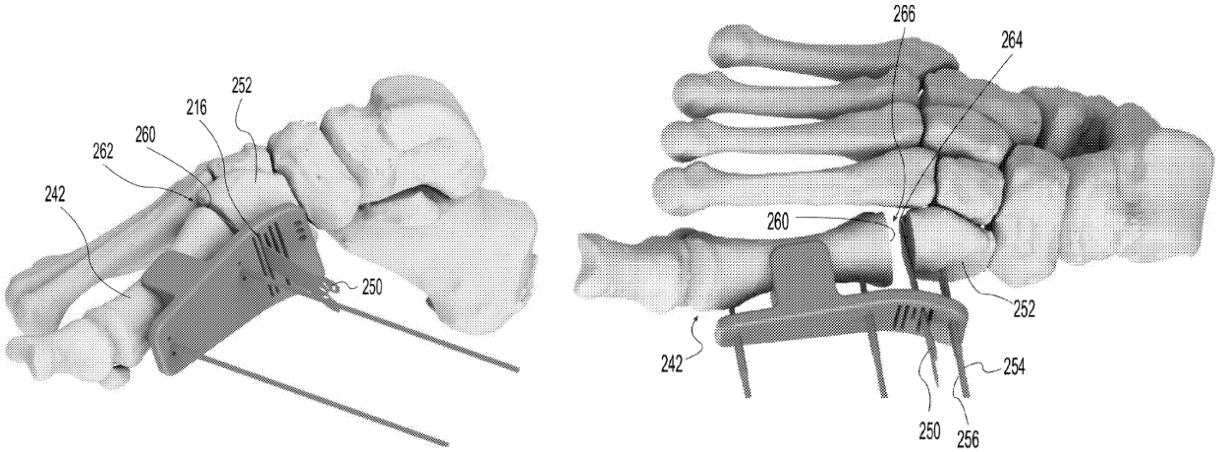
(describing deformities of the first ray of the human foot, including a bunion), [0057]-[0068] (describing method and associated instrumentation for correcting deformities of the human foot, including a bunion).

193. Fallin describes methods, implants, and instruments for bunion correction surgery. Ex.1005, Abstract; *see also id*., [0006], [0036] (describing "illustrative examples" for use of implants, instruments, and techniques for performing, specifically, an arthrodesis of a metatarsocuneiform joint). Specifically, Fallin describes methods and instruments "for performing an osteotomy" including "a fusion osteotomy at a metatarsocuneiform joint of the first ray of a human foot," *i.e.*, a first metatarsal-medial cuneiform arthrodesis used to realign the first ray for fusion. *Id.*

194. 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. Ex.1007, [0057]-[0068]. Like McGlamry, Fallin discloses using various known tools during the bunion correction surgery:

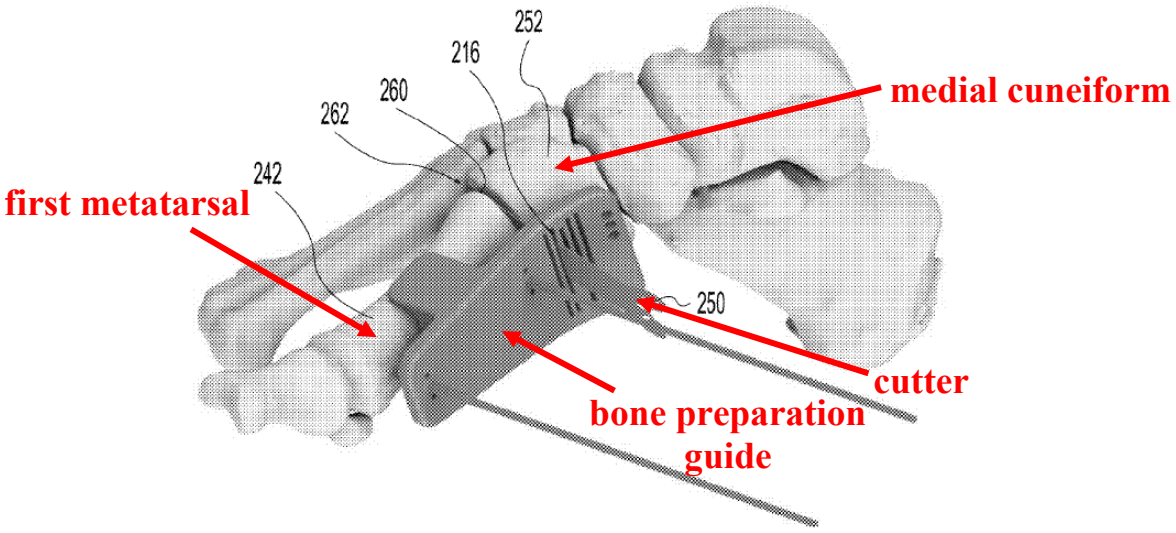
- Saws to cut the first metatarsal and medial cuneiform. Ex.1007, [0065], [0067]
- Tenaculum (e.g., clamps) to move the first metatarsal. Ex.1007, [0070].

- Shims to insert between the metatarsal and cuneiform and align the cutting guide. Ex.1007, [0064].
- In addition, Fallin discloses using a cutting guide that can be used when cutting the ends of the metatarsal and cuneiform. *Id.*, [0051]-[0056].



Id., Fig. 22 (left) (depicting Fallin's cutting guide being used to cut the metatarsal 242), Fig. 25 (right) (depicting Fallin's cutting guide being used to cut the cuneiform 252).

195. Fallin discloses "[t]he guide body 202 [of the osteotomy guide 200] 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].



Id., Fig. 22. Fallin further discloses inserting a saw blade through the first slot to cut the metatarsal. Fallin 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].

196. By July 2015, it would have been obvious to incorporate Fallin's osteotomy/cutting guide into McGlamry's procedure. McGlamry discloses a joint preparation step wherein the first metatarsal base and the distal end of the cuneiform are prepared (cut) along with a medial aspect of the second metatarsal. Ex.1005, 324. McGlamry describes this preparation step as a "vital portion of the procedure," since "[j]oint preparation is extremely important in efforts to obtain a bony union and to avoid a delayed and nonunion." *Id.* McGlamry states that a surgeon spends a "substantial period of time … preparing the [metatarso-cuneiform] joint" to prevent issues with bony union. *Id.* McGlamry also describes complications that could arise from mistakes in cutting the first metatarsal and medial cuneiform,

including "significant shortening" of the first metatarsal, delayed unions, nonunions, and malunions. *Id.*, 329.

197. McGlamry's bunion correction procedure involves a surgeon performing freehand resection of the metatarsal and cuneiform. Ex.1005, 324-329. Freehand resections rely on the surgeon's technical ability to avoid complications, and McGlamry instructs that significant time should be spent on this step. Id.; Ex.1021, 1:31-34. Freehand cutting also creates a potential for significant misalignment of the cut surfaces when the bones are brought together for union. Ex.1015, [0005]. By 2015, it was known that freehand bone cutting can be "very difficult to perform and can be rather imprecise," and any mistakes or inaccuracies made by the surgeon during freehand resection may "lead to complications such as nerve damage, poor quality bone healing, bone resorption, … increased operating time and increased blood loss." Ex.1021, 1:31-37, 1:45-50.

198. A POSA would have recognized that cutting guides, like Fallin's, can simplify and standardize the cutting steps in a bunion correction procedure like McGlamry's, and reduce the risk of the complications identified in McGlamry. *Id.*, 1:50-54 ("These significant disadvantages could be reduced or overcome with precise, quick and efficient bone cuts," such as those offered by a bone cutting guide). "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, in

another chapter, McGlamry's 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. *See* Ex.1007, [0056].

199. Reducing the time spent for joint preparation benefits the patient by reducing the time the patient spends under anesthesia. *See* Ex.1005, 803 (describing proper anesthesia as being "of paramount importance" for arthrodesis procedures). Lengthier periods of anesthesia can increase the risk of anesthesia related complications. Similarly, many metatarso-cuneiform arthrodesis procedures are conducted using a tourniquet to control bleeding. *See* Ex.1028, 349. Lengthier periods where a tourniquet is applied increases risks of complications. A POSA would have recognized this and understood that reducing the amount of time the patient is under anesthesia would be beneficial to the patient.

200. Simplifying a surgical procedure also makes the procedure more accessible to a broader population of surgeons (including less experienced

surgeons), which increases the availability of the procedure to patients. Simpler surgeries are easier to teach and generally easier to perform. Thus, simplifying McGlamry's procedure would make it accessible to a broader population of surgeons.

201. A POSA would have recognized that cutting guides like Fallin's also mitigate the complications identified by McGlamry. One identified risk is "significant shortening" of the first metatarsal. Ex.1005, 324-325. "Shortening" of the first metatarsal refers to the removal of excess bone during the resection of the metatarsal and cuneiform that leads to changes in the biomechanics of the foot, such as "transfer lesions plantar to the second metatarsal head as well as decreased hallux purchase," as well as functional disturbance of the foot and transfer metatarsalgia of the second and/or third rays. Ex.1005, 329; Ex.1008, 186. These changes to the biomechanics of the foot can cause pain in addition to the deformities mentioned and unmentioned.

202. 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. 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.

203. Fallin's bone cutting guide cuts a "relatively thin" portions of bone and "results in more precision and repeatability in the relative orientation of the cuts [to the metatarsal and cuneiform." Ex.1007, [0056], [0058], [0062]. By having a "predetermined relationship" of the cuts to the articulating ends of the bones of the metatarsocuneiform joint, Fallin's cutting guide allows the surgeon to visualize the cuts before making them. *See id.*, [0055] (discussing a joint alignment feature of the bone cutting guide that allows a surgeon to "visualiz[e]" the alignment of the guide to the metatarso-cuneiform joint). This visualization allows the surgeon better plan and defining the cuts before making them, thereby reducing the risk of excess bone removal.

204. Fallin's cutting guide would also reduce the risk of delayed unions, nonunions, and malunions identified by McGlamry. Ex.1005, 324. Delayed unions, nonunions, and malunions can occur in a bunion correction procedure when the cut ends of the metatarsal and cuneiform, do not form a proper fit after the first metatarsal is repositioned. *See* Ex.1005, 329 (informing surgeons that "[m]alunions associated with the procedure can be avoided with intraoperative radiographs to ***establish correct positioning*** [of the first metatarsal] in all three planes of motion") (emphasis added). The use of a cutting guide in McGlamry's procedure would

"easily and effectively achieve a union through normal biological healing." Ex.1015, [0068]. Fallin's cutting guide facilitates proper unions after osteotomy because it prepares complementary joint surfaces. *Id.*; Ex.1007, [0061] (describing complementary cut surfaces made through use of Fallin's osteotomy guide), [0068] (describing cut surfaces being brought together in "planar contact so that the bones fuse together in the new angular orientation").

205. Using Fallin's cutting guide in McGlamry's procedure would have been desirable because using Fallin's cutting guide would have been nothing more than the use of a known technique for cutting bones to improve McGlamry's known technique in the same way that the guides improved Fallin's technique. For example, as I discussed in detail above, Fallin's cutting guide would improve McGlamry's cutting steps by precisely defining the cuts of the first metatarsal and medial cuneiform. Ex.1005, [0062]. A POSA would have recognized by July 2015 that implementing Fallin's known bone cutting guide and technique utilizing such a guide (cutting the facing surfaces of a metatarsocuneiform joint) would improve a substantially identical procedure (McGlamry's metatarsocuneiform arthrodesis) in the same way, by, for example, reducing the likelihood of complications.

206. 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. *See, e.g.,*

Ex.1023, Abstract (describing a knee cutting guide that "is applicable to any bone-cutting procedure which might benefit from improved accuracy"); 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.").

207. McGlamry and Fallin disclose nearly identical metatarso-cuneiform fusion surgeries. *See* II.D, *supra*. Both bunion correction procedures include cutting the proximal end of the first metatarsal and the distal end of the cuneiform, and repositioning the first metatarsal relative to the cuneiform in three anatomical planes. 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 would have recognized that Fallin's cutting guide is readily substituted for freehand resection in bunion correction surgeries like McGlamry's to provide the known advantages of a cut guide. Thus, A POSA would have had a reasonable expectation of success in implementing Fallin's cutting guide in McGlamry's procedure.

208. Thus, McGlamry in view of Fallin renders obvious claim 4.

B. Claim 5

209. 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."

210. Fallin discloses that the bone preparation guide (osteotomy guide 200) includes at least one fixation aperture. As shown below in Fig. 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].

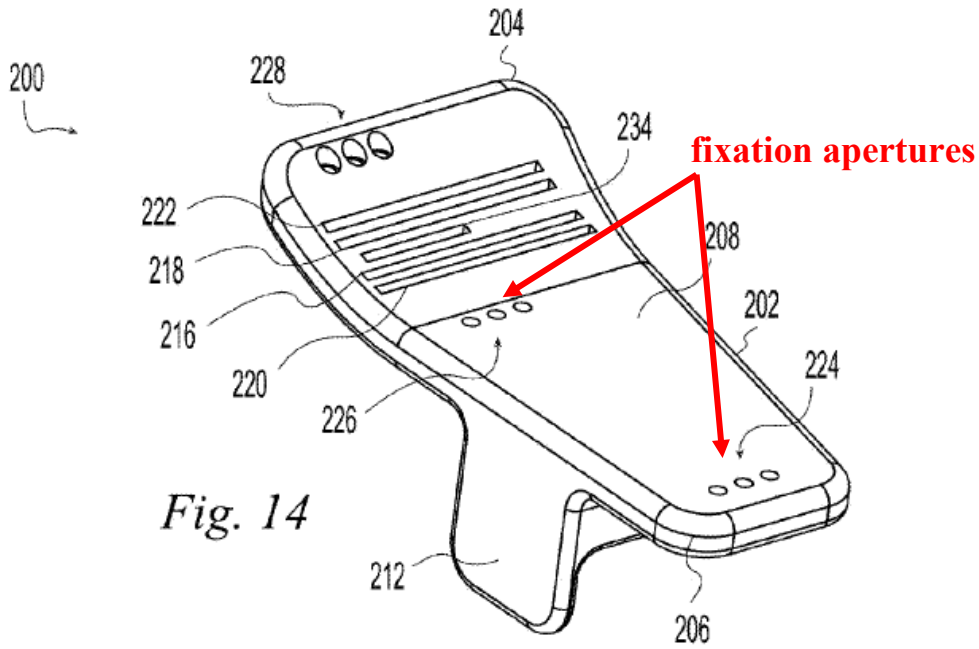
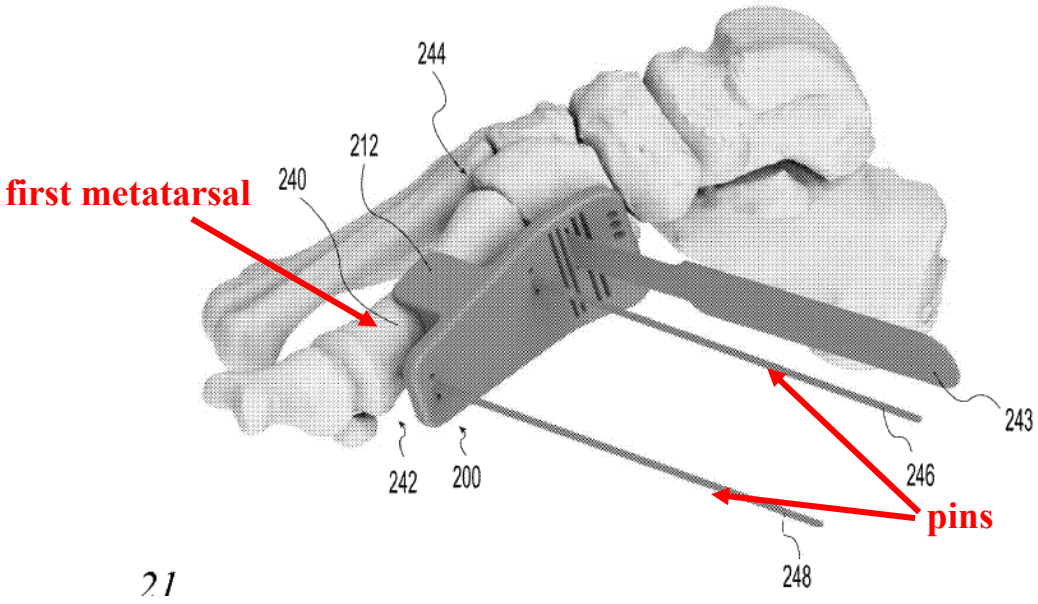


Fig. 14

Id., Fig. 14 (annotated).

211. Fallin further explains that at least one fixation pin is inserted through the holes 224, 226 to secure the guide to the first metatarsal. Fallin discloses "[p]ins 246, 248 are placed through the fixation holes 224, 226 to fix the guide 200 to the metatarsus 242." *Id.*, [0064]; *see also id.*, [0056].



Id., Fig. 21. A POSA would have recognized that Fallin's bone preparation guide should be secured to the first metatarsal while performing the resections as taught by Fallin to maintain the alignment of the guide slots with the bones. Thus, Fallin's bone preparation guide satisfies this limitation and McGlamry's technique, as modified to use Fallin's bone preparation guide, renders claim 5 obvious.

C. Claim 14

212. 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."

213. The '428 patent acknowledges that the order of surgical steps is not critical and that one order does not impart 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."). Specifically, the '428 patent states that "unless otherwise indicated, the steps described need not be carried out in the order described." *Id.*, 11:48-49

214. McGlamry identifies that steps of its bunion correction procedure can be performed in different orders. *See* Ex.1005, 324, 808-809. Like the '428 patent, McGlamry does not identify an advantage to the order of its cutting and adjusting steps relative to each other. *See id.* A POSA would recognize that the order of steps in an arthrodesis is unimportant as long as the metatarsal is correctly repositioned and there is close apposition of the resected bones. *See id.*

215. Fallin discloses cutting the first metatarsal, repositioning the first metatarsal relative to the medial cuneiform in at least one plane, and then cutting the cuneiform. Ex.1007, [0065]-[0068]. When using Fallin's guide in McGlamry's procedure, a POSA would recognize that Fallin's order could be used to optimize use of the cutting guide by following the steps provided by the inventors of the

cutting guide. *See id.* A POSA would have recognized that Fallin's order could be used in McGlamry's surgery because reordering of the steps constitutes nothing more than substitution of one known sequence for another, which McGlamry acknowledges.

216. Furthermore, there are only two options for the timing of cutting the cuneiform relative to adjusting the position of the metatarsal—before or after. *Id.* Both options were known in the art prior to August 2015. Ex.1005, 322-330, 808-809; Ex.1006, [0065]-[0068]. A POSA would have also recognized that could be used in McGlamry's surgery because it is one of a finite number of identified predictable solutions. *See id.* Moreover, a POSA would have recognized that choosing Fallin's order would have been nothing more than choosing between known alternatives to predictably achieve the same surgical endpoint. *See id.*

217. Because Fallin's order of steps produces the same outcome as McGlamry's order, a POSA would have a reasonable expectation of success in performing a method of bunion correction by first adjusting the position of the metatarsal and then cutting the cuneiform. After Fallin's steps are completed in the disclosed order, the resected end of the first metatarsal is positioned against the resected end of the medial cuneiform in the corrected position. Ex.1007, [0065]-[0067]; Ex.1005, 324-326.

218. Thus, McGlamry in view of Fallin renders claim 14 obvious.

D. Claim 15

219. Claim 15 depends from claim 14 and recites "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."

220. As I explained with respect to claim 1, McGlamry discloses an instrumented surgical procedure for correcting a bunion. *See* §VI.A.1, *supra*. Further, as explained with respect to claim 8, McGlamry discloses using a bone positioning guide in its bunion correction surgery. *See* §§VI.D, VII. McGlamry and Fallin also render obvious using a bone preparation guide as explained with respect to claim 4. *See* §IX.A, *supra*.

221. A POSA would have recognized that packaging the instruments for McGlamry's bunion correction surgery with Fallin's cutting guide would have been routine and predictable application of known surgical practice. McGlamry discloses that these surgical instruments are commonly arranged in sterile instrument kits, or "packs," that are opened in the operating room. Ex.1005, 12. The selection of a particular kit depends on the surgery being performed; McGlamry discloses surgical

kits for, *inter alia*, forefoot surgery and rearfoot/ankle surgery. *Id.*, 12-13. 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 kit so the surgeon has all of the instruments and implants for the procedure. *Id.*, 12-14.

222. A POSA would have recognized that a bone positioning guide (e.g., the Weber clamp) and a bone cutting guide (e.g., Fallin's cutting guide) should be included in a sterile kit for McGlamry's procedure. With a sterile kit, both tools would have been readily available, sterile, and ready for use at the start of the procedure. Having a kit with these instruments would reduce operating room set up time, simplify hospital inventory procedures, and reduce the risk of contamination by minimizing the number of separate packages introduced into the OR. Ex.1026, [0010] ("Sterilising and packaging each instrument separately is impractical because of the need to maintain organisation, minimise packaging cost and waste and avoid use of excessive space in the operating room."). This arrangement of instruments would also simplify hospital inventory. Ex.1026, [0002] ("Any surgical procedure typically requires a number of instruments. In order to simplify inventory and procedure in the operating room it is known to group the instruments required in a surgical procedure together in one or more trays."); Ex.1025, [0266] ("This pre-sterilized combination instrument, cartridge and implant can be packaged with a drill

and drill guide so that the medical procedure kit fully supports the surgical technique. Hospital costs savings are achieved because there is no hospital cleaning or sterilization required and the patients and hospital benefit from fewer infections and patient complications."); *see also* Ex. 1025, [0260], [0264].

223. A POSA would have recognized that assembling a kit of surgical instruments would have been nothing more than the use or prior art elements according to known methods. *See* Ex.1005, 12-14. A POSA would have expected to successfully assemble the kit because McGlamry describes the use of pre-arranged trays instruments for foot and ankle surgery. *Id*., 12-14. McGlamry further explains that these sets are sterilized and maintained as a unit, so the surgeon has all instruments and implants for the procedure. *Id.*

224. This would have been nothing more than the use of known elements according to known methods. The result of a sterile kit would have been predictable and common to a POSA.

225. Thus, McGlamry in view of Fallin renders claim 15 obvious.

E. Claim 17

226. McGlamry discloses the additional limitations of Claim 17 for the reasons explained for claim 17 in Section VI. *See* §VI.L, *supra*. Thus, McGlamry in view of Fallin renders claim 17 obvious.

F. Claim 18

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

1. Preamble

228. McGlamry discloses "[a]n instrumented surgical technique for treating a bunion deformity. *See* §VI.A.1, *supra*.

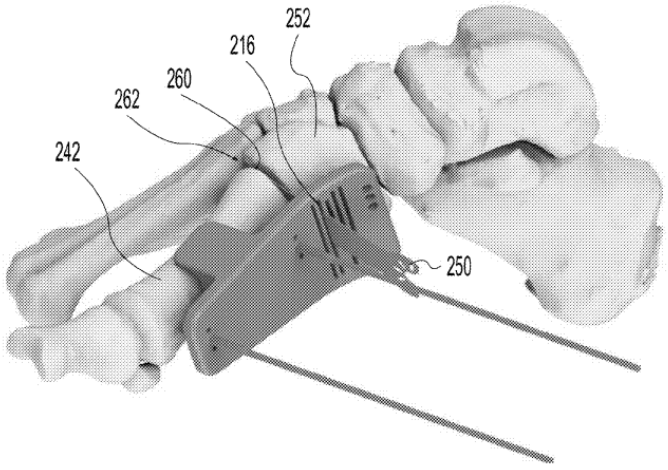
2. Limitation 18[a]

229. Limitation 18[a] recites the limitations of claims 4 and 5 in an independent claim format, namely "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."

230. As explained with respect to claims 4 and 5 above, McGlamry in view of Fallin render limitation 18[a] obvious. *See* §§IX.A, IX.B, *supra*.

231. McGlamry discloses cutting the first metatarsal. *See* §VI.A.3, *supra*. Fallin discloses positioning a bone preparation cutting guide that defines a cutting slot for cutting the first metatarsal during a bunion correction surgery like

McGlamry's. *See* §IX.A *supra*. Fallin's guide is positioned over the end of the first metatarsal to be cut. Ex.1007, [0064].



Id., Fig. 22.

232. Fallin's cutting guide defines a cutting guide slot 216 and has at least one fixation aperture to receive a fixation pin and fix the guide to the metatarsal. *See* §IX.B, *supra*. As discussed above, it would have been obvious to use Fallin's cutting guide to cut the metatarsal and cuneiform. *See* §IX.A, *supra*. It would have further been obvious to a POSA to place Fallin's cutting guide over the first metatarsal and secure Fallin's cutting guide to the bone as recited. *See* §IX.B, *supra*.

3. Limitation 18[b]

233. Limitation 18[b] 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."

234. The proximal portion of the first metatarsal and the second metatarsal includes the proximal third of each of the metatarsals. As explained with respect to limitation 1[a] and claim 7 in Section VI, McGlamry discloses inserting an instrument between a proximal third of the first metatarsal and a proximal third of the second metatarsal. *See* §§ VI.A.2, VI.E, *supra*. Thus, McGlamry discloses inserting an instrument between a proximal portion of the first metatarsal and a proximal portion of the second metatarsal.

4. Limitation 18[c]

235. Limitation 18[c] 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."

236. As explained above with respect to limitation 1[b] in Section VI, McGlamry discloses cutting an end of the first metatarsal with the instrument inserted between the first and second metatarsals. *See* §VI.A.3, *supra*. And as explained with respect to claim 4, it would have been obvious to use Fallin's bone preparation cutting guide to cut the metatarsal in McGlamry's bunion correction surgery. *See* §IX.A, *supra*. Use of Fallin's bone cutting guide would not affect the insertion of the instrument while the first metatarsal is cut in McGlamry's procedure.

5. Limitation 18[d]

237. Limitation 18[d] recites "moving the first metatarsal in at least one plane to treat the bunion deformity."

238. As explained for limitation 1[c] in Section VI, McGlamry discloses limitation 18[d]. *See* §VI.A.4, *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* Ex.1007, [0066] ("the metatarsus 242 is repositioned relative to the cuneiform 252 to change their relative position in one or more planes.").

6. Limitation 18[e]

239. Limitation 18[e] recites "cutting an end of a medial cuneiform opposing the end of the first metatarsal."

240. As explained for limitation 1[d] in Section VI, McGlamry discloses limitation 18[e]. *See* §VI.A.5, *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].

7. Limitation 18[f]

241. Limitation 18[f] recites "compressing the first metatarsal together with the medial cuneiform."

242. As explained above with respect to claim 12 in Section VI, McGlamry discloses compressing the first metatarsal and the medial cuneiform. *See* §VI.I, *supra*.

243. Fallin also discloses compressing the metatarsal and medial cuneiform. Fallin discloses 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 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].

8. Limitation 18[g]

244. Limitation 18[g] 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."

245. As explained with respect to limitation 1[e] in Section VI, McGlamry discloses moving the metatarsal in one or more planes. *See* §VI.A.4 *supra*. And as explained with respect to claim 12 in Section VI, McGlamry discloses that, after the metatarsal is moved, the metatarsal and cuneiform are compressed. *See* §VI.I, *supra*. Then, one or more bone fixation devices (screws and/or a medial locking plate) are

applied to fix the first metatarsal relative to the medial cuneiform for fushion. *See* §VI.A.6, *supra*.

246. 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* Ex.1007, [0058], [0065]-[0068], [0073]-[0075].

247. Thus, McGlamry in view of Fallin renders claim 18 obvious.

G. Claim 19

248. Claim 19 depends from Claim 18 and recites the additional limitations as Claim 6. McGlamry discloses the limitations of claim 19 for the same reasons explained above with respect to claim 6 in Section VI. *See* §VI.D, *supra*. Thus, McGlamry in view of Fallin renders claim 19 obvious.

H. Claim 20

249. Claim 20 depends from Claim 18 and recites the additional limitations as Claim 2. McGlamry discloses the limitations of claim 20 for the same reasons explained above with respect to claim 2 in Section VI. *See* §VI.B, *supra.* Thus, McGlamry in view of Fallin renders claim 20 obvious.

I. Claim 21

250. Claim 21 depends from Claim 18 and recites the additional limitations of Claim 8. McGlamry discloses the limitations of claim 21 for the same reasons explained above with respect to claim 8 in Section VI. *See* §VI.F, *supra.* Thus, McGlamry in view of Fallin renders claim 21 obvious.

J. Claim 23

251. Claim 23 depends from claim 21 and recites the additional limitations of Claim 10. McGlamry discloses the limitations of Claim 23 for the same reasons explained above with respect to Claim 10 in Section VI. *See* §VI.G, *supra*. Fallin also discloses moving the first metatarsal in a frontal plane. Ex.1007, [0058] ("…the metatarsus may be…rotated in the coronal plane to correct abnormal pronation/supination…"). Thus, McGlamry in view of Fallin renders claim 23 obvious.

K. Claim 24

252. Claim 24 depends from Claim 18 and recites the additional limitations of Claim 11. McGlamry discloses the limitations of claim 24 for the same reasons explained above with respect to claim 11 in Section VI. *See* §VI.H, *supra*. Thus, McGlamry in view of Fallin renders claim 24 obvious.

L. Claim 25

253. Claim 25 depends from Claim 18 and recites the additional limitations of Claim 14. McGlamry and Fallin render Claim 25 obvious for the same reasons

they render obvious Claim 14 as explained above in this section. *See* §IX.C, *supra*. Thus, McGlamry in view of Fallin renders claim 25 obvious.

M. Claim 26

254. Claim 26 depends from Claim 18 and recites the additional limitations of Claim 15. McGlamry and Fallin render Claim 26 obvious for the same reasons they render obvious Claim 15 as explained above in this section. *See* §IX.D, *supra*. Thus, McGlamry in view of Fallin renders claim 26 obvious.

N. Claim 27

255. 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 that fixation devices include "interfragmentary compression of three solid cortical screws or an interfragmentary compression of solid cortical screw along with a medial based locking plate.". Ex.1005, 326-7. Similarly, Fallin discloses fixation devices that include "one or more pins, plates, screws, rods or other suitable fixation is applied." Ex.1007, ¶75. Fallin also specifically discloses intramedullary implants (e.g., "rods"). *Id.* Thus, McGlamry in view of Fallin renders claim 27 obvious.

O. Claim 28

1. Preamble

256. McGlamry discloses "[a]n instrumented surgical technique for treating a bunion deformity" as explained with respect to claim 1 in Section VI. *See* §VI.A.1, *supra*.

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

257. These limitations are the same as limitations 18[a]-18[c]. McGlamry in view of Fallin renders obvious limitations 28[a]-28[c] for the same reasons they render obvious limitations 18[a]-18[c]. *See* §§IX.F.2-4, *supra*.

3. Limitation 28[d]

258. Limitation 28[d] 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 in view of Fallin renders limitation 28[d] obvious for the same reasons explained with respect to claim 21 in this section. *See* §IX.I, *supra*.

4. Limitation 28[e]

259. Limitation 28[e] 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 in view of Fallin render limitation 28[e] obvious for the same reasons explained with respect to claim 24 in this section. *See* §IX.K, *supra*.

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

260. These limitations are the same as limitations 18[e]-18[f]. McGlamry in view of Fallin render limitations 28[f]-28[g] obvious for the same reasons as explained with respect to limitations 18[e]-18[f]. *See* §§IX.F.6-7, *supra*.

6. Limitation 28[h]

261. Limitation 28[h] recites "fixating a moved position of the first metatarsal relative to the medial cuneiform for fusion using at least one bone fixation device." McGlamry in view of Fallin render limitation 28[h] obvious for same reasons explained with respect to limitation 18[g] in this section. *See* §IX.F.8, *supra*.

262. Thus, McGlamry in view of Fallin renders claim 28 obvious.

P. Claim 29

263. Claim 29 depends from claim 28 and recites the additional limitations of claim 20. McGlamry and Fallin render claim 29 obvious for the same reasons they render obvious claim 20 as explained above in this section. *See* §IX.H, *supra*. Thus, McGlamry in view of Fallin renders claim 29 obvious.

Q. Claim 30

264. Claim 30 depends from claim 28 and recite the additional limitations of claim 19. McGlamry in view of Fallin render claim 30 obvious for the same reasons they render obvious as explained above in this section. *See* §IX.G, *supra*. Thus, McGlamry in view of Fallin renders claim 30 obvious.

X. MCGLAMRY, FALLIN, AND DAVIDSON RENDER CLAIMS 4-5, 14-15, AND 17-30 OBVIOUS

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

265. 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 Section 4, which addressed the combination of McGlamry and Fallin. As explained in Section IX, a POSA would have recognized that Fallin's cutting guide could be used in McGlamry's procedure to improve resection of the bones. *See* §IX.A, *supra.* As explained in Section VIII, a POSA would have recognized that Davidson's retractor could be used in McGlamry's procedure to provide exposure and access. *See* §VIII.A, *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.1006, [0058]; Ex.1007, [0057]-[0068].

266. A POSA would have had a reasonable expectation of success in combining McGlamry, Davidson, and Fallin for the same reasons discussed above in conjunction with the combinations of McGlamry and Davidson and McGlamry and Fallin. *See* §§VIII.A, IX.A, *supra*. The cutting guide is placed on the medial (inner) side of the first metatarsal (Ex.1007, [0056]), and the instrument is placed on the lateral (outer) side of the first metatarsal (Ex.1005, 808-809; Ex.1006, Fig.19).

See also §VII.A.2, *supra*. Because the cutting guide and instrument are on opposite ends of the metatarsal, they would not interfere with one another.

B. Claim 22

267. Claim 22 depends from claim 21 and includes the additional limitations of claim 9.

268. As explained above in Section IX, McGlamry in view of Fallin renders claim 21 obvious. *See* §IX.I, *supra*. McGlamry and Davidson render claim 9 obvious as explained with respect to Section VIII. *See* §VIII.G, *supra*.

269. A POSA would have recognized that Davidson's retractor could be used in McGlamry's procedure alongside Fallin's cutting guide to provide the same advantages explained above with respect to claim 9 in Section VIII. *See id.* A POSA would have considered use of Davidson's retractor as a fulcrum and Fallin's cutting guide to perform resections in McGlamry's bunion correction procedure to be a straightforward combination of known surgical tools being used according to their established functions as explained in Sections VIII and IX. *See* §§VIII.G, IX.A, *supra*.

270. A POSA would have recognized that a combination of McGlamry's procedure, using Davidson's retractor as a fulcrum, and Fallin's cutting guide to perform the bone resection(s) constitutes nothing more than the use of known,

compatible surgical tools according to their established functions. Ex.1006, [0058]; Ex.1007, [0057]-[0068].

271. A POSA would have had a reasonable expectation of success in using Davidson's retractor and Fallin's cutting guide in McGlamry's procedure. The cutting guide is placed on the medial (inner) side of the first metatarsal (Ex.1007, [0056]), and the instrument is placed on the lateral (outer) side of the first metatarsal (Ex.1005, 808-809; Ex.1006, Fig.19). *See also* §VIII.A.2, *supra*. Because the cutting guide and instrument are on opposite ends of the metatarsal, they would not interfere with one another.

272. Thus, the combination of McGlamry, Fallin and Davidson renders claim 22 obvious..

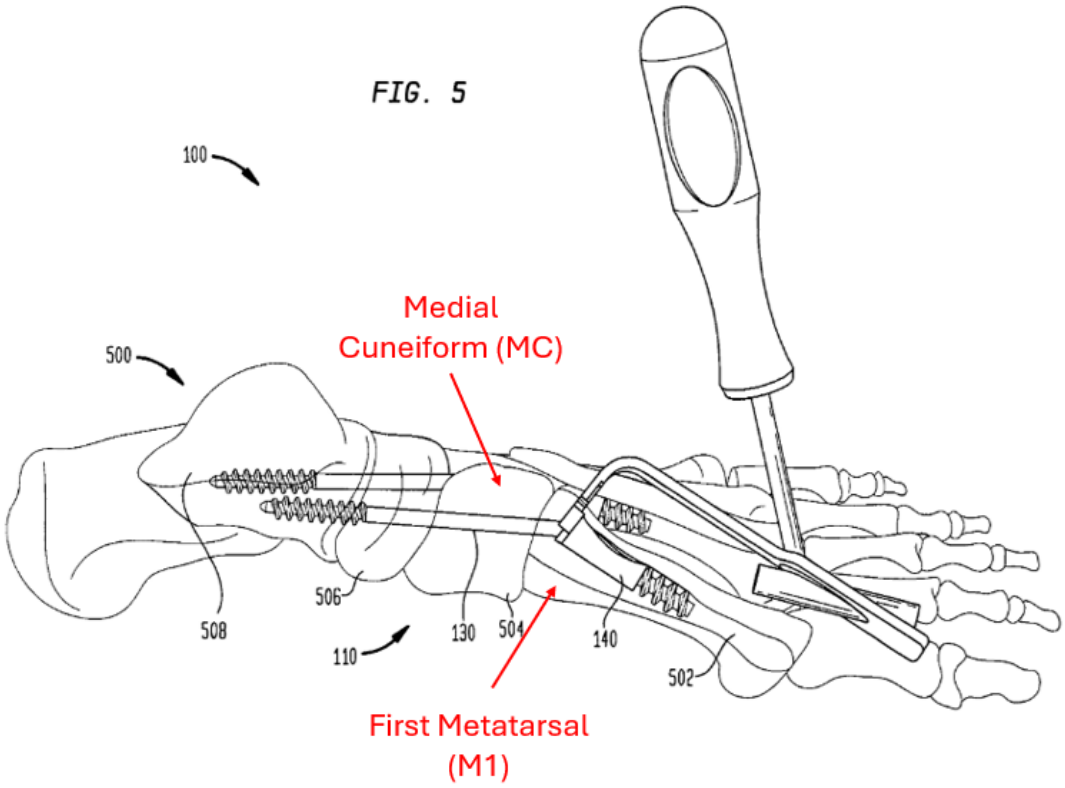
XI. MCGLAMRY AND TYBER RENDER CLAIM 17 OBVIOUS

273. 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.

274. As explained with respect to limitation 1[e] in Sections VI and VII, McGlamry discloses or renders obvious fixing the first metatarsal relative to the medial cuneiform. *See also* §§VI.A.6, VII, *supra*. McGlamry's discloses that "there are many different type of fixation that may be applied to the arthrodesis site (wires, screws, plates, etc.)." Ex.1005, 808 For example, McGlamry discloses that multiple

screws or a combination of screws and a fixation plate can be used as fixation devices. *Id.*, 326-327. A POSA would have recognized that different fixation devices can be used to secure the first metatarsal and cuneiform as long as the bones are held in close apposition to promote fusion. *Id.*, 808 ("Whatever method of fixation is utilized, the arthrodesis site must be held in close, stable apposition until full healing across the fusion site has occurred.") *Id.*

275. 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. The intramedullary implants can be used to treat a number of podiatric conditions including "hallux valgus deformities," i.e. bunions. *Id.*, 1:24-30. Tyber's intramedullary implant includes a proximal screw 130 and a distal screw 140. *Id.*, 5:15-18. As shown below, Tyber discloses that the "the intramedullary assembly is coupled to the medullary canals of the first metatarsal 502, medial cuneiform 504, navicular, and talus bones 508." *Id.*, 7:36-39. The intramedullary implant fixes the position of the first metatarsal is fixed relative to the cuneiform, maintaining the relative position of the bones. *Id.*



Ex.1008, Fig. 5 (annotated).

276. A POSA would have recognized that Tyber's implant could be used to fix the first metatarsal relative to the medial cuneiform in McGlamry's procedure. McGlamry discloses that there are multiple methods for fixing the metatarsal and cuneiform and that those methods of fixation are readily interchangeable. Ex.1005, 326-327, 808; Ex.1008, 1:24-30. A POSA would recognize that fixation methods are selected based on the patient. A POSA would use the best instruments to achieve fusion of the metatarsal and cuneiform in the correct position for a particular patient. *See* Ex.1005, 808. A POSA would have recognized that substitution of Tyber's implant constitutes nothing more than the substitution of one known fixation element

for another to achieve predictable surgical outcome (fixation of the metatarsal relative to the cuneiform).

277. A POSA would further recognize that implants like Tyber's intramedullary implant provides advantages over McGlamry's fixation methods. For example, Tyber's implant eliminates the need for multiple screws, which may be beneficial for some patients. *See* Ex.1008, Fig. 5. Tyber's implant also provides greater stability across the joint and supports the arch of the foot. Ex.1008, 8:29-34. Thus, substituting an implant like Tyber's intramedullary implant for McGlamry's fixation instruments constitutes nothing more than one known element for another.

278. A POSA would have had a reasonable expectation of success in substituting an implant like Tyber's implant for McGlamry's fixation techniques. Tyber discloses the intramedullary implant is placed across the metatarsocuneiform joint and used to treat deformities like bunions. Ex.1008, 8:29-40. Tyber's implant provides the stability of the "homerun screw" discussed by McGlamry's because, like the homerun screw, Tyber's implant extends across the metatarsocuneiform joint, fixing the corrected position of the metatarsal in all three planes and compressing the bones together. Ex.1008, Fig. 5, 8:16-22. A POSA would thus expect to successfully use Tyber's intramedullary implant in McGlamry's procedure to fix the metatarsal and cuneiform.

XII. MCGLAMRY, DAVIDSON, AND TYBER RENDER CLAIM 17 OBVIOUS

279. The combination of McGlamry, Davidson, and Tyber renders claim 17 obvious. As explained in Section VIII, it would have been obvious use Davidson's retractor in McGlamry's procedure. *See* §VIII, *supra*. As explained in Section XI, it would have further been obvious to use Tyber's intramedullary implant as the fixation device in McGlamry's procedure. *See* §XI, *supra*.

280. A POSA would have recognized that use of Davidson's guide and Tyber's intramedullary implant in McGlamry's bunion correction procedure constitutes nothing more than using known surgical tools according to their established functions. A POSA would have further recognized that Davidson's retractor would not interfere with the placement and use of Tyber's intramedullary implant during the fixation step. Accordingly, a POSA would have had a reasonable expectation of success in combining McGlamry, Davidson, and Tyber.

XIII. MCGLAMRY AND DACOSTA-219 RENDER CLAIM 17 OBVIOUS

281. The combination of McGlamry and DaCosta-219 renders claim 17 obvious.

282. As explained with respect to limitation 1[e] in Sections VI and VII, McGlamry discloses or renders obvious fixing the first metatarsal relative to the medial cuneiform. *See also* §§VI.A.6, VII, *supra*.

283. 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* Ex.1013, 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.

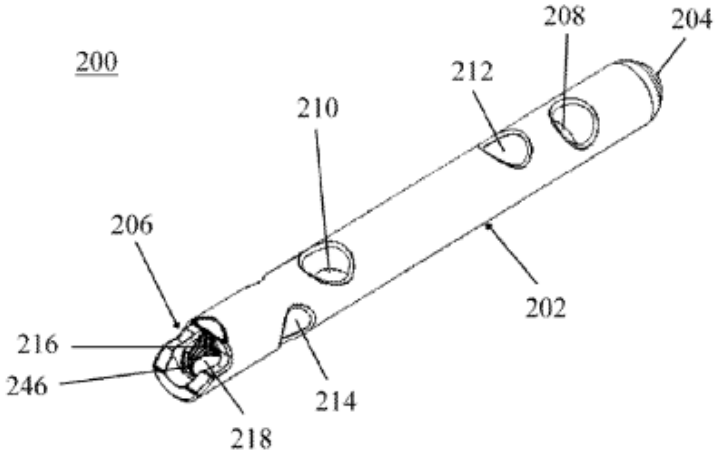
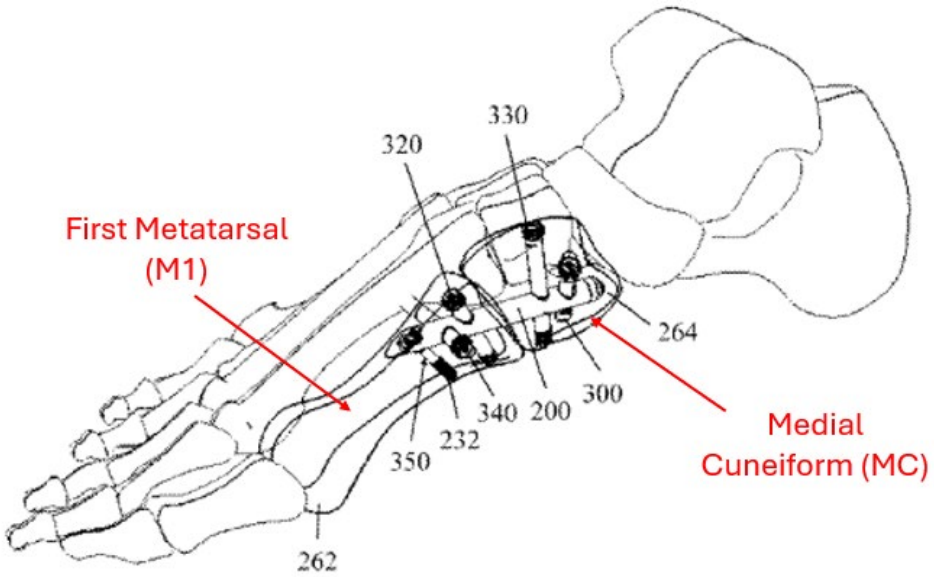


FIG. 9

Id., Fig. 9. As illustrated by Figure 32 below, 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.



Id., Fig. 32 (annotated). The intramedullary implant 200 is secured via fasteners 300, 320, 330, and 340 through the openings 208, 210, 212, and 214, thereby resisting longitudinal and rotational movement. *See id.*, 10:18-21, 14:22-15:24.

284. A POSA would have recognized that DaCosta-219's intramedullary fixation could be substituted for McGlamry's disclosed fixation devices because DaCosta-219's intramedullary device achieves the same 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.

285. A POSA would have recognized that DaCosta-219 provides advantages over traditional plates and screws used to fix the bones of the foot. 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 its intramedullary implant

overcomes these problems by improving compression and stability across the joint. *Id.*, 1:22-24.

286. A POSA would have further recognized that DaCosta-219's intramedullary implant decreases the likelihood of delayed or non-unions in McGlamry's procedure. DaCosta-219 also discloses its intramedullary implant reduces longitudinal and rotational movement across the fusion site through the placement of multiple pegs through positionally-varied fixation openings. *Id.*, 10:19-21. The decrease in rotational and longitudinal movement increases the stability of the metatarsal and cuneiform relative to one another. With increased stability, patients can engage in weight-bearing activities sooner, reducing the likelihood of a delayed union or nonunion. *See id.* 1:12-24.

287. A POSA would have recognized that substitution of DaCosta-219's intramedullary implant constitutes nothing more than the predictable substitution of one known fixation element for another to achieve the same results (stable fixation of the metatarsal-cuneiform joint for arthrodesis). A POSA would have also recognized that substitution of DaCosta-219's intramedullary implant for McGlamry's fixation elements constitutes nothing more than substitution of a known device to known technique ready for improvement.

288. A POSA would have had a reasonable expectation of success using DaCosta-219's intramedullary implant in McGlamry's bunion correction procedure

because DaCosta-219 discloses that the two may be substituted. Ex.1013, 1:22-24. Moreover DaCosta-219 discloses fixation of the metatarsal relative to the cuneiform using the intramedullary implant following arthrodesis of the metatarsal-cuneiform joint. *See id.*, 12:11-19; *see generally id.* 12:1-23:13, Figs. 13-32.

XIV. MCGLAMRY, DAVIDSON AND DACOSTA-219 RENDER CLAIM 17 OBVIOUS

289. The combination of McGlamry, Davidson, and Tyber renders claim 17 obvious. As explained in Section VIII, it would have been obvious use Davidson's retractor in McGlamry's procedure. *See* §VIII, *supra*. As explained in Section XIII, it would have further been obvious to use DaCosta-219's intramedullary implant as the fixation device in McGlamry's procedure. *See* §XIII, *supra*.

290. A POSA would have recognized that use of Davidson's guide and DaCosta-219's intramedullary implant in McGlamry's bunion correction procedure constitutes nothing more than using known surgical tools according to their established functions. A POSA would have further recognized that Davidson's retractor would not interfere with the placement and use of DaCosta-219's intramedullary implant during the fixation step. Accordingly, a POSA would have had a reasonable expectation of success in combining McGlamry, Davidson, and DaCosta-219.

XV. FALLIN AND DAVIDSON RENDER CLAIMS 1-7, 12-14, 16, 18-20, 25, AND 27 OBVIOUS

A. Claim 1

1. Preamble

291. To the extent the preamble is limiting, Fallin discloses "an instrumented surgical technique for treating a bunion deformity." Ex.1007, [0047]-[0049], [0057].

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. bone portion. *Id.*, [0058]. For example, Fallin discloses that:

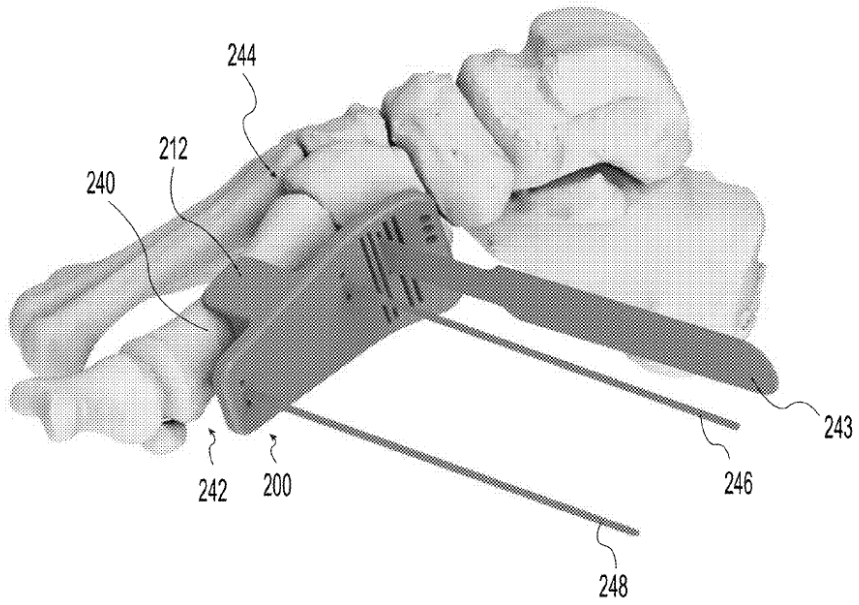
> a first cut may be made on one of the metatarsus and cuneiform to remove a portion of bone creating a first cut surface …. The bones may then be repositioned in one or more planes. For example, the metatarsus may be rotated laterally in the transverse plane … rotated in the coronal plane … and rotated 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].

2. Limitation 1[a]

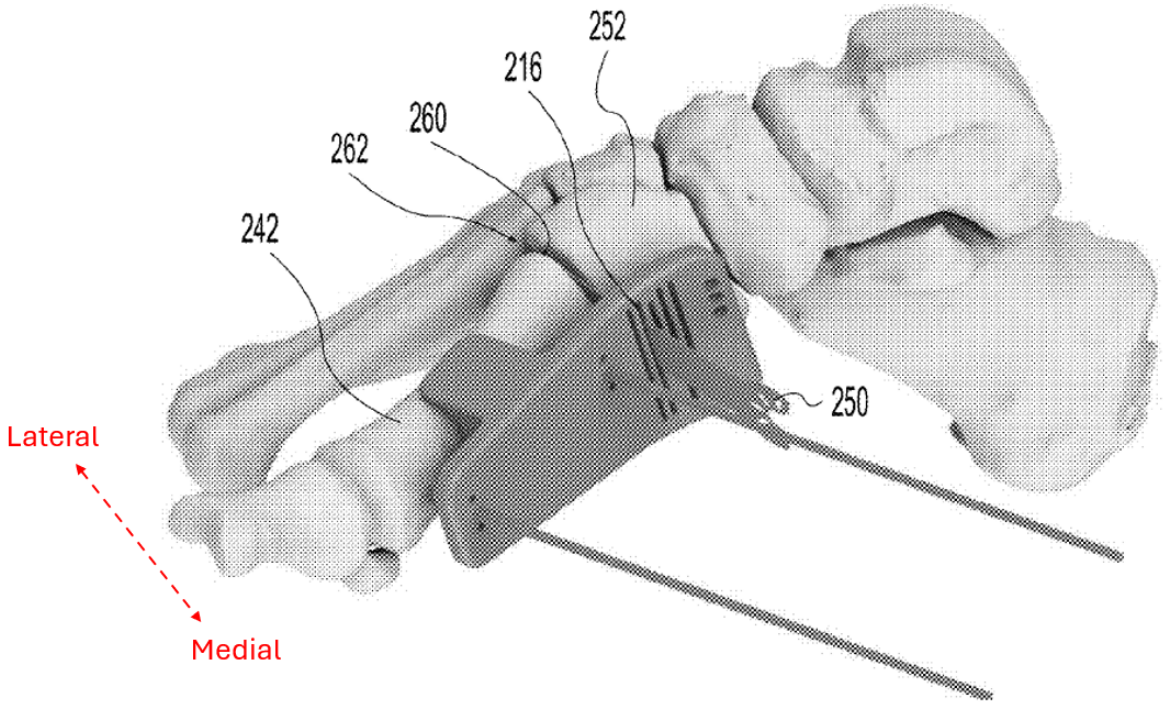
293. Fallin in view of Davidson renders obvious "inserting an instrument between a first metatarsal and a second metatarsal adjacent to the first metatarsal" as part of its bunion surgery technique.

294. 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 as shown below in Fig. 2. *See* Ex.1007, Figs.21-25, [0063]-[0064].



Ex.1007, Fig. 21.

295. During the cutting step (discussed below), a saw is inserted into the slots 216 of the cutting guide laterally, i.e. toward the second metatarsal. *Id.*, [0065].



Ex.1007, Fig.22 (annotated).

296. In these embodiments (e.g., Fig. 22 below), Fallin does not disclose a means for controlling the depth of the blade or shield tissues on the lateral side of the cut. Without anything to protect tissues on the lateral side (e.g., the second metatarsal, blood vessels, nerves, etc.), the saw may inadvertently contact the second metatarsal or tissues in the blade path such as the tissues shown in Figs. 4-5 of Fallin or the tissues shown in the anatomical diagram below.

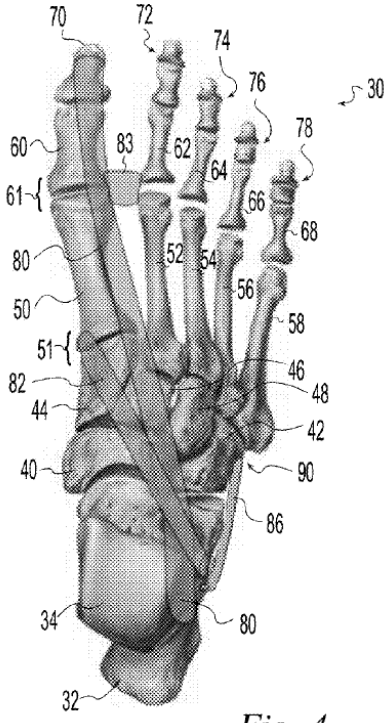
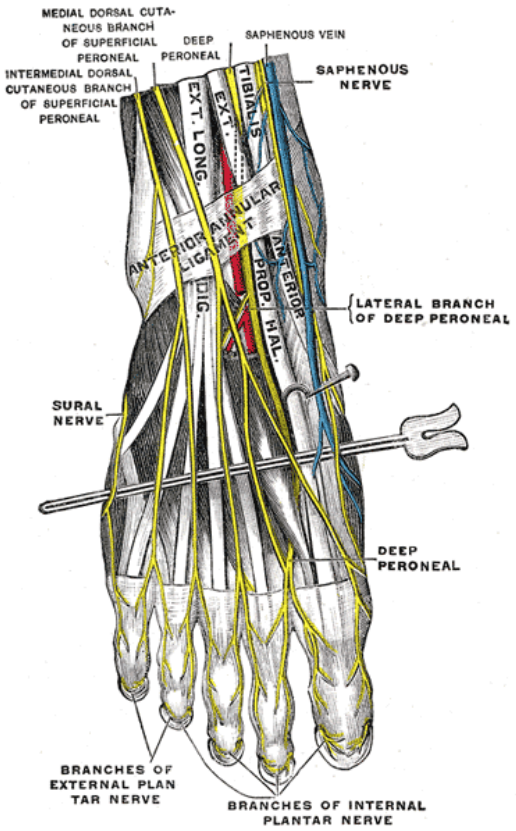


Fig. 4



(left to right) Ex.1007, Fig. 4 *Dorsal digital nerves of foot*, WIKIPEDIA (https://en.wikipedia.org/wiki/Dorsal_digital_nerves_of_foot), last accessed December 18, 2025.

297. A POSA would have recognized that Davidson's retractor could be used in Fallin's bunion correction surgery to protect tissues in the path of the saw (e.g., the second metatarsal, nerves, blood vessels) from damage. Davidson discloses that the retractors are used "osteotom[ies] of the midtarsal bones and proximal first metatarsal," e.g. metatarso-cuneiform fusion. Ex.1006, [0060]. In use, Davidson's 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]. For example, Davidson discloses that the retractor can be placed between the first and second metatarsals to isolate the first metatarsal and protect adjacent tissues during a corrective osteotomy. *Id.*, [0056]-[0058].

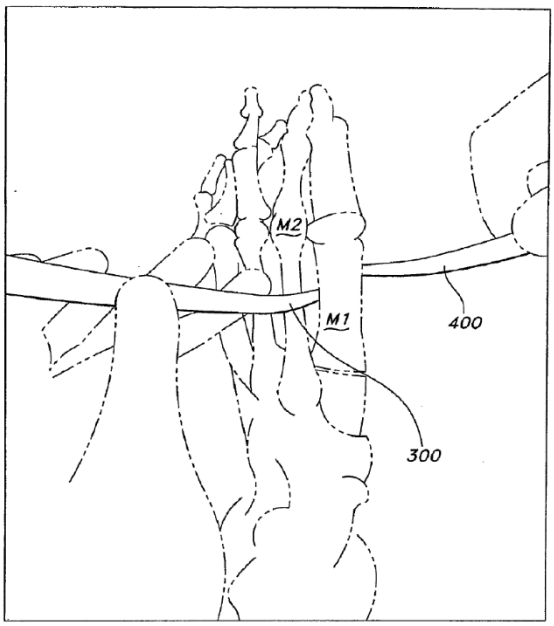


FIG. 19

Ex.1006, Fig.19. With Fallin's cutting guide positioned on the medial side of the first metatarsal, a POSA would have recognized that Davidson's retractor should be positioned on the lateral side of the first metatarsal—between the first and second metatarsal as disclosed by Davidson—to isolate the first metatarsal and protect tissues in the path of the saw during Fallin's bunion correction surgery. *See* Ex.1006, [0057]-[0058]. Once in place, Davidson's retractor provides a rigid barrier between the saw blade and the second metatarsal and other surrounding tissues.

298. A POSA would have recognized that Davidson's retractor could also be used to reposition the first metatarsal in Fallin's bunion correction surgery. Fallin discloses repositioning the metatarsal in the frontal, transverse, and sagittal planes. *See* Ex.1007, [0058], [0075]. A POSA would recognize that Davidson's retractors would provide additional leverage and control when repositioning the first metatarsal. Unlike larger tenaculum or the surgeon's hands, 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]. For example, Davidson discloses inserting the retractor into the small space between the first and second metatarsals and using the retractor 300 to reposition the first metatarsal. *Id.* A POSA would recognize that positioning Davidson's retractor between the metatarsals provide greater leverage and control when moving the metatarsal in the transverse and sagittal planes. With additional control, the surgeon can more easily and accurately reposition the metatarsal and avoid complications stemming from incorrect repositioning of the bones (e.g., malunion). *See id.*

299. Placing Davidson's retractor between the metatarsals during Fallin's procedure would have been nothing more than the use of a known technique (use of Davidson's retractor to protect tissues and move bones) to solve a known problem

(risk of damage to tissues and need to precisely reposition the metatarsal to correct the bunion deformity).

300. A POSA would have expected to successfully use Davidson's retractors in Fallin's procedure. Davidson discloses using the retractor during bunion correction procedures like Fallin's. Ex.1006, [0060]. Davidson discloses that the retractor can be placed between the first and second metatarsal. *See* Ex.1006, [0058], Fig. 19. In this position, Davidson's retractor controls the position of the first metatarsal and protects soft tissues between the metatarsals. *See id.*, [0057]. A POSA would recognize that Davidson's retractor could be predictably used in Fallin's procedure because Davidson discloses inserting the retractor between the metatarsals to protect soft tissues during corrective osteotomies like Fallin's bunion correction surgery.

301. Thus, Fallin in view of Davidson renders limitation 1[a] obvious.

3. Limitation 1[b]

302. Fallin in view of Davidson render obvious "with the instrument inserted between the first metatarsal and the second metatarsal, cutting an end of the first metatarsal."

303. 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]. As explained with respect to limitation 1[a],

a POSA would have recognized that Davidson's retractor could be placed between the metatarsals while cutting the metatarsal in Fallin's bunion correction method to protect tissues in the path of the saw. *See* §XV.A.2, *supra*.

304. Thus, Fallin in view of Davidson render limitation 1[b] obvious.

4. Limitation 1[c]

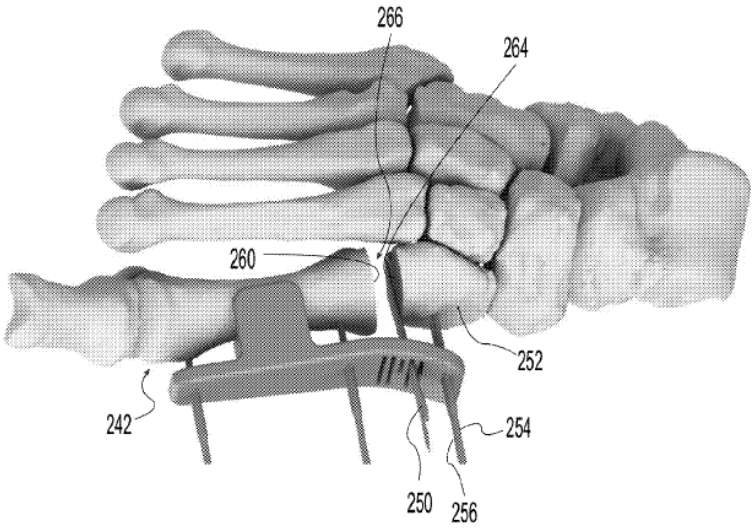
305. Fallin discloses moving the first metatarsal in at least one plane to treat the bunion deformity" as part of its bunion surgery. Ex.1007, [0066] ("[T]he metatarsus 242 is repositioned relative to the cuneiform 252 to change their relative position in one or more planes."). Fallin discloses moving the metatarsal three anatomical planes to treat the bunion deformity. *Id.*, [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].

306. Thus, Fallin in view of Davidson render limitation 1[c] obvious.

5. Limitation 1[d]

307. 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]. 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," as shown below in Fig. 25. *Id.* "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 Fig.25 below. *Id.*



Id., Fig.25.

308. Thus, Fallin in view of Davidson render limitation 1[d] obvious.

6. Limitation 1[e]

309. 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." Fallin discloses 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]; *see also* Ex.1007, [0058]. Fallin discloses that 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].

310. Fallin's disclosure satisfies "fixation device" under the plain and ordinary meaning discussed above in Section III.C. If a means-plus-function construction were applied, Fallin would still satisfy this limitation. The pins, plates, screws, and rod disclosed by Fallin are positioned across the metatarsal-cuneiform joint and are the same types of structures disclosed by the '428 patent. Ex.1007, [0058]; Ex.1001, 11:39-44 (disclosing fixation devices include "compressing bone screw, bone plate, …"), 14:26-30. Thus, the fixation devices disclosed by Fallin constitute corresponding structures (or equivalents) for fixing the moved metatarsal relative to the cuneiform for fusion. *Id.*

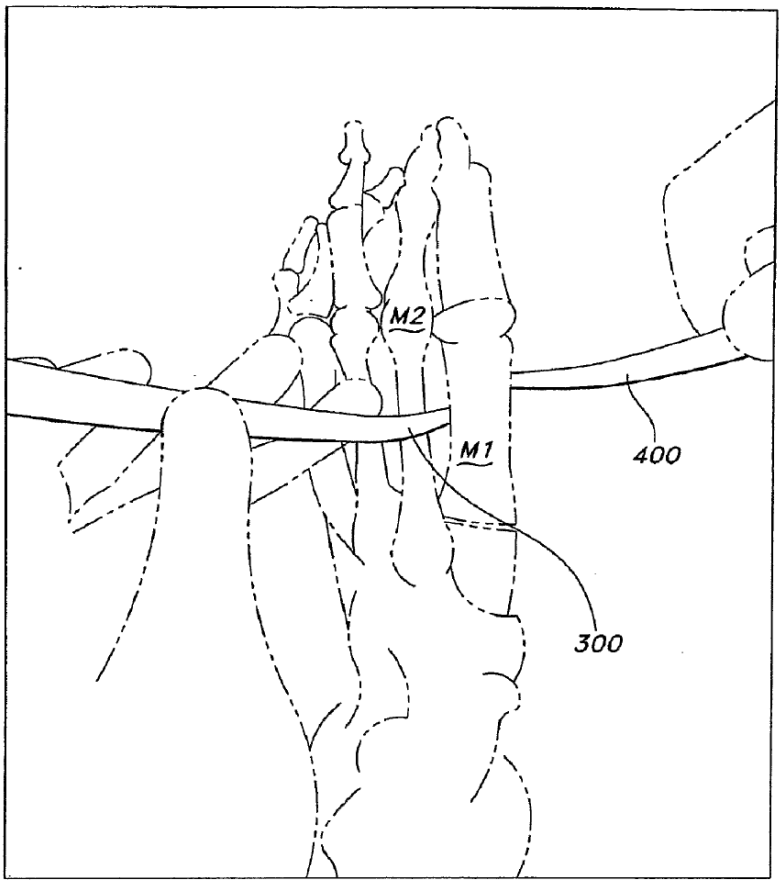
311. Thus, Fallin in view of Davidson renders limitation 1[e] obvious.

312. Therefore, the combination of Fallin and Davidson renders claim 1 obvious.

B. Claim 2

313. Fallin in view of Davidson renders claim 2 obvious. As discussed above with respect to claim 2 in Section VIII, Davidson discloses the additional limitations of Claim 2. *See* §VIII.B, *supra*. Davidson discloses that the retractor body is positioned between the first and second metatarsal such that the retractor

handle extends laterally over a dorsal surface of the second metatarsal as shown below in Fig.19. Ex.1006, Fig. 19.



Ex.1006, Fig.19.

314. Davidson's retractor and the placement of the handle over the second metatarsal would not change when Davidson's retractor is placed on the lateral side of the first metatarsal in Fallin's procedure. Davidson discloses that the retractor can be placed between the metatarsals in a corrective osteotomy involving the first metatarsal, including metatarsal-cuneiform arthrodesis. *See* Ex.1006, [0058]; *see*

also Ex.1016, 420 (inserting an instrument in the same manner during a metatarsal osteotomy). Thus, Fallin in view of Davidson renders claim 2 obvious.

C. Claim 3

315. 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." Davidson discloses the additional limitations of Claim 3. *See* §VIII.C, *supra*. Davidson discloses dorsal insertion of Davidson's retractor, which would not change when used in Fallin's procedure. Thus, Fallin in view of Davidson renders claim 3 obvious.

D. Claim 4

316. 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." As explained above with respect to claim 4 in Section IX, Fallin discloses the limitations of claim 4. *See* §IX.A, *supra*. Thus, Fallin in view of Davidson renders claim 4 obvious.

E. Claim 5

317. 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." As explained above with respect to claim 5 in Section IX, Fallin discloses the limitations of claim 5. *See* §IX.B, *supra*. Thus, Fallin in view of Davidson renders claim 2 obvious.

F. Claim 6

318. Claim 6 depends from Claim 1 and recites "after cutting the end of the first metatarsal, removing the instrument from between the first metatarsal and the second metatarsal."

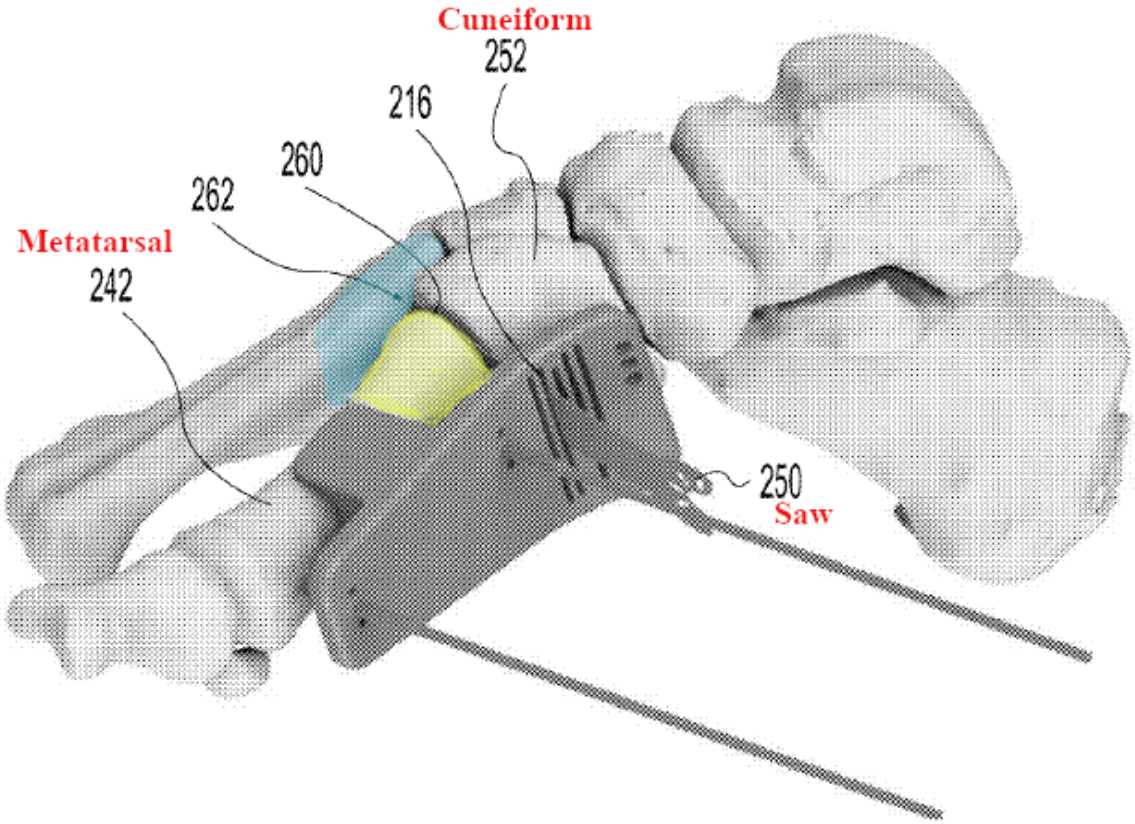
319. As explained above with respect to limitation 1[b] in this section, it would have been obvious to place Davidson's retractor between the metatarsals while cutting the first metatarsal as disclosed by Fallin. *See* §XV.A.3, *supra*. Fallin discloses that the osteotomy guide 200 is removed from the metatarsal after cutting the metatarsal, repositioning the bones, and cutting the cuneiform. Ex.1007, [0068]. A POSA would understand that the retractor would need to be removed from between the metatarsals after cutting is completed because the retractor cannot be left in the patient's foot. S*ee* Ex.1007,[0055] (Retractors are used "during surgery."). Thus, Fallin in view of Davidson renders claim 6 obvious.

G. Claim 7

320. Claim 7 depends from Claim 1 and recites "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."

321. Fallin discloses cutting the proximal end of the first metatarsal, which is within the proximal third of the first metatarsal (yellow) and the proximal third of the second metatarsal (blue) as shown in the annotated version of Fig. 22 below. Ex.1007, [0065].



Ex.1007, Fig. 22 (annotated).

322. As discussed above, a POSA would recognize that Davidson's retractor could be placed between the metatarsals on the opposite side of Fallin's metatarsal resection. *See* §XV.A.2, *supra*. Because Fallin's metatarsal resection is performed

at the proximal third of the first metatarsal, a POSA would position Davidson's retractor between the proximal third of the first and second metatarsal to protect surrounding tissues where the first metatarsal is resected. *See* Ex.1007, [0065]. Davidson's instrument would act as a physical barrier between the saw and the tissues (e.g., the second metatarsal, nerves, blood vessels, etc.) to prevent inadvertent contact between the saw and those tissues. *See id.*

323. Thus, Fallin in view of Davidson render claim 11 obvious.

H. Claim 12

324. Claim 12 depends from claim 1 and recites "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." 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].

325. Thus, Fallin in view of Davidson render claim 12 obvious.

I. Claim 13

326. Claim 13 depends from claim 1 and recites "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."

327. Fallin discloses that "[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]. As discussed above, a POSA would have recognized that Davidson's retractor could be placed between the metatarsals during Fallin's procedure to maintain control and stabilization of the first metatarsal in the corrected position while the medial cuneiform is cut. Ex.1006, [0057]; s*ee* §§XV.A.2-3 *supra*. A POSA would have recognized that Davidson's retractor should be inserted between the metatarsals to protect tissues on the opposite side of the resection as disclosed by Davidson. *Id.* A POSA would further recognize that placement of the instrument between the metatarsals may provide one or both of these functions.

J. Claim 14

328. Claim 14 depends from claim 1 and recites "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." As explained with respect to claim 14 in Section IX, Fallin discloses performing the steps in the order recited by Claim 14. *See* §IX.C, *supra*. Thus, Fallin in view of Davidson render claim 14 obvious.

K. Claim 16

329. Claim 16 depends from Claim 1 and recites "the at least one bone fixation device comprises at least one of a screw and a plate." Fallin discloses that the fixation device is one or more of "pins, plates, screws, rods or other suitable fixation is applied." Ex.1007, [0075]. Thus, Fallin in view of Davidson render claim 16 obvious.

L. Claim 18

330. Independent claim 18 recites the limitations of independent claim 1 and further recites the limitations of claim 4 (use of a cutting guide) claim 5 (fixation of the cutting guide to the first metatarsal), 7 (positioning of the instrument at proximal portion of the first and second metatarsals), and 12 (compressing the first metatarsal and medial cuneiform). The combination of Fallin and Davidson renders obvious the limitations of Claim 18 for the same reasons as Claims 1, 4-5, 7, and 12 in this section. *See* §§XV.A, X.V D-E, XV.G, XV.H, *supra*.

M. Claim 19

331. Claim 19 depends from Claim 18 and recites the additional limitations of Claim 6. Fallin in view of Davidson renders Claim 19 obvious for the same reasons explained above with respect to Claim 6 in this section. *See* §XV.F*supra*.

N. Claim 20

332. Claim 20 depends from Claim 18 and recites the additional limitations of Claim 2. Fallin in view of Davidson renders Claim 20 obvious for the same reasons explained with respect to Claim 2 in this section. *See* §XV.B,, *supra*.

O. Claim 25

333. Claim 25 depends from Claim 18 and recites the additional limitations of Claim 14. Fallin in view of Davidson renders Claim 25 obvious for the same reasons explained with respect to Claim 14 in this section. *See* §XV.J, *supra*.

P. Claim 27

334. 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." 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].

335. Thus, Fallin in view of Davidson renders claim 27 obvious.

VII. CONCLUSION

336. For the foregoing reasons, it is my opinion that Claims 1-30 of the '428 patent were anticipated and/or would have been obvious to a POSA in August 2015 in view of the prior art discussed above and the knowledge of one of ordinary skill in the art at the time of the alleged invention.

337. I reserve the right to supplement my opinions in the future to respond to any arguments or positions that Patent Owner may raise, taking account of new information as it becomes available to me.

338. I declare that all statement made herein of my own knowledge are true and that all statements made on information and belief to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Executed on: December 23rd, 2025 By Steven Neufeld (Dec 23, 2025 16:13:31 PST)

Dr. Steven K. Neufeld